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Big Picture Bioethics: Developing Democratic Policy in Contested Domains

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Big Picture Bioethics: Developing Democratic Policy in Contested Domains

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Françoise Baylis is a philosopher whose innovative work in bioethics, at the intersection of policy and practice, has stretched the very boundaries of the field. Her current research focuses on women's health with particular attention to assisted human reproduction and research participation. This work aims to move the limits of mainstream bioethics and to develop more effective ways to understand and tackle public policy challenges in Canada and abroad. Her most recent book is a collected edition (with Angela Ballantyne) on *Clinical research involving pregnant women*. Baylis holds the Canada Research Chair in Bioethics and Philosophy at Dalhousie University. She is an elected fellow of the Royal Society of Canada and of the Canadian Academy of Health Sciences. In 2016, she was awarded the Canadian Association of University Teachers Distinguished Academic Award.

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Michael M. Burgess is Professor and Chair in Biomedical Ethics in the School of Population and Public Health at the University of British Columbia. Burgess has collaborated with O'Doherty and Longstaff, among others, on the development of a model for public engagement based on theories of deliberative democracy research in health, science and technology policy. The model has been applied in 12 events in Australia, Canada, and the United States. Recent extensions include health care funding decisions and models for public participation in governance of learning health systems.

Donald Chalmers is Distinguished Professor of Law and Director of the Centre for Law and Genetics at the University of Tasmania. His major research interests are in medical research ethics and the regulatory aspects of genetics. He is a Fellow of the Australian Academy of Law. With colleagues, he has been awarded several ARC and NHMRC research grants. He was Chair of the NHMRC Australian Health Ethics Committee from 1994 to 2000, Deputy Chair of the NHMRC Embryo Research Licensing Committee (2003–2012) and a member of the NHMRC Human Genetics Advisory Committee (2006–2009). He chaired the Gene Technology Ethics Community Consultative Committee (2001–2010). He was Law Reform Commissioner in Tasmania (1991–1997). Internationally, he serves on the HUGO Ethics Committee, the International Cancer Genome Consortium Access Committee and the Global Alliance Regulation and Ethics Working Group.

Susan Dodds is Professor of Philosophy and Dean of Arts and Social Sciences at the University of New South Wales (UNSW Australia) and Adjunct Professor of Philosophy at the University of Tasmania, where she was Dean 2009–2016. Her research explores the intersections of ethics, political philosophy, moral psychology and feminist theory. She has served as Chair of the National Enabling Technologies Strategy (NETS) Stakeholder Advisory Council and was a member of the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (2012–2015). Dodds is a Chief Investigator and Ethics, Policy and Public Engagement theme leader in the Australian Research Council Centre of Excellence in Electromaterials Science (ACES).

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Eliza Goddard is a Research Fellow in the Ethics, Policy and Public Engagement programme within the Australia Research Council Centre of Excellence for Electromaterials Sciences (ACES) at the University of Tasmania. Goddard completed her PhD on the impacts of emerging bionic medical technologies on selfhood and social relations. Her current research draws on moral psychology, feminist philosophy, phenomenology and bioethics to explore questions concerning the role of the first-person perspective, and understandings of disability, in emerging medical technologies. She has published in neuroethics and feminist philosophy and authored reports for government and professional bodies, including on emerging technologies and community engagement frameworks.

Matthew Herder is Professor in the Faculties of Medicine and Law at Dalhousie University. Professor Herder's research interests cluster around biomedical innovation policy, with particular focus on intellectual property law and practices connected to the commercialization of scientific research.

Holly Longstaff specializes in applied ethics and policy analysis from a social science perspective. She is a Partner at Engage Associates Consulting Group and the ethicist for the BC Cancer Agency Research Ethics Board. She has also served as the Interim Associate Director for the Office of Research Ethics at Simon Fraser University and as the Communications Officer for the national board of the Canadian Bioethics Society. Holly has presented her research at conferences across North America and has published her work in a variety of journals including *Cell Stem Cell*, *Global Environmental Change*, and *Accountability in Research*.

Fiona J. Mackenzie completed her honours degree in history and philosophy of science at the University of Sydney, and was a research assistant on the Big Picture Bioethics project. Mackenzie is currently a freelance academic editor in Sydney.

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Cheluchi Onyemelukwe is Senior Lecturer at the School of Law, Babcock University, Nigeria. She is also the Executive Director of the Centre for Health Ethics Law and Development. Her work has included experiences in health law reform, health policy development and evaluation, and governance and regulation. Her experience has also included developing, drafting and researching health policies, legislation and regulations in university and government positions and legal practice in Nigeria and Canada. She is currently a member of the Advisory Council on Immunisations and Vaccines of the National Academy of Science, and a member of the Taskforce on Community-Directed School Health and Feeding Program in Nigeria. She has particular interests in regulation, research ethics, patients' rights, legal and ethical issues around HIV/AIDS and violence against women, and has published articles in these areas.

Wendy A. Rogers is Professor of Clinical Ethics at Macquarie University and Deputy Director of the Macquarie Research Centre for Agency, Values and Ethics. Her current research interests include the ethics of surgical research and innovative surgery, research ethics, vulnerability, public health ethics and issues to do with defining disease and the ethics of overdiagnosis. Rogers has published widely in leading bioethics and medical journals, and contributes to policy debates through membership of the Australian Health Ethics Committee and the NSW Ministry of Health Clinical Ethics Advisory Panel.

Kerry Ross is the Manger, Archives at the University of Wollongong. From 2005 to 2009, she undertook PhD research that explored the intersection of science and politics in the Federal and State policymaking debates around the introduction of genetically modified food crops in Australia. Kerry also worked as a long-term research assistant on a number of ARC projects in the years 2005 through to 2012.

Gene Rowe is an Independent Consultant at Gene Rowe Evaluations, Norwich, United Kingdom. Gene gained his first degree in Psychology at the University of

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Philip Ryan is Emeritus Professor in the School of Public Health at University of Adelaide. Ryan is a biostatistician and public health physician. He has a special interest in the design and conduct of intervention trials and all aspects of data collection and management in health research. He has been a member of many trial management committees and independent DSMBs.

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Jackie M. Street is Senior Lecturer in the School of Public Health, University of Adelaide. Street is an Australian National Preventive Health Agency Fellow 2013–2015 and a team member of the multidisciplinary NHMRC Capacity Building Grant-funded project, HealthCare in the Round 2009–2015. Her research focus is community participation in decision making in policy and health technology assessment. With a PhD from the University of London, she has qualifications and experience in both biomedical and social sciences and draws on both in her work.

Colin Thomson is Professor of Law and Academic Leader for Health Law and Ethics in the Graduate School of Medicine at the University of Wollongong. He has been a member and chair of several research ethics committees (1984–2004, 2010), a member and chair of the Australian Health Ethics Committee (1998–2002 and 2006–2009) and of NHMRC working parties that drafted the National Statement (1999 and 2007). He developed accreditation standards for leading HRECs (NSW Health) and conducted certifications of institutions for the NHMRC national approach to single ethical review of multi-centre research.

Abbreviations

AHEC	Australian Health Ethics Committee
AHMPPI	Australian Health Management Plan for Pandemic Influenza
ARC	Australian Research Council
ART	assisted reproductive technology
CAUT	Canadian Association of University Teachers
CIHR	Canadian Institutes of Health Research
SCOC	CIHR Stem Cell Oversight Committee
CEO	Chief Executive Officer
COAG	Coalition of Australian Governments
CMA	Canadian Medical Association
hES cells or HESC	human embryonic stem cells
NBCHR	Council of Bioethics on Human Research
NHMRC	National Health and Medical Research Council
iPS cells	induced pluripotent stem cells
PRE	Interagency Advisory Panel on Research Ethics
ICSCN	International Consortium of Stem Cell Networks
MRC	Medical Research Council
MREC	Medical Research Ethics Committee
NHRDP	National Health Research Development Program
NSERC	Natural Sciences and Engineering Research Council of Canada
PI	Pandemic influenza
PIPEDA	Personal Information Protection and Electronic Documents Act
PEPPPI	Public Engagement Pilot Project on Pandemic Influenza
RCTs	randomised clinical trials
RCNT	Royal Commission on New Reproductive Technologies
REB	Research Ethics Board
SSHRC	Social Sciences and Humanities Research Council of Canada

SSHWC	Social Science and Humanities Special Working Committee on Research Ethics
HOS	South Australian Health Omnibus Survey
SCN	Stem Cell Network
SCC	Supreme Court of Canada
TGA	Therapeutic Goods Administration
TCPS	*Tri-Council Policy Statement*

Chapter 1
Introduction

Susan Dodds and Rachel A. Ankeny

How should democratic governments make policy on ethically contentious health issues? In different countries, and among jurisdictions within countries, different answers have been generated to the same policy questions in medicine and public health: some of these answers are codified in actual law and others emerge as more informal practices. Many policy questions result in divergent or even conflicting responses across jurisdictions that are proximate to one another. Even countries that share many historical and institutional characteristics—such as Australia and Canada, our foci in this book—can come to similar or different policy responses, depending on a range of factors within the local context. In addition, the policy mechanisms for addressing contested bioethical questions, and more generally for the governance of controversial ethical issues, vary considerably, as do the processes for involving the public in policymaking.

This book addresses the problem of how to make democratically legitimate public policy on issues of contentious bioethical debate in medical research and practice. It explores alternative tools that bioethics can bring to the evaluation and critique of these types of policy responses beyond typical philosophical theory, with a focus on the processes for policymaking and how legitimate policy can be generated. It emphasizes the need to explore the 'big picture'—including the diverse contexts in which policy is generated—particularly in cases of contentious and emerging medical issues and technologies.

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Along the way it addresses two questions of political legitimacy which have both practical and theoretical implications: how should states make public policy on issues where there is ethical disagreement not only about the appropriate outcomes but even which values underlie the key issues at stake? What would constitute justified, democratic policy in such conflicted domains, and is it even possible to achieve?

The papers in this collection address this theme in three ways. First, some present new theoretical and interdisciplinary work on the limitations and possibilities of liberal democratic theory, in the face of substantive ethical disagreement about controversial health-related issues requiring policy responses. Special attention is paid to the political institutions and historical contexts that shape policy debates in Australia and Canada, as well as to the limitations (practical and otherwise) of engaging the public in policymaking. Secondly, some explore the tensions and interrelationships among ideas of legitimacy, participation, and justification in authorising regulation in liberal democracies. These explorations engage with a range of theoretical contributions to the field, including Jon Elster's 'deliberative turn' in democratic theory, various arguments regarding the role of citizen participation in democratic legitimacy (such as those proffered by Amy Guttman, Iris Marion Young, and John Dryzek, among others) and the significance of reason-giving and justification in accountable public policymaking (following Jürgen Habermas and Gerald Gaus). Finally, a series of examples of actual public policy processes are explored which draw on these theoretical concepts to analyse policy responses to controversial issues in health care or medical research. These cases articulate the 'on the ground' significance of theories for practical policymaking and test their adequacy. The iteration of theoretical and practical work allows the papers to draw some conclusions about the appropriateness of different theoretical approaches to practical cases.

Among the authors of this book are active participants in policymaking processes, as government-funded researchers or members of government bodies charged with developing or commenting on policy developments in bioethics; as contributors to the types of participatory, deliberative or consultative processes examined in our case studies; or as participants in various forms of ethical evaluation of novel research or technology applications. The authors work across a range of fields, including law, political science, philosophy, history, medical anthropology, science communication, public understanding of science, and social psychology, and share interests in using their fields to explore how citizens can meaningfully participate in and inform the development of policy on contentious issues.

The contributions in Part I articulate the challenges posed to liberal democratic theory by real life policymaking. People have diverse and strongly-held ethical, epistemic and social beliefs that shape the context of policy decisions. This diversity is apparent when citizens or experts demands a policy response to an issue for which there is no consensus about what the response should be, or even the metaphysical or epistemic basis for framing deliberation. Chapter 2 by Dodds and Ankeny frames this focal problem for the overall collection in some detail, defending the use of a 'big picture' approach to such dilemmas. It investigates what bioethics can bring to the evaluation and critique of policy responses, beyond the contents of its traditional toolbox composed of particular ethical frameworks or theories, arguing that our

evaluation of processes and policies cannot be conducted in a philosophical (or other type of) vacuum. Instead, there must be detailed analysis of the structural, institutional, political, and cultural factors that shape both how a particular ethical challenge will be understood in a particular jurisdiction and the policy frameworks available for addressing the perceived need for policy. The chapter argues that to the extent that the dominant approach to bioethical evaluation is framed within particular ethical frameworks—which we term 'bioethics as usual'— bioethics has been limited in its capacity to provide answers to this question, even though bioethicists are often consulted about such matters. We believe that a new method for the evaluation of policymaking processes on ethically-contentious issues that meet the demands of democratic justification is required (and it is hoped that this volume makes an important contribution to this method).

Chapter 3 by Dodds explores the important role of that trust plays in deliberative democratic processes and the need for deliberative publics to trust scientific and policy experts in democratic deliberation about developing technologies, as well as the need for experts to trust the claims and values of the publics affected by policies. The legitimacy of public policymaking that involves a reliance on the expertise of scientists, clinicians and policymakers depends crucially on the degree to which citizen-deliberators have warranted substantive trust in those experts to be motivated to act in a way that merits the trust they have been given. This chapter explores the nature of public trust in institutions, and the conditions that foster warranted trust in those circumstances where accountability is insufficient to ensure that experts will act in the interests of those who are reliant on their competent concern.

Chapter 4 by Ross, Dodds and Ankeny investigates one of the mechanisms used to acknowledge and address substantial ethical differences amongst individual politicians of the same party when forming policy on contentious issues. While Canada and Australia are examples of contemporary representative democracies in which the policy platforms of political parties seek to represent the interests and values of constituents, there is recognition that the significant ethical disagreements relating to some policy matters fall outside the normal party policy platforms. Political parties have sometimes drawn on the device of 'conscience votes' or 'free votes' in deciding regulation of bioethical issues in Australia to release ethically contentious debates from the strictures of party policy discipline. This chapter uses a series of key case studies in these contested areas of policymaking to investigate conscience votes, with particular attention to their implications for promoting democratic values including participation of those who are traditionally underrepresented.

Chapter 5 by Smith and Rowe draws on empirical work to demonstrate the possibilities and challenges of deliberative processes in bioethics, addressing the following questions: who facilitates deliberative events? What methods of deliberation are useful in bioethics policy contexts? How can deliberative processes be designed to allow fair and reasoned participation? What deliberative approaches suit different policy aims, such as shaping policy or responding to proposals? It draws on evaluations of multiple deliberative events to present conditions for good deliberative

practice, and identifies areas in need of further research to inform policy-focused public deliberations.

Part II begins the series of detailed case studies that deploy and test the theoretical work and concepts discussed in Part I.

Chapters 6 and 7 address the development of new regulation of human embryo research in Canada and Australia respectively, since the development of the technique for isolating and developing human embryonic stem cells in 1998. The two papers explore the process of policy development in each jurisdiction, the use of consultation and expert submissions, and the public justifications offered in reports and legislative debate. This section highlights the complications involved in developing definitive public policy using a process that identifies and acknowledges strongly-held and divergent ethical and epistemic perspectives in rapidly emerging areas of medical research.

Chapter 6 by Baylis and Herder, explores these processes in Canada and describes the development of various policy instruments over the past 20 years and analyses this history using a typology of modes of public consultation. It contends that the degree to which the views of Canadian residents and citizens on human embryo research have been solicited as part of the policymaking process has diminished significantly over the period in question, and that this trend is likely to continue, given the presence of powerful interest groups and policy communities who claim to 'speak for' Canadians.

Chapter 7 by Dodds and Ankeny examines a range of processes utilized in Australia to develop regulations or similar on embryo research, including the diverse mechanisms used during each of the policymaking stages to engage various publics, and the procedures for balancing conflicting values. It explores the ethical and democratic challenges posed by developments in embryo research as well as various difficulties that arose in engaging the Australian public during these policymaking processes, in order to investigate what the future prospects (and likely impediments) are for productive and meaningful public engagement in these contentious areas.

Since the adoption of the Declaration of Helsinki in 1964, individual countries have developed research ethics guidelines with a clear focus on the protection of subjects in health and medical research. Through the 1980s and 1990s, these guidelines shifted away from provision of broad principles to focus on giving guidance about the conduct of researchers. More complex and detailed documents emerged, governing the ethical acceptability of research, mandating the structure and processes of research ethics review committees, identifying institutional responsibilities for oversight of research and providing detailed guidance on specific areas or research methods that raise distinct ethical concerns. Part III explores recent efforts at developing comprehensive approaches to research ethics review through national guidelines in Canada and Australia.

Canada and Australia each developed detailed research ethics guidelines through processes that involved federal or commonwealth bodies outside the health and medical research realm. Each developed processes for revision of the guidelines involving an array of consultation processes and deliberation. The papers in this section explore the historical and institutional contexts within which these processes

for development and review of research ethics guidelines occurred, and detail how public and expert consultation processes have been able to shape the guidelines.

Chapter 8 by Downie and Onyemelukwe details the development in Canada of the Tri-Council Policy Statement covering publicly-funded research involving humans, and the application of the concepts of democratic legitimacy, transparency, representation, accountability, and community engagement in that process, against the backdrop of its historical, legal, and political context. It is argued that efforts were made to ensure basic democratic values in the process, but that these attempts should have been taken. The paper also draws lessons for future policymaking in this and other contentious areas.

Chapter 9, co-authored by former chairmen of the Australian Health Ethics Committee (Colin Thomson, Kerry Breen, and Donald Chalmers), provides an insight into the deliberations framing the development of various iterations of national research ethics guidelines from 1966 to 2007. This chapter provides the historical timeline of the developments, as well as articulating the status, scope, membership, and authority of the national agencies which were involved in developing the guidelines. This review identifies the ways in which the scope of the research ethics guidelines were expanded beyond medical and health research and the role of the various national agencies with interests in the funding, conduct, and use of research were included in the process of developing the guidelines. Over time the processes used in the deliberations have also changed, while retaining three key features: a statutory requirement for consultation, regard for submissions, and Council approval. The importance of the first two of these features for promoting deliberation in the development of national research ethics guidance is explored in more detail in Chapter 10.

Chapter 10, by Goddard and Dodds, explores the influence of public submissions on the developments of the latest edition of the Australian *National Statement on Ethical Conduct in Human Research* to assess the roles of submissions and arguments that were brought to the Australian Health Ethics Committee's working party that developed successive drafts of the guidelines. This chapter focuses on specific areas of the guidelines where there was clear interest in improving the guidance provided to research ethics committees and researchers and a level of dissatisfaction with the applicability of the existing guidelines, as well as significant changes between different drafts of the consultation drafts of the Statement through the revision process. This chapter assesses the process of the review in light of some of the characteristics of defensible deliberative processes articulated in Part I.

The final section, Part IV, addresses three different deliberative approaches for evaluating evidence, risks, and clinical responses in relation to emerging health policies: establishment of new diagnoses and clinical guidelines; vaccination policy in response to pandemic flu; and public health policy relating to human genetic tissue biobanks. This section focuses on contestations about evidence, expertise, ranking of social values, exploration of the nature of social goods, and allocation of public health resources, as matters for debate and justification. At the same time, this section explores the use of distinct deliberative approaches as means of achieving defensible policy in a range of expert and lay fora.

Chapter 11 by Ankeny and Mackenzie explores the development of three sets of clinical practice guidelines for chronic fatigue syndrome in Australia, Canada, and the United Kingdom in order to examine diverse approaches to the development of such guidelines by medical professionals and other 'experts' in concert with inputs from the public, particularly those affected by the disease condition. Decisions about diagnostic categories through clinical practice guidelines represent a central type of informal policymaking which affect the scope of publicly-regulated health services and directions for future research. It is argued that the processes explored reflect three contrasting modes of policy development, and that the differential levels of acceptance of these guidelines by a range of relevant parties can provide guidance as to which mode of policy development is likely to be most effective and acceptable particularly in the domain of controversial or contested domains within medicine.

Chapter 12, by Street, Marshall, Braunack-Mayer, Rogers, and Ryan, concerns public perceptions about who should have access to scarce antiviral drugs and vaccines in a flu pandemic. The use of a survey and of a deliberative forum as methods of public engagement are compared and evaluated as means of ranking competing demands within a public health care system. The chapter describes the design and outcomes of a South Australian survey and deliberative forum on approaches to resource allocation in response to a flu pandemic and evaluates these as distinct means of contributing public perceptions to policymaking decisions. It is argued that while surveys allow policymakers to gain an insight into the attitudes of a much larger, and potentially representative sample of citizens, they do not necessarily reflect informed deliberation by citizens. By contrast a deliberative public forum allows participants to hear, seek out, question, and reflect on relevant information shaping the policy. Nonetheless, running a deliberative forum is costly and draws on too few participants to provide confidence that the outcome is representative of the views of the community. The authors argue for combining a range of methods of consultation, survey, and deliberation to compensate for the limitations of each specific approach.

Chapter 13 by Burgess, Longstaff, and O'Doherty critically assesses the public deliberative methodologies used in British Columbia about the development of a biobank, which involved a deliberative event spanning two weekends with 20 citizen-deliberators. It is contended that the development of public and private genetic databases (biobanks) strains a number of dominant understandings in this area, notably those associated with the right to privacy of health information, the requirement of consent for research participation, and the key responsibilities of the state for public health. This chapter presents an example of how citizens' views can be incorporated into the regulatory and institutional design of biobanks, particularly in light of the tensions inherent in this domain.

Clearly this volume opens many additional questions which warrant attention in further research: for instance, what are the potential inequalities that existing deliberative approaches may overlook, and who is being systematically excluded?

Vulnerable or oppressed groups may struggle to participate and have their views recognised as legitimate in deliberative processes. What mechanisms could reduce this silencing of the oppressed, and also foster higher levels of reflective deliberation in the processes associated with policymaking?

These questions may prove more pressing than ever in times of strained governmental budgets and fiscal crisis, which put public health care systems under stress at the same time that global health challenges (such as SARS, Ebola or Zika) and genomic medicine pull health resources in different directions. The need for policymaking on ethically contentious issues can be predicted confidently as a regular feature of health and medical policy into the foreseeable future. The authors of the contributions to this book recognise that deliberative processes require investment of a great deal of money, time, and effort as well as a long-term commitment to developing citizens' skills in articulating and defending positions through public reasoning. Notwithstanding the costs of deliberation, citizens in pluralist democracies will continue to demand the opportunity to have their values and concerns taken into consideration in the development of policy, will hold policymakers accountable and demand justification for policy decisions, and will challenge the legitimacy of ethically contentious policy that does not respond to the concerns of affected parties. While some of the more rigorous deliberative processes discussed in this book will not be required for many policy decisions, others will require new, more robust, and defensible modes of deliberation in order to gain sufficient legitimacy to allow for defensible public policy.

Like all major collective projects, this collection owes debts of gratitude for material and intellectual support. This book arises from an Australian Research Council Discovery Project Grant "Big Picture Bioethics: Policy-making and Liberal Democracy" (DP0556068) which allowed the editors and partner investigators, Françoise Baylis and Jocelyn Downie, to explore and defend the proposition that ethically contentious health care and medical research policy demanded a different approach from what we have understood as "bioethics as usual". We would like to acknowledge the support of the ARC, our universities (Wollongong, Adelaide, Tasmania, Sydney, UNSW Australia, and Dalhousie) and the organisers and participants in a range of conferences, workshops and seminars who supported this endeavour: in particular colleagues at Dalhousie University, the University of Toronto, University of Western Australia, and Australian National University, and participants in the biennial World Congress of Bioethics and the Feminist Approaches to Bioethics satellite conferences. In particular we would like to thank the research assistants who worked on various stages of the project: Fiona Mackenzie, Kerry Ross, Brys Tanner, Cobi Smith, Matthew Herder, and Eliza Goddard. Eliza merits special recognition for her work in completing the final formatting and corrections. Chapters Three, Four, Six, Seven and Eight are revised versions (in some cases quite substantially revised and updated) of previously published journal articles, and we wish to thank the publishers for their permission to reproduce the chapters in revised form in this collection. All other chapters are previously unpublished research.

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Part I
Seeing the Big Picture: Democratically Defensible Policy Development in Liberal Democracies

Chapter 2
'Big Picture' Manifesto: Democratic Policymaking in Contested Domains

Susan Dodds and Rachel A. Ankeny

Introduction

Consider the following policy questions that have recently been debated in a number of democratically-governed countries around the world:

- Should human embryos be used for research purposes?
- Should access be restricted (or denied) to the 'morning after' pill or abortifacients?
- Should genetic modified organisms (GMOs) be grown as food crops?
- How should we decide when nanotechnology products are safe enough to be sold to consumers?

In different countries, and among jurisdictions within these countries, different answers have been generated to the same questions: some of these answers are codified in actual law and others emerge as more informal practices, often in the absence of specific regulations or direct state involvement. In addition, the policy mechanisms for addressing the questions, and more generally for the governance of controversial ethical issues, vary considerably, as do the processes for involving the public in policymaking.

With regard to embryo research, for example, the United Kingdom has a comprehensive and well-established regulatory framework which allows embryonic stem cell research, subject to the granting of a licence from the Human Fertilisation and

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Embryology Authority. Sweden and Spain also have detailed and comprehensive legislation with regard to embryo research. Canada has law restricting use of human embryos in public and private research organisations (the *Assisted Human Reproduction Act* 2004), as well as regularly updated guidelines applying to all research involving human embryos that is funded by the three national research funding bodies or is conducted in institutions receiving funding from those research funding bodies (see http://www.cihr-irsc.gc.ca/e/42071.html; Baylis and Herder, this volume, Chap. 6). In some EU countries, such as Austria, Italy, and Germany, research on embryos (including the derivation of embryonic stem cell lines) is banned, although some allow research with imported stem cell lines under specific circumstances; a few others, notably Ireland, have no specific regulations concerning embryonic stem cell research (see http://www.eurostemcell.org/stem-cell-regulations for more details). The United States has a complex federal situation, which originally hinged on restriction of federal research funds rather than an outright regulatory ban: prior to an executive order by President Barack Obama in 2009 which overturned previous legislation, federal funding was limited to non-embryonic stem cell research and embryonic stem cell research based upon embryonic stem cell lines which had been in existence prior to August 9, 2001. Some US states have laws that specifically ban (e.g. South Dakota, Ohio) or permit (e.g. New Jersey, California) embryonic stem cell research, while others do not have any specific legislation (National Conference of State Legislatures 2008). Australia has relatively detailed legislation governing embryonic stem cell research which has been modified over time and which emerged out of an extended policymaking process (see Skene et al. 2008; Dodds and Ankeny, this volume, Chap. 7), as does Canada (see Baylis and Herder, this volume, Chap. 6).

Ireland has prohibited access to all forms of abortion including abortifacients, which has resulted in women seeking these drugs outside of the county. Most other EU jurisdictions permit abortion including use of abortifacients although there is a wide variation in the restrictions under which use is permitted. After initial regulatory moves in Australia to ban the import of a particular abortifacient under import/export laws, emergency contraception is now available over the counter there, as well as to non-minors in the United States (Quedding et al 2011; Thompson et al 2013).

On GMOs, the United States has a very liberal approach compared to the EU, where GMOs are largely prohibited and the regulatory system is based on the process underlying the products rather than on the end products alone, as is the case in the United States and in the World Trade Organization regulations. The EU relies on a case-by-case analysis of risk, together with use of the precautionary principle. Australia has a mixed approach, with some individual states such as South Australia and Tasmania retaining moratoria on growth of GMO crops on the local level at the same time as various crops are being considered for licensure at the Commonwealth level, although its federal laws and regulations depend largely on a product-based approach through Food Standards Australia and New Zealand. Canada is one of the largest producers of GMO crops (corn, soy, canola, and sugar beets) with Health Canada holding responsibility for evaluating the safety of 'novel foods' including GM foods (Health Canada 2012). Despite these differences in approach to GMOs, the different jurisdictions share an underlying set of assumptions that the only valid

considerations for risk assessment should be scientific and related to potential harms to the environment or to human health, and not any wider economic or sociocultural criteria. Hence, despite differences in policy outcomes in this domain, this shared set of assumptions left little room for public participation in debates over GM policy, except until a new EU directive in 2001 included a requirement for public consultation (see Torgersen et al. 2002; Gottweis 2008).

Nanomaterials have been present in sunscreens for the last 8–10 years, with some questions about whether more rigorous testing is needed. In Europe, there has been an emphasis on the need for specialized testing, whereas in the United States, the products are not viewed as requiring any oversight beyond the usual consumer protection measures. In Australia, there has been debate about whether there should be special restrictions on the use of nanoparticles in sunscreens, depending in part on whether these products are viewed as therapeutic or cosmetic goods, with some attempts at public engagement about these issues (Petersen and Bowman 2012). The Australian government commissioned a review of the regulatory impact of nanotechnologies which indicated that the current regulatory systems were presumptively adequate to address known issues (health and environmental risks) associated with nanotechnologies and also identified a number of triggers for addressing regulatory gaps that could emerge in the further development of the technology (Ludlow et al 2007).

In the face of such diversity, what tools can bioethics bring to the evaluation and critique of these types of policy responses? Traditionally, the field of bioethics has approached policy questions and policy evaluation from within a particular ethical framework or theory derived from philosophical and political theory. For example, policy proposals can be assessed using an application of utilitarianism (or some other form of consequentialism), which will require determining the consequences of the policy for all those who are (or may be) affected by it. Alternatively an approach that centres on respect for personhood could be taken by considering the ways in which the policy options demonstrate respect for persons, promote personal autonomy, or protect individuals' rights (or undermine these values). A virtue ethic approach would seek to establish the meaning and significance of policy alternatives for the cultivation and expression of a range of relevant virtues. A communitarian approach to bioethics would assess the impact of alternative policy options in terms of their impact on a societal community or specific communities within a society. A principalist approach would deploy the principles of autonomy, justice, beneficence, and non-maleficence in determining whether a policy attended adequately to competing ethical demands.

For some types of questions and in circumstances where there is no fundamental ethical disagreement or conflict in values, where there are shared underlying concepts and epistemologies, where there is agreement about who is an 'expert' regarding a particular question, or where the main task is values clarification, mechanisms that draw on these standard approaches to bioethics might work well enough. But in the face of commitments to moral pluralism, transparency, and accountability, and where the empirical grounding of the policies may be rapidly changing as is the case with many emerging biotechnologies, then mere application of an abstract theoretical approach to a policy problem is not likely to be fruitful.

There is promising, recent work in empirical bioethics (a subfield which uses social science methodologies to contest or inform our understandings of ethical concepts and principles) has developed a range of critical methodologies for eliciting public valuations about ethically contentious matters, novel technologies and potential policy alternatives (e.g., see Hoffmaster 1992; Hope 1999; Haimes 2002; Hasman 2003; Hedgecoe 2004). Among the approaches that inform what we are term 'empirical bioethics' are medical anthropology, systems bioethics, historical institutionalism, and the sociology of medicine and health. Empirical bioethics is developing a range of critical tools for finding out what the ethical issues are in an area of policy and in determining public and expert views. The benefit of an empirical approach to aspects of bioethics is that it does not start from the assumption that ethicists can, for any given ethical debate, correctly articulate the ethical issues associated with a particular development in medicine or healthcare from the metaphorical armchair. Rather, applying ethical analysis to real life policy development ought to be informed by a level of empirical input—including input about what people are prepared to accept or endorse in a policy—and that empirical input itself should be subject to critical scrutiny. In our view, this empirical turn in bioethics can make some contribution to a more legitimate approach to bioethics, but as these approaches largely describe and analyse, but do not evaluate attitudes, practices, and institutions, these empirical approaches do not, in themselves yield defensible policy recommendations (as their practitioners are well aware).

Hence although the different ethical approaches traditionally deployed in bioethics as well as those approaches that are emerging under the banner of empirical bioethics can provide an ethical evaluation of alternatives in the narrowest sense, they are not adequate for the evaluation of the policymaking process itself, as an activity of states (or authorities created by state institutions). Such processes seek not simply a determinate outcome, but one that will be defensible to all those who are affected by the policy, whether or not they hold a particular ethical outlook. Taking one specific, traditional ethical approach hence fails to justify decision making at a policy level. Policies in liberal democracies are open to public questioning of justification and legitimacy, and in order to in fact be legitimate, there is a requirement that a range of processes be in place to negotiate a final decision, which often reflects compromise as well as consensus.

The task of formulating public policy is made more difficult by the need to (somehow) take account of the range of values held by members of pluralistic societies. Of course various philosophical approaches have devised solutions to developing policy under such conditions. Among the more widely accepted of these is a Rawlsian approach which assumes that citizens share a sufficient set of shared or overlapping values that can drawn on to achieve consensus about matters in the political realm, through a process of reflective equilibrium. In contrast, a Habermasian approach assumes the possibility of communication and justification in principle, but leaves the question about the scope of the political or public realm open; furthermore Habermasian approaches do not assume or require consensus.

Given that bioethics policy often occurs in contentious domains where the assumption of the ability to achieve an overlapping consensus seems empirically

unwarranted, a Habermasian-style solution appears to offer a more plausible starting point for evaluation of public policy on contentious bioethical issues. The question then remains as to whether such an approach can be adapted to with areas where there are multiple publics who take a stake in the policy issues under discussion. In addition, it is unclear how a policy could be agreed upon when those engaged in deliberation do not agree that they are willing to be moved by the reasons of others and where various parties are not committed to rational deliberation, conditions which often apply in bioethics policy debates. This then leads us to wonder how can the legitimacy of such policies be justified, when a country/jurisdiction is seeking policy in controversial bioethical domains?

These considerations, then, serve to shape the starting points of our project, which we call 'Big Picture Bioethics.' The project seeks to examine bioethics in its broader social and political contexts. In particular, it is interested in the rather large subset of issues in bioethics that have implications for the formation and critique of public policy. We wish to be able to evaluate the processes that have been used to develop these different public policies in response to ethically contentious issues. We focus on these types of issues not because we wish to presuppose that themes relating to what others have termed the '(new) politics of life' (see, e.g., Rose 2006; Gottweis 2008) have resulted in unique governance mechanisms or policy questions, but because we wish to investigate how bioethics (where these issues are core business) might better engage with such policy questions and processes. We do not presume that our evaluation of those processes and policies can be conducted in a vacuum, but rather that there needs to be adequate consideration of the range of structural, institutional, political, and cultural factors that shape both how a particular ethical challenge will be understood in a particular jurisdiction and the policy frameworks available for addressing the perceived need for policy. Our overarching question is *what approaches to bioethics can be used to assess how, and to what degree, the legitimacy of policies can be established when a jurisdiction is seeking to establish policy in a controversial bioethical domain?* This chapter outlines the framework within which we address that question.

We argue to the extent that the dominant approach to bioethical evaluation is framed within particular ethical frameworks (or by adopting principlist pluralist approaches that do not demand justification)—what we call (perhaps unfairly) "bioethics as usual"—bioethics has been limited in its capacity to provide answers to this question, even though bioethicists are often consulted about such matters. We believe that we need a new method for the evaluation of policymaking processes on ethically-contentious issues that meet the demands of democratic justification.

Legitimacy of Bioethics Policy

Our project starts with the view that public policy on contentious ethical issues requires a determinate (if not definitive) outcome, that the outcome is publicly justifiable, and that such justification needs to attend to the fact of ethical

disagreement. We use a framework based in deliberative democratic theory as a test of the relative legitimacy of a policy outcome: a policy is to be thought more legitimate if a greater proportion of those affected by the policy are able to view the process that led to that outcome as one that allowed their concerns to be articulated and answered, if those who are affected by the policy are able to articulate the reasoning that could justify how the policy process addressed competing views, and if those who were charged with developing policy are able to offer a justification for deciding the policy as they have.

The scope of policy deliberations we have in mind are precisely those where there is no widely accepted consensus on a matter of policy nor issues where it is widely accepted that the matter is largely or wholly a personal decision. How issues come to be understood as controversial material for policy debates is a matter of socio-historical contingency. The issues that we have in mind as central to this book are those which are considered to be ones with significant ethical content, where the matter is viewed by at least substantial portion of the citizenry (or their representatives) as requiring some form of public policy response, and where there are clear differences of view about how the ethical content should be reflected in policy. Where policy matters address issues of access to health care, regulation of medical research, or new developments in health technology, we describe them to be matters of "bioethics policy."

Policy relating to a health or medical issue typically falls into the category of bioethics policy where policymakers feel a need to establish the explicit legitimacy of the policy process and to involve members of the public, or an array of expert stakeholders in the policy development process. Frequently this arises when politicians or regulators feel obliged to make policy in areas where there is clear ethical disagreement and where they claim that the policy should reflect public values.

Bioethics policy is thus characterised by increased interest in procedural transparency, public accountability, and consultation, and deliberation or other input from a wider range of stakeholders than is the norm for other areas of health policy. The kinds of current bioethics policy issues raised earlier provide an indication of how the push for greater transparency, accountability, and stakeholder involvement may occur. First, these areas of public policy arise in contexts where technological or medical change is occurring rapidly and the policymakers lack definite advice about the values that may be affected by the policy. Secondly, because of the novelty of the area, policymakers may not know who is affected by the policy and how they will be affected, so may not be able to draw on existing representatives to provide advice and, third, they need to defend the policy which will not reflect the (unmediated) preferences of all affected.

The approach we are proposing seeks to develop a new framework for evaluating policy that assumes heterogeneous publics holding diverse views, and who may be able to communicate and deliberate but are unlikely to achieve overlapping consensus on particularly contentious ethical issues. We believe that this framework can be useful in the evaluation of a range of current policy debates. It is not intended to be an idealistic approach, as it seeks to attend to the local social, cultural, institutional,

and political factors that enhance or impede the development of democratically-legitimate policy. Rather, it offers a means of evaluation that can assess how close or how far particular processes of policy development are from "better" or "more legitimate" processes, and by attempting to identify the structural and institutional or social, cultural, and political factors that have served to limit the degree of legitimacy that can be conferred on that policy process.

Although this approach is primarily concerned with understanding the extent to which procedures can be developed for legitimate policymaking without invoking absolute or exclusive ethical commitments, our approach is not itself ethically neutral. Rather it assumes a set of norms of democracy, justification, and justice that should shape political institutions, policymaking, and policy implementation. The test for legitimacy developed here is a relative one, and we are open to the possibility that there may be some debates on ethically-contentious issues where the development of policy that meets a threshold level of legitimacy is impossible (at least for a particular population, at a particular historical point). Challenges to legitimacy may arise for a number of reasons including: an apparently monolithic hegemonic authority that makes it effectively impossible for particular alternatives or positions to be heard; the absence of a culture of public deliberation that may render formal processes for public reasoning ineffective; an array of "pathologies of deliberation" that may distort deliberative process (Sunstein 2003); the presence of overwhelming economic or geopolitical threats that divert the policy process; or, finally, substantive ethical disagreement about the ethical issues under consideration and the value given to these by key groups, relative to the values of democratic legitimacy and respect. However, it is not yet clear how intransigent any of these challenges to legitimacy will be, given alternative policy processes, alternative policy issues, and alternative socio-cultural or political situations. Therefore one of the tasks of our approach is to attempt to use this approach to identify that threshold and current debates for which such legitimacy may be unrealisable, in a given set of circumstances, through examination of "real life" policy processes.

Big Picture Bioethics

Our criticisms sketched above about the prospects for "bioethics as usual" or the familiar bioethical approach to the evaluation of public policy, have at their heart the sense that "bioethics as usual" is "little picture bioethics": it often relies on simplified case studies that intentionally obscure the complexity of real life policy implications; it tends to narrowly frame the range of ethical approaches relevant to policy decisions; it pre-frames salient empirical information in terms of competing expert or ethical positions; and it fails to attend to broader political and social contexts shaping public discourse. We present here our desiderata for a more legitimate approach to bioethics policy evaluation and (potentially) enhanced legitimacy in the development of bioethics policies. We believe that the following elements are

required: (1) a theoretical framework grounded in the normative demands of legitimacy and justice; (2) a method (or range of appropriate methods) for empirically identifying and assessing what is at stake in a particular policy debate; and (3) one or more processes for interpretation of the findings gained from experts, technicians, and the empirical findings on stakeholder views which are then used to generate coherent and determinate policy proposal justifications that are testable and contestable, and that foster informed debate and engagement. We call this a 'big picture' bioethics approach because it aims at encompassing the full range of concerns and understandings about an issue of bioethics policy at a given time within a jurisdiction; because it aims at approaches that respond to the arguments and concerns expressed within that public debate; because it recognises that the legitimacy of bioethics policy decisions is open to revision in light of changed information or social concerns; and because it appeals to the transparency of publicly articulated reasons and arguments for accountability. The following sections present in more detail the issues and requirements for each of these key elements to this approach.

Theoretical Framework: Justification and Deliberation

For any particular argument concerning the value of liberal democratic institutions, there is a challenge to establish the role of the state in, on the one hand, protecting and promoting certain basic rights of individuals or collective values (e.g., justice towards disadvantaged social groups) while on the other affording due regard to the value of democratic self-determination or popular sovereignty in the determination of political matters. While much of the writing of John Rawls (1971 onward), for example, is concerned to establish *just institutions* for the resolution of the complex coordination problem of overlapping individual interests, this approach is not readily applicable to concrete or specific policy development in the contested ethical terrain discussed here. What norms of policymaking are required to meet the demands of liberalism for justification and those of democracy for equal respect and public reasoning as tests of legitimacy? The two strands articulated below together point to the role of justification, deliberation, and public reasoning in establishing the legitimacy of policy affecting citizens.

Contemporary liberal theory emphasises the significance of justification in the moral defence of liberal conceptions of the role of the state. Jeremy Waldron has argued that the legitimacy of public policies depends, in principle, on the ability of the policy-maker to justify those policies to any reasonable member of the society (Waldron 1993, 44). For Stephen Macedo "[t]he moral lodestar of liberalism is…the project of public justification" (Macedo 1991, 78). The central issue for the state in developing policy can be framed within Charles Larmore's characterisation of political respect for persons:

> To respect another person as an end is to insist that coercive or political principles be just as justifiable to that person as they are to us. Equal respect involves treating all persons, to which such principles are to apply in this way. (Larmore 1990, 349)

The demand for justification, grounded in respect, concerns the nature of the limited authority of the state to use its coercive force to compel adherence to law. If the liberal individual is to submit to state authority, that authority must be able to provide a justification that can, in principle, be accepted by those individuals so compelled. The concern for justification generates a demand for public accountability and transparency of policymaking processes.

Within democratic theory, there has been considerable recent work on the significance of public deliberation for the realization of democratic values. In this work, deliberative legitimacy involves the participation of citizens in reasoning about what policies or institutions ought to be adopted (Fishkin 1995; Gutmann and Thompson 2003). The deliberative approach to democratic legitimacy emphasizes the use of argument to establish the justification for policy and processes of deliberation to establish political legitimacy. This approach is closely associated with the work of Jürgen Habermas (1975), but has been elaborated and refined by a wide range of democratic theorists. Habermas describes this model as a return to the "original meaning of democracy as in terms of the institutionalisation of a public use of reason jointly exercised by autonomous citizens: (Habermas 1996, 23). According to Jon Elster, the deliberative approach to democracy emphasizes the legitimation of policy that comes from the *transformation* of interests through processes of "collective decision making by all those who will be affected by the decision… and decision making by means of arguments offered by and to participants who are committed to the values of rationality and impartiality" (Elster 1998, 8).

Critical theorists and feminists who work on questions of justice and inclusion have drawn on the deliberative and justificatory ideals of the Habermasian approach, while articulating the range of institutional, procedural and structural impediments to inclusion, communication, and free and uncoerced participation. Iris Marion Young (1990, 2000), Seyla Benhabib (1996), and John Dryzek (2000) (among others) incorporate critical assessment of established power structures that may shape and limit deliberation and assess the significance of the historical absence or exclusion of oppressed groups from public reasoning fora.

In our view, a normative political theoretical framework based on critically informed justificatory and deliberative approaches to political legitimacy promises a sound basis for evaluating policy processes based on democratic norms that can be justified independently of particular ethical commitments. Is our approach to deliberative policy development unique? No, authors like Amy Gutmann and Dennis Thomson (2003) have argued for a form of deliberative democracy in health policy development and evaluation and others have argued for using "citizen juries" in development of contentious health policy (see also Dryzek 2000; Dolan and Cookson 1999). We are, however, extending the critical engagement with these approaches drawn from political philosophy by asking whether deliberative legitimacy is possible in areas of significant ethical contention, and, if they are, what institutions and mechanisms are required to enhance the process. Further, because we accept that there may be some ethical disagreements that challenge the capacity for this kind of political theory to generate legitimate policy, our project provides an important test for the limits of democratic legitimacy.

Empirical Evidence for Values Underlying Policy Debates

The process of 'participatory governance' has been defined as "the practice of consulting and involving members of the public in the agenda-setting, decision-making and policy-forming activities of organizations or institutions responsible for policy development" (Rowe and Frewer 2004, 512). We focus here on more formal mechanisms for public engagement in policymaking, although of course there are a range of more informal, yet commonly utilized, forms of public participation such as lobbying, public protests, media engagement, and communications via a variety of internet technologies (see Gottweis 2008). Where a deliberative, justificatory approach to policy development is adopted by a governmental-based entity, those involved in developing and deliberating about policy alternatives will need to develop mechanisms for identifying what is at stake for the public– the range of values, alternative perspectives, and contested interests –in a particular policy debate. There are a number of methodologies for eliciting more formal 'public valuations' about ethically contentious matters, novel technologies, and potential policy alternatives, and extensive discussions about the advantages (and limitations) of each option (for reviews, see Laroux et al. 1998; Mullen 1999; Ryan et al. 2001; Bellucci and Joss 2002; Rowe and Frewer 2004).

Opinion polls are common ways of determining what people believe about controversial bioethical issues, but they only allow assessment in terms of the particular questions asked at a specific point in time and also assume a basic level of public knowledge about the issue in question, hence often reinforcing a "deficit model" of the public's understanding of the underlying science or of the issue more generally. More importantly for purposes of this project, they also focus on individuals' opinions and not group beliefs, and do not allow interaction with the public to assess underlying values. More open-ended interviews of individuals or in groups do not presuppose particular answers (or types of answers), do not make as many assumptions about baselines of knowledge about an issue, and may allow respondents to pursue themes in much greater detail than more close-ended surveys. However, some commentators argue that even interviewees participating in relatively open-ended protocols may still tend toward conformist responses, such as those they think are socially desirable or acceptable (see e.g., Holm et al. 1996). Furthermore, surveys assume a certain "projectability" and generalisation of results which relies on the construction of a "docile social body" which can be reliably measured (Ashcroft 2003), an assumption that is not particularly warranted because the stability condition can only be assumed to hold for a limited time or within a limited population, particularly with regard to emerging or contentious issues.

In contrast, group-based approaches are claimed by some to be "optimal" allowing 'study of moral reasoning in real-life groups, discussing real-life dilemmas' (Holm et al. 1996). For instance, reasons for decisions or opinions can be elicited through conversation and deliberation within groups, such as citizen juries (for use of these with regard to bioethical issues, see e.g. Braunack-Mayer et al. 2010; for critiques, see e.g. Pickard 1998; Price 2000). Consensus conferences bring together

citizens with varied interests to gather their opinions on specific scientific and technical issues (see Laroux et al. 1998). Similarly, number of authors have drawn on the potential for public participatory approaches to contribute to technology assessment and public engagement with science (for example, O'Doherty and Einseidel 2013). The underlying concept is that any average citizen who is provided with the necessary time and resources to learn about a particular issue can understand complex considerations and make well-grounded decisions on the issue. Consensus conferences allow real-time assessment of the needs of participants in terms of further information required to be able to render a decision regarding a particular issue, and oftentimes it is the participants themselves who select the experts or presenters to be engaged (Joss and Durant 1995). These methods have the advantage of being open ended, and thus do not restrict respondents to a particular theoretical framework or set of background assumptions. The interviewer or facilitator's role also can be diminished (or eliminated in the case of consensus conferences), thus mitigating concerns about conformist responses. However, empirical research which focuses on capturing group decision making often suffers from other sorts of influences, notably that underlying values systems or reasons are not always made apparent and groups can tend toward compromise or even engage in strategic behaviours that may not reflect actual beliefs or preferences, and participants are largely self-selecting (Einseidel and Eastlick 2000).

Where the research question is related to group interests, group-based techniques may well be most appropriate, as they have been argued to encourage respondents to consider the common good and not merely individual interests (Bowie et al. 1995; Mossialos and King 1999). In some formats, such as in citizens' juries or consensus conferences, they may explicitly require participants to come to a jointly agreed decision. As it appears that within the type of justification sought for policy in bioethics legitimacy will need to be established through claims about the "common good" and the defence of these claims, attending to group deliberations and processes is more likely to provide useful empirical content. However, we would argue, as this empirical content will not be sufficient to determine the justifiability of policy, more theoretical ethical analysis of these empirical claims about the good (or goods) also will be required.

At the most basic level, all of the methodologies that can be encompassed under the rubric of public participation may perturb the status quo, in that research can become a social intervention. The public may come to expect to have a right to participate and expect to have a certain sort of role in decision-making in the future. As Ashcroft (2003, 9) argues, '"attitudes" are often "made", not "found", and may be unstable, or sensitive to framing effects and a variety of contextual factors more associated with the methodology chosen than with any underlying social variables'.

In summary, considerations when assessing whether a participatory mechanism will yield the desired results include:

1. access (who participates, what or who are they "representing", and who determines who participates?)

2. autonomy and influence of the participants (are they free to make decisions, and do the decisions actually have any impact?)
3. the framing and scope of the issue under discussion (is it limited enough for useful discussion, but not so limited so as to close off certain views? [cf. Irwin 2001])
4. ability to foster high-quality dialogue and debate
5. limitations of context (what are the pre-existing social and political structures which may close off deliberation and debate?)

Translation into Policy

Having drawn on the range of empirical information and discursive positions held within the public discourse relevant to a given area of bioethics policy, the next step for the policymaking process is the interpretation of the information provided by expert and public stakeholders and the transformation of that information into policy. Policymakers may think they are implicitly asking experts (for instance social scientists or survey makers) for this type of answer, but often instead only unprocessed, descriptive information is provided. There is a need for bodies charged with making policy recommendations that respond to the arguments and evidence provided (Cohen 2005; Dodds and Thomson 2006). Depending on the complexity and political sensitivities involved, this could be a one-step process or a two- (or more) step process that respond to and refine information and arguments. These processes need to be sensitive to differences in the salient features of policy issues: ideally where policies will have significant impact on citizens' lives there will be the time and resources for iterative consultation and testing of both the empirical information about what is valued, the range of stakeholders whose perspectives are relevant and responses to policy alternatives. This would yield one or more clear policy recommendations that are framed as an argument for the policy recommendation grounded in the evidence considered.

Where the policy matter requires legislation, the interpretation of arguments and information to frame policy recommendations may be separated from the specific policy debate in the political forum of legislatures. In several parliamentary jurisdictions, contentious bioethical debates are recognised as transcending party politics and party discipline, so that political representatives can exercise independent judgement on a "free" or conscience vote. In other cases, political parties may draw on an articulated "party line" in response to the bioethics policy matter which will shape responses to the interpretation of arguments and concerns from the broader public debate.

According to the big picture bioethics approach, these processes for interpretation and policy formation will be more legitimate and defensible where they provide arguments for the policy direction taken that are responsive to the arguments presented in public debate, where the reasoning is transparent and accountable, and where aspects of the policy that rest on contentious or speculative factual claims are

open to regular review. Our approach points to a need to make the processes of clearly articulating the empirical data and the advice more transparent in legislative processes, and also need to recognize that these are time-sensitive and contextual to resist entrenching outdated values or decisions.

Conclusions and Implications

Big picture bioethics aims at the evaluation of public policymaking processes on the basis of their informed, democratic legitimacy, where (as stated above) a policy is more legitimate if a greater proportion of those affected by the policy are able to view the process that led to that outcome as one allowing their concerns to be articulated and answered, if those who are affected by the policy are able to articulate the reasoning that could justify how the policy process addressed competing views, and if those who were charged with developing policy are able to offer a justification for deciding the policy as they have. Hence legitimacy is clearly a matter of degree, and arises as part of a process (rather than as a simple product); policies will need to be continuously contested and revised in order for a high degree of legitimacy to hold.

We recognise that this kind of democratic legitimacy of bioethics policy may not, in practice, be possible in a given jurisdiction, in relation to a particular area of policy. For example, there remains a question of whether legitimate (in our sense) public policy can be developed in areas where there is ethical "standoff", and particularly where various groups or publics refuse to engage in good faith in deliberation. A similar problem may occur in cases where the public has become "disengaged" following a gap between what the state promised and what it was able to do, resulting in disillusionment (Jasanoff 1997).

However, this question is not only a theoretical one but one that must be considered in light of empirical evidence about a range of policymaking processes examined within their sociopolitical contexts. An advantage of the big picture bioethics approach is that it can allow for this possibility without resorting to the view that policy that does not reach a threshold of legitimacy ("legitimate-enough bioethics policy") is wholly without defence. There may be circumstances where a *modus vivendi* among contested positions can be achieved: this could occur where intractable ethical differences are recognised as being inextricably tied up with specific policy issues (for example, the use of human embryos in research) and that the most defensible policy positions that respond to the greatest range of arguments and concerns raised by lay and expert stakeholders in the public debate cannot bridge these fundamental ethical differences. A *modus vivendi* response may be achieved, which clearly articulates that impasse while articulating a policy approach that has sufficient support to be justifiable (Ivison 2002). Those whose commitments are not adequately addressed within the policy outcome can retain pressure on legislators to respond to their unmet arguments and concerns, rather than being simply silenced by majoritarian democratic process.

This chapter has sketched an approach to evaluating bioethics policies and policy development processes which avoids assumptions about consensus, which are endemic to most of what is said about policymaking processes within liberal democracies that seek to attend to diversity. In addition, the approach favoured is non-substantive in the sense that it does not prescribe a particular moral framework, beyond a commitment to democratic legitimacy. It draws on both empirical information about opinions and values of a variety of publics, and the problematization of that empirical evidence informed by political theoretical debates.

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Chapter 3
Participation and Trust: Conditions and Constraints on Democratic Deliberation

Susan Dodds

Introduction: Publics, Engagement and Participation

In recent years, science policymakers in countries across Europe, and in countries like Canada and Australia have sought to expand the accountability of their policymaking processes through increased public participation, as well as seeking to establish the democratic legitimacy of policy through articulated reasons and arguments, rather than simply aggregating votes or preferences. Processes that ground democratic accountability in public participation in policymaking have paralleled development of deliberative sources of democratic legitimacy. To some degree the two are different sides of the same set of concerns, in seeking to ensure that policymaking on contentious issues that affect a range of publics involves those publics in the policy discussions as participants in the deliberations–both as sources of input and as reasoners about the policy matter.

A fundamental component of any effective deliberative and participatory mechanism is trust—particularly public trust in scientific institutions and government regulators associated with such participatory processes. I argue that because of the epistemic context in which public deliberation about policy concerning emerging and controversial ethical issues occurs, policymakers should take into consideration both lay public and expert contributions to knowledge. The legitimacy of dependence on expert authority in identifying relevant considerations in the debate and in responding to concerns or hopes raised lay publics will depend, in part, on the well-founded trust of those publics in the relevant experts. That trust cannot be secured simply through the constraint of accountability mechanisms on experts. As a result, while public engagement processes *may* contribute to public trust in science and

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policymakers, public involvement in discussions of emerging and controversial issues cannot *create* the conditions for the legitimacy of public policy outcomes that occur in conditions where trust is either absent or unwarranted. Legitimate public deliberation about public policy in this domain depends on a number of conditions, of which a threshold of well-founded trust in policymakers and scientific and technological experts is one essential part.

Public engagement in discussions about appropriate policy concerning emerging and controversial ethical issues, it is argued, promotes democratic values of political reasoning, accountability and non-domination. Public participation does so through drawing publics into understanding of, and reasoning about, matters that may affect wide populations; by challenging the authority of both scientific and regulatory technocrats to provide responses that address the array of articulated public concerns and by reducing the ability of those with greater access to epistemic or material resources to influence public policy on matters that are (or are thought should be) of wider public concern.

Nonetheless, many of the very same people who endorse public engagement as a means of achieving democratic ends are also wary of the misuse of these events, and of the potential that policymakers' enthusiasm for public engagement will be abused or misplaced in the absence of a real commitment to the value of participants' knowledge contribution (Wynne 2006; Irwin 2006; Irwin and Wynne 1996). Brian Wynne, for example, notes the use of a range of public engagement strategies as "moves to 'restore' public trust in science by developing an avowedly two-way, public dialogue with science initiatives" but then shows that, in many cases, the dialogic aspirations of public engagement revert to reliance on a deficit model, namely the view that the public lacks understanding of science and that expert positions, properly understood would be endorsed by publics through the engagement process. He argues that there is as much work to be done to redress the "scientific deficits of understanding of publics" as there has been done to redress the claimed "deficits" in public understanding of science (Wynne 2006, 216). Similarly, where publics engage in deliberation, but they subsequently find that their participation has had no effect on policy or practice (i.e. where the deliberation does not influence decision makers), then the effect on public confidence in the technological and scientific experts and policymakers can be more damaging than in cases when they are given no opportunities to have a voice at all: "in the absence of real influence, the illusion of voice can lead to even greater frustration and disenchantment than having no voice at all" (Delli Carpini et al 2004, 333). Public trust hence can be fostered, abused or lost through public engagement concerning emerging and controversial ethical issues: a critical issue given that trust is vital to any engagement process.

Deliberation, Pragmatism and Democracy

The current political interest in the use of a range of "public talk" processes to secure public support for developments in science and related policy areas parallels a range of developments in democratic theory that emphasise the engagement of

publics in political processes of public reasoning, including works on participatory democracy and republican theory (e.g., Dagger 1997: Young 2000), public justification (Gaus 1996) and deliberative democracy (e.g., Dryzek 2000; Elster 1998; Gutmann and Thompson 1996, 2003; Habermas 1996; Goodin 2003). These theorists share a concern to shift from "mere aggregation" of preferences reflected in voting procedures to a more complex mix of 'talk,' dialogic reason-giving and reflection, expression of the diversity of viewpoints, mutual respect and deliberation on a shared outcome (which need not necessarily be supported by consensus (see Chap. 2 for more on consensus)). Theorists working in this area view deliberative approaches as offering responses to the apparent de-politicisation of the citizenry in advanced capitalist democracies where the expansion of the market has displaced civic engagement. Public participation and direct public accountability are aimed at redressing diminishing trust in public institutions and the demise of the commitment to civic virtue by both citizens and public officials. Deliberative democrats seek to restore legitimacy to democracy by restoring a collectivist notion of the "general will" authorising political authority.

For the political philosopher Jürgen Habermas (1996, 28) the justification of political decisions is founded in the 'procedures and communicative presuppositions of democratic opinion- and will-formation'. Deliberative approaches to democracy emphasize the legitimation of policy that comes from the transformation of interests through processes of

> …collective decision making by all those who will be affected by the decision or their representatives: this is the democratic part. Also…it includes decision making by means of arguments offered by and to participants who are committed to the values of rationality and impartiality: this is the deliberative part (Elster 1998, 8)

Within deliberative approaches to democracy, public engagement or deliberative events play a role in the democratisation of knowledge by demanding that experts give an account of their reasoning and recommendations on policy that, in principle, citizens can endorse (Chambers 2003; Delli Carpini et al 2004). That is, citizens can consent in an informed manner to being subject to the policy because, while they may lack the expertise to judge the technical matters, the reasoning supporting the policy is clear and comprehensible to them, they have been given opportunities to challenge or question the experts on the matter, and the expert reasoning is responsive to the concerns or values that the citizens have expressed as shaping the context within which the policy can be developed if it ultimately has their endorsement.

Noting the fact that actual deliberative processes occur outside of Habermas' "ideal speech" situations, Fishkin argues that such processes exist on a continuum of completeness of reason-giving, of participants' preparedness to consider arguments presented, of available information, and so on related to the legitimacy of deliberative processes, where legitimacy is understood as accountability:

> When arguments offered by some participants go unanswered by others, when information that would be required to understand the force of a claim is absent, or when some citizens are unwilling to weigh some of the arguments in the debate, then the process is less deliberative because it is incomplete in the manner specified. In practical contexts a great deal of incompleteness must be tolerated. (1995, 41 cited in Delli Carpini et al 2004, 317).

Where deliberators are faced with very incomplete processes, then they cannot in principle endorse the reasoning supporting the policy and hence cannot give it their consent.

One source of the "deliberative turn" in political theory is an earlier democratic tradition found in the pragmatism of the late nineteenth and early twentieth century philosophers James, Peirce and particularly Dewey. In short, pragmatic approaches endorse the maxim that "we clarify a hypothesis by identifying its practical consequences" (Hookway 2008). Where policy matters are the subject of inquiry, the identification of practical consequences of hypothetical responses occurs through discussion, consultation, persuasion and debate. Dewey importantly viewed democracy as a form of social inquiry: problem solving through public deliberation (Festenstein 2005). John Gastil sees Dewey's understanding of full deliberation as involving "a careful examination of a problem or issue, the identification of possible solutions, the establishment or reaffirmation of evaluative criteria, and the use of these criteria identifying an optimal solution" (2000, 22). James Bohman notes that for the pragmatists "deliberative democracy must have at least two aspects: not only free and open debate and discussion, but also socially organized deliberation on how best to achieve effective consensual ends" (1999, 590).

On a pragmatist approach, science and democracy require a 'community of inquiry', governed by consensus about norms of evidence. However, given (i) that some expert knowledge may be necessary to achieve the best evidence and optimal solution to a given problem, and (ii) that "no single person, expert or lay, fully understands all of the intricacies of any specific decision" (Bohman 1999, 591), there is a need for an epistemic division of labour, combined with robust processes for public deliberation. This democratic inquiry brings the reasoning of experts into deliberative evaluation alongside lay public values, concerns and understanding of what is at stake in relation to the policy in question: "These processes extend and deepen the public awareness of the problems under discussion, and help to inform the 'administrative specialist' of social needs." (Festenstein 2005). This approach is not technocratic, but relational and accountable to affected publics.

Trust and Epistemology

For the pragmatist, the pursuit of knowledge is inherently social and dialogic: it is through the process of reasoning and testing of reasons in relation to their practical consequences that we are able to make claims of knowledge or claims that a particular hypothesis has been established. Further, because no one is an expert on all matters, knowledge is socially distributed: "If inquiry is democratically organised, then socially distributed knowledge is not represented anywhere but in the group as a whole." (Bohman 1999, 594). Pragmatists hold the view that any individual's claim to knowledge depends on the social distribution of expertise and the public testing of knowledge claims. As a result, each individual must rely on the effectiveness of

the social norms of reasoning and the accountability of experts in forging their own interests based on that knowledge.

This requisite reliance raises the problem of *trust* in large and complex societies (Bohman 1999, 592). According to Bohman, there is a tension between the epistemic efficiency of relying on the authority of experts and the democratic value of public inquiry by citizens to determine the terms of social cooperation, which is best understood as a between the quality of political decisions and their legitimate authority (see Estlund 2008). Bohman argues that the tension can be resolved through democratic deliberative processes that address the *credibility* of expert authority and the *legitimacy* of norms of cooperation between expert and lay publics. Trust in expert claims to knowledge hence is democratic where two conditions are filled: "It must establish free and open interchange between experts and the lay public and discover ways of resolving recurrent cooperative conflicts about the nature and distribution of social knowledge" (1999, 592).

Justified trust in experts, then, is not blind acceptance of the epistemic authority of the scientist or technologists. Rather, it is a trust founded in a critical evaluation of the norms and institutions that support the claims of expertise; deference to the authority of the expert is democratically justified where the claim to expertise on the issue is acceptable to citizens who are engaged in the project of social cooperation.

Scepticism about whether trust in expert authority is warranted is found in Irwin's calls for critical public scrutiny of scientific expertise and for experts to engage in open debate about the value and risks of relevant scientific developments so that citizen-deliberators are in a position to weigh the merits of the scientific arguments for themselves (1995). Similarly, deliberative democracy theorist, John Dryzek argues that an effective citizen voice in economic and technological developments requires a citizenry that is appropriately circumspect in its response to the authority of experts, and that the citizenry withhold trust where they have reason to doubt that it is well placed:

> …distrust of experts does not mean that everyone has to become an expert. Instead, it can mean approaching expert testimony with a sceptical attitude, perhaps questioning the credentials of experts, seeking corroboration for any contentious claim, refusing to believe an expert if his or her research is funded by the offending industry, or if his or her record indicates an axe to grind. (2000, 165)

The authority of experts in democratic deliberation depends on their abilities to foster and secure well-founded public trust through their demonstrated accountability for the positions they defend in democratic deliberative fora (cf Jasanoff 2005). However, scepticism about the trustworthiness of experts reflected in Irwin's and Dryzek's arguments suggests that deliberative public reasoning may ultimately fail in the absence of pre-existing confidence in information providers, policymakers and other relevant experts.

Trust and Hope as Conditions for Effective Deliberation

In the previous section I argued that the democratic legitimacy of policy decisions reached through deliberation depends, in part, on the accountability of deliberators and policymakers to the concerns of citizens and in the use of expertise to determine public policy. However, the prospect that deliberators, and especially experts, will be held accountable for their advice is not sufficient to protect citizens against the social and political domination of experts, nor is it sufficient to ensure the legitimacy of policy based on deliberation governed by norms of accountability. The absence of trust between deliberators and experts or policymakers can threaten the effectiveness of deliberative processes' abilities to elicit knowledge and understanding: it can threaten the accountability of experts or policymakers in responding to the concerns and arguments of participants. Lack of trust can, therefore, threaten the legitimacy of any policy outcome generated by the deliberative process.

Citizens who believe that they are vulnerable to domination or subordination through expert claims to knowledge may withhold their willingness to participate as true democratic deliberators, because they anticipate that they will not experience the social distribution of knowledge necessary for fostering a deliberative democratic process. As a result, such citizens will not endorse the outcome of the (supposedly) deliberative process as legitimate. Further, citizens who distrust policymakers to make policy that is respectful of the values and concerns of the citizenry may withhold their contribution to the deliberative process, refusing to offer up their values, interests and concerns to the test of public reasoning if they lack trust in the overall process. In this case, the policy deliberations will lack relevant information against which to evaluate and test policy alternatives and will fail to respond to the actual interests and concerns of the citizenry. Because participation in any deliberative process requires participants (especially those who are already most vulnerable to being affected by the results of a proposed policy outcome) to make themselves vulnerable to the democratic process, democratic participation requires the trust of deliberators in the deliberative process as a precondition in order to effectively engage their reason and to be politically legitimate.

A further level of complexity arises from the reflexive nature of trust and the multipartite nature of public policy deliberation about emerging and controversial technological and scientific issues. In order for a deliberative process to successfully engage the reasoning of all parties, a diverse range of members of the lay public need to hold a threshold of trust in the experts who interpret the significance of issues and concerns raised by the public in response to expert knowledge regarding a particular policy decision; and they must have sufficient trust in policymakers to use the interpreted information which they have contributed to the policy deliberations in a manner that will not harm the interests of lay public. Further, in order to be able to understand themselves as able to participate effectively as citizens in contributing to the deliberation, lay participants need to have a level of self-trust and self-respect (Anderson and Honneth 2005). In other words they must have confidence in themselves as being about to make good judgements about matters of

relevance to them and also that they believe their judgements on these matters merit consideration by other deliberators/citizens. Similarly, in order for experts to be able to faithfully interpret and engage with the lay publics' reasoning and concerns, they need to trust and respect participants, and in order to faithfully reflect that input in policy deliberations, they also need to place trust in policymakers to use their findings appropriately. Experts also need to have the self-trust in the form of confidence in their own judgements and self-confidence regarding their knowledge and interpretation of the matters under debate. Policymakers similarly need to trust lay participants, experts and their own authority and political expertise in order for the deliberative process to be effective.

But then what precisely is trust, and how is warranted trust to be ascertained? At the interpersonal rather than institutional level, "trust is an attitude that we have towards people whom we hope will be trustworthy, where trustworthiness is a property, not an attitude" (Macleod 2006). Trust requires that the person who trusts (the truster) accepts her vulnerability to the person trusted (the trustee), because the trustee might not 'pull through' for the truster. Or, as political theorist Mark Warren puts it, "[t]rust…involves a judgement, however, tacit or habitual, to accept vulnerability to the potential ill will of others by granting them discretionary power over some good" (1999, 311). The attitude of trust is more likely to occur where the truster accepts the risks that trusting entails, including the risk of betrayal; is inclined to expect the best of the trustee; and has a level of confidence in the competence of the trustee (at least with regard to the entrusted realm). According to the philosopher Annette Baier (1994), trust also involves the belief that the trustee is motivated by goodwill towards the truster and, according to Karen Jones (1996) that the trustee is motivated by her awareness that the truster is counting on her. Trust is warranted when the truster is justified in believing (or hoping) that the trustee is trustworthy. However, because trust invariably involves vulnerability, trust must be extended beyond cases where the truster has sufficient evidence of trustworthiness to guarantee that trust is warranted (I don't have to trust you when I am certain that you cannot betray my trust; I must trust you when I can't force you to make good on my trust). Hence Victoria McGeer describes *substantive trust* (or what Trudi Govier 1997 refers to as *thick trust*) as trust that has two related features:

> (1) it involves making or maintaining judgements about others, or about what our behaviour should be towards them that go beyond what the evidence supports; and (2) it renounces the very process of weighing whatever evidence there is in a cool, disengaged and purportedly objective way. (2008, 240)

For McGeer the challenge is to explain why substantive trust can be rational. She argues that substantive trust is rational in so far as our hopes for the trustee provide a kind of active affective scaffolding that brings out from the trustee the hoped-for actions:

> [I]n trusting others and so hoping for their trust-responsive care and competence, we ask something substantial of them. … [B]y way of such hopeful scaffolding, we also give trusted others something substantial in return—namely, a motivationally energizing vision of what they can do or be. (2008, 249)

For McGeer,

> our hopeful investment of trust in others can often elicit—or, better, empower—trust-responsive behaviour of the sort we seek: namely, acts and attitudes on the part of trustees that live up to our hopeful vision of what they can do and be, particularly with regard to showing competence and care in the domain in which we trust them. (2008, 250)

Thus, in the interpersonal case, trust is supported by the capacity for our hopeful investment in others to give trustees the agential capacity to "pull through" for us. While such optimism in the capacities and motivations of others can be misplaced or disappointed, it can also draw out of trustees the best that they can be and can justify the trust of truster.

Trust and distrust do not cover the range of attitudes that people can have to one another or to institutions and experts. The absence of trust does not necessarily imply distrust. Disinterest may frequently characterise our attitudes to those who we neither trust nor distrust, where those people are not in a position to harm our interests and where we are unlikely to be reliant on them. Distrust shares some characteristics with trust: it is the attitude that we have towards those who we fear are untrustworthy; it is resilient (once our trust is lost it is hard to regain); it often extends beyond evidence of untrustworthiness; it is shaped by knowledge and experience; and it is an attitude that shapes our epistemic uptake of the claims of the person who is distrusted (McGeer 2008; Govier 1997; Warren 1999). When an individual has come to distrust another, especially where their distrust is substantive, distrust is particularly resilient. It is for this reason that one cannot assume that deliberative democratic processes, even where accountable and respectful of participants' knowledge and understanding, will foster sufficient trust amongst participants who have become distrustful. Where participants lack trust in the deliberative process, the policy outcome of that process will also lack legitimacy.

So, how much does this analysis of the interpersonal case help us to assess the rationality of trust in collectives or institutions? As Russell Hardin notes, modern political communities are too complex for citizens' trust in governments to be warranted most of the time. "In general, citizens cannot know enough of what they must know in order to be able to trust government." (Hardin 1999, 23). Our inclinations to trust systems or institutions (rather than individuals) depends on a number of additional factors, including our social circumstances and those of the institution or system, the number and diversity of sources of knowledge about the matter being entrusted and the institution's or system's reliability, the systems of accountability that frame the institution or system's authority and the degree to which we believe that the institutional systems of accountability are framed so as to protect or promote our interests (see Govier 1997). Not surprisingly, members of groups that have had previous negative or prejudicial experience of social systems or institutions typically feel most vulnerable to those institutions and are least likely to invest their future trust in those systems, even when the individuals who represent the institutions in principle are trustworthy, motivated by concern and care for others, and are accountable, competent and reliable. Fostering trust in public institutions takes

more than a few trustworthy individuals, it takes evidence of the trustworthiness of the institutional system and its processes of accountability.

Conclusion

Creating the conditions for democratic legitimacy through public participation requires more than the establishment of deliberative decision making processes that engage publics. Those who have touted the value of public participation as a means of generating public trust in science or policymaking more generally arguably have grasped the wrong end of the stick. This essay has argue that public participation in deliberative democratic decision making as a means of legitimating policy outcomes depends on there being warranted substantive trust in the democratic institutions that invite public deliberation present before such deliberation begins. As Warren notes, it is easier to recognise trust and deliberative decision-making as complementary to democratic theory than it is to establish that political deliberation I and of itself produces public trust (1999, 340) Opportunities for robust public reasoning can contribute to the level of institutional trust over time if they are properly handled to respectfully honour the trust of participants. However, such processes of public engagement and reasoning cannot themselves generate trust where trust is already limited or absence. In fact as has been shown, such processes may serve to erode already faltering public trust, and hence it is necessary to pay attention in advance to pre-existing levels of public trust, low levels of which may make attempts at public participation highly ineffectual.

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Chapter 4
Conscience Votes in Australia: Deliberation and Representation

Kerry Ross, Susan Dodds, and Rachel A. Ankeny

In Australia, federal parliamentarians are expected to vote according to pre-existing party policy or under instructions from party elites. In rare cases, a party may endorse a 'conscience vote' on a particular bill, freeing members from the obligation to maintain party discipline and allowing them to vote according to their individual 'conscience'. In recent years, conscience votes have been most often granted in Australia in response to highly-contentious ethical policy questions, a shift which began in 1973 with the *Medical Practice Clarification Bill 1973* to decriminalise abortion in the Australian Capital Territory.[1] Between 1973 and 2006, the major political parties allowed their members a conscience vote 17 times, the majority of which can be classified as being about bioethical issues (e.g. euthanasia, access to abortion and embryo research).[2] To date, there has been little critical research that

[1] See Donley Studlar (2001) for a critical international comparison of 'morality politics' as a distinctive area of political study, and Marvin Overby et al. (1998) for a Canadian comparison.

[2] The following is a list of conscience votes in the Australian Federal Parliament since 1973 (this list cannot be verified as being complete since conscience votes are not recorded as such on the Parliamentary record): *New and Permanent Parliament House Motion (as to site) 1973; Medical Practice Clarification Bill 1973; Sexual Relationships – Social educational and legal aspects – Proposed Royal Commission Motion 1973; Death Penalty Abolition Bill 1973; Homosexual Acts and the Criminal Law Motion 1973; Parliament Bill 1974; Family Law Bill 1974; New and*

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evaluates the democratic effects of conscience votes. This paper considers this issue alongside of the increase in numbers of women MPs during this period. We assess the concordance between public opinion and the outcomes of federal Parliamentary conscience votes in the past three decades, showing that there has been more consonance between them in recent years, and that this is likely to be due to the impact of the array of modes of women's participation on matters subject to conscience votes. This is demonstrated through the analysis of six key case studies of ethically-contentious conscience votes from the period under discussion in light of three democratic ideals: accountability, representation and deliberation. To the extent that there is a recent resurgence of interest in democratic ideals within political philosophy, it is worth exploring their manifestations in concrete political practice. (Among the recent works that discuss democratic ideals of accountability, representation and deliberation are: Dryzek 2000; Fishkin 1995; Goodin 2003; Gutmann and Thompson 1996; Mansbridge 2003; Sandel 2005; Young 2000).

Background

A conscience vote, or a 'free' vote as it is sometimes known, occurs on a Bill, Motion or Report either because a party does not have a policy position on an issue or because the party decides that members should be 'permitted to exercise their responsibility in accordance with conscience' (Harris 2001, 277). In such cases '… members are not obliged by the parties to follow a party line, but vote according to their own moral, political, religious, or social beliefs' (Penguin 1988, 86). In most cases, in the Australian Federal Parliament, conscience votes are granted in both the House of Representatives and the Senate, and the three major parties (Australian Labor Party [ALP], the Liberal Party [Liberal] and the National Party [NPA]) each grant a conscience vote on the same issue. In some cases, a single party will permit a conscience vote: the *Death Penalty Abolition Bill 1973* and the *Sex Discrimination Bill 1984* are two examples where only one party allowed their members a conscience vote (See McKeown and Lundie 2002 for additional examples). Anyone may call or lobby for a conscience vote to be permitted by a party; the final decision

Permanent Parliament House Motion 1974; Termination of Pregnancy – Medical Benefits Motion 1979; Family Law Amendment Bill 1983; Sex Discrimination Bill 1984; Procedure Committee Motion 1987; Euthanasia Laws Bill 1996; Constitution Alteration (Establishment of Republic) Bill 1999; Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (this Bill was split to become the *Research Involving Human Embryos Bill 2002* and *Prohibition of Human Cloning Bill 2002* due to the distinct nature of these two issues; the former Bill was then subject to a conscience vote by all parties whereas the latter was decided through the usual practice of voting according to party policy); *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005 (2006); Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* (list up to 2002 from McKeown and Lundie 2002 and Harris 2005: 280–1, with additions taken from Commonwealth Parliament 2006, Bills list).

usually rests with the party leader, informed by the party caucus (McKeown and Lundie 2002). There are no formal party policies in relation to conscience votes.

Allowing a conscience vote is a pragmatic way of addressing divisive policy questions. In most cases a conscience vote is allowed to accommodate diverse moral or ethical views within the party, as a conscience vote is preferable to members voting against party policy and 'crossing the floor'. In other cases a party may endorse a conscience vote and challenge other parties to do likewise to reveal disunity within the opposing party (McKeown and Lundie 2002; Jaensch 2002). Allowing a conscience vote may also distance a party from community backlash on controversial issues as 'a party can stand back and claim no responsibility for decisions on social issues which may have electoral implications' (Jaensch 1996, 172). In the cases discussed in this paper, for example, it is arguable that the contentiousness of the issues arises not so much from the ethical debates at their heart, but from the political potential for religious concerns (relating to sanctity of life or the moral status of the human embryo or fetus) to influence party policy relating to health, choice and welfare. In the absence of a conscience vote on an ethically-charged issue, individual parliamentarians may choose to cast a vote as a matter of conscience without party endorsement and against party policy by 'crossing the floor' during a division to vote with the opposing side. Defying party policy in this way is thought to indicate a politician's moral rebuke of party policy and rarely occurs in the Australian Federal Parliament due to strong party discipline.

A second procedural device for allowing parliamentarians to express views that fall outside Party policy is the private Member's or Senator's bill. The device of allowing individual parliamentarians to introduce a bill as a private Member's (in the House of Representatives) or private Senator's bill (in the Senate) allows a similar degree of freedom from the 'party machine' without directly challenging party policy. Typically, private Member's or Senator's bills are introduced to provoke a review of a law, or to allow parliamentarians to take a largely symbolic stand on an issue that may be of particular interest to their electorate. Very few private Member's or Senator's bills introduced by parliamentarians who are members of the governing party succeed in being debated.

Conscience votes are rarely granted when a party has a strong policy stance on the issue. Aside from matters of procedure, conscience votes have been granted in relation to issues of personal morality such as abortion, euthanasia, homosexuality and gambling; issues subject to the moral authority of the state such as capital punishment and war crimes; and issues that encompass elements of both these categories such as family law, drug reform, *in vitro* fertilisation (IVF) and biotechnology-related medical research (Warhurst 2008). Not all legislation related to ethically difficult questions has been subject to a conscience vote, despite sometimes heavy lobbying from party members or the public. Recent examples include the refusals of John Howard's government to allow a conscience vote on the decision to go to war in Iraq (Oakes 2006) and in relation to legislation to disallow access to IVF for single or lesbian women (Zinn 2002).

During the period 1950–2004, there were 439 instances in which parliamentarians crossed the floor, of which 63 % were Liberal Party Members, 26 % were NPA

Members and only 11 % were ALP Members (McKeown and Lundie 2005). The most notable shift in terms of parliamentarians crossing the floor has occurred within the Liberal/NPA coalition which held power until 2007. Only four parliamentarians crossed the floor in Howard's first 7 years of office (1996–2003) compared to 31 in the 7 years of the previous coalition government under Malcolm Fraser (1975–1983) (Hudson 2003). Diminishing the scope for parliamentarians to cross the floor may well have contributed to the increased significance of conscience votes in recent years as a response to diverse moral and ethical views within the coalition (Warhurst 2008).

Case Studies

The following case studies were selected as key examples of the legislative processes in relation to ethically-contentious areas of public policy. Where possible, public opinion data was drawn from various published polls generally accepted as valid sources of public views.

Medical Practice Clarification Bill 1973

In the late 1960s and early 1970s, abortion was the subject of divisive public debate in Australia as women's groups lobbied for liberalisation of abortion laws. Public opinion was wide-ranging, with a 1973 McNair Anderson poll showing that up to 83 % of Australians believed that abortion should be legalised under some circumstances (Betts 2004).[3] These figures are consistent with a poll taken in Sydney by the Women's Electoral Lobby, which found that 80 % of the public (2000 respondents) supported liberalisation of abortion (Anonymous 1973b).

In the lead-up to the 1972 Federal election, the coalition Prime Minister William McMahon used the abortion issue to destabilise the campaign of the ALP leader Gough Whitlam. Having indicated his personal support for liberalisation of abortion law, but refusing to adopt it as ALP policy, Whitlam sought to deflect anti-abortion sentiment and appease the pro-abortion lobby by agreeing to a conscience vote on the issue if he were elected and promising a private Member's bill would be introduced into Parliament (Lilburn 2000; Coleman 1988). Whitlam was elected Prime Minister on 5 December 1972 and some months later the *Medical Practice*

[3] McNair Anderson Poll (1973): Question: 'Which (of these responses) comes closest to your opinion? Abortion should be legal:…In all circumstances, that is, "abortion on demand" [response rate: 23 %]; In cases of exceptional hardship, either physical, mental or social [20 %]; If the mother's health, either physical or mental, is in danger [21 %]; Only if the mother's life is in serious danger [19 %]; Abortion should not be legal in any circumstances [13 %]; No opinion/no response [4 %].' (Betts 2004).

Clarification Bill 1973 was introduced as a private Members' bill by the ALP's David McKenzie and Tony Lamb. The Bill sought to decriminalise abortion in the Australian Capital Territory, which legislatively is under the control of the Federal Government. (Papua New Guinea and the Northern Territory (the only other territory on the Australian mainland) were also included in an earlier draft of the Bill but were deleted by amendment during the passage of the Bill through the Parliament (Jones 1973).)

In Parliament, 207 petitions were tabled, most of them opposing the Bill, with the Speaker at the time commenting that it was, to his knowledge, the greatest number of petitions tabled on a single issue since Federation (Anonymous 1973a). The Bill was debated in the House of Representatives by an all-male parliament and was defeated on 10 May 1973, 98 votes to 23 (House Votes and Proceedings 1973–1974 24, 171). Reflecting on the vote some years later, Susan Ryan (1992) wrote: 'The debate was conducted in an all male chamber, the women were outside rallying, organising, shouting through loud hailers, preparing for disappointment. I decided that next time we should be in there making the laws.'

This conscience vote raises a number of key issues. Between 1901 and 1973 there had only been three women MPs in the House of Representatives and seven women in the Senate, and in 1973 there were no women in the Australian Federal Parliament. In the decades after the 1970s, the number of women parliamentarians increased sharply (Sawer 2003); the outcomes of conscience votes reflect this trend (see Table 4.1). The use of a private Member's bill to spark a conscience vote is also significant. Karen Coleman (1988, 77) writes that when particularly divisive issues such as abortion demand political action, a private Member's bill 'can be employed in an attempt to shield the party from overt identification with the measure.' Lastly, this Bill provides an example of how a political party can distort the intent of a conscience vote for political gain. In late December 1972, the defeated McMahon stated that the Liberal Party would determine their vote on this issue in the party room and not in the parliament (Lilburn 2000). According to the record, however, both the ALP and the Liberal Party indicated that their members were allowed a conscience vote when the Bill came before the Parliament in early 1973. Yet McMahon's earlier comment appears to have held sway, as all Opposition members voted against the bill. Coleman (1988, 82–83) writes: 'Certainly for the Opposition, voting on the bill was not a reflection of individual positions on the question…rather by showing a unified front, they were concerned to highlight dissension within the Labor party over abortion.'

This Bill provides a clear example of how party members sometimes vote along *de facto* party lines in a conscience vote. It is notable however that there has not been a repeat of such a clear example of political allegiances uniformly shaping a supposedly 'free' vote, as will be seen in the case studies below.

Table 4.1 Conscience votes in Australia 1973–2006

Medical practice clarification bill 1973

	Total votes			Men			Women			Public opinion polls
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
House of representatives							No women MPs			
ALP	23	40	*63*	23	40	*63*				In favour of some legal access to abortion[a]
Liberal	_	38	*38*	_	38	*38*				
CP	_	20	*20*	_	20	*20*				
Total votes	23	98	*121*	23	98	*121*			0	
% of vote	**19** %	81 %								**80–83** %

Bill defeated

[a]McNair Anderson poll 1973 (cited in Betts 2004)

Sex discrimination bill 1984

	Total votes			Men			Women			Public opinion polls
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
Senate										
ALP[a]	24	_	*24*	18	_	*18*	6	_	*6*	
Liberal	11	8	*19*	8	7	*15*	3	1	*4*	
NPA	_	4	*4*	_	4	*4*	_	_	_	
AD	5	_	*5*	4	_	*4*	1	_	*1*	
Total votes	40	12	*52*	30	11	*41*	10	1	*11*	
% of vote	77 %	23 %		**73** %	27 %		**91** %	9 %		
House of representatives										
ALP[a]	67	_	*67*	61	_	*61*	6	_	*6*	No relevant polls available[b]
Liberal	17	14	*31*	17	14	*31*	_	_	_	
NPA	2	12	*14*	2	12	*14*	_	_	_	
Total votes	86	26	*112*	80	26	*106*	6	_	*6*	
% of vote	77 %	23 %		**75** %	25 %		**100** %	0		

[a]No Conscience vote for ALP

[b]See Gallup Poll 1982 for closest comparison

Euthanasia laws bill 1996

	Total votes			Women			Men			Public opinion polls
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
House of representatives										
ALP	22	21	*43*	21	18	*39*	1	3	*4*	
Liberal	53	11	*64*	40	9	*49*	13	2	*15*	
NPA	11	2	*13*	11	2	*13*	_	_	_	

(continued)

Table 4.1 (continued)

Euthanasia laws bill 1996										
	Total votes			Women			Men			Public opinion polls
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
Ind	2	1	*3*	2	1	*3*	_	_	_	
Total	88	35	*123*	74	30	*104*	14	5	*19*	
% of vote	72 %	28 %		71 %	**29** %		74 %	**26** %		
Senate										
ALP	9	18	*27*	6	12	*18*	3	6	*9*	Support law reform to allow euthanasia [a] [Against the bill]
Liberal	21	6	*27*	17	2	*19*	4	4	*8*	
NPA	5	1	*6*	5	1	*6*	_	_	_	
AD	1	6	*7*	1	1	*2*	_	5	*5*	
Green	_	2	*2*	_	1	*1*	_	1	*1*	
Ind	2	_	*2*	2	_	*2*	_	_	_	
Total	38	33	*71*	31	17	*48*	7	16	*23*	
% of vote	54 %	46 %		65 %	**35** %		30 %	**70** %		**60–80** %

[a]Newspoll (1995–1996)

2002 Research involving human embryos bill										
	Total votes			Men			Women			*Public opinion polls*
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
House of representatives										
ALP	53	6	*59*	35	6	*41*	18	_	*18*	
Liberal	39	18	*57*	31	14	*45*	8	4	*12*	
NPA	6	6	*12*	5	5	*10*	1	1	*2*	
CLP	1	_	*1*	1	_	*1*	_	_	_	
Ind	_	3	*3*	_	3	*3*	_	_	_	
Total	99	33	*132*	72	28	*100*	27	5	*32*	
% of vote	75 %	25 %		**72** %	28 %		**84** %	16 %		
Senate										
ALP	20	8	*28*	11	6	*17*	9	2	*11*	
Liberal	15	11	*26*	8	10	*18*	7	1	*8*	
NPA	_	3	*3*	_	3	*3*	_	_	_	
CLP	1	_	*1*	1	_	*1*	_	_	_	
AD	7	_	*7*	5	_	*5*	2	_	*2*	
Green	1	1	*2*	_	1	*1*	1	_	*1*	Support use of excess embryos in research[a]
Ind	1	2	*3*	_	2	*2*	1	_	*1*	
PHON	_	1	*1*	_	1	*1*	_	_	_	
Total	45	26	*71*	25	23	*48*	20	3	*23*	
% of vote	63 %	37 %		**52** %	48 %		**87** %	13 %		**70** %

[a]Morgan Poll (2001)

(continued)

Table 4.1 (continued)

Therapeutic goods amendment (Repeal of ministerial responsibility) bill 2005 (2006)

	Total votes			Men			Women			*Public opinion polls*
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
Senate										
ALP	21	7	*28*	10	5	*15*	11	2	*13*	
Liberal	14	17	*31*	7	16	*23*	7	1	*8*	
NPA	1	3	*4*	_	3	*3*	1		*1*	
CLP	1	_	*1*	1	_	*1*	_	_	_	
AD	4	_	*4*	2	_	*2*	2	_	*2*	
Green	4	_	*4*	1	_	*1*	3	_	*3*	
Family First	_	1	*1*	_	1	*1*	_	_	_	
Total	45	28	*73*	21	25	*46*	24	3	*27*	
% of vote	62 %	38 %		**46 %**	54 %		**89** %	11 %		
House of representatives[a]										
ALP	54	5	*59*	34	5	*39*	20	_	*20*	
Liberal	37	35	*72*	29	29	*58*	8	6	*14*	Support women's access to the 'abortion pill'[b]
NPA	3	8	*11*	2	7	*9*	1	1	*2*	
CLP	_	1	*1*	_	1	*1*	_	_	_	
Ind	1	1	*2*	1	1	*2*	_	_	_	
Total	95	50	*145*	66	43	*109*	29	7	*36*	
% of vote	66 %	34 %		**61** %	39 %		**81** %	19 %		**68** %

[a]No formal final (third) vote on Bill – numbers are taken from second reading vote and are thus indicative only

[b]Morgan Poll (2006a)

Prohibition of human cloning for reproduction and the regulation of human embryo research bill (2006)

	Total votes			Men			Women			*Public opinion polls*
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
Senate										
ALP	17	8	*25*	7	5	*12*	10	3	*13*	
Liberal	10	19	*29*	4	17	*21*	6	1	*7*	
NPA	_	3	*3*	_	4	*4*	_	_	_	
CLP	_	1	*1*	_	1	*1*	_	_	_	
AD	4	_	*4*	2	_	*2*	2	_	*2*	
Green	3	_	*3*	1	_	*1*	2	_	*2*	
Family first	_	1	*1*	_	1	*1*	_	_	_	
Total	34	32	*66*	14	28	*42*	20	4	*24*	
% of vote	52 %	48 %		**33** %	67 %		**83** %	17 %		

(continued)

Table 4.1 (continued)

Prohibition of human cloning for reproduction and the regulation of human embryo research bill (2006)

	Total votes			Men			Women			*Public opinion polls*
	For	Against	*N*	For	Against	*N*	For	Against	*N*	
House of representatives[a]										
ALP	43	15	*58*	25	13	*38*	18	2	*20*	Support use of human embryos in stem cell research; Support cloning for research purposes[b]
Liberal	38	33	*71*	28	28	*56*	10	5	*15*	
NPA	1	11	*12*	1	11	*12*	_	_	_	
Ind	_	3	*3*	_	1	*1*	_	2	*2*	
Total	82	62	*144*	54	53	*107*	28	9	*37*	
% of vote	57 %	43 %		**50** %	50 %		**76** %	24 %		**58–80 %**

[a]No formal final (third) vote on Bill – numbers are taken from second reading vote and are thus indicative only

[b]Morgan Poll (2006b) and Research Australia (2006)

AD Australian Democrats, *ALP* Australian Labor Party, *CLP* Country Liberal Party, *CP* Australian Country Party, *Family First* Family First Party, *Green* Australian Greens, *Ind* Independent (no party affiliation), *Liberal* Liberal Party of Australia, *NPA* National Party of Australia, *PHON* Pauline Hanson's One Nation Party

Euthanasia Laws Bill 1996 – Private Member's Bill

On 25 May 1995, the Northern Territory (NT) passed the *Rights of the Terminally Ill Act 1995* making it the first place in the world to legalise voluntary euthanasia. The legislation caused intense public debate both within Australia and internationally, and a range of special interest groups mobilised in response (Cica 1996–1997). The law survived a number of challenges in the NT Legislature and the Supreme Court; however, under the Australian constitution, the Federal Government has the power to overturn territory law. In September 1996 a private Member's bill, the *Euthanasia Laws Bill 1996*, was introduced in to the Commonwealth parliament by Liberal MP Kevin Andrews with the intent to override (and thus repeal) the NT's *Rights of the Terminally Ill Act 1995*. The Bill was overwhelmingly supported in the House of Representatives and passed on 9 December 1996 (HVP 1996 58, 998), 88 votes to 35. The voting was much closer in the Senate where the Bill passed on 24 March 1997, 38 votes to 33 (SJ 1997 92, 1740).

Although the ALP and the coalition parties (Liberal and NPA) allowed their members a conscience vote on this Bill, it is telling that each leader (Liberal Prime Minister John Howard, NPA Tim Fischer and ALP Kim Beazley) indicated their

opposition to euthanasia and their support for the Bill repealing the NT Act. Howard's support was such that the Bill was included in an already overburdened Parliamentary schedule. One coalition member who opposed the bill criticised the move: 'It was an extraordinary thing to do, Howard coming out like that had more impact than any other single thing during the debate. It put so many people under pressure to fall into line that it really wasn't a conscience vote' (Brough 1997). Whether due to their more conservative social views or to the pressure they felt to follow the party line, coalition members were generally far more supportive of the Bill than their ALP counterparts in both the Senate and the House of Representatives.

The parliamentary decision to overturn the NT Act was at odds with the views expressed within the Australian community. Newspaper reports at the time consistently showed that 70–80 % of the public supported legislative change to allow voluntary euthanasia (Contractor 1997; Dodd 1997) and a nationwide NewsPoll showed public opinion was 79 % in favour of euthanasia in 1995 and 63 % in 1996.[4] The outcome of the conscience vote indicates that women parliamentarians were more inclined to support the NT euthanasia Act in line with public sentiment (see Table 4.1). An academic study on the euthanasia Bill suggests that there had been more women parliamentarians, the outcome of the Bill would have been different, particularly in the Senate, even though this was not a 'women's issue' per se. Together with the unique style of deliberation women brought to the parliamentary debate, the authors suggest that '…the sexual integration of our political institutions is fostering greater overall representation of a "different voice"' (Broughton and Palmieri 1999, 43).

However, they also caution that given the under-representation of women in the Parliament, women's voices, under normal parliamentary practice, are often overwhelmed by the male-dominated party line. Thus conscience votes can be viewed as providing an important forum for more representative policymaking as they largely remove the everyday political barriers faced by women parliamentarians so that '… women's distinctive contribution may then be heard' (Broughton and Palmieri 1999, 30). It could be that women parliamentarians were influenced by constitutional concerns and Territory powers. However, an alternative interpretation of this episode supported by the evidence is that where women parliamentarians are freed from the demands of party solidarity, they are better able to vote in a manner that reflects the diversity of views held by Australians.

[4]The decline in 1996 may reflect the wording of the question that mentions 'lethal injection.' NewsPoll (1995 and 1996) Question: 'Thinking now about euthanasia where a doctor complies with the wishes of a dying patient to have his or her life ended. Are you personally in favour or against changing the law to allow doctors to comply with the wishes of a dying patient to end his or her life?' Strongly in favour 61 %; Partly in favour 18 %; Partly against 3 %; Strongly against 12 %; Don't know 6 %. NewsPoll (1996) Question: 'And are you personally in favour or against changing the law to allow doctors to perform active euthanasia, for example, by giving a patient a lethal injection?' Strongly in favour 39 %; Partly in favour 24 %; Partly against 11 %; Strongly against 17 %; Uncommitted 9 %.

Research Involving Embryos and Prohibition of Human Cloning Bill 2002

A national debate over the use of embryos for research purposes was triggered by the release of a House of Representatives Inquiry in 2001 (Andrews Report 2001). This Inquiry, in part, was spurred by developments in human embryonic stem cell research and reports of the cloning of Dolly the sheep. The majority recommendations (6:4) of the Inquiry supported research on surplus IVF embryos created before 5 April 2002 but called for a ban on reproductive cloning and a three-year moratorium on therapeutic cloning (cloning for research purposes). At this time, only three States regulated embryo research by law. The Federal government saw these recommendations as an opportunity to enact Federal legislation to provide nationally consistent regulation (MacDonald 2003). The *Research Involving Embryos and Prohibition of Human Cloning Bill 2002* was introduced into the House of Representatives in June of 2002 by Prime Minister Howard. After some debate, the Bill was split in two, allowing MPs the opportunity to vote against human cloning but in favour of embryo research. The subsequent *Research Involving Embryos Bill 2002* was overwhelmingly passed in the House of Representatives on 25 September 2002, 99 votes to 33 (HVP 2002 48, 455). The Bill passed through the Senate on 5 December 2002, 45 votes to 26, the government having limited discussion and ordered its members to vote after 47 h of debate (SJ 2002 56, 1218; Metherell 2002).

All political parties allowed members a conscience vote on this Bill, although each party leader indicated his private view prior to the vote. Views were particularly divided among senior members of the coalition (MacDonald 2003, 26). However as one reporter noted, Howard's decision to introduce the Bill personally was 'a blow to opponents of the Bill as it signal[led] the strength of his conviction' (Tingle 2002). ALP leader Simon Crean went so far as to state that it was ALP policy to support the use of excess embryos for research but he nonetheless allowed a conscience vote to 'respect the individual position that some of our colleagues have' (MacDonald 2003, 26).

According to an opinion poll taken in November 2001, the Australian community supported legislative moves to support licensed embryo research, with 70 % of respondents approving the use of excess embryos for research purposes. The same poll showed that 55 % of Australians also supported 'therapeutic cloning', or cloning to create embryos for research (Morgan Poll 2001).[5] The views of women

[5] Poll questions: 'Should couples with excess embryos after infertility treatment or IVF be able to choose to donate these embryos for research rather than discard them?' Yes 70 %; No 19 %; Undecided 11 %. 'A very important new avenue for research using human embryos involves taking cells called stem cells from the inside of a five day old embryo. The embryo is no longer capable of further development. Scientists are working on techniques to turn stem cells extracted from an embryo into any type of cells in the body such as nerve cells and muscle cells to treat diseases such as heart disease, Alzheimers, cancer, spinal injuries and many more. Put simply, stem cells can be

parliamentarians were again more in line with public sentiment; overall, the male vote was split 97 to 51 for the Bill, while women were split 47 to 8 for the Bill.[6]

The strong views and debate generated by the Bill suggest that despite criticism from some quarters, particularly over political views being expressed prior to the parliamentary debate, the process more closely followed the intent of a conscience vote than did the previous cases discussed. A paper on the deliberative value of the debate found that

> Allowing a conscience vote in the Federal Parliament has also had the desirable effect of freeing politicians from party discipline and encouraging them to educate themselves about the issues. This is evident in the quality of the parliamentary speeches made on the bill in the House of Representatives. (Hall 2004: 31)

Debates surrounding the 2002 Bills indicate that conscience votes can allow parliamentarians to be moved by the evidence and argument of experts thus enhancing the possibility for democratic deliberation. (However we demonstrate the limitations of the actual deliberation on these bills in Ankeny and Dodds 2008 and Dodds and Ankeny 2006.) What is undisputable in this case (and the euthanasia vote) is that conscience votes on issues relating to reproduction and human life reveal a gender schism and women's parliamentary presence enhances representation.

Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005

In 1996, Independent Senator Brian Harradine introduced a 'restricted goods' amendment during the passage of the *Therapeutic Goods Amendment Bill 1996*. This amendment defined non-surgical abortifacients as a restricted good and shifted the authority for their use from the Therapeutic Goods Administration (TGA) to the Commonwealth Minister for Health, and was supported by the Howard coalition government and the ALP opposition but opposed by the Democrats. Abortifacients subsequently became the only therapeutic goods to be subject to ministerial approval, and the move amounted to a ban on 'abortion pills' such as mifepristone (popularly known as RU486).

By 2005, mifepristone was legal and in widespread use in countries including the United Kingdom, the United States and New Zealand (Buckmaster 2005–2006). In October 2005, the Democrats signalled they would introduce amendments to the upcoming *Therapeutic Goods Amendment Bill 2005* to overturn the Harradine

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extracted from human embryos to be used in the treatment of many diseases and injuries. Do you approve or disapprove?' Approve 70 %; Disapprove 19 %; Undecided 11 %.

[6] Poll question: 'As with any transplant some patients may have problems with their bodies rejecting stem cells. To overcome this, a patient's own genetic material can be inserted into an egg to create an embryo that will be used to extract stem cells. The process is called nuclear transfer or therapeutic cloning. Do you approve or disapprove?' Approve 55 %; Disapprove 32 %; Undecided 13 %.

amendment (Allison 2005). This sparked heated debate particularly within the coalition. The Commonwealth Minister for Health, Tony Abbott, who held strong pro-life views, used the issue to reignite the abortion debate. One female coalition MP threatened to cross the floor if Prime Minister Howard did not allow a conscience vote (Maiden 2005). In early November, the ALP indicated its support for the amendment and the Party caucus voted to allow a conscience vote (Karvelas 2005). In late November with the Bill about to come before Parliament, Howard granted his party a conscience vote but meanwhile asked the Democrats to forgo the amendment and introduce a private Senator's bill (Stafford 2005). In the end it was decided that the proposed amendment to the Bill would be postponed until immediately after a conscience vote on the private Senator's bill which, if carried, would negate the need for the amendment. If the private Senator's bill were to fail, the amendment would then be voted on, with Howard indicating that there would then be no conscience vote allowed for coalition members (AAP 2005).

By 2006, the number of women in Parliament had increased significantly, as they composed 24.7 % of the House of Representatives and 35.5 % of the Senate (Commonwealth Parliament 2006). Broken down into percentage of women per party, it is clear that the major conservative parties lag behind their more progressive counterparts in both houses; Australian Labor Party 33.3 %, Liberals 20 %, National Party 16.7 % in House of Representatives; ALP 36.4 %, LIB 24.2 %, NP 16.6 %, Australian Democrats 50 %, Green 75 % in the Senate. In early 2006 four women Senators (Democrat Lyn Allison, Liberal Judith Troeth, National Fiona Nash, and ALP Claire Moore) co-sponsored a private Senators' bill, the *Therapeutic Goods Amendment (Repeal of Ministerial Responsibility for Approval of RU486) Bill 2005*, to hand authority for the administration of abortifacients back to the TGA. A conscience vote was allowed by all major parties and, after intense lobbying (Peatling 2006a; Polimeni 2006), the Senate voted in favour of the bill, 45 votes to 28, on 9 February 2006 (SJ 2006 71, 1855).

Strikingly, the outcome of the conscience vote in the House of Representatives on 16 February 2006 (HVP 2006 85, 954) was not recorded by a final count, as is the norm. The Bill was passed on a 'voice vote' with one political reporter commenting: 'Howard did not press for a division, a formal vote that would have tallied the scale of the defeat for his and the Health Minister's position' (Hartcher 2006). One Liberal proponent of the Bill, (then) MP Malcolm Turnbull, asked explicitly that his vote be recorded by the speaker but to no avail (Peatling 2006b). Despite the failure to formally count the final vote, the outcome has been reported as roughly 70 % in favour of the Bill. The second vote immediately prior to the third and final vote was 95 in favour to 50 against and the ABC 7.30 Report claimed that 91 of 150 MPs voted in favour of the Bill (ABC 2006). The report did not indicate whether all of the remaining 59 votes were cast, as in some cases MPs are absent from Parliament or choose to abstain from voting for various reasons. In terms of women's votes, one report indicated that all 20 ALP women MPs voted in favour of the Bill with 10 out of 17 Coalition women MPs also casting their vote for the Bill (Summers 2006).

The case of the *Therapeutic Goods Amendment Bill 2005* was striking for reasons other than the disunity it caused in the coalition government. The Bill

highlighted the now significant role of women parliamentarians in policymaking. In the Senate where the vote was recorded, it is clear that the higher proportion of women and the cross party support among them was decisive in the Bill's passage. There may be a number of reasons why women's greater presence in Parliament affected the outcome. Among these is that with an increase in the numbers of women holding seats, there are greater opportunities for women to use conscience votes strategically, on issues that more directly affect the interests of women (such as laws relating to reproductive technology, abortion and embryo research), to maximise the effect of their presence in the legislative process, despite their remaining in a minority. For example, once freed from the constraints of party discipline, women parliamentarians can engage in 'critical acts', directly enjoining the men in their party to attend to the significance of the issues for the lives of women (see Dahlerup 1988 cited in Celis and Childs 2008), or they may be able to work across party lines with women in strategic positions in the other parties to create new coalitions to push for an outcome that alters the culture of the institution (see Kanter 1977, cited in Celis and Childs 2008).

Public opinion polls in relation to the availability of RU486 showed once again that women parliamentarians were more representative of community views. A NewsPoll in January 2006 found that 68 % of Australians approved of its use (Hartcher 2006),[7] and a Morgan Poll in February 2006 supported this with 62 % of Australians polled agreeing that RU486 should be made available to Australian women (Morgan Poll 2006a).[8] Moreover, Senator Nash was quoted as saying that this bill was 'the first time in the history of this place that four members of different parties have co-sponsored a private Senator's bill' (Summers 2006). Inspired by the passage of the Bill through the Senate, Anne Summers echoed the view of a number of women parliamentarians when she wrote, 'Maybe women have finally achieved the critical mass that many have argued was the precondition to women having any real power in Canberra' (Summers 2006).

As Sue Dunlevy (2006) has commented: 'If nothing else, the gender divide on RU486 has proven once and for all that the only way women can truly be represented in parliament is if there are women in Parliament.' Dunlevy identifies five women Senators from five parties involved in the passage of the Bill: in addition to the four Senators who introduced the Bill (Allison, Troeth, Nash and Moore), Senator Kerry Nettle (Greens) worked to ensure the Bill's passage. Dunlevy

[7] ARHA (2006) and NewsPoll (2006). This particular NewsPoll was commissioned by pro-choice group, the Australian Reproductive Health Alliance (ARHA). Question: 'Now thinking about the topic of abortion**.** Abortion is already available in Australia using surgical methods. However there is a drug called RU486 which can be used by doctors to terminate a pregnancy, without surgery, within the early stages. Would you personally be in favour, or against RU486 being made available in Australia for use by qualified medical practitioners?' In favour 68 %, Against 21 %, Neither/don't' know 9 %, Refused 2 %.

[8] Poll question 'Now thinking about the "Abortion Pill". There is currently a proposal to introduce the drug RU486, also known as the "Abortion Pill", into Australia. Do you think the "Abortion Pill" should be made available to Australian women, or not?' Yes, make available 62 %; No, not make available 31 %; Can't say 7 %.

foreshadowed that this shift may have a significant impact on future policymaking as women unite to agitate for legislative change in the Parliament.

> Fired up by their unity on the abortion drug, the five women senators [from the five key parties] suggested this may just be the beginning of a new form of women's politics. The same day these women took a public stand on RU486, Prime Minister John Howard faced a mini-revolt in his own party room over another women's issues–childcare. (Dunlevy 2006)

Although this Bill was a particularly complicated one, representing a mixture of Constitutional, procedural and bioethical issues, it heralded a shift in gender politics among the sitting parliamentarians, as was reflected in the events surrounding the legislative responses to the Lockhart Review report on embryo research later in 2006.

Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006

In December 2005, the report of the Legislation Review Committee (LRC) on the *Prohibition of Human Cloning Act 2002* and the *Research Involving Human Embryos Act 2002* was tabled, reigniting the embryo research debate in Australia. The report, which became known as the Lockhart Review after its Chair, the former Federal Court Judge the Hon John Lockhart AO, was commissioned 'to consider and report on the scope and operation of each of the Acts' (Senate Committee Report 2006) and to make appropriate recommendations on the future direction of human embryonic stem cell research and cloning for research purposes in Australia. The major parties (including the coalition) announced that they would permit conscience votes on any legislative changes that might be proposed.

A draft bill incorporating all of the LRC recommendations was subsequently tabled for discussion by Democrat Senator Natasha Stott Despoja and Labor Senator Ruth Webber. Subsequently, a more conservative bill, the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006* was introduced as a private Senator's Bill by Liberal Senator Kay Patterson on 19 October 2006. The process leading to the passage of the Bill was another example of cross-party cooperation among female parliamentarians in relation to ethically-contentious policy. Public and Parliamentary debate on the Bill centred on proposals in support of the creation of human embryos for research using somatic cell nuclear transfer (SCNT) and creation of human-animal chimeras, all of which were allowed under the proposed Bill in accordance with the recommendations of the LRC (Ankeny and Dodds 2008). Limits imposed on research under the Bill (again in line with the LRC recommendations) included strict prohibitions on the implantation of cloned embryos into a woman and on allowing cloned embryos to develop beyond 14 days. Following amendments (including removal of

permissibility of chimera research), the Bill passed through Senate on 7 November 2006 in a close conscience vote, 34 in favour and 32 against (SJ 2006 115, 3009). As with the RU486 Bill, the final conscience vote in the House of Representatives was not recorded although it passed 'on the voices' on 6 December 2006 (Anonymous 2006). (The second vote immediately prior to the third and final voice vote recorded 82 members voting in favour and 62 against the Bill [HVP 2006 145, 1635].)

Three Liberal Ministers (Health Minister Abbott, Treasurer Peter Costello and by then Employment Minister Andrews) opposing the Bill were joined by Liberal Prime Minister Howard and the freshly-elected Labor opposition leader Kevin Rudd (elected Prime Minister in late 2007), citing their personal moral objections (Anonymous 2006; Burke 2006; *Canberra Times* 2006; King 2006). An appeal to 'conscience' was also the motivation for some of those supporting the Bill, with Liberal Education Minister Julie Bishop saying, 'I cannot in all conscience stand in the way of the only ray of hope available to sufferers of devastating and debilitating disease and injury' (King 2006).

According to a Morgan Poll conducted in June 2006, an overwhelming majority of Australians (82 %) supported human embryo stem cell research, with 80 % supporting the merging of an unfertilised egg with a skin cell (Morgan Poll 2006b).[9] A November 2006 poll released by pro-research group Research Australia, found that the majority of Australians (58 %) supported such research, with the lower percentage suggesting that Australians are a little more conservative when asked about this research with reference to the term 'therapeutic cloning' (Research Australia 2006).[10]

[9] Poll question: 'A very important new avenue for research using human embryos involves taking cells called stem cells from the inside of a five day old embryo. The embryo is no longer capable of further development. Scientists are working on techniques to turn stem cells extracted from an embryo into any type of cells in the body such as nerve cells and muscle cells to treat diseases such as heart disease, Alzheimers, cancer, spinal injuries and many more. Put simply, stem cells can be extracted from human embryos to be used in the treatment of many diseases and injuries. Do you approve or disapprove?' Approve 82 %; Disapprove 13 %; Undecided 5 %. Question: 'Scientists can now make embryonic stem cells for medical research by merging an unfertilised egg with a skin cell. In this case, no fertilisation takes place and there is no merger of the egg and sperm. Knowing this, do you favour or oppose embryonic stem cell research?' Approve 80 %; Disapprove 11 %; Undecided 9 %.

[10] Poll question: 'While normal embryonic stem cells are important for producing normal cells to potentially repair or replace diseased and damaged tissues, they have a limited use for researchers in understanding how diseases are established and develop. It is proposed that the laws governing stem cell research be extended to allow Somatic Cell Nuclear Transfer (SCNT), also known as therapeutic cloning, which involves creating a stem cell from a patient's cell but does not involve the union of an egg and sperm. Theoretically, SCNT is the same technology that has been used to reproductively clone animals (such as Dolly the sheep), but the Australian scientific community does not support reproductive cloning and the use of SCNT to clone a human will continue to be explicitly prohibited and be a criminal offence under Australian laws. Do you strongly support, somewhat support, neither support nor oppose, somewhat oppose, or strongly oppose the extension of the current Australian laws to allow therapeutic cloning of nuclear transfer embryos for health and medical research?' Strongly support 30 %; somewhat support 28 %; neither support nor oppose 19 %; strongly oppose 10 %; somewhat oppose 8 % can't say 6 %.

Yet again, the views of the Australian public in relation to this Bill were better represented by women parliamentarians, with 83 % of women (as opposed to 33 % of men) in the Senate and 76 % of women in the House (as opposed to 50 % of men) supporting the Bill. In other words, the passage of the Bill appears to have been contingent upon the presence of women in Parliament. This shift in power has not escaped the notice of the international media (e.g., Bartlett 2006 writing in South Africa) or experienced Australian political commentators, such as Michelle Grattan (2006), who suggested that the impact of women in the Parliament might even extend to re-shaping the political landscape of their male counterparts:

> The women's push has been especially bad news for [Tony] Abbott, whose strong Catholic views mean he's been on the other side of issues like RU486 and therapeutic cloning. Not only have they beaten him hands down, they've also set back his deputy leadership ambitions. He'd poll badly among Liberal women, and there are now enough of them to make a difference.

Conclusion

The use of conscience votes in the Australian parliament in the past three decades demonstrates a number of democratically significant features, at least in regards to policy on some specific ethically-contentious issues. The Liberal Party, which was traditionally more tolerant of members who crossed the floor according to their individual conscience, when in power no longer tolerated such dissent except in difficult policymaking areas where consensus within the party was impossible. In such cases, the party has been forced to subject policy decisions to a conscience vote to avoid public displays of disunity.

The number of women parliamentarians has increased substantially, and it appears that when they are unleashed from the requirements of party solidarity through a conscience vote, they can significantly influence the outcome on key issues. It is notable that in the case of the RU486 Bill and the Research Involving Human Embryos Bill, women MPs' voting patterns were not aligned with public views as such, but were more radical and thus offset the more conservative votes of their male counterparts in a manner that led to an outcome better representing public opinion overall.

We are not arguing here that when women hold elected positions their presence will necessarily lead to legislative outcomes that better reflect the views of the electorate; nor are we claiming that women hold more progressive views than do men on all issues. Nor do we wish to unreflectively endorse the idea that women bring 'a different voice' to moral and other deliberations that is in some sense feminine, and which is grounded in an ethic of care and relationality (see Gilligan 1982). Rather, we view the data from Australian conscience votes as contributing to the evidence for viewing women's participation in parliamentary institutions as shifting the way that politics is done (Celis and Childs 2008). This is not to make an essentialist claim about women's political behaviour or morality. Rather, we support the view

articulated by Young (2000) that women are more likely to share a social perspective, grounded in their (gendered) social positions and in the life experiences that they are more likely to have had than men. These social positions and experiences then shape the questions women seek to answer in politics, and their expectations, assumptions and reasoning about social matters (Young 2000). Many of the policy debates here are likely to raise issues which have special resonance for women due to their connection to their life experiences, which include reproductive decisions, attention to health (their own and that of those they care for) and access to health services, as opposed to concerns primarily about economic issues (Campbell, 2004). Thus women may, collectively, have a different set of political priorities from those of men.

Women's political concerns may also be better championed by women politicians, once they are elected to office. This is not to say that elected politicians who are women will inevitably represent women's interests (nor that all women share a set of distinctive interests), but rather that on key issues affecting women, women in Parliament may be better able to use the formal, party room and informal political processes to achieve outcomes that are viewed as promoting the interests of women (as in the case of the ad hoc coalitions formed among strategically-placed women politicians from across the political spectrum in relation to the Therapeutic Goods Amendment [Repeal of Ministerial Responsibility] Bill, 2005 and the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Bill [2006]). The point being made here is that a necessary condition for women's interests to be *substantively* represented in politics is that there are a reasonable number of women in elected office (Celis and Childs 2008; Campbell and Lovenduski 2005). It certainly appears that Australian women parliamentarians, particularly senators from minor parties where cross-party collaboration is essential for effectiveness, have taken the lead to press for cooperative policy development on issues concerning bioethics.

Are conscience votes more or less democratic than the discipline of party policy? Although there is criticism that more vulnerable parliamentarians may still adhere to a *de facto* party line or vote a particular way out of fear of public backlash, the case studies outlined here indicate that conscience votes can provide more favourable conditions for representative and deliberative democratic policymaking than normal Parliamentary processes. In our view, the ability to use conscience votes in very specific cases may allow issues which would otherwise be discounted as 'political minefields' or too readily polarised to be more carefully considered and debated, and hence to achieve the goals of deliberative democracy. In the case of those examples where there was considerable pressure brought to bear on politicians from religious quarters, a conscience vote *per se* need not have yielded careful deliberation, as parliamentarians may well have sought to avoid being associated with decisions that could provide opponents with powerful supporters (as has been seen in the United States where politicians are identified with "pro Choice" versus "pro Life" positions). We would argue that the deliberative legitimacy of conscience votes is best realised when parliamentarians, freed from Party discipline, are able to draw on their experiences to articulate what the interests at stake are in a policy debate, to

develop arguments to articulate the significance of those interests and to weigh up the range of interests on the issue without reverting to ready policy positions. Conscience votes encourage an increased level of lobbying and deliberation, which suggests that parliamentarians are more informed about these issues than otherwise. Thus they are more likely to attend to the views expressed by their constituents and to be moved by arguments of their parliamentary colleagues without regard to the party of the person making the argument (as can be clearly seen in the cross-party coalitions that united over the bills related to RU-486 and embryo research). Voters may have good reason to believe that their efforts at persuasion of their elected representatives will be more effective where the representative has the freedom of a conscience vote. For these reasons, conscience votes may enhance deliberation and accountability.

However, because of the strength of political parties in Australia, and the dependence of most parliamentarians on party support, conscience votes provide only limited opportunities for critical dissent. They enable parties to avoid public displays of disunity where a small number of vocal opponents would otherwise cross the floor, while enforcing party unity on all other matters. Further, given the lack of any requirement for MPs to articulate reasons for votes or to reflect constituents' views, or even for the Parliament to record the final vote by members, parliamentarians are not forced in any formal way to bear responsibility or face voters' reactions. Finally, by allowing conscience votes on contentious public issues, centrist political parties are able to avoid initiating policy development in areas where they would be required to demonstrate leadership, or anticipate rather than follow public sentiment on divisive or unpopular matters.

There is one democratic value that appears to be clearly supported by the cases of conscience votes discussed here: representation of voters' attitudes or values. The introduction of more women into the Australian Parliament, in combination with the strategic use of conscience votes, has made a significant contribution to more representative policymaking, at least in the ethically-contentious domains discussed in these case studies. The last three case studies in particular indicate that women are more inclined than male parliamentarians to take a position that reflects majority public opinion in response to contentious policy questions, regardless of party affiliation. One explanation for this could be that although the demographic characteristics of parliamentarians still fail to reflect the broader community (elected representatives are Whiter, richer and better educated than the Australian population as a whole), women representatives appear to bring perspectives to the legislative debate that better reflect the population's views (at least on the issues for which a conscience vote has been allowed). We can speculate that if the membership of Parliament were to better reflect the diversity of the Australian populace (for instance having greater ethnic diversity, or fewer representatives with inherited familial wealth or from families with long political histories), then there would be further opportunities for legislative debates to substantively represent voters' interests. An alternative explanation of women's involvement in conscience votes may be, at least in the case of bills initiated in Senate as private Senator's bills, that the higher proportion of women senators among minority (progressive) parties allows

these policy initiatives to challenge the arguably more conservative impulses of the major parties. The available evidence clearly demonstrates that conscience votes allow alternate views on contentious policy questions to be represented which may otherwise have been overwhelmed by normal 'party line' political decision-making (See Table 4.1).

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Chapter 5
Deliberative Processes in Practice

Cobi Smith and Gene Rowe

Introduction

Deliberative democracy theories are being practically tested internationally in a range of formats. The growing pool of evaluations of deliberative events in which the public participate mean we can begin to draw conclusions about what can work and why, by addressing a series of questions. Who organizes deliberation and for what purpose? What methods of deliberations suit different aims? What conditions lead to fair deliberations and useful outcomes? How can this fairness be demonstrated?

Deliberation can occur in public and private spheres. People deliberate in their own minds while making decisions, without any communication with others. Organizations can deliberate internally with little regard to the perceptions and expectations of outsiders. In this chapter, we are interested in public deliberative events. That is, deliberative events that actively seek to involve citizens in decisions that they would not otherwise have power to influence. We are interested in deliberative events rather than broader political or media discourse–the types of events that are the subject of research within public participation and deliberative democracy theory. Within bioethics, these processes can take the form of citizen juries, health technology assessments or other models for public participation, which have been listed elsewhere (Rowe and Frewer 2005). What these different methods have in common is shared principles and goals, which will be discussed within this chapter. These shared principles and goals allow conclusions to be drawn about what

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kind of conditions can lead to goals being achieved, and how principles can be translated into practice.

Organizations run public deliberative events for different reasons. We are focused on deliberations related to bioethics, though experiences regarding issues in other areas can support the conclusions drawn here. Some events aim to raise public awareness rather than influence policy; in this chapter, we are focused on public deliberation linked to policy. Policies are made not only by governments. Private organizations have internal and external policies, some of which impact the public. As well as local, state and national governments, other authorities engage with the communities in which they operate. For example in the sphere of bioethics, local health authorities or hospitals, which may operate at arm's length from local government, can lead deliberations. In environmental ethics, farmer's associations can be a form of local authority. In the context of deliberative democracy it can seem politically incorrect to label one partner in a deliberative process a 'local authority', in the same sense labeling someone as an expert can cause problems. However in policy contexts, an organization with local authority is typically one driving the implementation of policies, so it is a useful label in the context of public deliberations about policy decisions.

How deliberative events can demonstrate success when it comes to policy impact is a question in need of further research. Most evaluations have been focused on the processes of single events, and are usually done by event organizers rather than people observing the broader political context (Rayner 2003). Demonstrating success is contingent on defining aims and objectives that can be evaluated. Useful questions that can be evaluated include who are you seeking to include in your deliberative process? What is the aim of the process? The process can be aimed at reaching a specific decision on a given topic or providing consultative input for strategy planning. Those processes aimed at reaching a specific decision are easier to evaluate for accountability, as the process of reaching the decision and then acting on the decision can be made transparent. This chapter draws primarily on research involving the evaluation of multiple participatory events, although individual examples also are mentioned. Rather than addressing specific examples of deliberative events that are successful or not, this chapter outlines the questions and options organisers of deliberation should consider so they can meaningfully evaluate the utility of deliberative processes in practice.

Putting Theory Into Practice

For deliberative theories to become practice, someone must facilitate action. So what organizations or individuals run public deliberative events, within the sphere of bioethics? Academic researchers can initiate deliberation (O'Doherty and Burgess 2009; Rowe and Frewer 2004; Dolan et al. 1999). Some researchers have attempted to generate citizen-led deliberation (Powell and Colin 2009). Researchers can collaborate with local authorities to run deliberations with the aim of informing

Table 5.1 Areas of consensus about "good deliberation"

Representativeness and inclusivity	Everyone interested in and affected by a decision was represented; barriers to participation and representation were removed.
Fair deliberation	Everyone was able to share their views. Interaction allowed mutual understanding between participants to develop.
Access to resources	Sufficient resources, including information, expertise and time, were provided for effective participation.
Transparency and accountability	Objectives and boundaries were made clear to participants and outsiders. How participation would inform decision making was explained.
Learning	Participants, specialists, decision makers and institutions learnt from the process.
Independence	The process was facilitated and managed in an independent and unbiased way.
Efficiency	The process was cost effective and timely.

Adapted from Chilvers (2008)

local policy (Abelson et al. 2007; Abelson 2003; Litva 2002; Lenaghan 1999; Lenaghan et al. 1996), or authorities may initiate deliberation in their own right (Bowie et al. 1995; Dixon and Welch 1991).

What form should deliberations take? There are several established methods for deliberative public engagement, some of which are more suited to policy aims than others (Rowe and Frewer 2005; Morrell 2005). Mitton et al. (2009) assessed 391 articles about public consultation to create a table of events that were focused on public involvement in priority setting. The final list was composed of health-related examples from the United States, the United Kingdom and New Zealand. Using Rowe and Frewers' (2005) framework, they identified four types of participatory processes: type 1, citizens' juries or consensus conferences; type 2, negotiated rule making or task forces; type 3, deliberative polling or planning cells; and type 4, town meetings that involve voting. Participants in events using face-to-face deliberation reported more satisfaction with outcomes.

Evaluating Deliberative Events

There are now several frameworks for evaluating deliberative events (Webler 1995; Fiorino 1990; Laird 1993; Renn et al. 1995; Santos and Chess 2003; Rowe and Frewer 2000, 2004, 2005). Areas of consensus about what should be evaluated as constituting "good deliberation" have been summarized by Chilvers (2008) and are adapted here (see Table 5.1):

In Chilvers' own research, he found organizers of deliberative events emphasized the importance of processes being fit for purpose and adaptable (2008). Nagel (1992, 1967), who specifically focused on participation in policy decisions, also

emphasized transparency and accountability issues. Two of his four questions for evaluation focused on whether participant recommendations were binding and for what purpose officials had sought citizen participation. As with all evaluations, understanding the aims and objectives of the activity being evaluated is important for measuring success. In deliberative processes, this clarity of purpose is important for transparency and accountability during the deliberative process as well as evaluation following.

Evidence of Fairness

Given there is no consensus on what makes how to define success in deliberative processes, demonstrating fairness is a more realistic goal for evaluation (Martin et al. 2002; Tenbensel 2002). For Chilvers (2008), fairness is about people being able to express their views and develop mutual understandings. Fairness is related to process and representation as well as individual participants' experiences. Knight et al. (1997) call fair process procedural equality, and quote Kenneth Arrow (1977) in outlining three conditions for the enforcement of procedural equality in deliberation.

The first of these conditions is unrestricted domain, which means that people reflecting all interests were able to participate in reaching deliberative outcomes. Who participated is an important consideration; how participants were recruited should be evaluated for fairness and representation. Besides the democratic value of equal opportunity to participate, diverse perspectives allow participants to learn from each other and consider the broader picture (Delli Carpini et al. 2004). On the other hand, heterogeneous groups can require more facilitation and individuals may gain less satisfaction from the process (Stewart et al. 2007). Single representatives of particular views may not be enough to level potential power differences within deliberation; an individual may feel intimidated if other perspectives have greater representation in a group (Martin et al. 2002; Stewart et al. 2007).

There can be tension between unrestricted domain and the expectation that all participants commit to reasonable discussion, which John Rawls emphasized for effective deliberation in his Theory of Justice (1999). It can be difficult to reconcile diverse viewpoints to reach agreed outcomes. Organizers can take responsibility for procedural fairness and fair representation, but fairness during deliberations relies on the mindset of individual participants. Good facilitation and communication can bring out the best in participants' deliberative skills, but the attitudes and behaviours of participants are ultimately their individual choices. Bruni et al. (2008) argue that representation is not as important as having a diversity of fair-minded people who can articulate a range of values. Daniels (2000) described fair-minded people as "those who seek mutually justifiable grounds for cooperation", who "must agree that the reasons, evidence, and rationales are relevant to… the shared goal of deliberation" (Daniels 2000, 1301).

Restricting participation to those deemed to be "fair-minded" participants is a more comfortable prospect for local authorities experimenting with deliberative processes for policy. For example, a member of the United Kingdom's National Institute for Health and Clinical Excellence (NICE) appraisal team expressed concern with the participation of "emotional" patients in NICE processes, preferring representatives who would "maintain a degree of professionalism" (Quennell 2003). But Knight et al. (1997) are among several scholars to point out that such patient views and interests are valid, even though they may not be conveyed in a rational and unbiased manner. They argue perceptions of reasonableness should not be a strict condition of participation, standing in the way of unrestricted domain. Navigating how to balance diverse representation in participants' views and personalities with the need for practical, actionable outcomes is a challenge for deliberative practitioners, and how this is navigated is a worthy question to address in evaluation.

Before excluding people perceived as biased or irrational it is worth considering how transparent processes and good facilitation can encourage a fair and cooperative mindset among participants. Powell and Colin (2009) argue that all citizen engagement projects should include capacity building and training for citizens; people should not be expected to instinctively know how to deliberate effectively. On the other hand, organisational or cultural change within institutions may be required for meaningful deliberations, rather than putting the onus to learn new skills on public participants (Newman et al. 2004). Young (1990) discusses in depth how oppression can be inherent in a process or structure. Without conscious planning to enforce fair-minded attitudes, deliberation involving laypeople and experts may give rise to criticism of laypeople's credibility and legitimacy (Milewa 2006). A part of procedural fairness and facilitation is working to eliminate or at least minimize inequalities between participants so that arguments, not individuals, are the subject of scrutiny and the cause of persuasion.

Minimizing power differences and inequalities involves allowing time for advance preparation and discussion of information during the deliberative process. This enables people to build their confidence in decision making and supports the expression of divergent views. Clearly defining participant responsibilities can also increase participant confidence and process fairness (Gibson et al. 2005). Allowing people to abstain from making a final decision reinforces the acceptability of divergent views. While consensus may be ideal, transparently recognising that a final decision is agreed but not endorsed by all participants can be preferable to a consensus reached by a process in which power imbalances were overlooked.

Following *unrestricted domain*, the latter two of Knight and Johnson's (1997) conditions for procedural equality are focused on the obligation for organizers to promote fair-mindedness among participants: namely *anonymity* and *neutrality. Anonymity* means that the deliberative procedure must treat all participants equally, regardless of characteristics such as socioeconomic background or religious affiliation, to use Knight and Johnson's examples. Resisting stereotypical assumptions about patients, clinicians or administrators is a particular issue for deliberations in bioethics, if participants are to be treated equally. Thirdly, *neutrality* requires that the procedure not favour a particular outcome; this condition is linked to

accountability and the importance of transparent aims and objectives, mentioned earlier and addressed in more detail next. These conditions demonstrate why deliberations with people defined as stakeholders rather than citizens struggle to demonstrate fairness. If participants are recruited as stakeholders, such as representatives of patient groups or religious movements, it is more difficult for them to reason and deliberate as individuals open to different arguments, as they have come to the deliberation representing a particular position. Similarly, it may be more difficult for other participants to consider the arguments or preferences of others fairly, knowing others are representing different interests to their own, as defined through their stakeholder status.

Deliberative Outcomes and Accountability

There has been little published on the policy outcomes of participatory deliberative events, aside from scholars lamenting the lack of evidence in this area (Tenbensel 2002; Contandriopoulos 2004; Mitton et al. 2009), and criticism of event planners who fail to consider outcomes in the first place (Powell and Colin 2009). Knight and Johnson (1997, 292) believe it would be "next to impossible" for any deliberative process to embody the procedural equality they outline. Rayner (2003, 167) notes that a general problem in evaluating outcomes is the inability to establish a causal link between the process and its outcomes. In other words, how do we know that public deliberation played a decisive role in reaching an outcome? Deliberations that lead to decisions unacceptable to policymakers could arguably be evaluated as failures (Webler 1995). On the other hand, if public deliberation results in a decision aligned with the pre-existing preferences of policymakers, what evidence is there that deliberation was actually useful and relevant, more than a mere formality?

Causal relationships are infamously difficult to demonstrate in the social sciences, no less in assessing the impact of public deliberations on policy (Bernert 1983; Collins 1989; Goldthorpe 2001; Pötter and Blossfeld 2001). However other aspects of accountability can be evaluated, which is where transparency becomes essential. As explained earlier in this chapter, accountability and transparency have been highlighted as particularly relevant in evaluating policy-focused public deliberations. How can deliberations be assessed for accountability and transparency, in the absence of causal links with outcomes? Daniels and Sabins' (1997) conditions of accountability for reasonableness have been summarized by Martin et al. (2002), and have been further refined here to apply to a broader range of deliberations than in their original setting:

1. Relevance: rationales for decisions must be evidence-based and use fair-minded reasoning.
2. Publicity: rationales must be publicly available.
3. Appeals: appeals or revisions must be possible.
4. Enforcement: the process must be regulated to enforce the first three rules.

Gibson et al. (2005) proposed an addition to these conditions of accountability for reasonableness:

5. Empowerment: power differences must be minimized.

The issues of empowerment and enforcement were discussed in the last section of this chapter in relation to procedural fairness, while relevance relates to having transparent aims and objectives, which has been emphasised throughout. The remaining two conditions, namely those regarding publicity and appeals, are primarily related to outcomes rather than processes and shall now be addressed.

Abelson et al. (2007) analysed the accountability of health technology assessment methods in Canada under three headings: publicity of outcomes and rationales; citizen engagement; and availability of appeals. Their research included assessments with varying levels of citizen engagement – those with little public engagement were outside of the scope of this chapter, given the focus on public deliberative processes.

Publicising outcomes and the rationales behind deliberation is an important and relatively straightforward way for event organizers to promote accountability; such information is essential for effective evaluation. Not only is publicising outcomes and rationales good practice for transparency and accountability, it allows bigger picture research and analysis, such as this book, to get value from a deliberative event. The public information emerging from deliberations could form part of an evidence base for influencing policy beyond the scope that the organisers of deliberation anticipated. Transparency about how outcomes were reached and what processes were used in recruitment in public information about a deliberative event not only supports fairness but also supports other researchers and policymakers in fairly interpreting the information.

Processes for appeal of decisions are applicable in contexts that lead to direct recommendations, such as NICE's decisions on health technologies (Milewa 2006; Dyer 2007; Sellars and Easey 2008). However the use of appeals is poorly suited to public deliberations that do not result in binding recommendations, as there is little to appeal. Other scholars have emphasized the importance of iteration and review in deliberative processes (Powell and Colin 2009; Peacock et al. 2009). Iteration and review perform similar functions to appeals, in that they allow new information to be included and acknowledge that continued deliberation might form part of the process. Whereas appeals have negative connotations, suggesting the process or decision under appeal was unsatisfactory, reviews allow greater public input without undermining previous contributions. Mitton et al. (2009) found that nearly 60 % of deliberative processes are episodic rather than one-off. Committing to future deliberations and review processes expresses an organization's commitment to accountability and transparency, demonstrating that public deliberation is not seeking simply to legitimize a predetermined outcome, as Nagel (1992) cautioned may sometimes be the case.

What Process for Policy?

Organizers of deliberative events have emphasized the importance of deliberative methods being adaptable and fit for purpose (Chilvers 2008). Particular deliberative methods may not be feasible for some policy decisions (Bishop and Davis 2002; Abelson et al. 2007), so organizers must consider for what purpose public deliberation is initiated. This brings us back to the importance of clear aims and objectives. At this time, there is insufficient evidence to provide clear guidance on which methods should be used for which types of policy aim (Mitton et al. 2009). However the need for organisers to consider the context of their participative events is evident; poorly planned public deliberation is not necessarily better than none at all–and indeed, may be much worse, leading to outcomes such as a diminution of trust in the organizers, greater cynicism amongst the participants involved, and policy recommendations that are based on biases and misunderstandings. Nagel (1992, 1966) argues that left unstructured, "intensified voluntary participation can prove antithetical to the egalitarian values on which democracy ultimately rests".

Newman et al. (2004) also discuss the importance of policy context. Specifically they discuss how different types of engagement and collaboration can introduce "tensions between national policy priorities and local views and priorities" (Newman et al. 2004, 213). Facilitators of deliberation can feel frustrated if their sponsoring institution resists implementing suggested changes, as can participants if their contributions are not recognized in policy outcomes. For instance, a patient involved in the United Kingdom's health technology decision making processes (Quennell 2003, 42) said: "…we're always being told how important we are…and NICE value our input. Yet we're never told how they value our input and why they value our input". Demonstrating how and why contributions were valued relies on having well-defined expectations of participants at the outset, and transparent plans for the use of outcomes.

When Should Deliberation Happen?

At what point in policymaking should public preferences be sought? Nagel (1992) was sceptical about the purposes of participation. He suggested that officials may use public participation to "pass the buck" on controversial issues, to "test the waters" when devising a program, to try and reach consensus, or more broadly to legitimize a decision. It is unlikely that participants will feel that cynically designed deliberative processes merit their participation, but they may support deliberative processes that aim at consensus or clarification of participants' preferences among several preformed policy options. Anand (2002) cautions that we should not expect more openness and transparency in decision making to lead to consensus, given the challenges of bringing together a range of viewpoints discussed earlier in this chapter. Clarifying public preferences is a more realistic and achievable outcome.

Public deliberation can aim to inform strategic direction, or can consider more specific decisions about particular projects (O'Donnell and Entwhistle 2004). Martin et al. (2002) criticized much deliberation as being merely consultative rather than directly involving the public in specific priority setting. Tenbensel (2002) said that to be transparent, deliberations must keep information to a minimum so that assumptions can be made simply, avoiding biases in interpretation of public preferences. Sabik and Lie (2008) looked at eight countries' methods of prioritizing health care and considered their impact on policy and practice. Their work was not exclusively focused on public deliberation, though they analyzed citizen involvement in different countries and generally found it wanting. They conclude that when commissions outlined principles for decision making, they were too abstract or broad to be useful. In contrast, some countries "anchored the discussion of priorities in concrete policy determinations" allowing specific recommendations to affect policy and practice (Sabik and Lie 2008, 9). This research suggests that deliberative events addressing specific decisions may be more useful for policymakers than those designed to influence strategic directions. Deliberation on specific decisions allows the scope of information to be contained; broader strategies can be less concrete and therefore open to more accusations of bias or misinterpretation. Another reason for focusing public deliberations on specific decisions is that those decisions can be questioned in appeal and review processes, while more amorphous strategy statements are more difficult to pin down for review or questioning later. In these sense deliberations about specific decisions can be more accountable than those about direction or broader strategy.

However public deliberation event that is broad and consultative rather than focused on binding decisions is not without merit (Tenbensel 2002). Just because it is more difficult to evaluate the role of public participation in strategic or far-ranging policy decisions does not exclude it from being useful. Rayner (2003, 168), while criticizing the lack of outcomes of public participation, acknowledges "the constitutional difficulty that legislatures may have in binding themselves to decisions made by less representative bodies". Deliberative processes need to demonstrate procedural fairness before outcomes can be considered binding policy. Focusing on fairness can overcome concerns about representativeness, anonymity and neutrality that plague deliberative processes, particularly those that recruit participants as stakeholders rather than public citizens.

Conclusion

In this chapter, we have discussed the issue of using deliberative processes in policymaking. Our main concern has been to highlight the areas of uncertainty and tension that exist within this research domain, and raise–if not answer–a series of pertinent questions about whether deliberative events serve their purpose.

We have addressed deliberative processes in practice, after introducing this chapter in the context of deliberative democracy theory. An advance in theory could be

the development of a typology of contexts, in a similar manner to existing typologies of methods (Rowe and Frewer 2004), so that policy situations may be defined and differentiated in a unitary framework.

If evaluation is concerned with the satisfaction of participations, processes that are transparent and understandable regarding what is expected of participants is desirable. If evaluation is concerned with whether organisations make use of deliberative outcomes, events deliberating about specific decisions are preferable to those about long-term strategies, given that concrete outcomes can be reviewed, understood and accounted for.

What is clear is that there are diverse perspectives on what it means for deliberation to be successful, although certain concepts, such as related to fairness of representation and process, are becoming common metrics. It is equally clear that deliberative processes are used (and sometimes misused?) for diverse purposes, and that different methods may be fit for different purposes. Understanding the policy context for a deliberative process is essential for its effective design and evaluation.

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Part II
Regulation of Embryo Research

Chapter 6
Policy Design for Human Embryo Research in Canada: 1989–2015

Françoise Baylis and Matthew Herder

Introduction

In Canada, research involving in vitro human embryos is circumscribed by law promulgated by the federal Parliament and research guidelines issued by the Tri-Agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). To be precise, the use of human embryos is governed by the Assisted Human Reproduction Act, S.C. 2004, c.2 (hereafter *AHR Act*), which prohibits some types of human embryo research under threat of criminal sanction (maximum penalties are a fine of $500,000, 10 years imprisonment, or both). As well, human embryo research is governed by the *2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (hereafter, *TCPS2*) (CIHR et al. 2014).

Unlike the *AHR Act*, which covers both publicly- and privately-funded embryo research, the *TCPS2* only governs federally-funded researchers and their institutions. As a condition of funding, researchers are expected to adhere to the *TCPS2* and institutions that receive Agency funding must sign an Agreement with the

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CIHR, NSERC and SSHRC certifying compliance with the *TCPS2* (Agreement 2013). Where the *AHR Act* and the research guidelines overlap, the *AHR Act* takes precedence; where the *AHR Act* is silent, the research guidelines set the standard for federally-funded research.

There are two parts to this chapter. The first part provides a chronological description of policy developments related to human embryo research in Canada over the past 25+ years, with particular attention to efforts at public consultation. We begin with a review of the policy processes leading up to, and following on from, the promulgation of the *AHR Act* (see also, Norris and Tiedemann 2015). We then review the development and introduction of the *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (CIHR 2002) as revised in 2005, 2006, 2007, and 2010 and finally integrated into the TCPS 2 chapter 12, section F in December 2014. We do not review the history of the *TCPS2* given the broad scope of these research guidelines. We do, however, include information on the substance of these guidelines where relevant. The second part of the chapter critically examines the history of policy design for human embryo research in Canada, applying a typology of modes of public consultation developed by Eric Montpetit (2003). Our effort to better understand the various episodes of policy design and their corresponding outcomes reveals a depreciating linkage between policy development related to human embryo research and the input of Canadians through public consultation.

Policy Design for Human Embryo Research in Canada: A Brief Chronology (Table 6.1)

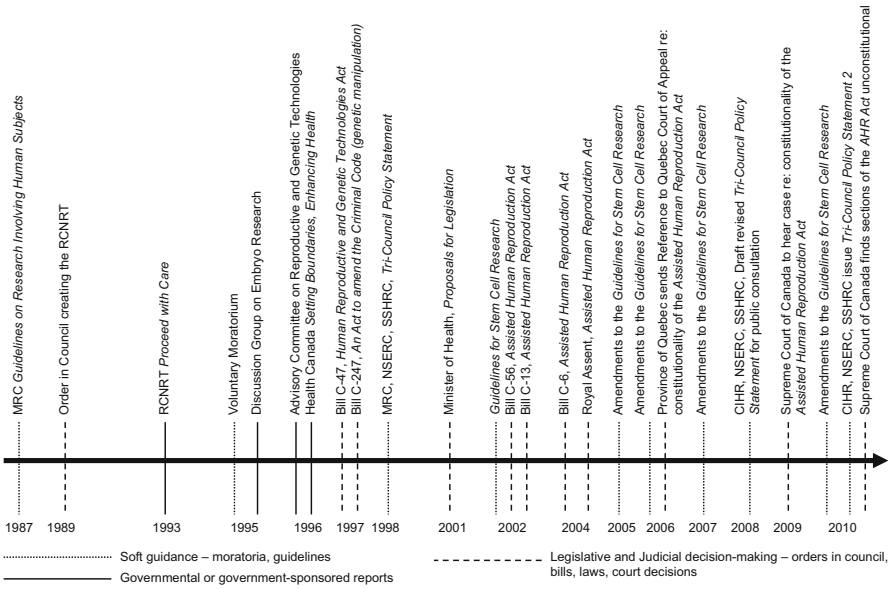
From the Royal Commission to the AHR Act

On October 25, 1989, following a couple of years of intense lobbying, Canada's Royal Commission on New Reproductive Technologies (RCNRT 1990) (hereafter the Royal Commission) was announced (Roberts 1999). The Commissioners represented the fields of medicine, law, religion, and sociology. The Royal Commission's explicit mandate was to,

> inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied. (RCNRT 1993, 3)

The Royal Commission had two overarching tasks: to provide an opportunity for public involvement in policy design; and to assess the relevant medical and scientific developments (Massey 1993). In planning for public participation, the Royal Commission "set up an extensive Public Consultation Program to give Canadians from all walks of life and from all regions of the country the opportunity to contribute to the work, as it studie[d] the origins, effects and impacts of the technologies" (RCNRT 1990, 3).

Table 6.1 Summary of Canadian policy development related to human embryo research



The final report spanned two volumes and contained 293 policy recommendations. Although the financial cost was significant (according to Montpetit $28 million (2003)), the Royal Commission's efforts to raise awareness of its work and the issues, to stimulate conversation and debate at the community level, and to receive input from Canadians were unprecedented. In total, over 40,000 Canadians "participated in clinical studies and national surveys, attended Public Hearings and Private Sessions, sent letters of opinion and written submissions, or left their thoughts on […] toll-free telephone lines" (RCNRT 1992, 1) (see Appendix 6.1). On the basis of this public consultation effort, the Royal Commission reported a "consistent and widespread demand for national leadership and action in relation to [new reproductive technologies]" (RCNRT 1993, 11).

In its final report, *Proceed with Care*, the Royal Commission recommended that the Canadian government develop a comprehensive legislative response to new reproductive technologies, including human embryo research (RCNRT 1993). (See Appendix 6.1) At the time, the Medical Research Council of Canada *Guidelines on Research Involving Human Subjects* provided three basic parameters around when, why, and what types of human embryos could be used in research (MRC 1987, 35). In contrast, the Royal Commission provided considerable more detail and specifically recommended that research on embryos be "restricted to the first 14 days of development"; that embryo research related to "ectogenesis, cloning, animal/human hybrids, and the transfer of zygotes to another species be prohibited, under threat of criminal sanction"; that "clinics and researchers be permitted to use human zygotes for research only with the fully informed consent of the persons who have donated

the gametes used to create the zygote"; and that a "woman's or couple's consent to donate zygotes generated but not used during infertility treatment for research never be a condition, explicit or implicit, of fertility treatment" (RCNRT 1993, 636–37, 639, and 640, Recommendations 183, 184, 186, and 187, respectively). The Royal Commission also recommended that embryo research be subject to licensing requirements (RCNRT 1993, 645, Recommendation 193).

In the spring of 1994, the Health Policy Division, Policy and Consultation Branch of Health Canada initiated a consultation on the findings of the Royal Commission with over 50 stakeholders from groups as diverse as disabled communities and anti-abortionists (Health Canada 1996b, 14). The predominant views in Canada at that time reflected competing beliefs about the moral status of the developing human embryo. For some, the human embryo had near-person status. For others, the human embryo was a mass of tissue that did not deserve special protections.

In April 1995, Health Canada established a nine-member multidisciplinary Discussion Group on Embryo Research (hereafter Discussion Group) "to propose logically, ethically, and socially justifiable policy in this area" (Discussion Group 1995, 36), and more specifically to address the following question: "Should experimentation on human embryos, including pre-implantation diagnosis, be permitted in Canada?"

In July 1995, while the work of the Discussion Group was in midstream, then-Minister of Health Diane Marleau announced a voluntary interim moratorium on nine new reproductive and genetic technologies, many of which (directly or indirectly) concerned embryo research. Practices governed by the interim voluntary moratorium included: sex-selection for non-medical purposes; commercial pre-conception or "surrogacy" arrangements; buying and selling of eggs, sperm, and embryos; egg donation in exchange for in vitro fertilization (IVF) services; germline genetic alteration; ectogenesis (creation of an artificial womb); the cloning of human embryos; formation of animal-human hybrids by combining animal and human gametes; and the retrieval of eggs from cadavers and foetuses for donation, fertilization or research (Health Canada 1995; Health Canada 1996a). At the same time the voluntary interim moratorium was announced, the federal government outlined its plan to develop regulations for sperm donation (for artificial insemination and in vitro fertilization), and to develop (in consultation with the provinces and territories) a comprehensive legislative framework for new reproductive and genetic technologies.

The Discussion Group submitted its final report in November 1995. It concluded that embryo research should be permitted in Canada and issued 20 policy recommendations (see Appendix 6.2), all of which assumed that a National Regulatory Body would be created to approve and oversee human embryo research (Discussion Group 1995, 2).

In January 1996, amidst concerns about the degree to which researchers and clinicians were conforming to the voluntary interim moratorium, an Advisory Committee on the Interim Moratorium on Reproductive and Genetic Technologies (soon after renamed the Advisory Committee on Reproductive and Genetic Technologies) was created to monitor compliance and advise the federal govern-

ment. Later that same year, in June 1996, the prohibitions bill was introduced into the House of Commons by then-Minister of Health David Dingwall. Bill C-47 the *Human Reproductive and Genetic Technologies Act* aimed to reflect "the views of Canadians that certain practices are unacceptable and violate the principles of human dignity" (Health Canada 1996b, 6). The Bill prohibited, under threat of criminal sanction, 13 discrete practices, including all of the practices listed in the voluntary interim moratorium. At the same time the Bill was tabled, Health Canada published *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (hereafter *Setting Boundaries, Enhancing Health*). This document outlined the government's two-part legislative plan: "outright prohibition of unacceptable technologies through legislation; and development of a legislated regulatory regime to manage acceptable technologies" (Health Canada 1996b, 5). This document was to inform the next consultation phase.

Before the legislative process for Bill C-47 was completed a federal election was called, and the bill died on the order paper. After Parliament reconvened in the fall of 1997, Health Canada was instructed to undertake new public consultations on the basis of which new legislation could be drafted.

In May 2001 then-Minister of Health Alan Rock presented the House of Commons Standing Committee on Health with *Proposals for Legislation Governing Assisted Human Reproduction* (Health Canada 2001). A year later, in May 2002, comprehensive legislation on new reproductive technologies, Bill C-56, *An Act respecting assisted human reproduction* was introduced in the House of Commons. Notably, parts of Bill C-56 overlapped with the *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* introduced in March 2002 by CIHR (Baylis 2002). This Bill, which aimed to establish a legislative and regulatory framework for assisted human reproduction and embryo research, also died on the order paper when Parliament was prorogued in September 2002. When Parliament resumed in October 2002, Bill C-56 was reinstated as Bill C-13 at the same stage in the legislative process as prior to prorogation—this had not happened with the previous bill (Bill C-47). On March 11, 2004, Bill C-6 (formerly Bill C-13) completed all legislative stages. On March 29, 2004 the *AHR Act* received Royal Assent bringing to an end 15 years of policy development (Health Canada 2008).

In 2006, however, the Government of Québec filed a reference with the Québec Court of Appeal challenging the constitutionality of several sections of the *AHR Act* (Attorney General of Québec 2006). The Québec government argued that health was a provincial responsibility. The federal government insisted that the *AHR Act* was a valid exercise of its authority to act to safeguard morality, safety, and public health.[1] In June 2008, the Québec Court of Appeal opined that the federal government did not have the constitutional authority to legislate this (and other) provisions under its criminal law power. In August 2008 the Attorney General of Canada filed an appeal to the Supreme Court of Canada (SCC). On April 29, 2009 the SCC heard the appeal and on December 22, 2010 released its decision (Reference re *Assisted*

[1] Françoise Baylis prepared an expert opinion for the federal government in relation to the Québec reference (see, Baylis 2006).

Human Reproduction Act 2010 SCC 61). The SCC held that some of the contested sections, including section 10, which governs the use of in vitro embryos, were unconstitutional (Baylis 2011). Because the case was initiated by a reference from the Québec government, the SCC's decision was advisory rather than legally binding. No provincial or federal government in Canadian history, however, has ignored an SCC advisory decision in a reference case. In 2012, the federal government made significant changes to the *AHR Act*, some of which aimed to implement the SCC's decision (*An Act to implement the certain provisions of the Budget* 2012).

Notably, the constitutional challenge did not affect the prohibited activities: human cloning; creating an embryo for research (except for the limited purpose of improving or providing instruction in assisted human reproduction procedures); creating an embryo from an embryo or a fetus; maintaining an embryo in vitro for more than 14 days; purchasing gametes, embryos; creating or transplanting a chimera made from a human embryo; creating a hybrid for the purpose of reproduction; using reproductive material without consent; and obtaining gametes from a donor under the age of 18 except for the purpose of preserving the sperm or ovum or for the purpose of creating a child to be raised by the donor(s). All of these remained legally prohibited activities in Canada (see Appendix 6.3).

Guidelines for Research Involving Human Embryos

The 1st edition of the *TCPS* (the Canadian guidelines governing research involving humans) came into effect in 1998 (MRC et al. 1998), before James Thomson and John Gearhart announced their respective successes in deriving human pluripotent stem cells (Thomson et al. 1998; Shamblott et al. 1998). These guidelines stipulated in Article 9.4 that:

> It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for these purposes, research involving human embryos may be considered to be ethically acceptable but only if all of the following apply:
>
> (a) The ova and sperm from which they were formed are obtained in accordance with Articles 9.1 and 9.2;
> (b) The research does not involve the genetic manipulation of human gametes or embryos;
> (c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
> (d) Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes. (MRC et al. 1998, 75)

At the time, in the absence of explicit Canadian policy or law on human embryonic stem cell (hES cell) research, in late 2000, the CIHR struck an *ad hoc* Working Group on Stem Cell Research (hereafter Working Group). This nine-member group

included six scientists/clinicians (one of whom was Chair), two philosophers (one of whom was Françoise Baylis), and one lawyer (CIHR WG 2001). Amidst a slew of governmental and quasi-governmental reports trumpeting the promises of hES cell research but tempered, to varying degrees, by the attendant ethical concerns (Chapman et al. 1999; NBAC 1999; United Kingdom 2000; Vogel 2000), the Working Group was mandated to evaluate whether CIHR should fund research to derive and study human pluripotent stem cells and, if so, under what conditions.

On March 29 2001, the CIHR initiated a three-month public consultation on a Discussion Paper prepared by the Working Group, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives* (CIHR WG 2001). There was a national press conference announcing the electronic publication of this document on the CIHR website. As well, the document was disseminated electronically to all CIHR-funded institutions (which essentially includes every academic research institution in Canada). There were 116 responses to the Discussion Paper: 89 from individuals and 27 from "special interest groups, professional groups, health charities, [and] governmental agencies" (CIHR WG 2002). "Many" of these responses highlighted concerns about the moral status of the human embryo, the need to utilize adult stem cells instead of embryonic or foetal stem cells, the potential coercion of couples involved in fertility treatment(s) or women undergoing therapeutic abortion, the slippery slope to cloning and eugenics, and the lack of governance for private sector research. "Some" of these responses expressed concern about likely research delays resulting from the introduction of an oversight mechanism, the skewed composition of the Working Group (too many scientists and no lay representation), and the ambiguity of the term "moratorium" in the Discussion Paper. Finally, a "few" respondents noted that CIHR's chosen medium of consultation—the web—precluded certain segments of society from participating in the process (CIHR WG 2002).

On March 4 2002, with the legislative process for the *AHR Act* underway, the CIHR released its guidelines entitled *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (CIHR 2002). The guidelines stipulated that research to derive and study human pluripotent stem cell lines from embryos, fetal tissue, amniotic fluid, the umbilical cord, placenta, and other body tissues (either from persons or cadavers) was eligible for funding, but that research involving the creation of human embryos for research purposes, the use of somatic cell nuclear transfer to develop stem cell lines, the mixing of human or non-human stem cells with a human embryo or fetus, and the mixing of human stem cells with a non-human embryo or fetus was not eligible for funding.

Until June 2005 there were no revisions to the original 2002 *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research*. At that time, and again in 2006, 2007, and 2010 revisions were recommended by the CIHR Stem Cell Oversight Committee (SCOC) and approved by the three federal funding Agencies (CIHR, NSERC and SSHRC). The approval was by the three federal funding Agencies because, as of 2005, the guidelines applied "to all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an Institution that receives any Agency funding" (CIHR 2005b).

Unfortunately, the initial (albeit limited) effort at public consultation in drafting the original 2002 stem cell guidelines did not have a precedent-setting effect. Successive revisions to these guidelines in 2005, 2006, and 2007 were all made without the benefit of public consultation. Breaking with that tradition, in October 2007 the CIHR SCOC initiated a four-month online consultation (from October 19, 2007 to February 15, 2008) concerning Section 5 of the 2002 Guidelines. Section 5 ("Creating a national registry") promised that CIHR would "establish an electronically accessible national registry of human embryonic stem cell lines generated in Canada" (CIHR 2002). Such a registry was intended to "minimize the need to generate large numbers of stem cell lines, which should decrease the need for donation of large numbers of embryos" (CIHR 2002). The 2007, four-month online consultation asked whether all human pluripotent stem cell lines derived under the auspices of an institution that receives Agency funding must be listed with the registry, or whether the inclusion rule should only be applied to lines created using Agency funds. (Further explanation given below).

There were no revisions to the stem cell guidelines in 2008 or 2009. Then, in June 2010, two major changes were introduced. First, the SCOC's purview was extended to include oversight of research involving induced human pluripotent stem cells (iPS cells) (CIHR 2010). Second, following on the 2007–2008 online public consultation, the scope of the national stem cell registry was clarified to specify that human iPS cell lines would not be listed in the registry, but that all other "human pluripotent stem cell lines derived directly from embryos under the auspices of an institution that receives any Agency funds must be listed with the registry and made available by the researcher to other researchers, subject to reasonable cost-recovery charges" (CIHR 2010).

Later that same year (2010), the *TCPS2* was published. This was the first time in 12 years that the guidelines for research involving humans were significantly revised (prior to this, only minor amendments were introduced in 2000, 2002, and 2005). Given that the incorporation of the stem cell guidelines into the *TCPS* was promised in the 2003 *Interim Tri-Agency Measures for Human Pluripotent Stem Cell Research* (and repeatedly referenced thereafter in successive versions of the *Updated Guidelines for Human Pluripotent Stem Cell Research* (2005, 2006, 2007, and 2010)), it was expected that the Panel on Research Ethics (the organization responsible for revisions to the 1st edition of the *TCPS*) would put an end to the ethical exceptionalism in the oversight of hES cell research in Canada (Baylis and Downie 2011, 2012). This was not to be the case, notwithstanding the fact that at least some of the public consultations on revisions to the *TCPS* were at pains to underline this long-standing commitment (e.g., Baylis 2009, 2010).

While the *TCPS2* did not include guidelines on research involving human pluripotent stem cells, it did include minor revisions to the guidelines for research involving human embryos. The current guidelines stipulate in Article 12.8 that:

> Research involving embryos that have been created for reproductive or other purposes permitted under the *Assisted Human Reproduction Act*, but are no longer required for these purposes, may be ethically acceptable if:

(a) the ova and sperm from which they are formed were obtained in accordance with Article 12.7;
(b) consent was provided by the gamete donors[2];
(c) embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
(d) research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended. (CIHR et al. 2010, 184)

It would take another 4 years, before the three federal funding Agencies would make good on their promise to incorporate the stem cell guidelines into the *TCPS*. Only in December 2014, after many years of lobbying on the part of some scholars (including Baylis 2009, 2010; Baylis and Downie 2011, 2012), were the stem cell guidelines finally integrated into the revised *TCPS2* (CIHR et al. 2014). According to the official record, this change was motivated by a desire "to unify all Agency guidance on the ethics of human research into one document" (CIHR 2014a). Notably, however, whereas the rules governing human pluripotent stem cell research now appear in the same document as the rules for all research involving humans, the authority to develop, interpret, and implement these rules rests with a separate oversight body—namely, CIHR's SCOC. For all other research involving humans, this responsibility rests with the Panel on Research Ethics. As CIHR explains on its website, the

> SCOC will continue to provide ongoing review of the relevant section of TCPS 2 (2014), chapter 12, section F to ensure continuing relevance, submitting its recommendations to the CIHR Governing Council. Governing Council would then submit its endorsed recommendations to the Panel. The Panel would then submit proposed revisions to the three Agencies (CIHR, NSERC & SSHRC) for review and approval by their Presidents. (CIHR 2014a)

As we detail in the second part of this chapter, the problematic revisions to the *Updated Guidelines for Human Pluripotent Stem Cell Research* and the *TCPS2* dovetail with a troubling trend in policy design for human embryo research—namely, the diminishing participation in policy development by Canadians. As best we can discern, of late, Canadians who are not members of special interest groups or policy communities have been spoken for, rather than spoken with, in matters relating to the oversight of human embryo research. We show this by reinterpreting the foregoing history of embryo research policy development through a typology of modes of public consultation developed by Montpetit (2003).

[2] For a critical review of consent forms used by researchers who provided hES cell lines approved for use by CIHR, see Krahn and Wallwork (2011).

Policy Design for Human Embryo Research in Canada: A Brief Analysis

Legitimacy in policy design depends, in large measure, on achieving the right balance between output-oriented legitimacy and input-oriented legitimacy. In very general terms, output-oriented legitimacy is usually expertise-based, while input-oriented legitimacy is always citizen-centered. Or, following Montpetit, "[o]utput-oriented legitimacy is conferred onto public policies to the extent that they are viewed as enhancing the public good, independently of who has conceived them. To obtain such policies, policymakers have traditionally relied on experts" (Montpetit 2003, 97). Conversely, "[i]nput-oriented legitimacy…depends on the extensiveness and intensiveness of public participation in the making of policy. Legitimacy here is conferred upon policies when a large public feels it has been consulted and heard" (Montpetit 2003, 97).

In a helpful analysis of policy design for assisted human reproduction in Canada, Montpetit looks beyond the variety of instruments available for public consultation (e.g., advisory committees, focus groups, sequential consultations, consensus conferences, information-technology-supported dialogues or surveys, citizen juries, and toll-free numbers), to critically examine the institutional and cultural contexts in which these instruments are used in pursuit of input-oriented legitimacy for public policies (Montpetit 2003). From an input-oriented legitimacy perspective, "[p]olitical choices are legitimate if and because they reflect the 'will of the people'–that is, if they can be derived from the authentic preferences of the members of a community" (Scharpf 1999, 6).

Input-oriented design processes require public involvement and as such they have a higher potential than output-oriented design processes to reduce the legitimacy deficit (Montpetit 2008). But this potential comes at a price. Public policy consultation can be difficult–cumbersome, confusing, time-consuming and expensive – particularly if there is a genuine commitment to diversity, where the goal is not only to hear from more people (i.e., a wider array of individuals), but also to hear from more standpoints (i.e., a wider array of ideas).

Montpetit defines three triangulated modes of public policy consultation–consultation conducted in a mode of communicative action, strategic consultation, and rule-guided consultation. In turn, he explains how each of these modes of consultation characterizes a particular style of political interaction between those who are responsible for public policy consultation and those who are consulted.

With communicative action as the mode of public policy consultation, genuine dialogue and deliberation are the hoped-for modes of interaction. Those responsible for public consultation and those consulted may have preconceived ideas and preferences about what policies should be generated, but they are willing to set them aside and to learn from each other, as a means to the end of better policy development. According to Montpetit, "[p]ublic consultations here are neither strategic instruments nor mere obligations in the policy design process, but rather, opportunities to argue in pursuit of unforeseen ideas to resolve policy problems" (Montpetit

2003, 101). As Montpetit, Scharpf, and others concede, however, a problem-solving orientation to policy design is a most rare occurrence because it requires of policy designers that they accept challenges to their preferences and give up control over the outcome of the public consultation process. In short, it requires a commitment to genuine discourse and this may not always be feasible or desirable.

With strategic consultation, those who are responsible for policy design and who initiate the public consultation have clear policy preferences for which they are seeking input-oriented legitimacy. In this instance, the goal of public dialogue is not to generate policy options, but rather to effectively communicate policy preferences and persuade those who are consulted to support the preferred policy option.

With rule-guided consultation, the principal aim is to satisfy political obligations, as when politicians demand public consultation in an effort to increase the input-oriented legitimacy of the policies they intend to promulgate. This mode of public consultation may or may not have an impact on the original policy intent and orientation, depending upon the fit between the preferences of the civil servants directed to undertake the consultation and the publics that are consulted.

Here we re-canvass the various policymaking exercises on human embryo research undertaken by the federal government and the CIHR over the last 25+ years using Montpetit's framework.

Communicative Action and the Law on Embryo Research

In Canada, the legislative process that ends with the introduction of the *AHR Act* in 2004 begins with the Royal Commission in 1989. The Royal Commission's mandate, as outlined in the Order in Council did not explicitly name "identifying the views and values of Canadians" among its objects. It is nonetheless clear that the Royal Commission regarded this as integral to its investigative methodology, ethical analysis, and final output. This, in part, owes to the nature of Royal Commissions established under the federal *Inquiries Act*, R.S.C. 1985, c. I-11, and the function that Royal Commissions have historically performed in Canada (Massey 1993).

According to Montpetit, the Royal Commission was an opportunity ripe for communicative action. Indeed, some 40,000 Canadians contributed to the Royal Commission's work. While some complain that this number is misleading insofar as it includes some 15,000 survey respondents in the rate of public participation (Massey 1993, 245), current lore and government policymakers certainly have it that the Royal Commission succeeded in articulating "Canadian values".

Critics insist, however, that the Royal Commission failed to achieve communicative action owing, in part, to the inherent limitations of public hearings as a technique of public participation, and the nature of the deliberations among Commissioners.

First, the centerpiece of the public consultation effort undertaken by the Royal Commission was the public hearing. According to Christine Massey, there are a

number of serious weaknesses with this technique relative to the goal of public engagement:

> Some of the most common drawbacks are: procedural rules which make it difficult to initiate two-way communication; intervenors who are not representative of the total population; and the lack of impact on the final decision. Abuses to which the public hearing lends itself are: a habit of inadequate notification; the selective or elite involvement in the hearings; and an overemphasis on providing information rather than receiving it. (Massey 1993, 238)

Of particular concern among this list of weaknesses is the fact that royal commissions typically privilege the powerful:

> … commonly, royal commissions give voice and legitimacy to those groups in our society who already have it. While all intervenors may officially be equals in the hearings process, those with financial and/or legal interest in the issue tend to be given greater status. Advocacy groups, especially those with more diffuse memberships, suffer most. (Massey 1993, 239)

With specific reference to the Royal Commission the record shows that professional organizations, especially those representing the scientific and medical communities, were able to engage more effectively in the public hearing process than women's advocacy groups. In part, this is because no collective voice emerged to represent the full diversity of women's views.

Second, with regard to the nature of the deliberations among Commissioners, Janet Hatcher Roberts (past-Deputy Director of Research and Evaluation for the Royal Commission) reports that there was considerable mistrust among the Commissioners along the axis of medical bias:

> Concepts such as "weight of evidence," relative effectiveness, and meta-analysis were considered suspect because some Commissioners felt they were driven by medical models of evaluation. … while to a certain degree their questioning was relevant, significant effort was given to social, feminist analysis of these issues and to integrate this analysis with the other medical, social, and economic analyses. Yet, the polarization remained and in fact became more pronounced as the Commission did its work. (Roberts 1999, 20)

Part way through the Royal Commission's deliberations four Commissioners filed a lawsuit against the Royal Commission and the Canadian government alleging a flawed public engagement process and an unclear research agenda (Roberts 1999). These Commissioners were fired, as a result of which they lost their standing before the court, and the lawsuit was dropped. Two new Commissioners were appointed and the reconstituted Royal Commission went on to publish a comprehensive set of recommendations.

Now, according to Montpetit, truth-seeking is a feature of public consultation in the mode of communicative action, and so the question arises: were the Commissioners genuinely "prepared to put their preferences on the back burner for the sake of truth-seeking … [in an effort to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101). Arguably, this question cannot be answered authoritatively except by individual Commissioners who can speak to their willingness (or not) to entertain challenges to their ideas and preferences.

However, the Royal Commission's troubled history suggests that the answer to this question may be "no".

Strategic Consultation and the Law on Embryo Research

Between the publication of the Royal Commission's final report *Proceed with Care* (RCNRT 1993) and the publication of Health Canada's paper *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Health Canada 1996b) outlining the planned federal legislation, a strategic public consultation was undertaken by the federal government to validate the Royal Commission's recommendations. With this second wave of consultations, unlike the previous one undertaken by the Royal Commission, there were clear and somewhat fixed policy preferences, namely the policies recommended by the Royal Commission. As Montpetit explains,

> Several officials of the Health Policy Division responsible for ART policy design after 1993 were either close to the Royal Commission, or actual former employees of the commission. It was therefore difficult for the Health Policy Division to accept challenges to the … recommendations for limited prohibitions of ART practices and for the establishment of a regulatory commission to oversee standing practice – when so much effort and money had been invested in them. (Montpetit 2003, 105)

While the strategic public consultation undertaken at this time revealed considerable disagreement between various interest groups (researchers and the medical profession, consumers, women's groups, pro-life groups and the provinces), Health Canada concluded that the Royal Commission's findings were valid. It acknowledged, however, a need for additional consultation on embryo research and a need for further consultation with the provinces and territories. A Discussion Group on Embryo Research was established in April 1995 and its final report was issued in November 1995 (Discussion Group 1995). Subsequently, Health Canada published *Setting Boundaries, Enhancing Health* and Canadians were invited to provide written comments on the proposed legislated regulatory regime. However, as reported by Montpetit, at this point in the process at least some Health Canada officials were not keen on further public consultation:

> It was basically the government's position paper. That was the government thing: we looked at all the stuff, we talked to all these people, this is now what we're going to do. Some people within government would refer to it as a discussion paper, and I'd say, "no, we've discussed, we're finished discussing. This is what we're going to do, we're going to pass legislation, and it's going to look like this." And so it was [Bill C-47]. (Montpetit 2003, 106)

Rule-Guided Consultation and the Law on Embryo Research

After Bill C-47 died on the order paper and Parliament was reconvened in the fall of 1997, staff members at Health Canada were instructed to consult with the Canadian people on the matter of assisted human reproduction so that their views could inform the drafting of a new bill. Staff in the Health Policy Division of Health Canada, however, considered further public consultation unnecessary as evidenced by the limited consultation that followed in 1999. What little public consultation took place had a limited objective: to satisfy a government directive. No doubt, for some, a certain amount of policy design fatigue had set in and there was little (or no) desire to hear from, or even persuade, Canadians. Meanwhile, many Canadians expressed increasing frustration with the ongoing delays in acting on the recommendations of the Royal Commission.

For reasons that are not clear, the public consultation task was moved from the Health Policy Division of Health Canada to a special project division. Eventually this task was moved to the House of Commons Standing Committee on Health when then-Minister of Health Alan Rock presented the Standing Committee with *Proposals for legislation governing assisted human reproduction* (Health Canada 2001). In the months that followed, a number of interested "experts" (including Françoise Baylis) appeared before the Standing Committee.

In 2004 the *AHR Act* received Royal Assent, at which time work began on the development of regulations pursuant to the legislation. Public involvement activities for this rule-guided consultation included a number of topic-specific workshops with different constituencies. For example, medical fertility clinics and laboratories of assisted reproduction services were consulted on the licensing and regulation of controlled activities and the obligations of licensees regarding health reporting information. Before this, patients/consumers of assisted reproduction services were consulted on the development of regulations under the *AHR Act* with respect to: aggregate outcomes of AHR procedures; health reporting information; counseling; and information to be made available to the public by Assisted Human Reproduction Canada. Nothing came of these public consultations, however, ostensibly because of the pending constitutional challenge.

When the *AHR Act* was amended by the federal government in March 2012, in part in response to the SCC decision of December 2010 (according to which several sections of the *Act* were unconstitutional), there were no public consultations.

Communicative Action and Research Guidelines for Embryo (Stem Cell) Research

The mandate of the CIHR Working Group on Stem Cell Research was very modest compared with that of the Royal Commission. The Working Group was not expected to develop an ethical framework for stem cell research, but rather to work within

existing frameworks as found in the final report of the Royal Commission (1993) and in the 1st edition of the *TCPS* (MRC et al. 1998). This meant, for example, that the permissibility of *ex utero* human embryo research up to day 14 was not subject to debate and discussion. Within this limit the Working Group was to advise CIHR on the research use of human embryos (and other human tissues) to derive and study human pluripotent stem cells. As well, the Working Group's mandate did not include public consultation; this was undertaken at the initiative of (some) members of the Working Group.

Consistent with the goals and objectives of communicative action, and in an effort to simulate some form of dialogue, all comments received from the Canadian public were summarized and distributed to members of the Working Group for consideration. Some of these comments informed the Working Group's discussions and influenced the drafting of the final report. Other comments (especially bulk form letters that addressed issues beyond the limited mandate of the Working Group) had little impact. All comments from the public received a formal reply in aggregate in an Appendix to the Working Group's final report. Here there was an attempt to explain whether and how the public input had been included in the final policy recommendations. As appropriate, links were drawn between expressed concerns and measures taken by the Working Group to address those concerns in its final report.

There were, for example, concerns about the composition of the Working Group and about use of the web to solicit feedback from Canadians. With respect to the first concern, the Working Group was in the awkward position of having to generate an explanation for a decision into which it had no input. For good or ill, the Working Group defended its membership stressing the need for scientific expertise and noting that some members (presumably, the two philosophers and the sole lawyer) had no personal commitment to the pursuit of stem cell research. With regard to the second concern, about whether the consultation mechanism (posting a Discussion Paper on the CIHR website and inviting written comments) was an effective means of soliciting public input, the Working Group offered the following comment acknowledging the possibility of bias:

> The original mandate of the Working Group did not include a public consultation phase and it was initially anticipated that the Working Group would report back to the Governing Council of CIHR by June 2001. The consultation was done at the initiative of the Working Group and an extension of the reporting deadline was sought. The Working Group and CIHR also made sure that the document received wide media coverage to ensure that its existence became known to interested parties. The goal was never to do a full survey of Canadians' views on this topic – that would have required a different mandate, budget and time frame. Although the Group's survey of public opinion was limited and possibly biased, it did identify many issues that informed the final report. (CIHR WG 2002)

In this reply (as in others) there is evidence of a willingness to be challenged, a key feature of communicative action. Is there also evidence of a willingness to set aside preferences "for the sake of truth-seeking … [to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101). This is much less clear and arguably this is where the issue of membership bias in favour of the research community is most germane. It is not clear (indeed it is doubtful) that a

majority of the members of the Working Group were able or willing to adopt a true problem-solving orientation to policy design regarding stem cell research in Canada. The Working Group was advisory to CIHR, a federal granting Agency with a clear preference to fund at least some human pluripotent stem cell research (albeit within a clear ethical framework).

Strategic Consultation and Research Guidelines for Embryo (Stem Cell) Research

In October 2007 the CIHR SCOC initiated a four-month strategic public consultation on a discrete business issue of critical importance to the future of hES cell research in Canada (CIHR 2007b). This consultation is here described as strategic because, in our view, those conducting the consultation had a clear policy preference for which they were seeking input-oriented legitimacy; namely, to exempt certain hES cell lines from the requirement that they be available to other researchers on a cost-recovery basis. The goal of the consultation was not to generate policy options (as would be the case with consultations conducted in the mode of communicative action), but rather to persuade those who were consulted to support the preferred policy option. Below we explain the strategic nature of this public consultation.

At the time the CIHR SCOC consultation was initiated (October 2007), the *Updated Guidelines for Human Pluripotent Stem Cell Research* had, since 2005, been tri-Agency guidelines and not merely CIHR guidelines. As such, since 2005 the requirement that hES cell lines derived in Canada be (1) included in an hES cell registry and (2) available to other researchers on a cost-recovery basis applied to hES cell lines established through research funded by one or more of all three federal research granting Agencies or conducted in Agency funded institutions—not just hES cell lines established through the use of CIHR funds (as per the 2002 Guidelines). Vestigial wording in s. 6.0 from the 2002 Guidelines created confusion, however. The preferred policy option in 2007 was to amend this requirement so that only those hES cell lines established with funding from one or more of all three federal research granting Agencies would be available to other researchers on a cost-recovery basis, while hES cell lines established in Agency funded institutions, but without Agency funding, would be exempt from this requirement.

The online survey included the following statements followed by a simple request for agreement (i.e., endorsement of the preferred policy options):

> SCOC suggests that the registry include the following [hES cell] lines to be subdivided into two distinct lists:
>
> 1. lines established through research approved by SCOC and with funding from any of the Agencies (not just CIHR). These lines would be listed in the registry and made available by the researcher to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?*

2. lines established through research approved by SCOC and carried out in an institution that receives Agency funding, but whose derivation was not directly funded by an Agency. These lines would be listed in the registry but there would be no requirement for the researchers to make the cell lines available to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?* (CIHR 2007b)

The information provided to prospective survey participants in support of the first policy choice explained the need to expand the registry in the following terms:

> The planned incorporation of the Guidelines into the *Tri-Council Policy Statement* (TCPS) is an argument in favor of expanding the scope of the registry. Such incorporation would, *per force*, expand the registry's scope because compliance with the TCPS is required for all research conducted in institutions receiving funds from the Agencies. It is also felt that the registry would be less useful if it did not include all hES cell lines derived under the auspices of an institution receiving Agency funds. (CIHR 2007b)

The reference to "expanding the scope of the registry" was inaccurate, however, as was the suggestion that this would happen, *per force*, with the planned incorporation of the *Updated Guidelines for Human Pluripotent Stem Cell Research* into the *TCPS*. In point of fact, the first policy option was merely a statement of the *status quo* since 2005. As explained above, since then the *Updated Guidelines for Human Pluripotent Stem Cell Research* (as stipulated therein) already applied in their entirety to "all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an institution that receives any Agency funding" (CIHR 2005b, s. 7.0), specific references to CIHR notwithstanding. This is because "NSERC and SSHRC joined CIHR in agreeing to a Tri-Agency approach requiring adherence to the Guidelines as a condition for Agency funding of research. This will apply until the Guidelines are formally incorporated into the TCPS" (CIHR 2005b, s. 3.0). Further, the *Guidelines for Human Pluripotent Stem Cell Research: Policy Details* explained that:

> New or ongoing human stem cell research that is:
>
> 1. funded by the Agencies; or
> 2. conducted under the auspices of an institution that receives any Agency funding, whether on site or off site; or
> 3. conducted elsewhere with any source of funding, by faculty, staff or students from an institution that receives Agency funding, must be in conformity with the Guidelines. (CIHR 2005c)

It follows that *all* hES cell lines established with Agency funding or conducted under the auspices of an institution that received any Agency funding had to be included in the Canadian stem cell registry and be made available to other researchers on a cost-recovery basis. This fact suggests that the SCOC's strategic public consultation may also have been strategic in the pejorative sense, viz. "calculated to take advantage of" those consulted. To be clear, there was no need for the SCOC to recommend statement (i) as this was already required in the *Updated Guidelines for Human Pluripotent Stem Cell Research*. But if the SCOC consultation was only about statement (ii), it would not have been possible for the SCOC to present the recommendation to exempt certain hES cell lines from the requirement that they be "made available to other researchers, subject to reasonable cost-recovery charges"

(CIHR 2007a, s. 6.0) as a reasonable limit on an effort to otherwise increase the availability of Canadian hES cell on a cost-recovery basis— i.e., the impression created with statement (i). Indeed, a public consultation limited to statement (ii) would have made transparent the intention to limit (not expand) the availability of hES cell lines on a cost-recovery basis and this could have undermined public support.

The results of the strategic public consultation on expanding the scope of the hES cell registry were made public in June 2009, more than a year after the survey was conducted and the results were discussed by the SCOC (CIHR 2009). In response to the second question about hES cell lines at an institution that receives Agency funding, but whose derivation was not directly funded by an Agency, a majority of respondents (19) agreed that these hES cell lines need not be made available on a cost-recovery basis. A lower, but nonetheless relatively significant, number of respondents (12) disagreed with the proposed policy change, with "[s]everal respondents [noting] that the lines should be made available on a cost-recovery basis, regardless of the funding source" (CIHR 2009).

At the same time the survey results were made public, a national electronically accessible registry of hES cell lines was finally created. Initially, there were no hES cell lines listed in the registry despite the fact that at least four such lines had been derived in Canada and approved by the SCOC for research use. This was at odds with the *Updated Guidelines* according to which all hES cell lines established through research funded by one or more of the federal funding Agencies or conducted in Agency funded institutions were to be (i) included in an hES cell registry and (ii) available to other researchers on a cost-recovery basis, specific reference to CIHR notwithstanding. This was also in direct conflict with the clear reach-through provision in the *TCPS* and Agency-institution Memorandum of Understanding. Confusingly, CIHR initially characterized listing lines in the registry as a voluntary decision: "[i]nvestigators with lines derived under the auspices of an institution that receives Agency funding *will be asked if they wish to voluntarily list their cell lines*" (CIHR 2014b).[3] In June 2010, instructions on participation in the registry were amended clarifying that all hES cell lines derived under the auspices of an institution that received Agency funding was mandatory. In July 2010 four hES cell lines were listed in the registry. At May 2016 the total had not changed.[4]

Of note, CIHR explained the history of the *National registry of human embryonic stem cell lines* in such a way as to ignore the fact that in 2005 the *Updated Guidelines* were the remit of all three federal funding Agencies, not CIHR alone. In describing the National registry, CIHR stipulated in error that "prior to June 30, 2010, only human embryonic stem cell lines derived in the course of CIHR-funded projects were required to be listed in the registry" (CIHR 2014b).

[3] The text cited here appeared on the CIHR website when accessed in 2009, at which time it was properly cited in Baylis and Herder (2009b). It has since been amended.

[4] The website for the National registry of human embryonic stem cell lines was last updated on December 19, 2014. http://www.cihr-irsc.gc.ca/e/39580.html Accessed 29 May 2016.

Policy Design for Human Embryo Research in Canada: What Might the Future Hold?

As we look to the future, we note an important shift in the landscape of policy design for human embryo research in Canada–in the past 10 years, there has been no concerted effort to dialogue with Canadians about embryo research. Meanwhile, there is reason to think that the views of Canadians on the scope of acceptable hES cell research may have changed, or be in a state of flux. This is especially true given recent international debates on laws and policies governing germline genetic interventions with mitochondrial replacement technology and gene editing using CRISPR/Cas 9.

The science and practice of human embryo research is fast paced and there are frequent media reports of national and international political controversies, hoped-for-cures, and human tragedies. Against this ever changing, scientific, political, and social backdrop, it is possible that available information about the views of Canadians is outdated. This suggests the need for additional policy consultation, but there appears to be little appetite for this. Moreover, from the perspective of some, it would be preferable to access the contributions of interest groups and policy communities (i.e., tightly interconnected groups closed to a limited number of influential state actors (Montpetit 2004, 72)) as these might more easily contribute to cohesive public policy.

In Canada, the earliest of the knowledgeable, well-organized, well-connected, and well-funded policy communities with an interest in stem cell research was the Stem Cell Network (SCN). Since then a number of other such research communities have been created including the International Consortium of Stem Cell Networks in 2004, the Cancer Stem Cell Consortium in 2007, the Canadian Stem Cell Foundation in 2008, the Centre for Commercialization of Regenerative Medicine in 2011, and the CellCAN Regenerative Medicine and Cell Therapy Network in 2014.

The Stem Cell Network

The SCN is a non-profit organization created in April 2001 through the federal Network of Centres of Excellence program to serve as an interdisciplinary hub for researchers and clinicians across Canada engaged in the field of stem cell research. As currently described, the SCN mission is to be "a catalyst for Canadian research that translates stem cell research into new therapies, commercial products and public policy" (SCN 2015a). From the beginning, the SCN has had a clear interest in embryo policy in Canada.

The SCN research program began in earnest in January 2002 when individual projects received funding.[5] At this time, the House Standing Committee on Health

[5] This is a reference to the time at which individual research groups received monies through the SCN to begin their research.

was reporting back to the federal government on the draft legislation on assisted human reproduction, and the CIHR Governing Council was considering the final report of the *ad hoc* Working Group on Stem Cell Research. To this point in the policy process, individual members of the SCN may have had an impact on the legislation via presentations to the House Standing Committee on Health (see, for example, Baylis 2001) and on the guidelines *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research* (CIHR 2002) via membership on the Working Group. The SCN as a discrete organization did not participate in policy design. However, in the two years between the adoption of *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research* (CIHR 2002) and the passing of the *AHR Act* (2004), this changed. While the legislation was being debated in Parliament, SCN members testified before House and Senate committees and lobbied members of Parliament. Some SCN members spoke on behalf of the Network, others spoke on their own behalf. Some spoke in support of the legislation; some spoke against.

With the introduction of the *AHR Act* much of the overt advocacy activity temporarily quieted, but thereafter the SCN adopted a number of different strategies to enhance its influence.

First, in November 2005 the SCN created a multidisciplinary Policy Development Committee with a mandate "to consider issues of public policy relevant to stem cell research and with input from members and other stakeholders to develop draft position papers for approval by the SCN Board as representing the official views of the Stem Cell Network" (SCN 2006).[6] Since its inception the SCN's Policy Development Committee has published a total of 11 ethics and policy 'white papers' aimed at shaping public policy.[7]

The Committee's first position paper was on the "Use of human embryos for stem cell research". This paper which advocated the research use of fresh embryos aimed to legitimize (after the fact) research by an SCN researcher that resulted in the derivation of Canada's first hES cell lines. This paper also aimed to shore up the *Updated Guidelines for Human Pluripotent Stem Cell Research* which had been expressly amended in 2005 by the CIHR Governing Council (CIHR 2005a) "to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research" (CIHR 2005b).[8]

In Canada, consistent with the *TCPS2*, only embryos "no longer required for reproductive purposes or other purposes permitted under the *Assisted Human Reproduction Act*" can be used for research. Prior to 2005, it was generally understood (consistent with practice in IVF clinics) that "embryos no longer required for reproductive purposes" included (1) poor quality embryos unsuitable for embryo transfer or freezing and (2) frozen embryos not intended for thawing and embryo transfer (see, Rivard and Hunter 2005, 135–136; Baylis and McInnes 2007, 64 and

[6] The initial co-Chairs were Janet Rossant, previously the Chair of the CIHR *ad hoc* Working Group, and Bartha Knoppers, previously a Commissioner with the Royal Commission.

[7] http://www.stemcellnetwork.ca/index.php/ethical-legal-and-social-issues/

[8] Whereas typically practice is made to conform to guidelines, in this instance guidelines were made to conform with practice. The 2002 Guidelines did not discuss the use of fresh versus frozen embryos for hES cell research. Once it became clear that researchers were using fresh embryos for hES cell research, the 2005 Guidelines were amended to legitimize this research. For a detailed discussion of this see Baylis and McInnes (2007), and McLeod and Baylis (2007).

66). This understanding changed with the 2005 *Updated Guidelines for Human Pluripotent Stem Cell Research* which allowed fresh embryos to be considered in excess of clinical need regardless of whether these embryos were suitable for transfer or freezing (CIHR 2005b). This policy change was made despite the fact that asking women infertility patients to donate their fresh embryos to hES cell research is: (1) contrary to the Canadian Medical Association (CMA) Code of Ethics and the physician's primary obligation to promote patient interests (Nisker and White 2005b); (2) contrary to women's reproductive interests, (Baylis and McInnes 2007; McLeod and Baylis 2007); (3) challenges the process of informed consent (Nelson et al. 2008); and (4) unnecessary—a majority of hES cell lines have been derived from frozen embryos "in excess of clinical need", and poor quality embryos that have reached the blastocyst stage are a robust source of normal hES cells (Lerou et al. 2008).

Second, in a further effort to influence "the regulatory landscape" for stem cell research, the SCN set about developing a policy framework that would advance the interests of the stem cell research community:

> To deliver its message to political leaders and to the public, the Network organized presentations on Parliament Hill, expert testimony to the Standing Committees of the House of Commons and the Senate, letters and briefing notes to every MP and senator and participated in extensive engagement with the media, including over 300 appearances by Network researchers in the national press, TV and radio.[9]

Third, SCN policy objectives were also pursued through research and academic publications in collaboration with those responsible for the oversight of stem cell research. Consider, for example, an early collaboration between members of the SCN and members of the CIHR SCOC who together published an article defending the use of fresh embryos in hES cell research (Cohen et al. 2008).[10] The CIHR SCOC is the national oversight committee mandated to: i) provide CIHR Governing Council with policy advice on ethical and scientific issues (including advice on the development, interpretation, and implementation of the rules governing stem cell research), and ii) to provide ethics review of stem cell funding applications (many of which would be submitted by SCN researchers). To avoid potential, apparent, and actual conflict of interest, CIHR SCOC members should not have been collaborating with SCN researchers on policy matters that directly impact research that is subject to SCOC review. While the SCN's website explicitly describes its strategic program examining the social, ethical, and legal implications of stem cell research as being "arms-length",[11] the above example of collaboration suggests otherwise, and speaks to the skill of the SCN in advancing its policy objectives.

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[9] http://www.stemcellnetwork.ca/index.php/evidence-based-policy-making/

[10] At the time this article was published (May 2008), three of the authors (Knoppers, Isasi, and Nagy) were SCN-funded researchers, Cohen and Dickens were former SCOC members, and Brandhorst, Leader, and Evans were current SCOC members. In our view, it is possible (likely) that the former SCOC members were current SCOC members at the time the original manuscript was prepared. In the body of the article the authors acknowledge that five of the authors "are current or former members of the SCOC" (Cohen et al. 2008, 417). In the acknowledgements, three of the authors "thank the Canadian Stem Cell Network for funding support" (Cohen et al. 2008, 420). Nowhere in the article is there a statement about conflict of interest.

[11] http://www.stemcellnetwork.ca/index.php/ethical-legal-and-social-issues/

Fourth the SCN has also been successful in collaborating with various health charities that are well-positioned to support SCN policy objectives. It is generally understood that in some domains, not-for-profit organizations such as health charities have been co-opted by private interests (Batt 2010). The pharmaceutical industry, for example, has been quite successful in utilizing health charities as a means to "inform" patient populations about drugs "of questionable benefit" (Angell 2004; Herxheimer 2003). In the realm of stem cell research, the risk of capture does not appear to be an issue—not because health charities interested in hES cell research have a unique immunity to capture, but rather because their interests appear to be broadly aligned with those who promote hES cell research, including the SCN. As at 2009, the SCN counted 43 health charities/not-for-profit organizations among its partners. In addition to joint investment in research, partners collaborate with the SCN "on education and public awareness initiatives in order to encourage public dialogue on the potential of stem cell research in the context of a realistic understanding of where we are today" (SCN 2009).

The official positions of individual charities/not-for-profit organizations on stem cell research have not been uniform. Nonetheless, to the extent that the SCN has been able to coordinate a common front between the research community and the health charities/not-for-profit sector, it has succeeded in creating an impression of enthusiastic public support for the research efforts of stem cell scientists and the efforts to create a more permissive research environment.

Fourth and finally, the SCN has been able to advance its policy interests through its research portfolio, which included a Strategic Program on Public Policy & Ethical, Legal & Social Issues. This program aimed to support research that "focused on projects … of interest to policymakers and to an ELSI [Ethical, Legal and Social Issues] core facility.…Guided by the SCN's Clinical Trials committee, the facility prioritizes *where the Network can have the most impact in easing the ethics/regulatory/policy pathways* and undertakes or co-ordinates work to address the hurdles" (emphasis added) (SCN 2008).[12]

In summary, the SCN has been able to effectively participate in public consultations on human embryo research through its Policy Development Committee, its diverse collaborations (with CIHR's SCOC and with various health charities/not-for-profit organizations), and its own research agenda. The future is uncertain, however. Federal funding for the SCN through the Networks of Centres of Excellence program has come to an end and it is looking for other funders. If it is successful in attracting research funds, interest in contributing to policy initiatives as opportunities arise will probably continue. If it is not successful in attracting additional research funds its policy influence may or may not wane. While individual researchers and research teams might be pursuing their research independently, it is easy to imagine that with 14+ years of research collaboration, past SCN members could

[12] This wording originally appeared in a description of the Stem Cell Network Strategic Program IV: Public Policy & Ethical, Legal & Social Issues published in 2008 at http://www.stemcellnetwork.ca/research.php. This was eliminated from the SCN website following the publication of Baylis and Herder (2009b). The text cited can be retrieved through www.archive.org by: (1) inserting http://www.stemcellnetwork.ca/ in Search box; (2) selecting the date May 26, 2008; and (3) following the 'Research' footer at the very bottom of the page.

effectively mobilize should there be future opportunities to inform/influence public policy on human embryo research in Canada.

Future Policy Design Consultations

For many and varied reasons, for the past 15 years, the SCN has been well positioned to influence future policy consultations on human embryo research in Canada. First, as a Network of Centres of Excellence in stem cell research, the SCN carried with it the traditional authority of science. Second, having world class researchers among its members was an additional source of power and authority, as was its leadership role in creating the International Consortium of Stem Cell Networks (ICSCN) (ICSCN 2005). The mandate of the ICSCN is to facilitate international cooperation and to pursue collaborative research in areas of mutual interest including "stem cells and public policy". Third, the SCN readily assumed an air of reasonableness owing to its efforts at internal self-regulation (i.e., SCN policy documents) and its acceptance of external oversight (e.g., research review by the CIHR SCOC). Fourth, as noted above, there were structures and partnerships in place to produce and promote highly cohesive policy positions on human embryo research. Fifth, there was the weight of the SCN's financial interest in human embryo research. The SCN's total budget from the Networks of Centres of Excellence program from 2001 to 2017 is $CAD 83.3 million (SCN 2015b). A portion of this research budget directly funded hES cell research and was also used to leverage additional research funds. Sixth, through its partnerships with industry and specific initiatives like the creation of Aggregate Therapeutics Inc., or more recent entities like Centre for Commercialization of Regenerative Medicine (CCRM 2015), the SCN's full embrace of commercialization was in keeping with the federal government's core science and technology policy objectives (Herder and Dyck Brian 2008; Government of Canada 2007).

For all of the above reasons, the SCN's participation in policy design commanded significant attention and constituted a considerable counterweight to the contributions of interested Canadians. The consequences of this power imbalance could be damaging to future public consultation efforts (and the legitimacy of any policy decisions that might flow from such efforts) in at least two ways. First, public consultations may be more apt to be undertaken by interested experts (not the government) for strategic purposes and may intentionally privilege participation by the medical and research communities over participation by interested "non-expert" Canadians. Second, insofar as future public consultations are primarily strategic in nature (and driven by the research community), these consultations may mask important differences between values that come to be identified as "Canadians values" and the actual values of average Canadians.

In either of these instances, input-oriented legitimacy would be seriously compromised. In the first instance, the information generated through the public consultation would come largely from a discrete "interested" constituency but be (mis) described as "public" input. In the second instance, the issue would not be biased participation so much as biased interpretation.

Conclusion

The public consultations that have contributed to the formulation of current embryo research policy in Canada (legislation and research guidelines) have not been free from controversy. But at least conflicting views and interests of Canadians have been relatively transparent which, in our view, is essential for informed and respectful debate, not to mention strengthening the input-oriented legitimacy of any resulting policy.

However, over the years, Canadians have been less and less involved in policy design for embryo research. One plausible reason for the decline in citizen engagement is the sheer cost of meaningful public consultation. This requires a significant investment (in both time and resources) in public education, data collection, and analysis. Another equally plausible reason for the decline is the belief among some civil servants and politicians that the time for public consultation has passed.

We are less convinced. As noted above, legitimacy in policy design depends, in large measure, on achieving an appropriate balance between output- and input-oriented legitimacy. What is "appropriate" will depend on: i) what policies are already in place; ii) what consultation efforts preceded the introduction of these policies (and, more precisely, whether relevant and diverse constituencies were consulted and heard); iii) what power dynamics currently exist between various interest groups and policy communities; and iv) the nature of the policy choice under consideration. In our view, the best way to ensure that no one particular set of interests dominates the agenda in this ever-shifting area of public policy is to regularly assess (and as needs be adjust) the balance between output- and input-oriented legitimacy.

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Appendices

Appendix 6.1: Royal Commission on New Reproductive Technologies, Proceed with Care

Consultations and communications

Input from Canadians

Public and Private Hearings: more than 550 Canadians took part in and presented briefs to public hearings across the country.

Submissions and Letters of Opinion: 500 written submissions and opinions up to September 1993.

Personal Experiences and Private Sessions: 500 individuals wrote to the Commission about their personal experiences or participated in private sessions held across the country.

Information Meetings: to consult organizations such as public health associations, women's groups, religious organizations, groups representing people with disabilities, the legal and medical professions, the research community, and the pharmaceutical industry.

Search Conference: three-day session involving 32 experts in fields such as health, law, bioethics, and religion, as well as representatives of people with disabilities.

Public Opinion Research: more than 15,000 surveyed; surveys explored awareness, values, and attitudes.

Toll-Free Telephone Lines: to facilitate participation in the Commission's consultations for people who might have found it difficult or inconvenient to participate through hearings or submissions; to provide access to information about the Commission and its work; more than 6000 calls received.

Informing Canadians

Research Reports Released: Commission released 14 research studies during its mandate.

Newsletter Published: 50,000 copies of semi-annual newsletter, Update, detailing our research and other activities, were distributed through mailing list and public events.

Distribution and Information: 250,000 pieces of information distributed during the life of the Commission, such as information kits, brochures on the public participation and research programs, newsletters, speeches; information for use by community newspapers, journals, and opinion and editorial page editors; and information distribution also by cable television and satellite networks.

Media Activities: more than 1,000 media interviews were given and more than 7,000 media articles appeared about the Commission and its work.

Appendix 6.2: Discussion Group on Embryo Research

Summary of recommendations

Recommendation 1

No research on human embryos should be allowed unless it is approved and overseen on an ongoing basis by a National Regulatory Body (NRB). Violations should be subject to criminal sanction.

Recommendation 2

Human embryo research should be allowed only:

1. after the exhaustion of useful inquiry using animal or other non-human models;
2. when demonstrably necessary for the improvement of the human condition;
3. when of the highest scientific quality as determined by rigorous peer review; and
4. when approved by the NRB.

This recommendation should be incorporated in the appropriate legislation.

Recommendation 3

In keeping with current internationally accepted norms, research involving developing human embryos, ex utero, should not be permitted later than 14 days after conception. This limit should be subject to modification should there be new and compelling ethical or scientific justification to do so. This recommendation should be incorporated into appropriate legislation.

Recommendation 4

Viable human embryos should only be used in research where a compelling case is made that non-viable embryos cannot be successfully employed. This recommendation should be incorporated into appropriate legislation.

Recommendation 5

For acceptable regulation of RHE, a National Regulatory Body must provide a process of oversight of the clinical practice of reproductive technologies, in cooperation with the appropriate provincial licensing bodies and professional organizations.

Recommendation 6

After the woman/couple has arrived at a settled intention not to use their embryos for gestation, they should be given the choice of donating them to another woman/couple for gestation or donating them for research or directing that they be discarded. This recommendation should be incorporated into appropriate legislation.

Recommendation 7

Any use of embryos for purposes other than consented to by the woman/couple should be subject to criminal sanction.

(continued)

Recommendation 8

Medical procedures related to infertility treatment should be undertaken with the sole objective of the medical well-being of the woman undergoing the procedures and the resulting offspring. Medical management should be directed toward minimizing risk and maximizing the likelihood of a successful pregnancy. Procedures must not be altered in any way that compromises the medical interests of the woman and the offspring, even if doing so would make ova or embryos available for research. This recommendation should be incorporated into appropriate legislation.

Recommendation 9

While approved clinical procedures exist which involve manipulation of the embryos, appropriate mechanism for their approval and monitoring should lie within the clinical domain.

This recommendation should be incorporated into appropriate legislation.

Recommendation 10

Fertilization of human ova for research is prohibited unless the National Regulatory Body considers the research proposal to contain an exceptional circumstance in which anticipated benefits to society or future offspring require that the experiment occur. Such knowledge would have to be unattainable by other means. Violations should be subject to criminal sanction.

Recommendation 11

All research or experimentation on a human embryo (including but not restricted to human cloning, chimeras, production of interspecies embryos and transgenic human embryos) without the explicit approval of the National Regulatory Body should be prohibited. Failure to secure such explicit approval should constitute a criminal offense.

Recommendation 12

In the absence of a National Regulatory Body vested with the powers listed in Recommendation 19, fertilization of human ova for research and research into human cloning, chimeras, production of interspecies embryos and transgenic human embryos should be banned without exception.

Recommendation 13

PGD should only be offered in the context of structured, clinical trials approved and monitored by the National Regulatory Body.

Recommendation 14

Even if proven to be safe and effective, PGD should only be available to diagnose the most serious of genetic conditions as established on a list by a National Regulatory Body, because of its potential social and health impacts.

Recommendation 15

Commercialization of gametes and embryos for research should be prohibited both within Canada and in the context of importation and exportation. Violations of this recommendation should be subject to criminal sanction.

(continued)

Recommendation 16

Payment for gametes or embryos shall not exceed the out-of-pocket expenses for the donors and the costs of handling, storing, transporting and transferring the gametes and embryos. Violations of this recommendation should be subject to criminal sanction.

Recommendation 17

Reduction in the price of IVF or other medical services should never be exchanged for gametes or embryos for use in research. This recommendation should be incorporated into appropriate legislation.

Recommendation 18

A multi-perspectival National Regulatory Body should be created by Parliament through legislation without delay. This body should have jurisdiction over all aspects of reproductive technology. This legislation should also specify which conduct should be subject to criminal sanctions.

Recommendation 19

The National Body created through Recommendation 18 should include but not be limited to the following powers with specific reference to RHE:

1. setting of technical standards of investigation, clinical practice, and education within an ethical framework;
2. ongoing exploration of emerging ethical issues in RHE;
3. approval of research protocols and monitoring of approved investigation;
4. accreditation and supervision of facilities and licensing of practitioners and researchers using human gametes or embryos, in cooperation with the appropriate provincial and national organizations;
5. defining violations and breaches of conduct, and the enforcement of sanctions;
6. development of a strategy for information management related to such priorities as registries, research outcomes and clinical practice guidelines;
7. undertaking other functions as detailed in recommendations in this report.

Recommendation 20

The mandate of the NRB should allow for delegation of powers (other than whose falling within criminal jurisdiction), and development of partnerships with the provinces as well as regional and professional bodies.

Appendix 6.3: Assisted Human Reproduction Act

Prohibited activities

Prohibited procedures

5. (1) No person shall knowingly

(a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;

(b) create an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;

(c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;

(d) maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended;

(e) for the purpose of creating a human being, perform any procedure or provide, prescribe or administer any thing that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease;

(f) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;

(g) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;

(h) for the purpose of creating a human being, make use of any human reproductive material or an *in vitro* embryo that is or was transplanted into a non-human life form;

(i) create a chimera, or transplant a chimera into either a human being or a non-human life form; or

(j) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form.

Offers

(2) No person shall offer to do, or advertise the doing of, anything prohibited by this section.

Payment for prohibited act

(3) No person shall pay or offer to pay consideration to any person for doing anything prohibited by this section.

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Chapter 7
Public Engagement and Deliberation in Human Embryo Research Governance in Australia 2001–2011

Susan Dodds and Rachel A. Ankeny

Introduction

This chapter identifies and evaluates Australian processes for developing policy regard to embryo research, including the legislative process, the work of a legislative review committee, parliamentary debates, and the production of the National Health and Medical Research Council guidelines for such research. We examine various mechanisms used during each of these policymaking stages to engage various publics, and the procedures for balancing conflicting values, which were particularly evident given the strong promotion of biotechnology investment by government side by side with vigorous opposition to certain technologies by segments of the Australian community. We explore the ethical and democratic challenges posed by developments in embryo research as well as various difficulties that arose in engaging the Australian public during these policymaking processes, whether these might prove to be impediments to the development of justifiable and legitimate life sciences research policy in Australia, and what the future prospects are for productive and meaningful public engagement in these contentious areas.

In liberal democracies, the task of formulating public policy is complicated by the need to take account of the range of values present in heterogeneous societies. These values are often inadequately articulated using standard forms of political representation, and hence various types of public engagement are used, such as

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public submissions, focus groups, surveys or polls, citizens' juries, and consensus conferences. Although public engagement can have different goals, including education, gaining public trust in or acceptance of emerging technologies, or influencing the direction of scientific research, we focus on its use as part of policymaking processes because of the centrality of public engagement to claims about what makes justifiable and legitimate policy. Citizens now play indispensable roles in generating politically relevant knowledge; their views often are treated as seriously, or more so, than those of professional experts (Delli Carpini et al. 2004; Jasanoff 2004). Standard forms of scientific and political authority have been drawn into question, as many emerging technologies are controversial primarily because of conflicts in how they are evaluated and valued. Hence, policies failing to take account of public values run a serious risk of lack of legitimacy and credibility (Irwin and Wynne 1996).

Prior to 2002, research on human embryos was not regulated directly by federal law. The National Health and Medical Research Council (NHMRC) had developed a series of guidelines concerning embryo research that were regularly reviewed and revised, and several Australian states had legislation regulating both embryo research and assisted reproductive technology (ART). State-based legislation varied considerably, ranging from no regulation through law—relying entirely on the NHMRC guidelines and the judgment of individual research ethics committees in some states such as New South Wales—to quite comprehensive legislation, for instance in Victoria (which arguably as a result meant that the regulation was rapidly outstripped by technological developments).

As early as 2001 in Australia, there were explicit calls for public engagement about issues associated with human embryo research. These focused on strategies to involve "the public" in discussion and deliberation about ethically contentious issues, to seek input on relevant policy in this field, and to foster well-informed policy debate (for example, Andrews Report 2001; Knowles 2002). Australian federal and state governments have adopted the position that areas which involve ethically contentious issues, such as abortion, euthanasia, and reproductive technologies, need to be addressed in a different manner from other areas of health policy. Public engagement processes and alternative mechanisms for deliberative policy formation hence are adopted where the regulation addresses clearly contentious issues in bioethics and are pursued through a range of approaches or strategies: special reports and committees of inquiry; legislative review processes; "conscience" votes on legislation; or regulation through bodies with explicit responsibility for providing ethical guidance.

In the case of the regulation of human embryo research, all four of these strategies were utilized. Legislation was developed following the *first* strategy: a series of Senate hearings and an inquiry into human cloning and stem cell research that occurred in 2001–2002 eventually resulting in the Research Involving Embryos Act (Cth 2002) and the Prohibition of Human Cloning Act (Cth 2002). These Acts included clauses requiring the establishment of a legislation review committee within 3 years to recommend amendments to the legislation using the *second* strategy, establishment of a legislative review process. This review occurred in 2005, leading to recommendations for amendments to the 2002 Acts. The vote on both the original Acts and the amending legislation, the Prohibition of Human Cloning for

Reproduction and the Regulation of Human Embryos Research Amendment Act 2006, involved each major political party granting a conscience vote. In this way, the *third* strategy for addressing ethically contentious policy issues was deployed by releasing politicians from party restrictions. The *fourth* strategy, regulation through bodies with jurisdiction over ethical matters, was also deployed, in 2007, when the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) was required to revise its ethical guidelines on the use of assisted reproductive technology in clinical practice and research (NHMRC 2004) because of amended Commonwealth legislation.

One reason for singling out these areas of policy for extraordinary processes to secure public engagement may be genuine uncertainty about public attitudes on the issues, or about how the issues will affect citizens' lives. Governments then may seek input from citizens and other stakeholders through more direct means than political representation. Further, where governments recognize that the issues involved are not likely to generate consensus or near consensus, they may wish to explore the reasoning given for alternative positions to assess which views are defensible, which are inconsistent with democratic respect, and which may be misinformed or not viable. In other words, governments may be seeking a source of legitimacy for regulation, grounded in policy informed by the best available justification, which reflects informed opinion about the state of the science and current public values.

This chapter investigates the informal and formal Australian public policy processes with reference to human embryo research since 2001, and the degree to which they were structured to listen and respond to plural and conflicting values among Australian citizens. We examine the mechanisms used to engage various publics and the procedures for balancing conflicting values. These are evaluated in relation to their inclusiveness of diverse perspectives; the degree to which the policy debate is participatory; the degree to which the deliberators were informed of the state of knowledge (or uncertainty) relevant to the debate; and whether the policy development was characterized by discursive reasoning. We are particularly concerned with the ways in which diverse views were sought in developing the reasoning underlying the regulatory decision-making, and the privileging of certain vantage points that may have been built into the processes. In addition, we analyze the degree to which policymakers attempted to respond to the divergent opinions reflected in the public and political engagement over policy decisions.

But What Makes Policy Legitimate?

Public engagement, stakeholder involvement, and the discursive testing of competing arguments for policy recommendations are each characteristic of an approach to democratic political legitimacy that seeks to move beyond the purely formal processes which are marks of aggregative democracy. Conventionally, government policy is deemed legitimate if bureaucratic "experts" acting on the authority of a duly elected political representative decide it, or if it is made through a process of a

duly elected representative legislature (Mansbridge 1980; Young 2000). These formal processes may be complemented by opportunities for all affected members of a polity (normally citizens) to shape the policy, hence promoting participation in decision-making. Attempts to achieve this type of participation usually involve explicit efforts by citizens, often acting in groups, or through their representatives to arrive at policy recommendations by means of inclusive, informed, transparent, and accountable processes of collective reasoning. The aim of such processes of collective reasoning is to allow outcomes to be recognized as having been fairly decided through the criterion known as deliberation. Through such processes, public justification (understood as publicly defensible argument) for policy is constructed. These processes also can make explicit who is affected and what is actually at stake for them, hence creating participatory legitimacy. Participatory legitimacy is based on the idea that everyone likely to be affected by policy should have the opportunity to air his or her views and concerns as part the policymaking process. For those using this deliberative democratic approach to policymaking, legitimacy is closely tied to the degree to which those affected can shape policy and the quality of collective reasoning used in public decision-making. This approach involves the legitimation of policy through the transformation of interests via processes of

> collective decision making by all those who will be affected by the decision or their representatives: this is the democratic part. Also…it includes decision making by means of arguments offered by and to participants who are committed to the values of rationality and impartiality: this is the deliberative part. (Elster 1998, 8)

For deliberative legitimacy to be reached in a contentious regulatory domain, public and stakeholder input is needed so that policymakers can avoid the risk of pre-judging policy outcomes. In the case of human embryo research, there was (and continues to be) genuine uncertainty about the diversity and intensity of citizens' values and concerns, particularly their views concerning the potential benefits and risks of the technologies. Information is limited about how citizens' current values may be affected by potential scientific and social developments (see Dodds 2013). Assessment of embryo research regulation also requires adequate knowledge of the current state of the science, including areas that are contested and in dispute. Therefore, policymakers need to have access to a diversity of scientific, social, legal, and cultural information for policy formation in ethically contentious domains to claim legitimacy.

Based on these considerations, we outline the characteristics required for a policy process to claim some level of deliberative, participatory, and justificatory legitimacy, as legitimacy is never all or nothing but a matter of degree. These characteristics are used in subsequent sections of this paper to analyze the policy processes that occurred in Australia in 2001–2007 with regard to embryo research. First, the involvement of the public and various stakeholders needs to be characterized by inclusive engagement without presumptions about who should count as stakeholders and where traditionally excluded or oppressed voices are recognized and included (Young 2000). Second, there needs to be adequate citizen participation in the policy process to ensure that it is informed by the values,

concerns, and arguments of those who are affected. Third, policymakers need to ensure that the input they receive is well informed and reflects current knowledge of the technical and social aspects of the issues through a suitably critical approach to the promotion of public understanding of science (Irwin 1995). Fourth, the process of soliciting input from various publics and stakeholders should occur as a form of discursive participation, where participants give reasons and respond to counter-positions offered, rather than being framed as an adversarial contest with one correct answer.

These strategies are directed at achieving outcomes broadly viewed as defensible, rather than one group "winning" the argument (Gambetta 1998; Dryzek 2000). Public and stakeholder participation needs to occur under conditions of respectful deliberation based on well-placed public trust that public engagement processes will affect policy outcomes, rather than serving as a perfunctory consultation process that at best allows for the venting of opinion—what Alan Irwin has referred to as "public talk" (2006, 318). Finally, policy recommendations should include not only the outcomes of deliberative processes, but also justifications for those outcomes, thus allowing the underlying reasoning to be open to challenge in light of changing information or developments (what is termed "contestable justification") (Ivison 2002). Where a policy on ethically contentious issues has been formulated through processes of deliberation and where the justification of policy relies on certain social, scientific, or legal circumstances, built-in processes for policy review allow deliberations to be re-opened if these circumstances change.

We now offer a brief background to the regulatory history of embryo research in Australia before evaluating four of the key policymaking strategies relating to human embryo research: (1) the processes leading to the 2002 Commonwealth legislation concerning embryo research (2) the 2005 legislative review committee process; (3) the parliamentary conscience votes in 2006; and (4) the development of the NHMRC embryo research guidelines in 2007.

Human Embryo Research Regulation in Australia

Australia is a federation of six states (New South Wales, Victoria, Queensland, South Australia, Western Australia, and Tasmania) and two territories (the Northern Territory and the Australian Capital Territory). The states are self-governing within the constitutional limits of the federal structure. The territories have self-governing, regional governments, but do not have the constitutional status of statehood. The Commonwealth (federal) government has a limited range of legislative responsibilities, which includes power to legislate regarding corporations, commerce, trade, and interstate trade. Both state and federal legislatures can make law regarding criminal offences. The Commonwealth provides the bulk of funding for research in universities and hospitals as well as health care resources. The states have direct responsibility for many areas of law and policy, including health law, provision of health services (hospitals), and education. Legislation associated with assisted reproductive technology (ART) and embryo experimentation had been accepted as,

constitutionally, a matter for state governance. In proposing the legislation concerning embryo research and cloning, the Commonwealth government chose to make use of its corporations power within the Constitution (Section 51 (xx)) to impose consistent law across the country that would provide a framework for future state legislation and override current state legislation that was inconsistent with the Commonwealth law.

An example of an earlier attempt at national legislation related to embryo research was the Human Embryo Experimentation Bill, introduced in 1985 by Senator Brian Harradine. This bill caused the formation of a Senate Select Committee chaired by Senator Michael Tate (Tate 1986). The resulting Tate Report concluded that the bill not be further considered, and instead recommended regulation at the Commonwealth level with cooperation from the states and territories, as well as establishment of a national body to issue research protocols and licenses for embryo experimentation. The Harradine bill was never passed by Parliament, and the guidelines recommended Commonwealth regulatory mechanisms of the Tate Committee were never pursued.

Some of the first Australian legislation relating to human embryonic stem cell research had its roots in earlier state legislation in Victoria (1984, 1995), South Australia (1988), and Western Australia (1991), all of which banned destructive research on embryos. This legislation also provided guidelines for storage of embryos for ART and their destruction after a set period (which differed from state to state), as well as a ban on human cloning (although cloning was defined differently in each state). The original Victorian legislation had a strict regulatory system that included criminal penalties, which was replaced in the later act by a licensure system for ART clinics and providers. Research that destroys or diminishes the potential for an embryo to be re-implanted was prohibited, which effectively prohibited hESC research. Both the South Australian and Western Australian legislation also included licensure systems and codes of practice for ART providers, but were slightly more permissive with regard to the research activities allowed.

In most other states, committees were convened to examine ART practices. In addition, in New South Wales, the Law Reform Commission issued a set of detailed reports, none of which resulted in legislation (Chalmers 2002). Some states, such as New South Wales, also had additional, specific guidelines requiring ethics committee oversight. In the states and territories without embryo research legislation, researchers were primarily bound by the NHMRC's Ethical Guidelines on Assisted Reproductive Technology (1996) (NHMRC 1996) and the National Statement on Ethical Conduct in Research Involving Humans (1999) (NHMRC 1999), which provided a form of quasi-regulation (see Nicol et al. 2002).

The NHMRC is the main source of formal ethical guidelines for publicly funded health and medical research, a function administrated through the Australian Health Ethics Committee (AHEC) (see Dodds and Goddard, this volume, Chap. 10; Thomson et al; this volume, Chap. 9). On the issue of embryos, the NHMRC Guidelines in effect prior to 2002 focused on ART services (these providers often also conduct research), and only in this context did the Guidelines address issues of embryo experimentation and (implicitly) human cloning. Under the Guidelines,

sanctions for infringement are not criminal, but relate to loss of research funding or more informal penalty mechanisms. The Guidelines recognized the divergence of values among Australians in relation to embryo research, and clearly limited work with human embryos to 'therapeutic procedures which leave the embryo, or embryos, with an expectation of implantation and development' (NHMRC 1996, 10). This type of therapeutic research required approval by a human research ethics committee (see Harvey 2008).

The Guidelines also prohibited the production of embryos for purposes other than use in ART, as well as experimentation aimed at the 'development of human embryonal stem cell lines with the aim of producing a clone of individuals' (NHMRC 1996, 15). Finally, the Fertility Society of Australia administers an accreditation committee for ART clinics, which requires compliance with a code of practice that also makes the NHMRC guidelines binding for private clinics; this puts in place a form of self-regulation, though some critics have argued that the system is not adequately independent and that formal legislation would be preferable (Nicol et al. 2002).

Following news about the cloning of Dolly the sheep, the Commonwealth government, through the Minister of Health and Aged Care, requested more detailed advice on cloning from AHEC, including recommendations for a regulatory model that could articulate with international regulations and guidelines. In response, AHEC specifically recommended that all states and territories introduce legislation to regulate and limit research on human embryos based on the NHMRC Guidelines. In addition, AHEC explicitly recommended that 'informed community discussion' on the potential risks and benefits of cloning techniques should be fostered by the Health Minister (AHEC and NHMRC 1998, 43).

Strategy One: Special Inquiry into Ethically Contested Regulation

In August of 1999, following continuing popular media coverage of developments in cloning and hESC research, the Commonwealth Health Minister Dr. Michael Wooldridge requested a review of the AHEC report by the Federal Parliament's House of Representatives Standing Committee on Legal and Constitutional Affairs. Two years later, the Andrews Report (named after committee chair Mr Kevin Andrews, MP) was released. In preparing this report, the Committee not only reviewed the existing AHEC Report, but also initiated a public consultation process. The Committee invited submissions from the general public through a website established for the Committee as well as publicity in major newspaper outlets; it also solicited submissions from various governmental agencies, religious representatives, medical and scientific organisations, community representatives likely to have interests in the topic including disease support groups, legal scholars, and bioethicists. The Committee held two public fora early in 2000, at which various

spokespersons from religious, bioethical and scientific perspectives were asked to make presentations; attendees could ask questions or make statements following these presentations (AHEC and NHMRC 1998).

The Andrews Report recommended the establishment of federal legislation for the regulation of both publicly and privately funded research on human cloning and stem cells, writing that 'the questions raised by human cloning and research involving the use of embryos are complex social and ethical questions and should not be left to individual ethics committees to decide. Nor should the answer to such fundamental questions depend on geography or source of funding' (Andrews 2001, xxvi). Commonwealth legislation in this area would override existing piecemeal state legislation and also be separate from regulations governing ART. The Report proposed a 3-year moratorium on the use of somatic cell nuclear transfer (SCNT) for creation of human embryos and on human reproductive cloning. It proposed that any supernumerary ('surplus') embryos from ART clinics could be used for research that damaged or destroyed the embryos, so long as these projects had the consent of the couple whose tissues were used in the creation of the embryos, had been approved by ethics committees, and had been issued a 'license'; these rules would apply equally to private and public researchers working in Australia.

While the Andrews Committee's deliberations were ongoing, the Council of Australian Governments (COAG) – an organisation that fosters discussion between state, territory, and Commonwealth heads of government in an effort to promote consistent legislation – was also debating the regulation of cloning and related technologies. In mid-2000, the Australian health ministers agreed to develop 'a national framework to prevent the exploitation of human cloning,' and in 2001, COAG began to negotiate nationally consistent legislation to prohibit human cloning (COAG 2001). At a meeting in April of 2002, the members of COAG agreed to ban human cloning and to foster a regulation scheme to govern research involving the destruction of existing excess ART embryos that would be nationally consistent. This latter decision was part of a trade-off designed to balance community concerns with the desire 'to enable Australia to remain at the forefront of research which may lead to medical breakthroughs in the treatment of disease' (COAG 2002). The premiers of New South Wales, Victoria, and Queensland—the states with the largest research presence in this field—had threatened to allow stem cell research even if the Commonwealth Government sought to ban it. As a compromise, it was agreed that only embryos created prior to the COAG meeting held on April 5, 2002, could be used for research. This restriction, set to expire in 2005, was introduced to prevent the deliberate creation of embryos intended only for research purposes during that moratorium. The states also agreed to develop state legislation to complement the federal legislation.

In June 2002, when the House of Representatives of the Commonwealth Parliament began to consider the Research Involving Embryos and Prohibition of Human Cloning Bill, a considerable amount of debate had already occurred and the COAG guidelines were already in place. The proposed bill prohibited human cloning, as had already been agreed to by the states via COAG, and only allowed

experimentation on supernumerary embryos with oversight, again in line with the COAG decisions.

Prime Minister John Howard quickly announced that a 'conscience vote' would be allowed on the bill, an extremely unusual provision that allows voting across party lines and in line with ministers' personal values and moral beliefs (see Chap. 4 on Conscience votes). For some this practice is considered to run contrary to representative democracy. Others, however, argue that this is no less consistent with representative democracy than voting along party lines when the matters being voted on are not related to policies aired during the election process. The phrasing of the original bill did not allow a vote in opposition to both cloning and all forms of embryo experimentation, as it explicitly allowed some forms of embryo experimentation. For this reason, the bill was split by the House of Representatives in late August of 2002 into the Prohibition of Human Cloning Bill and the Research Involving Human Embryos Bill. Both bills were passed by the House of Representatives. When the two bills were sent to the Senate, the Senate Community Affairs Legislation Committee (chaired by Senator Sue Knowles) established a Selection of Bills Committee of Inquiry that reviewed both bills and delivered a report suggesting considerable disagreement: from a six-member committee came a report containing five distinct positions (Knowles 2002). Nonetheless, the Senate unanimously passed the Prohibition of Human Cloning Bill in mid-November and the Research Involving Human Embryos Bill was passed by a slim Senate majority in early December. Both bills received Royal Assent and became law in December 2002.

In arguments concerning ethically contentious areas of policy development, particularly in cases where scientific knowledge, theories, and techniques are rapidly changing, it is typically assumed that policymakers should assess and track public attitudes toward the relevant scientific developments and to weigh the competing concerns carefully. In the case of the development of the Australian human embryo experimentation and cloning legislation, these assumptions are evident in a number of the Parliamentary reports, including the Andrews Report, various contributions to the Knowles Report, the AHEC submission, and statements by state and federal representatives following the passage of the Acts. For instance, the Andrews Report clearly states its concern about the necessity of public consultation in the development of policy concerning human cloning and embryo research:

> These are not matters to be decided behind closed doors by scientists or lawyers, however expert and sincere, without widespread community consultation. Nor are they matters that can be resolved by doing nothing. As a society we are confronted with profound issues that require ongoing attention and discussion (Andrews 2001, xiii).

The Andrews Report also expresses view that debate about the significance of scientific advances should be encouraged within the scientific community and should inform regulation: 'So that regulation in this area is appropriate to these benefits and risks [of developments in treatment of human diseases], the debate and consultation over the issues arising from the scientific advances in science should be as informed as possible' (Andrews 2001, 3).

Similarly, in submissions to the Andrews Report and in the subsequent debate that led to the passage of the federal legislation, various politicians, ethicists, and legal commentators claimed that there was need for continuing public debate on the social and ethical consequences of hESC research and the potential for therapeutic cloning (Knowles 2002). For example, Senators Stott Despoja, Lucas, and Webber argued for 'better mechanisms to educate and involve the public in bioethical issues. We need to ensure that the public has access to information, that they are educated about the issues in language they understand, and that they feel able to make their voices heard on the issues' (Knowles 2002, 170). They recommended a process similar to the U.S. Presidential Commission on Bioethics, which they viewed as constructed to articulate and present 'a variety of views rather than reaching a single consensus opinion. Such a process, properly constituted, could help facilitate a greater understanding of bioethical issues here in Australia' (Knowles 2002, 170–171). Senators Barnett, Heffernan, Hutchins, and others, citing the submission by the GenEthics Network (GenEthics 2002) objecting to NHMRC review, were not convinced that a subcommittee of the NHMRC was the most appropriate body to review the legislation, because it would not provide for proper representation of public concerns about the legislation. They argued:

> …review by a joint house parliamentary committee, comprising representative numbers of each party [would be] more appropriate. There are serious ethical issues that this review needs to take into account, and not only are members of parliament appropriate representatives of community concerns, but furthermore, it is appropriate that legislators have a role in the review of contentious legislation such as this (Knowles 2002, 134–135).

Despite these various statements apparently seeking to open up public discussion about the issues raised by hESC and cloning, there are good reasons to question whether all of those who made such calls genuinely sought open public debate about the legislation. One notable feature of such calls in relation to hESC research was their emphasis on issues around the scientific, social, and ethical potential of the research, where this was understood as largely separable from the economic and financial potential of the research. Although politicians from various perspectives raised questions about the economic impact of hESC research and cloning, the constitutionality of federal regulation, states' interests in attracting the biotechnology industry into their areas, and the risk that 'cutting edge' scientists currently employed by Australian research institutions might leave the country to pursue their research elsewhere, these were not among the issues suggested for inclusion in the public debate. The mandate for the public debate was tightly circumscribed, focusing on a narrow range of ethical issues, without any clear argument to support such a limited focus (Andrews 2001, 10, 23). The processes leading to the passage of the Prohibition of Human Cloning and Research Involving Human Embryos Acts in 2002 do not offer a model of participatory democratic public policy development, despite the many references to a need for public consultation, engagement, and deliberation.

Strategy Two: Independent Legislative Review

The 2002 Research Involving Human Embryos Act and the Prohibition of Human Cloning Acts prohibited all human cloning and allowed licenses to be granted for experimentation only on supernumerary embryos created before 5 April 2002. This was consistent with agreements in April 2002 by Australian state health ministers to foster a nationally consistent regulation scheme to govern embryo research (COAG 2002). Deliberate creation of human embryos intended only for research purposes was banned during the moratorium, and both Acts were scheduled for review by the end of 2005. Accordingly, a six-member independent legislative review committee (LRC) was convened in June 2005. The LRC's mandate was to review the scope and operation of existing legislation, particularly in light of developments in technology in relation to assisted reproductive technologies (ART), medical and scientific research, the potential therapeutic applications of such research, and changes in community standards since 2002. The LRC also was asked to consider the applicability of establishing a national stem cell bank and the effectiveness of monitoring and compliance schemes, such as licensing provisions.

Following processes for public engagement, the LRC recommended a continued prohibition of (1) human reproductive cloning; (2) implantation for reproductive purposes of human embryos created by nuclear transfer or means other than fertilization of egg by sperm; and (3) implantation of animal embryos into humans or human embryos into non-human animals. It also recommended continued use of excess ART embryos for research subject to certain licensing conditions, and the establishment of a national stem cell bank. More controversially, the LRC expressed support for somatic cell nuclear transfer, or 'therapeutic cloning', and transfer of human somatic cell nuclei into non-human animal oocytes to create chimeric embryos for research, as well as a number of other alternative techniques for creating human embryos. All of these permitted procedures required licenses from the NHMRC and placed a 14-day limit on development of such embryos before destruction (Australian Government 2005). The report was presented to the Minister for Ageing, the Hon Julie Bishop MP, on 19 December 2005 and was immediately referred for tabling in both Houses of Parliament and for presentation to state health ministers.

The LRC was explicitly required to consult with the Commonwealth, State, and Territory governments and "a broad range of people with expertise or experience in relevant disciplines", a mandate addressed through written submissions and invited testimony on the scope and operation of the two Acts (LRC 2005b). In its reports, the LRC described the various stages and types of expert and public engagement which included information provision (website, issues paper, literature review, media releases); collection of written and oral submissions on technical, scientific, legal, ethical and religious perspectives; public discussion forums; meetings with researchers, regulators and politicians and review of research on Australian attitudes towards stem cell research (through Biotechnology Australia).

In its report, the LRC indicated that it sought to reflect the range of views expressed through the public engagement processes noted above. In addition, there are signs of attention to the need to engage in a policy process that could have deliberative, participatory, and justificatory legitimacy, though the process was more successful in terms of some criteria than others. For example, although attempts were made to seek direct input from stakeholders, notably via calls for written public submissions, the structure of the process tended to privilege expert views as well as those of pre-identified and well-organized community groups, particularly those taking religious perspectives. Although the LRC report makes extensive use of quotations from a number of submissions, contributions by researchers, clinicians, ethicists, representatives of religious organizations, and government agencies are disproportionately quoted.[1] Hence engagement was less inclusive than it might have been, as there were few opportunities for participation by those not already identified as "stakeholders" except in a limited manner through Biotechnology Australia's studies of public attitudes. In regard to deliberative processes, these were almost non-existent, and largely reflected so-called "passive" consultative processes (see McGurk et al. 2006, 810).

On the criterion of the critical promotion of public understanding of science, however, the LRC process was quite successful, in as much as it published an Issues paper which was generally in plain English and which provided relevant detailed scientific and technological information, including noting disagreements or gaps in knowledge within the field, in advance of seeking public submissions. There also were facilitated discussions among stakeholders in some cities, which allowed arguments and ideas to be openly pursued. But while these sessions had potential to foster discursive participation, as well as create conditions for deliberation, experts primarily attended them and they were limited in duration and scope.[2] As was the case with the issues outlined in the call for public submissions, the discussion topics structuring these sessions were not open-ended but were directly tied to the LRC's limited mandate. They related particularly to the scope and operation of the Acts with respect to new technological developments since the implementation of the original Acts (LRC n.d.). The limited number and types of participants led to conversations that generally focused on debate about the definition of the embryo in the LRC's Issues paper. On the positive side, the facilitated discussions used hypothetical scenarios to highlight points of disagreement, encouraged interchange between participants, and seemed to be aiming not to reach definitive conclusions but to air arguments and concerns.

The LRC itself, based on its report and first-person accounts by participants (Skene et al. 2008), claims that discursive participation and respectful deliberation were prioritized. However, it is unclear whether there was anything inherent in the

[1] We should place on the record the authors were among those who were invited to contribute to the public consultation process and the submissions made by the authors were quoted in the report.

[2] Academics were well represented in Brisbane and Sydney. In Melbourne, there were also carers and people with conditions that might be treatable using stem cell therapies as well as a number of pro-life organization representatives (see LRC 2005a, Appendix; LRC 2005b).

mandate or structure of the process that would have fostered these processes. Attention to creating conditions for deliberation instead may have occurred because of the background and expertise of members of the LRC, several of whom were well versed in bioethics and/or legal negotiation and mediation. The limited amount of time permitted for public engagement as well as the highly structured framing of the debate meant that there also were limited opportunities for developed or iterative deliberative processes, for instance in comparison to some of the Australian Law Reform Commission processes.

The LRC process performed reasonably well in terms of the criteria for review of the deliberative processes for contestable legitimacy. An explicit recommendation of the need for re-review was made, along with a recommendation for continued public education in the relevant areas of science. Although re-review might provide opportunities for public engagement, the latter recommendation seems to endorse a unidirectional form of science communication, the so-called "deficit model" of public understanding of science (Wynne 1991; Ziman 1991), which often in practice does not invite participation or deliberation. However, the process could be seen as going a considerable way towards fulfilling the criterion of contestable justification. The LRC report included both the outcomes of the processes of public engagement and justifications for the policies proposed including their underlying reasoning for recommendations and an assessment of the difficulties in the process, particularly the complexities of engaging various publics. For instance, it detailed many issues that the LRC encountered in attempting to address its terms of reference, including the need to assess the Acts in the light of "developments in community standards", as it found "that the social and moral concerns raised by ART and embryo research could not be explained simply by reference to a single 'standard' or set of values, beliefs or interests held by a single community" (2005a, 161). Nonetheless:

> In looking for common ground, the Committee noted that there are certain moral values that are held in common by all communities, such as a commitment to social justice and equity, and to the care of vulnerable members of society…Hence the Committee came to the view that consideration regarding the use of embryos for research needed to take account of both the value that different communities attach to the embryo, and the social and moral value that communities attach to the treatment of disease and the amelioration of infertility. (ibid.)

The LRC report clearly noted the diversity of views expressed, but also that:

> Each of these views is sincerely held and it was apparent to the Committee that all those who made submissions were motivated by a desire to do what is best for our society. However it was also clear to the Committee that these views could not always be reconciled. (ibid.)

The report thus sought to explain how the LRC worked its way through the moral morass of conflicting and non-reconcilable views to generate its recommendations. In framing the recommendations, the LRC considered that the higher the potential benefits of an activity, the greater the need for ethical objections to be of a high level and widely accepted in order to prevent the activity (ibid., 162). Procedurally, this claim is crucial as it attempts to make explicit the reasoning used, although there are

a number of definitional problems inherent in this weighing exercise, notably, how benefit and harm are to be measured, by whom, and so on. In particular, the relative weight assigned to the claimed benefits of human embryonic stem cell research relative to ethical objections about such research was the key argument used to support the LRC's recommendations in favor of the use of "excess" ART embryos for research, as well as the use of somatic cell nuclear transfer and the creation of chimeric embryos for research.

Strategy Three: Conscience Votes

In Australia, federal parliamentarians are expected to vote according to pre-existing party policy or under instructions from party elites. A conscience vote, or a "free" vote as it is sometimes known, occurs on a Bill, Motion, or Report either because a political party does not have a policy position on an issue or because the party decides that members should be "permitted to exercise their responsibility in accordance with conscience" (Harris 2001, 277). In such cases, "members are not obliged by the parties to follow a party line, but vote according to their own moral, political, religious, or social beliefs" (Penguin 1988, 86).

Permitting a conscience vote is a pragmatic way of addressing divisive policy questions, and accommodating diverse moral or ethical views within the party (see also the chapter on Conscience votes in this volume, Chap. 4 by Ross, Dodds and Ankeny). This is because a conscience vote is preferable to members voting against party policy and "crossing the floor". Conscience votes encourage an increased level of public engagement, lobbying, and deliberation, which suggests that in these cases parliamentarians may be more informed than otherwise. Thus, they are more likely to attend to the views expressed by their constituents and to be moved by the arguments of their parliamentary colleagues without regard to the party of the person making the argument. Voters may have good reason to believe that their efforts at persuasion of their elected representatives will be more effective where the representative has the freedom of a conscience vote. Further, there are additional pressures on elected representatives for transparency regarding the reasoning underlying particular decisions, so that outcomes can be recognized by citizens as having been fairly decided and informed by citizen responses to the issues. For these reasons, conscience votes may enhance deliberation and accountability within a Parliament.

In the case of embryo research, the existing Bills, together with the LRC recommendations, were put on the parliamentary agenda for debate in 2006. Discussion centered on the more controversial proposals in support of somatic cell nuclear transfer and the creation of human–animal chimeras for experimentation. Limits imposed on research under the Bill included strict prohibitions on the implantation of cloned embryos into a woman and on allowing cloned embryos to develop beyond 14 days. There was also a requirement that the NHMRC develop "objective" criteria for determining when a human embryo is unsuitable for implantation. The debates garnered considerable media attention, and interchanges between members of the

electorates and their representatives were documented in Hansard, along with the debates themselves. All major parties announced that they would permit conscience votes on any legislative changes that might be proposed.

Democrat Senator Natasha Stott Despoja and Labor Senator Ruth Webber subsequently tabled a draft Bill incorporating all of the LRC recommendations for discussion. Later, a more conservative Bill, the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006, was introduced as a private Senator's Bill by Liberal Senator Kay Patterson in October 2006. Following amendments (including removal of permissibility of chimera research), the Bill passed through Senate on 7 November 2006 in a close conscience vote: 34 in favor and 32 against. The final conscience vote in the House of Representatives was not recorded although it passed "on the voices" on 6 December 2006 (Anon 2006). Opposing the Bill were three Liberal Ministers (Health Minister Tony Abbott, Treasurer Peter Costello, and Employment Minister Kevin Andrews), the Liberal Prime Minister John Howard, and the freshly elected Labor opposition leader Kevin Rudd (who was subsequently elected as Prime Minister in late 2007). They cited their personal moral objections to the Bill (Anon 2006; Burke 2006; King 2006). An appeal to "conscience" was also the motivation for some of those supporting the Bill, with Liberal Education Minister Julie Bishop saying: "I cannot in all conscience stand in the way of the only ray of hope available to sufferers of devastating and debilitating disease and injury" (King 2006).

In terms of the characteristics necessary for legitimacy, the processes associated with the parliamentary conscience votes on embryo research score fairly well in terms of what actually occurred. Among a number of senators, direct input from the electorate was actively pursued and received, and the reasoning underlying people's views was assessed, although the process itself did not in any way guarantee either of these.

Similarly, although neither required nor guaranteed by the conscience vote process, there is evidence in Hansard that many parliamentarians sought detailed information about scientific and social issues associated with embryo research through consultation with a range of experts, including those who participated in the LRC. However, the parliamentary conscience vote process did not create opportunities for inclusive engagement, as engagement was reduced to the usual forms of political representation and heavily privileged the positions of established "experts", including the LRC members. Nor did it explicitly seek to create conditions for respectful deliberation, though some level of public trust may have been engendered by the relative transparency of the parliamentary processes. Transcripts in Hansard and informal reports indicate that a number of politicians attempted to justify their positions and to make explicit their underlying rationales (see Australian Senate 2006). Senators Bartlett, Wong, and Colbeck, to pick just three, each commented on the quality of the debate, their own reasoning for their positions and, the basis for the positions presented in the debate Senator Bartlett underlined this, saying: "Given the importance of the issue before us, we need to examine more the substance of the arguments that need to be considered" (Australian Senate 2006, 16). However, as the ultimate output of this type of process is a vote for or against legislation rather

than a justificatory process, there were few opportunities for detailed justification of the outcomes and hence limited possibilities to fulfill the criterion of contestable justification. Nonetheless, the need to review the Bill over time was explicitly noted, and a further review of the legislation was chaired by Peter Heerey in 2011.[3]

Strategy Four: NHMRC Ethical Guidelines

The Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 was slated to come into effect on 12 June 2007, and as part of its mandate, the Australian Health Ethics Committee (AHEC) of the National Health and Medical Research Council (NHMRC) was required to review and revise its existing guidelines concerning embryo research – the 2004 Ethical guidelines on the use of assisted reproductive technology in clinical practice and research.[4] The inclusion of the NHMRC and AHEC in the embryo research regulation process is recognition of the distinction between law and ethics: that what is ethically desirable (or reprehensible) should not necessarily be directly reflected in law, and that the law is a relatively "blunt instrument" so further ethical guidance and interpretation is typically required following the introduction of legislation.

In 1998, following evidence of the potential for cloning technologies, AHEC had proposed that all States and Territories introduce legislation to regulate and limit research on human embryos based on the NHMRC guidelines (1996). The AHEC explicitly recommended that the Health Minister should foster "informed community discussion" on the potential risks and benefits of cloning technologies (AHEC and NHMRC 1998, 43). In response, the 2001 Andrews Report noted that AHEC should be charged with "developing and implementing a strategy to consult and involve the public in consideration of the issues arising from this research and encourage debate on the potential and implications of the research" (Andrews Report 2001, xx). However, the National Health and Medical Research Council Act (1992) only explicitly requires a public consultation process on guidelines for human research that "has regard for" submissions, without further details about what the process should include. For instance, it provides no details as to what would count as critical evaluation or assessment of submissions in relation to the matter at hand, as opposed to merely reading and noting submissions. In mid-April 2007, the NHMRC issued a consultation draft of AHEC's revisions to the existing

[3] The consultations process for this review included a call for public submissions and invitations and invitations to present at hearings of the review committee. There were 264 written submissions, of which 158 were provided in confidence (LRC 2011).

[4] These had been revised after information about the production of Dolly the sheep using cloning technologies become public in 1997. The Commonwealth government requested more detailed advice on cloning from AHEC, including recommendations for a regulatory model to align with international developments.

ART guidelines, including guidelines directly related to embryo research as well as so-called objective criteria for determining when a human embryo is unsuitable for implantation, and hence potentially eligible for research. The NHMRC requested public submissions on these draft guidelines within 1 month. The original draft document focused on providing ethical guidance concerning processes and consent for human egg and embryo donation, and concerning research on human embryos deemed unsuitable for implantation and those created by somatic cell nuclear transfer. However, the original document did not appear to fully recognize some aspects and implications of the new legislation. For instance, at times it made it sound as though some research practices (for example, somatic cell nuclear transfer) were still prohibited even if they could be pursued with a license. It also failed to mention explicitly any of the processes through which the revised guidelines were produced. As a consequence of the tight timeframe and what was fairly limited publicity, only 93 submissions were received.

Of the submissions made public,[5] 40 % were from individuals and 60 % were from organizations, including research institutes and ART clinics, religious and women's organizations, and disability or illness support groups. The final revised guidelines were completed as required by mid-June 2007 (Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research (20007)), and reflected minimal changes to the existing 2004 document "to the extent necessitated by changes to the PHC Act and the RIHE Act brought about by the Amendment Act" (NHMRC 2007, 7). An examination of the processes surrounding the production of the revised guidelines in terms of the characteristics necessary for legitimacy reveals that both the formal requirements for the process and the actual processes in which AHEC engaged were very limited. Direct public input occurred only via responses to the standard call for written submissions, and the response rate was extremely low due in part to the tight deadline imposed as well as limited publicity about the call for submissions. There is no evidence of any attempt to promote critical public understanding of science either within AHEC's own processes or externally, though there may have been an assumption that this had been secured by the promotion of public understanding of science that occurred in the LRC and parliamentary processes. There is also no evidence of overt attempts to broaden inclusive engagement, since, as already noted, public engagement was limited to written submissions.

More explicitly, AHEC's mandate does not foster discursive participation, as it only requires "having regard to" any public submissions made, and there is no evidence in AHEC's documents of any further processes of reasoning or exchange that would fulfill the requirements for discursive participation. The lack of transparency in AHEC processes thus poses an impediment to the conditions for creating public trust. The final document reflected only those changes needed to make the guidelines consistent with the legislation. It is unclear whether the consultation process allowed participation beyond the articulation of opinions on what the legislation

[5] In making submissions to the public consultation individuals or groups could elect to make a confidential submission to the review committee.

required of the guidelines. Similarly, with regard to the criterion of contestable justification, there was no information about how AHEC came to its conclusions or how they weighed public contributions. The documents issued focused only on outcomes rather than any justifications for the recommendations. Finally, the process fares poorly with regard to the criterion of the need for review over time, as there was no explicit discussion of when, or under what conditions, AHEC might need to review the guidelines. The 2007 guidelines have not been revised in light of the 2001 legislative review.

Conclusions: Reflections on the Future of Deliberative Policymaking Processes

In many respects the forms of public engagement and deliberative legitimacy we have outlined above are consistent with what Irwin has identified as "unsubstantiated words and empty rhetoric" (Irwin 2006, 318). Despite apparent general goodwill on the part of the committees and parliamentarians to engage various publics in most stages of the processes associated with the governance of human embryo research in Australia in 2001–2007, structural issues and other impediments undermined the promise of "public engagement". These limitations are important to consider for future life sciences policy development in Australia and elsewhere given the current dynamic of strong governmental promotion of biotechnology investment, which occurs alongside vigorous questioning of, and opposition to, certain technologies by various communities, particularly religious groups. Examination here of attempts to reconcile demands of concrete policymaking in real time with the goal of honoring significant differences in strongly held values suggests likely difficulties in relying on policy-recommending committees such as the LRC to resolve differences in the absence of a culture of public deliberation and specific expertise on how to foster deliberative processes. Depending heavily on written submissions provided within minimal timeframes, privileging expert testimony, and emphasizing representative processes may well result in the exclusion of many relevant stakeholders. Some may believe they do not have a stake in the issues under debate until the issues and the associated policy debate are brought to their attention through the fostering of deliberative opportunities.

In all four stages of the policy development process examined in this paper, there were prohibitive timelines, limiting the amount of participation in which participants could engage, as well as minimal deliberative processes for engaging various publics.[6] In both the LRC and AHEC processes, there also was a lack of clarity about how public engagement and deliberations might shape or change the

[6] It is arguable that other bodies which examine similar controversial bioethical issues, but which have different mandates, more effectively attend to establishing and fostering processes and frameworks for deliberation, such as the Australian Law Reform Commission and the New Zealand Bioethics Council.

outcomes, or whether they were largely proforma processes which ultimately would be subservient to the parliamentary ones. The pre-framing of the scope of debate limited inclusion of certain arguments and presupposed certain forms of reasoning as acceptable (see also Harvey 2008, 37). For example, only changes in public views since 2002 were to be considered by the LRC, which raised concern among a number of stakeholders. Finally, the processes tended to be reactive to public opinions expressed rather than creating conditions for inclusive deliberation.

Our conclusion based on this review of the attempts in the area of embryo research to foster participatory and deliberative legitimacy is not, ultimately, as pessimistic as it might first seem. We recognise the challenges facing those who would seek to develop models for open deliberative discussion of policy that could then inform legislators. However, we do not believe that the challenges are insurmountable or should be avoided. Indeed, within Australia there is a precedent for more deliberative policy formulation in relevantly similar areas to hESC research and human cloning, namely the process that framed the report of the Australian Law Reform Commission (ALRC) and AHEC on genetic privacy entitled Essentially Yours: The Protection of Human Genetic Information in Australia (ALRC and AHEC 2003). While the process may not be without criticism, it suggests a way forward for developing practical strategies for consultation that are directed towards the ideal of legitimacy grounded in processes of public reasoning. The process for arriving at the genetic privacy report followed an iterative deliberative process for bioethical policymaking. Public consultation began with the release of an Issues Paper, setting out the key issues relevant to development of policy in the area of genetic privacy, from the perspective of legal, ethical, and scientific experts (members of an expert advisory committee established as part of the Inquiry, and with reference to the position of various relevant international bodies). The Issues Paper was circulated widely in hard and soft copy as the first step in the public consultation process. Nearly a year later, the matters raised in that Issues Paper together with the response to that paper by key stakeholders (and other expert input) were refined into a Discussion Paper that was again widely circulated in hard copy and on the internet to promote public education and debate on the issue of genetic privacy.

The direct community consultation process involved a number of face-to-face meetings and public submissions. There were also 15 open public fora in capital cities and regional centres, at which members of the Inquiry's Working Group presented information about the issues and process of the Inquiry; questions and comments from the people who attended also were recorded, opening up debate among members of the public and experts. Over 200 meetings were held between the ALRC and AHEC team and key stakeholders, including meetings with international bodies. Over 300 written submissions were received, most of which were made available publicly through the Inquiry's website. The Inquiry made 144 recommendations to state and federal legislators (ALRC and AHEC 2003, 97–102). The submissions received and contributions made to the public meetings can be viewed as more genuinely reflecting a process of deliberation within which the participants were seeking to understand, explain, and persuade others with regard to matters relevant to policy development, rather than 'scoring points' in a political bargain for

a specific legislative outcome. It is possible for these intensive iterative consultation processes to be subverted by well-organised groups reflecting one perspective held in the community. Nevertheless, legislation that is developed as a result of this type of process can make a claim to legitimacy based on public deliberation—unlike legislation that has not had the benefit of such a process.

The limitation found in the Australian embryo research policymaking processes indicate that there is a need to trial different mechanisms beyond calls for submissions to enhance both the quality and quantity of direct input from a variety of publics, as well as to ensure different types of fora for formal and more informal public engagement. These mechanisms should seek not only to elicit public opinion but also to foster cultures of respectful deliberation and debate, in addition to allowing for ongoing promotion of critical public understanding of science without privileging expert scientific knowledge. In turn, there should be more engagement of those traditionally viewed as non-experts as well as those typically or systematically excluded in current processes.

There are, of course, good reasons for being cautious about "institutional claims to have embraced a new social contract of dialogue, transparency and consultation", as Irwin has noted with respect to his evaluation of policy processes associated with genetically modified organisms in the United Kingdom (2006, 302). Australian attempts to "engage the public" in policy development relating to human embryo research provide another excellent example of the need for this caution and for better "scientific understanding of publics", or for recognition that public mistrust of science is much more complex than a simple matter of ignorance (Wynne 2006). This Australian case study highlights the ways in which rhetoric may exceed processes for public engagement and how existing regulatory structures can impose real limitations on public engagement with policy development in real time, indicating that more proactive processes are needed. This case study also illustrates that public engagement with science and technology has become highly political, as a variety of actors, including legislators, increasingly recognize public views as an important source of legitimation for their positions.

Perhaps the most striking lesson for ethically contentious areas of public policy development in Australia is the need to recognize that the framing of contentious issues and of public engagement itself significantly affects who participates and who is considered a "relevant" stakeholder. More attention is needed to promoting transparency and accountability in governance processes, as otherwise public trust will not be achieved or maintained. Finally, few formal mechanisms currently exist for providing reasons for policy decisions. Such mechanisms are necessary to foster deliberation and for any useful review over time of policy, given the rapidly changing nature of these technologies. In the absence of careful consultation and engagement allowing public participation to be informed and critical, we cannot reliably claim to know which groups within the community are most concerned about a particular issue and why. In sum, any policy processes seeking public engagement about highly contentious bioethics issues need to be inclusive and provide appropriate information about the issues under discussion. Attention to these issues will better ensure that all those affected have effective voices in what should be a

deliberative process, not solely those who have been best able to express their concerns in the past. Such deliberative processes are a critical part of the process of rethinking the development of new trajectories for bioethics policy.

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Part III
Human Research Ethics Guidelines

Chapter 8
The Tunnel at the End of the Light? Development of the Tri Council Policy Statement in Canada

Jocelyn Downie and Cheluchi Onyemelukwe

Introduction

There have been several cases of unethical practices in research involving humans in different countries in which research subjects were harmed, beginning with research malpractice during the Second World War. The ensuing scandals resulted in the enunciation of several international ethical guidelines, such as the *Nuremberg Code* (1947, Article 1) the *Helsinki Declaration* (WMA 2000) the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for International Organizations of Medical Sciences 2002) the *ICH Harmonized Tripartite Guideline for Good Clinical Practice* (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use 1997), the *European Convention for Human Rights and Biomedicine* (*Convention on Human Rights and Biomedicine*, 1997, ETS No 164) and most recently, the UNESCO Declaration on Bioethics and Human Rights (UNESCO 2005). In Canada, the case of the LSD experiments conducted by Dr. Cameron and his colleagues without the consent of the participants in the 1950s, as well as the cases of *Halushka v University of Saskatchewan* (*Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608) Sask. C.A.) and *Weiss V Solomon* (*Weiss c. Solomon*, [1989] A.Q. no. 312 (C.S. civ.)), where the research risks were not fully disclosed to the individuals involved, have been

Professor Bernard Dickens used the expression "the tunnel at the end of the light" in his presentation at the 1998 Canadian Bioethics Society Annual meeting in Toronto when he was reflecting on the process of the drafting and ultimate publication of the Tri-Council Policy Statement.

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documented. The more recent cases of Dr Olivieri and Apotex, which raised ethical questions about conflicts of interest and the duties of researchers to make available important information about studies in which they are involved,[1] and the death of James Dent in a gene transfer trial in Toronto (Downie 2003), emphasize the fact that research ethics remains a current and important issue in Canada.

The significance of research ethics in Canada was recognized by the three major funding agencies – the Social Sciences and Humanities Research Council, the Medical Research Council, and the Natural Sciences and Engineering Research Council–when they began a process of developing research ethics guidelines in 1994. That process culminated in the Tri-Council Policy Statement on Ethics in Human Research (TCPS) in 1998. The TCPS has since become the foremost policy guideline for the governance of research involving humans in Canada.

The establishment of the TCPS was thus an historic step in Canada's research ethics landscape, and thus deserves attention. As McDonald points out in the first treatment of this subject (McDonald 2009), it is important to have a sound historical understanding of Canada's research ethics history, not only for purposes of academic interest, but also to inform future policymaking. McDonald brings an insider's perspective to the process of creating the TCPS, having served as Deputy Chair of the Tri-Council Working Group—the group that drafted the document which evolved into the TCPS—from 1996 to 1998. In his paper, McDonald calls for more objective discussion and reflection on the process of bringing into being the TCPS (McDonald 2009, at 21).

In this paper, then, we answer that call. We investigate the motivation for this historic step. A decade after this historic process was completed we consider, also, with the possible clarity that retrospection can bring, the historical, legal and political context in which the process took place. We examine the extent to which the process of producing this policy demonstrated such important democratic concepts as legitimacy, transparency, accountability, representation and community engagement.

To secure public trust or citizen confidence, broad public consultation and civic engagement, which typically indicate a certain level of transparency and representation, are becoming an increasingly important part of the developing public policies in democracies such as Canada. The concepts of democratic legitimacy, transparency, accountability, representation and community engagement are essential in designing effective policy responses to public problems. This is no less so in an area such as research involving humans, where the issue of public trust and confidence is crucial to success. The objective of this paper is to highlight the extent to which these values have shaped research ethics policy in Canada and draw lessons for how future policies in this area and other areas that are possibly as contentious may profit from this experience. In this paper, we argue that efforts were made to ensure these basic democratic values in the process, but that these attempts should have been taken farther. In the following sections, we consider in more detail the process of

[1] For a description of the cases mentioned here, see Downie 2003.

developing the TCPS and critically examine the application of the concepts of democratic legitimacy, transparency, representation and accountability in that process.

The examination undertaken in this paper is particularly timely as the TCPS is currently under revision.[2] Although the process of drawing up a second edition is ongoing, we also consider, briefly, the direction in which that process appears headed, and what, if any, lessons can be drawn from the process of putting in place the current edition.

History and Background of Research Ethics in Canada up to Development of the Tri-Council Policy Statement

To understand the context in which the Tri-Council Policy Statement on Research Involving Humans was created, it is perhaps best to begin with a short history of research ethics guidelines in Canada. Below we recount briefly the history of research ethics guidelines in Canada, the motivation for creating the Tri-Council Policy Statement and describe the importance of the policy in research ethics and governance in Canada.

In the 1970s, the Canada Council, a federal agency which administered grants for research in the arts, social sciences and humanities established a Consultative Group on Ethics. This group was charged with developing general ethical principles for researchers. These principles were attached as appendices to the guidelines to be followed by applicants for Council grants, but they did not really serve as serious constraints to researchers since the Council management never ensured that they were adhered to (Rocher 1999; Adair 2001, 28–29). The Social Science and Humanities Research (SSHRC), after becoming independent of the Canada Council, also adopted its own set of guidelines in 1977, entitled: *Ethics: Guidelines for Research with Humans* (SSHRC 1979; McDonald 2000, 81). Rocher notes that these guidelines were basically a replication of the guidelines drawn up by the Consultative Group on Ethics. As he further notes, these guidelines arguably had little influence on researchers in the social sciences and humanities who, for the most part, showed little awareness of their existence (Rocher 1999). These guidelines were amended several times (The Feminist Health Care Ethics Network 1998, 257, note 2).

The Medical Research Council (MRC) also established ethics guidelines in 1978 (MRC 1978). These guidelines were subsequently revised in 1987 (MRC 1987).[3] The guidelines were used by researchers. However, they did not enjoy universal application, partly because of ambiguity in certain respects, as well as consultation by research ethics boards of other guidelines (Verdun-Jones and Weistubb 1996,

[2] The final draft of this revision prepared by the Interagency Advisory Panel on Research Ethics (PRE) is expected to be submitted to the funding agencies in February 2010. See Interagency Advisory Panel on Research Ethics (2008).

[3] See Starkman 1998, 272–3.

320). The Natural Sciences and Engineering Research Council (NSERC) had developed no research ethics guidelines, although it had the largest research budget of the three agencies (McDonald 2000, 82; Feminist Health Care Ethics Research Network 1998, 257, note 2). However, research funded by the NSERC was subject to the SSHRC or MRC guidelines, depending on which was most appropriate.[4]

With these guidelines in place, why was there a further move to implement a common ethics policy for research involving humans for the three Councils? Several controversies relating to research involving humans in the immediately preceding years appear to have been contributory. A 1992 incident, where a Concordia University professor murdered four of his colleagues after his complaints to his university of improper scientific conduct in research funded by the NSERC went unheeded, resulted in the Tri-Council Policy Statement on Integrity in Research and Scholarship in 1994 (MRC, NSERC, SSHRC DATE; Adair 2001, 28).[5] This policy required universities to develop procedures to deal with complaints of scientific misconduct (Adair 2001, 28, note 12). This policy paved the way for the three Councils to begin the process of developing a policy for research ethics (Adair 2001, 30). Other incidents of ethical misconduct which took place during this period, including falsifications of patients' records in a breast cancer study by Roger Poisson, a breast cancer researcher at St. Luc Hospital in Montreal, and other researchers' use of fraudulent data in several publications, may also have influenced the three Councils to seek a common solution with regards to ensuring high research ethics standards in Canada (Adair 2001, 29; Kinsella 2010; Altman 1994; Angell 1994). A 1994 report by the Royal Commission on New Reproductive Technologies, which recommended legislation to govern certain scientific activities, could also have motivated the decision by the three Councils to put in place a policy, in an attempt to preempt possible legislation on aspects of research involving humans (Kondro 1998, 1521).

In *The Governance of Health Research Involving Humans in Canada*, a report produced by the now defunct Law Commission of Canada, McDonald notes other specific reasons which necessitated the development of the Tri-Council Policy Statement. The process of developing the TCPS took place in an atmosphere of increasing changes in the types and complexity of research in Canada and around the world, including research into genetics and reproductive technologies. Thus the reasons for establishing a common ethics policy included that the existing guidelines were dated and thus did not cover new areas of research and recent technologi-

[4] Interagency Advisory Panel on Research Ethics. Introducing the TCPS: Development of Canadian Guidelines. http://pre.ethics.gc.ca/english/tutorial/00_intro_overview_context.cfm. Accessed 14 Apr 2008.

[5] Some commentators have also observed that the study undertaken by the National Council of Bioethics on Human Research (NBCHR) (now the National Council on Ethics in Human Research), which found that the MRC guidelines did not provide a functional environment for research ethics in Canada and that there existed a disarray in procedures and processes in Canadian REBs was motivated the establishment of the policy on integrity. The NBCHR recommended many procedural revisions, including increased regulation of REBs and research ethics in Canada. See Kinsella.

cal advances in the areas of biology and medicine. Further, the existing guidelines did not cover some disciplines implicated in research involving humans, including some interdisciplinary research and did not reflect newer thinking in the ethics of human research. The changes in international ethical guidelines in the norms in certain areas of research, particularly areas dealing with research involving collectivities, research involving women, and research in developing countries exposed inadequacies in the existing guidelines and served to highlight the need for developing new guidelines. Certainly these issues could have been taken care of by revising the existing guidelines.[6] However, it was also considered that to have separate guidelines for behavioural and biomedical research did not reflect the increasingly accepted ideas of the importance of integrated and interdisciplinary health research. Rocher notes that: "A growing number of social sciences researchers were involved in projects in the medical community as co-researchers or contributors: sociologists, anthropologists, demographers, researchers in administration. The disparity in ethical standards seemed blatant and was becoming particularly awkward" (Rocher 1999; Baer 1996). In addition, it became recognized that there were common moral values which govern all types of research, including such values as those found in the need to obtain informed consent and the avoidance of harm (McDonald 2000). Moreover, as the Councils pointed out, they had an obligation to the Canadian public to ensure that research supported by them met ethical standards (McDonald 2000) A set of guidelines which would have universal application and which would ameliorate the problems raised by employing different guidelines therefore appeared necessary.[7]

Although these reasons seemed clear enough, some in the research community raised issues with the need for one common ethics policy for all disciplines concerned with research involving humans. Fears were expressed that the policy would hinder research.[8] These concerns notwithstanding, the Presidents of the three funding Councils established the Tri-Council Working Group on Ethics in 1994, with a mandate to "to replace existing guidelines with regulations and policies" (Kinsella 2010). After several consultations and revisions, the final document–the Tri-Council Policy Statement–was published in 1998. The TCPS replaced the previous guidelines of the SSHRC and the MRC. It is an evolving document which means that it will undergo (and has already been undergoing) changes as new developments occur. These changes are administered by the Interagency Advisory Panel on Research Ethics (PRE) created in 2001, and which reports to the funding agencies.[9]

[6] This had been the initial task set by the Chair of the Working Group, that is, the revision of the MRC guidelines. See Working Group on Ethics Guidelines for Research with Human Subjects, Minutes of Meeting, Toronto, June 1994 at 7, cited in Feminist Health Care Ethics Research Network 1998, 234.

[7] See McDonald (2009) for an overview of the motivations for creating the TCPS.

[8] See for example, Scissons 1997.

[9] Interagency Advisory Panel on Research Ethics. About us: Mandate. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/mandate-mandat/. Accessed 14 Apr 2008.

With respect to the significance of the Tri-Council Policy Statement (TCPS), it occupies a central place and plays a crucial role in research ethics and governance in Canada, both for historical and practical reasons. As an historical document, it was the first ethical guidelines produced in Canada which addressed all research involving humans. Thus McDonald notes that, "Where TCPS represents a major change from the former regime governing RIHS (research involving humans) at Canadian universities and hospitals is in its creation of a unified set of prescriptions for all research involving humans to replace the previously separate reviews for behavioural research governed by SSHRC Guidelines and biomedical research governed by MRC Guidelines" (McDonald 2000).

The historical and practical importance of the TCPS is further emphasized by the transformation of the Medical Research Council and the National Health Research Development Program (NHRDP) into the Canadian Institutes of Health Research (CIHR). This followed the 1998 work of the National Task Force, comprising leaders in Canadian health research, which found that the health research system was highly fragmented and that a more organized forum for promoting health research was required. It recommended that the government increase funding for health research, and create a modern organization consisting of networks which would fashion an integrated health agenda, bring together all fields of health research and encourage collaborations between these areas and multidisciplinary research (Prescott 1999). The CIHR was created in 2000 by an Act of Parliament (Canadian Institutes of Health Research Act 2000, c. 6), following the federal government's promise earlier in the 1999 federal budget (Health Canada 1999; Finance Canada 1999; Public Health Agency of Canada Health 1999). One of the main motivations for the creation of the CIHR, then, was to bring together different disciplines which deal with health research. It is also one of its mandates under the CIHR Act.[10] The efforts to enact the TCPS, with its focus on all types of research involving humans, seem therefore prescient. The increase in government funding of health research that has come with the creation of the CIHR also increases the need to ensure high ethical standards for such research. The TCPS provides a policy for the research funded by the CIHR.

Practically speaking, its broad scope ensures that protections are available for research participants in different kinds of research involving humans.[11] It requires all research institutions to subject research involving humans to ethical review (CIHR et al. 1998, Article 1.1). It provides for the structure, the composition and the authority of Research Ethics Boards (REBs) (CIHR et al. 1998, Articles 1.2 and 1.3). Further, the Councils which provide funding for many research projects in various institutions will only fund institutions which provide certification that they are in compliance with the TCPS (CIHR et al. 1998, 1).[12] This stipulation applies to all research involving humans in the institutions, not only to the portion of research

[10] See section 4 of the Act for other objectives of the CIHR.

[11] This has, however, been criticized by several researchers in the humanities.

[12] Even with increasing commercial funding of research, the three Councils remain, as Palys puts it, "an important and valued source of research funding in Canada." See Palys 1996a.

funded by the agencies. It thus applies, indirectly, to research which is funded by other sources, including by private or commercial organisations. The certification process requires the entering into a formal "Memorandum of Understanding" with any of the three funding agencies or all, as the case may be, which requires the institution to comply with the TCPS.[13] In addition, sanctions may be imposed on institutions and researchers who fail to comply with the requirements of the TCPS.[14] Moreover, other funding bodies, including provincial or federal funding bodies, require compliance with the TCPS. These include several Canadian federal government organizations such as the National Research Council Canada (NRC), the Canadian Space Agency, Health Canada and National Defence, provincial funding bodies such as the Nova Scotia Health Research Foundation and the Manitoba Health Research Council.[15]

But the impact of the TCPS goes beyond just funding issues and may have other practical implications. For instance, some professional organisations like the College of Physicians and Surgeons require physicians, to obtain approval from research ethics boards which comply with the TCPS, or any other research ethics review body that they deem fit. Failure to comply with this requirement could lead to disciplinary action against such physicians by such organisations.[16]

Also, it has legal implications for researchers and research participants. For example, many research institutions make compliance with the TCPS a condition of employment for their researchers (McDonald 2000, 80). In this regard, Dickens describes the legal impact of a policy statement like the TCPS on researchers: "If a research funding agency makes due observance of a code, guideline or policy statement a contractual condition of an award of funding, breach is enforceable by legal action against a party to the agreement for breach of contract. The same is true when, for instance, a university, hospital or other research centre engages research staff and supervisors with an express condition in their contracts of research employment that research will be conducted and supervised in accordance with relevant codes, guidelines and/or policy statements" (Dickens 2000, 98–99). Furthermore, although the TCPS is only a policy statement emanating from the three funding agencies and therefore not an authoritative legal instrument, there is also the possibility, in dealing with such matters as the legal liability of researchers to research participants, that courts in Canada may invoke standards set in it (Hadskis 2007, 263).

The TCPS is therefore a major policy document in Canada's research ethics landscape, having implications for research participants, researchers, research institutions and research funding. Hirtle notes that "the 1998 introduction of the Tri-Council Policy Statement was a turning point for research ethics in Canada.

[13] See the Memorandum of Understanding online at: http://www.nserc-crsng.gc.ca/institution/mou_e.htm. Accessed 20 Mar 2008.

[14] See for example, the CIHR 2010.

[15] See Panel on Research Ethics.2009. FAQs: About the TCPS. http://www.pre.ethics.gc.ca/eng/panel-group/faq/tcps-eptc/. Accessed 14 Oct 2009. See Hadskis 2007, 263.

[16] See Hadskis 2007, 263.

Researchers' awareness of their ethical responsibilities for the research they conduct and of the boundaries of "acceptable research" increased" (Hirtle 2003, 137).[17] As the primary policy for research ethics in Canada, it is necessary that it be recognised as legitimate not only by those whose behaviour it seeks to affect, that is the researchers, but more generally the citizens who are potential research participants.

It is a reasonable undertaking, therefore, to investigate the process by which the TCPS came into existence, especially in the light of the necessary consensus that must have been sought between the different stakeholders that were involved or interested in the process. It is also important to inquire into what lessons can be drawn from that process. Below we consider, then, the political and legal context in which the process took place.

The Canadian Political and Legal Context and the Process of Developing the TCPS

As discussed above, in 1994, at the initiative of the Ministry of Health, and the Ministry of Industry and Commerce, the three major funding bodies–the MRC, the SSHRC and the NSERC–set up the Tri-Council Policy Working Group on Ethics (hereafter, the Working Group). The Working Group consisted of researchers sponsored by the three funding bodies and the goal was to create a common set of ethics guidelines which would regulate research involving humans in Canada (The Feminist Health Care Ethics Research Network 1998, 23; McDonald 2000, 81). Although it was the intention to create a 'code,' the document that emerged became a 'policy statement,' which nonetheless serves the same purpose as a code in that it governs all research involving humans (Palys 2003). The political context in which the process of developing the TCPS occured is particularly important, especially given that the purpose of this paper is to investigate whether and how values such as democratic legitimacy, accountability and transparency, (values that are typically associated with the political context) affected the process.

Canada operates a democracy. Thus, not only should decision making by government entities be in the public interest, democratic processes in policymaking should accord with the values of Canadians. Dodds and Thomson rightly point out that:

> The legitimacy of policy in democracies depends, in large part, on the public deliberative processes that informed the policy: not on the substance of the policy, but on the process of public reasoning used to determine it….people who will be affected by policies should have the opportunity to express their views about the matter in the process of policy debate, and their contribution to the debate should not be artificially constrained by that process (for

[17] The author notes, however, that a common conclusion in reports and the literature is that research ethics is becoming a matter of following rules and procedures—a bureaucratic process—as required by funding agencies or regulators and implemented by REBs. See also McDonald 2000.

> example, an imposed limit on the range of ethical issues that can be considered as part of the policy debate, or constraints on the form of submissions to the policy-makers). The ideal is to ensure that individuals have an authentic and effective voice in participating in public deliberation about topics that affect them. Policy makers draw on that public debate and engagement in setting the policy: the policy is thus informed by the public deliberations of the people affected by the policy. (Dodds and Thomson 2006, 331–332)

Barnes and others also note that: "Opening up decision making systems to wider influence is seen as a means of improving the legitimacy of decisions and enhancing the responsiveness of the services that are provided" (Barnes et al. 2004). Legitimacy, then, does not only affect the acceptability of the policy but also its usefulness to those who would utilize it.

Although writing specifically about legitimacy in governance, Montpetit's description of two understandings of legitimacy is useful in the context of the development of the TCPS. According to him, legitimacy could be said to consist of output-oriented legitimacy and input-oriented legitimacy. Output-oriented legitimacy is conferred on public policies by virtue of their promotion of the public good, regardless of who has conceived them. This sort of legitimacy relies on policymaking by experts. With input-oriented legitimacy, on the other hand, legitimacy is bestowed upon public policies when the public is conferred with. These two kinds of legitimacy are, however, not necessarily mutually exclusive and may work best together, resulting in experts and the public acting together to create effective policies (Montpetit 2003, 97). The creation of the TCPS appears to portray this kind of unity between input-oriented and output-oriented legitimacy. The Working Group, consisting ostensibly of experts, charged with drafting the guidelines by the three Councils invited input from the research community and the general public. Such public consultation demonstrated the desire for the guidelines which would emerge to be a result of a transparent, democratic process which would foster inclusiveness by addressing the concerns of different groups within Canadian society, and result in a legitimate document which would be widely applicable. The question, however, is the extent to which this aspiration was met.

Further, the Councils which sought to put in place the TCPS are government entities, disbursing government monies, raised from taxation dollars paid by the general populace, for the purpose of ensuring the conduct of research projects that would be of eventual benefit to Canadians. It is therefore a reasonable assumption that the process of putting in place the TCPS would be sensitive to, and take into cognizance the democratic values accepted in such a country. Such values include transparency, which involves an open process which takes into consideration the views of the stakeholders, that is, those who may be affected by the eventual policy which would be the result of a democratic process. The stakeholders in the process of making the TCPS included the funding bodies, that is, the three Councils who had a responsibility to ensure that research funded by them was conducted in an ethical manner, universities and teaching hospitals where much research is conducted and which employ the researchers, the researchers whose conduct the TCPS was put in place to regulate, research subjects or participants whose interests and safety the TCPS is meant to protect, and consumers of researchers who have a right

to safe products of research conducted in an ethical fashion. Were these stakeholders sufficiently represented and consulted with, in the process? How much input did these stakeholders have in the process of enacting the TCPS? Did the process thus exhibit sufficient democratic legitimacy, transparency, community engagement and representation?

Aside from the political context in which the development of the TCPS took place, the legal context is also important because in a society ostensibly governed by the rule of law such as Canada, the legal foundations of any important venture such as research involving humans affecting Canadians remain powerful. The legal context for research involving humans in Canada was, and continues to be, complex. At the time of the creation of the TCPS, Canada had no national or overarching legislation that governed all research involving humans. That is still the position today (Hirtle 2003, 137). When the process of developing the TCPS began, there was (and there still is) a variety of institutions, and legal and less formal rules, which govern research involving humans including clinical research. There are, however, various provincial statutes which deal with aspects of research involving human participants.[18]

There was no legislation or other legal rule which mandated the Councils to establish the TCPS or which dictated the process for the development of a statute. The legal basis for engaging in the process of developing the TCPS is therefore not readily apparent. As Dickens has noted elsewhere, "the law applies almost inadvertently to the enterprise of biomedical research" Dickens 2000, 93). Many have noted the complexity and ambiguity that is a result of the mosaic of rules and policies forming the basis of the governance of research involving humans. This mosaic may be considered an impediment to transparency which could adversely affect public trust (Hirtle 2003, 137). Also, considering the central importance of the TCPS to research, the research community, and the general public, it is arguable that a clear legal basis for the policy would have been very desirable.

It was within this political context of democratic values and unclear legal background that the Working Group developed the TCPS. It was an extensive process, which included soliciting of reactions from the research community, the principal parties that would be affected. This included the publication of an issues discussion paper by the Working Group in November 1994. A draft of the Code of Ethics was published in April 1996, which was distributed for comments from the academic community (Tri-Council Working Group on Ethics 1996). This draft elicited over 250 comments from the academic community (Dinsdale 1998). A final draft Code of Ethics was prepared in light of the comments received by the Working Group and was published in July 1997 (Tri-Council Working Group on Ethics 1997). Broad

[18] Quebec's Civil Code has provisions on research involving humans. Other provinces have legislation which impact research involving humans in several respects, including Newfoundland which has recently passed a legislation making ethics review a law. Also, Health Canada, in its role as the federal health regulator regulating drugs and medical devices under the *Food and Drugs Act* has introduced regulations governing the conduct of clinical trials for drugs, the *Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials) (Clinical Trials Regulations)*.

formal and informal consultation, extensive discussion, and analysis followed each of these publications (Rocher 1999; Christie et al. 2004, 67). In addition, the Working Group consulted other guidelines and codes of ethics for research involving humans, disciplinary and professional codes, as well as the work of scholars on the ethics of research involving humans from different fields, including law, philosophy, religious studies, social sciences, engineering, and health sciences (Tri-Council Working Group on Ethics 1996). After the third document was published in 1997, the Working Group revised the document and submitted it to the Councils. The Councils made several revisions to the Working Group version and published the final version of the TCPS in May 1998.

Evaluation of the Process of Developing the TCPS

To evaluate how well the Working Group succeeded in satisfying the aspiration for democratic legitimacy, transparency, accountability, representation, and community engagement it is necessary to consider several issues. In terms of legitimacy, was there an inherent conflict of interest issue raised by the creation of an ethics guideline by Councils whose major purpose is to promote research? In terms of accountability and representation, what was the composition of the Working Group? Did its membership reflect a broad range, or diversity, of persons? Apart from representation on the Working Group, broad-based consultation of the public would also be necessary to meet the criterion of community engagement. As stated above, such a body must solicit the perspectives of stakeholders and affected parties during the data-gathering and policy formation process (Weijer 1997). What was the nature of public participation in the development of the TCPS? How broad was the consultation?[19] Further, it is also essential to determine how the consultations were carried out, and the level of transparency, including whether or not there were open meetings to which the public were invited. Finally, it should also be considered whether the input received from various groups and the concerns expressed therein were duly considered. Did such input reasonably influence the outcome of the consultations, and to what extent was such input reflected in the final document, the TCPS? Each of these issues are considered respectively below.

Some commentators on the development of the TCPS observed early what they considered to be a conflict of interest arising from the role of the Councils as research funders and therefore promoters as well as ethical guidelines sponsors.[20] There is a strong argument that a conflict of interest exists. However, given that the Councils acknowledged their responsibility to ensure that the research funded by them is conducted in an ethical manner, it was not necessarily a bad idea to put in place the TCPS given the vacuum that existed at that point. In addition, a conflict of

[19] In this respect, Montpetit observes that: "Input-oriented legitimacy emerges not just when people are listened to and heard but when more people are listened to and heard" (Montpetit 2003, 102).

[20] See for example, Palys 1996a.

interest situation could be counterbalanced by taking extra steps to ensure the independence of the process. In other words, the desire to ensure that federally-funded research meets the highest possible ethical standards was appropriate, and the meeting of this desire would require further steps including ensuring the independence of the drafters of the ethical guidelines from the Councils.

Beyond a conflict of interest issue, the view of Working Group regarding the breadth of their mandate, would also influence the degree to which the concepts of democratic legitimacy, transparency, accountability and representation, and community engagement were utilized in the process. It would, for instance, affect how much time was given for communications to be received and how broad the consultations would be. In their article outlining the formal and informal process by which they sought to influence the Working Group, the Feminist Network, a group of interested feminists which made representations to the Working Group observed generally that:

> It was very clear from the beginning that our vision of the appropriate task for the Working Group was much broader than the one it has envisioned for itself. The specific questions asked, the time line set, and private conversations with some members of the Working Group all indicated that initially the Working Group was planning simply to tinker with the existing MRC Guidelines, making minor correction here and there and broadening the scope of the Guidelines to make them relevant to the other two granting agencies. (Baylis et al. 1999, 247)

Assuming this to be a correct picture of the mandate that the Working Group initially envisioned,[21] it is easy to see that the values of democratic legitimacy, transparency and community engagement could not fully have been realised in the process of developing the TCPS. The final product from the Working Group involved far more than tinkering and reflected a much broader interpretation of their mandate. The scope of the mandate would, for instance, have affected how much time was given for communications to be received, how broad the consultations were, and how well any comments received would be reflected in the resulting policy. As the discussions that follow indicate, there were problems in these areas, possibly arising in part from the Working Group's initial narrow view of the scope of its mandate. Confusion over mandate threatened, at the very least, the realization of the value of community engagement.

What was the composition of the Working Group? What was the process of appointing these members? What were the rationales for choosing them? In this regard, as Weijer et al, observe, "As a matter of democratic legitimacy, guidelines written to govern research involving a particular community should include community members in the guideline-writing committee" (Weijer et al. 1999, 277). Broadly speaking, then, it may prove useful, for democratic legitimacy and transparency purposes, that the Working Group include representation from different communities involved as potential participants in the research process. Information is not readily available in the public domain regarding the manner or rationale for choosing members of the Working Group. It would appear that members, who were

[21] And this would appear to be the case, see McDonald 2009, 13.

considered to be experts in areas considered relevant, mainly from the university research community, were chosen by the Councils and appointed individually. Thus, as is clear from the drafts of the Code available publicly, members of the group were drawn from different backgrounds and disciplines. They included doctors, lawyers, philosophers, psychologists and ethicists.[22] The composition changed several times before the last draft was produced. Palys criticised the process, noting that the members of the Working Group did not adequately represent the diversity in the research community. Representatives of socially and scientifically marginalized groups including, Aboriginal, Black, Third World, or radical Feminist academics and groups were not included as part of the Working Group (Palys 1996a). The Feminist Network also observed that their efforts to influence the committee were hampered in part by the lack of a gender balance in the composition of the committee, as well as a lack of sufficient numbers of feminists on the Working Group (Baylis et al. 1997, 8). It has also been suggested that a non-researcher from a vulnerable community may have been a valuable addition to the Working Group (Palys 1996a). Perhaps, at the inception of the process, there was an assumption that consultation of various groups rather than representation in the group would suffice to bring the required diversity into the resulting document. It would appear therefore that the composition of the Working Group left much to be desired, from the process of choosing experts to serve, to the diversity of the experts chosen to serve. In our view, although the Working Group should not have been too large in order to allow for meaningful exchange of ideas, there could and should have been greater diversity. In order to realize the goal of representation of those directly affected by the policy being developed, it would have been appropriate to include not only experts in the Working Group but also lay persons who had previously participated or were currently participating in research, and also members of different communities (for example, there were no individuals from Aboriginal communities nor any past or present research participants) and, only one third of the members of the Working Group were women. Greater diversity and better gender balance would have been more appropriate.

The second issue that arises for discussion is that of community engagement. In this respect, how broad were the consultations leading towards what eventually became the TCPS? Were the different stakeholders sufficiently consulted, and adequate time given for their input to be received? McDonald points out that "The Working Group received over 2000 pages of comments from over 250 respondents – almost all the respondents were from the research community – individual researchers, disciplinary groups, university and hospital administrators, research ethics boards, university departments and research institutions as such. In light of those comments and further discussions, the Working Group produced a final version of the Code and submitted it to the Councils in May 1997" (McDonald 2000, 82). Despite the seeming breadth of these consultations and the many comments

[22] They also included ex-officio members plus two ex officio members, the Honourable Mr. Justice T. David Marshall, chair of the MRC's Standing Committee on Ethics, and Dr. Abbyann Lynch, president of the National Council on Bioethics in Human Research. See Squires 1994.

received by the Working Group, several criticisms of inadequate consultation were leveled against the Working Group. One of main sections that received criticism for failure to seek sufficient consultation was the section on collectivities, which was originally to include aboriginal communities as well as groups such Ashkenazi Jews and others. The aboriginal communities were not formally consulted.[23] The section on aboriginal communities was eventually eliminated from the TCPS because there had been no formal consultation with the communities.[24] The CIHR has now established specific guidelines for health research involving humans in aboriginal communities after wide consultation with these communities (CIHR 2007). Other criticisms were also leveled by different groups at the time regarding insufficient dissemination of various drafts to the research community and inadequate time to comment on the drafts (The Feminist Health Care Ethics Network 1998, 247). The Working Group refuted these accusations.

Although it is important that the process include broad consultations of stakeholders in the research process, this would be meaningless if the results of such consultations did not influence the resulting document in significant and positive ways. Another important issue to examine, therefore, is whether, and the extent to which the comments solicited by the Working Group affected the outcome. Rocher notes that the results of the consultations by the Working Group and the comments received resulted in three broad changes to the final document. According to him the document "initially strongly marked by philosophical reflection, it became much more pragmatic; efforts were made to eliminate as much of the overly legalistic wording of the *Code* as possible; attempts were made to make it a document which, while unique, could be adapted for diverse applications" (Rocher 1999). Despite these changes, however, criticisms about the process have come from areas such as research involving communities (discussed above), research in the humanities, and research involving women. With research in the humanities, there has been much criticism about the TCPS by those who use different theories and methods than are typical in medical research protocols. The biomedical model of ethics review draws in part from the history of research ethics, beginning mainly with scandals in biomedical research and the reactions of different organisations and governments to them. The application of ethics, and the use of the biomedical model of ethics review has therefore attracted criticism from researchers in the social sciences and humanities (McDonald 2000, 82; Guillemin 2004).[25] Whatever the merits or lack

[23] Information from conversation with Prof. Bernard Dickens (May 8, 2008).

[24] Indeed in Section 6 of the TCPS, it is pointed out that: "During the drafting of this Policy Statement, suggestions were made to create a section dealing with research involving Aboriginal Peoples. The Agencies, however, have not held sufficient discussions with representatives of the affected peoples or groups, or with the various organizations or researchers involved. The Agencies have therefore decided that it is not yet appropriate to establish policies in this area. The text of Section 6, which builds on the extensive literature on research involving Aboriginal Peoples, is intended to serve as a starting point for such discussions" (TCPS, 1998, Section 6). See also, McDonald 2000, 82.

[25] Another essay however suggests that the criticisms may not stand under scrutiny. See Ells and Gutfreund 2001.

thereof of such criticism, one wonders, if, and how much of such criticisms, were made and attended to prior to the process of establishing the TCPS. With reference to research involving women and the TCPS process, one could draw from the experience of the Feminist Network. They sent comments to the Working Group pointing out that adopting alongside other perspectives, a feminist viewpoint, would allow greater fairness to women who were or would become involved in research as subjects. The issues they sought to address in their communications with the Working Group included the exclusion and underrepresentation of women in research even where the research goals were directly related to women's issues, the risk of exploitation of women subjects in research and research priorities and agendas which reflected oppressive views and attitudes. They noted that that their efforts to influence the process met with some success - initial drafts of the Working Group's guidelines were "sensitive to many of the issues we had raised in our first submission", but that they did not go nearly far enough in addressing the issues raised in their communications (The Feminist Health Care Ethics Network 1998, 251). More importantly, the last Policy which eventually emerged after revisions by the Councils did not reflect many of these changes. As is discussed below, these omissions were not peculiar to this particular group.

In any event, the Feminist Network made a specific point which has significance for the subject of this paper. In the areas in which they did not meet with much success with the Working Group, they concluded that they failed to take into consideration the political implications of the changes that they sought to bring about in the ethics guidelines under preparation and that more active political lobbying of the Working Group and, even more importantly, the Councils to which the Working Group was accountable would have been more effective.[26] While this argument has merit and is no doubt a realistic view, it is arguable that if the Councils truly recognized the value of democratic legitimacy, transparency, accountability, representation, and community engagement, there would be little need for the academic community and other groups to take cognizance of, and focus on such external factors as politics. Instead the focus would be on the most inclusive and ethical arguments which, despite the differing perspectives necessarily held by different stakeholders, place the research subjects at the centre. The ideal and the real are, however, different matters. It would appear that implicit in a discussion of the degree of difference made by the comments submitted by different persons, groups and communities is a question of power, politics and access. While some, like the Feminist Network, had difficulty in having certain sections amended or added, others may perhaps have been more successful because of greater access to, or more intense political lobbying of the Working Group or the Councils. For instance, the Canadian Association of University Teachers (CAUT) and other interested parties succeeded in "securing the deletion of the section on research involving collectivities and its replacement by a section limited to research involving Aboriginal peoples" because of their view that the section on collectivities would also limit research

[26] See generally, Baylis et al 1997.

on public entities and, consequently, academic freedom (McDonald 2001, 17).[27] There was therefore a certain degree of public participation, but perhaps not enough consideration of the issues raised in the consultations. Because there were no open meetings to which the public was invited,[28] and not all the documents submitted as part of the consultation are in the public domain, and with a decade having now passed, it is difficult to ascertain precisely how much public participation there was, how broad the consultations were, and how much the input affected the outcome of the deliberations of the Working Group. But from the examples used here, it is arguable that more could have been done in terms of improving participation, community engagement and transparency.

In addition, there were significant deficiencies with respect to transparency about the consultation process. A website with a record of the consultations held, the time periods for comments, and the comments received, would have been helpful in promoting transparency and addressing any issues regarding the adequacy of the consultations or time given for receipt of comments.

Finally, the evaluation must touch upon whether or not the input received from various groups and the concerns expressed therein were duly considered, and whether or not such input reasonably influenced the outcome of the consultations and to what extent was such input reflected in the final document, the TCPS. The issue of the final control over the content of the guidelines is perhaps the most significant with respect to the democratic values at stake in the TCPS development process; so many of the values were implicated and the steps taken by the Councils were so corrosive to the values. The Working Group finished their last draft and submitted it to the Councils. In the final analysis, the Councils had the last word on the guidelines. Indeed, Palys critiquing the first draft of the Code had noted that:

> Though there is mention made that the members of the Working Group will engage in revision of the document during the fall of 1996, the TCWG gives itself no obligations regarding the extent to which commentaries by members of the academic community will be considered, nor is there any indication that the research community will ever have an opportunity to express its consent to be governed by the principles espoused in the TCWG's final draft. Quite the contrary, the only persons to be consulted regarding the final document are "the Councils", who will offer their "ultimate approval", apparently on behalf of those they command. Such a choice hardly seems to embody the spirit of power-equality and emphasis on "human dignity and respect" that the TCWG's draft Code espouses as an ideal. One can only wonder why those on the Councils are not subject to the same high standards that are expected of researchers. (Palys 1996a)

McDonald, expressed similar fears, noting towards the end of the process that:

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[27] Ted Palys, for instance, in his criticism of the 1997 draft of the Working Group's Code notes a change of a tone in the document different from the tone employed in the previous drafts. This must have been a result of the consultations and communications received by the Working Group. See Palys 1997 and Palys 1996b. See Adair 2001, 30–31 describing his partial success with having several wordings changed at the Council level. He had been a member of the Working Group.

[28] Open meetings, it must be noted, are not necessarily always the best option in all policymaking situations. As Weijer notes, "openness is a clear expression of commitment to democratic process, but closed meetings may allow for greater consensus building" Weijer 1997.

> The code was a complex undertaking. Many difficult, agonizing choices were made during the process. My concern, especially with the three-person committee's short deadline, is that the enormous learning experience of Working Group members will be lost at this point and that, inadvertently, through lack of knowledge of these complexities, e.g., the 2500 pages of correspondence in the 1996 consultations and verbal communications from data reviews, their work will endanger the document's integrity. There is a real danger that they will not give back to the community something which is recognizably a result of the Tri-Council Group's final draft and the consultation process. The councils have to make some decisions about how to minimize those dangers, while moving the document forward quickly. (Canadians for Health Research 1997)

Others like Lowy even suggested that pressure was being put at the time on the Councils to water down the earlier Working Group's version of the Code or even block their approval of the Code entirely because it was considered unduly restrictive (Lowy 1997).

These comments appeared to foreshadow what did eventually occur at the end of the Working Group's mandate, when the document which ostensibly had received input from the research community went to the Councils. A number of significant changes were made to the draft at the Councils' stage. The introduction to the final version of the TCPS stated that it was "prepared by the Councils by revision of the Working Group's Final Report in light of consultations between mid-1997 and May 1998" (CIHR et al. 1998). However, it will be noted that the Councils did not invite more input from the research community, or even from the Working Group as a body, but merely revised the document themselves (McDonald 2000, 82). In this way, much of the value received from consultations of the Working Group and the helpful communications that they received may have been lost. An accusation of lack of transparency was therefore made against the Councils. In this regard, McDonald, points out that:

> The Councils have been criticized for a behind the doors revision process and a lack of public consultations – especially compared to the very open process used by the Working Group in revising the 1996 draft *Code*. (McDonald 2000, 82)[29]

He adds that: "Members of the former Tri-Council Working Group have publicly and privately expressed concerns about the quality and coherence of the revisions made to the 1997 draft *Code*" (McDonald 2000, 82). Some of the substantial changes made at the Councils stage included changes related to research involving women already discussed above. Although the Working Group had, following comments submitted to it, expounded on the role of, and protection of women involved in research, and there was a discussion of the complexities surrounding the setting of a fair and inclusive research agenda, this section was eliminated by the Councils. In this respect, McDonald noted that the Working Group did not believe that mere tinkering with the ethics review process provided enough protection for the interests of women in research (McDonald 2001, 2, footnote 21). However, for reasons best known to the Councils, this section was completely removed (Baylis et al. 1999, 253). In McDonald's words, this replacement was "the most tepid of statements in

[29] See also Baylis et al. 1999.

regard to the just distribution of the benefits of health research to men and women" (McDonald 2001).

Another area in which there was substantial difference is the difference in approach to the issue of public health research. Public health research was dealt with under the Privacy and Confidentiality Section in the Working Group's draft Code, but according to Joly, the Chair of the Working Group, was not addressed in the final version of the TCPS leaving "this area of research …in a grey zone and the nature of the regulations to be applied are almost totally undefined."[30] There were other more minor amendments as well, including the use of the term "research subject" in place of the term "research participants" used by the Working Group (McDonald 2001, 2, footnote 2).[31]

One could therefore argue that, particularly at the Councils' stage, much of the consideration formally or informally given to the concepts of democratic legitimacy, transparency, accountability, representation, and community engagement at the Working Group stage of drafting the policy guidelines was lost. Arguably, therefore, although significant attention had been given to criticisms of the TCPS at the draft stage (Palys 2003), at the final Councils' stage it became almost a dictatorial process in which the Councils had the last word on what constituted ethical standards for research involving humans in Canada, with insufficient consideration given to the wishes of other stakeholders in the process at the final but perhaps most crucial stage. Needless to say, it is difficult and perhaps even impossible to accommodate every viewpoint in developing an ethical policy guideline as wide-ranging as the TCPS, and that in seeking consensus on areas in which there may be major differences of opinion, certain standards may have to be sacrificed. However, one would have expected more attention to be paid to these very important concepts which affect not only the process but also the substance of such an important policy.

The Development of a Second Edition of the Tri-Council Policy Statement

When the TCPS was adopted in 1998, the Councils agreed to make it an evolving document, accommodating changes in the field of ethics and research and making amendments accordingly over time. The Interagency Panel on Research Ethics

[30] See Joly 2001, 155. The Code stated: "Public health officers may be mandated by law to undertake research and in such cases REB approval is not required; this does not, however, exempt public health officers from seeking REB approval when the research is outside their mandate. In such case, REB approval is mandatory and, in all cases, respect for persons must be observed." The TCPS has no equivalent provision.

[31] See also, for instance, Flagel 2000. In the area of psychological research, the word "deception" which was allowed in the Working Group's draft code was eliminated in order to ensure that it would pass through the scrutiny of the Department of Justice. See Adair 2001, 31. See also, McDonald 2009, 18.

(PRE) was therefore created in 2001 to administer these changes and to support the development of the TCPS.[32] In addition, PRE also provides advisory opinions on issues in the TCPS, answering written queries from researchers, research ethics committees, and administrators.[33] It consists of 12 volunteer members who are experts in different research areas.[34] Since its creation, the PRE has been engaged in several consultations on different aspects of the TCPS. More recently, they have been engaged in the process of preparing a second edition of the TCPS, which is expected to be ready sometime in 2010.

The PRE in December 2008 presented a Second Edition of the TCPS (PRE 2008) for public comment. A final draft is due to be submitted in 2010 (PRE 2008). Given that consultations on the new draft are currently ongoing, it is perhaps too early to analyse with much depth the differences in the processes of development of the two editions. However, it is apposite to consider what may be different thus far.

In what way, then, does the process of drawing up the second and forthcoming edition of the TCPS differ from the first? And what lessons have been drawn or should be drawn, from the first edition? In trying to answer these questions, we seek to raise again questions relating to legitimacy and the inherent conflict of interest issue raised by the creation of an ethics guideline by Councils whose major purpose is to promote research. In terms of accountability and representation, what was the composition of the PRE and the Working Committees? Does its membership reflect a broad range, or diversity, of persons? Has there been sufficient broad-based consultation of the public necessary to meet the criterion of community engagement? It should also be considered whether the input received from various groups and the concerns expressed therein are being duly considered. Will such input reasonably influence the outcome of the consultations, and to what extent will such input be reflected in the final document? These are not easy questions to answer, particularly in light of the fact that the second edition is still in the process of being finalized and will not be so until the Fall of 2010. And yet, they are questions that need to be asked in order to address the concerns that arose in the process of creating the current edition of the TCPS. Some of the answers attempted here are obviously only speculative and preliminary, given that the process is still continuing. Below, we reflect on that ongoing process and consider the lessons that may have been, and should be, learned from the process of developing the current edition. We begin with a brief consideration of the political and legal context in which the development of the second edition is taking place. We then consider some of the new content of the draft second edition. Finally, we examine the process and what, if any, lessons could be learned from the process of drawing up the current edition.

First, it is important to note that the political landscape remains largely unchanged and that the legal landscape has changed somewhat, but not drastically. Other federal legislation which have an impact on research ethics governance such as, the

[32] Interagency Advisory Panel on Research Ethics. About Us: Mandate. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/mandate-mandat/. Accessed 14 Oct 2009.

[33] Ibid. See for instance, Jones 2007.

[34] Ibid.

Canadian Institutes of Health Research Act enacted in 2000, *Personal Information Protection and Electronic Documents Act* (PIPEDA) enacted in 2000, and the *Assisted Human Reproduction Act* which was enacted in 2004, all of which contain several research-related provisions, have been developed since. What this means is that there is more legislation which has implications for the conduct of research in addition to guidelines.

The forthcoming edition[35] has benefited from the current edition in different ways. In terms of content, the new edition has adopted some of the content that featured in the Working Group's draft Code. An obvious example is the use of different terminology such as the adoption of the term "research participant." The term "research participant" had earlier been proposed by the Working Group and was used in its Code.

Apart from provisions which have their roots in the Working Group's Code, many revisions are also the product of consultations and comments received by various working groups since the PRE was established in 2001. Other areas have therefore benefited from the insight of working groups, expert panels, and interpretations provided by the PRE since its establishment. One of the areas in which work has been done by the PRE is in the area of social sciences and humanities research, an area in which concerns were raised during the process developing the TCPS, and even afterwards. One of the main concerns, pointed out above, was the concern raised by social science and humanities researchers about the TCPS and how it affected the kinds of research in which they engage. Accordingly, in 2003, the PRE created the Social Science and Humanities Special Working Committee on Research Ethics (SSHWC). The SSHWC was charged with advising the PRE on the development of the TCPS in relation to the social science and humanities research communities. In 2004, after consultation with the social science and humanities research community, they made public a report: *Giving Voice to the Spectrum* (PRE 2004), which addresses the concerns raised in social science and humanities research in contrast to biomedical research. A very clear effort is made to include issues in social sciences and humanities, using specific examples, and clearly pointing out when any discussion relates only to biomedical research in the second edition. There has been an effort to use more illustrations and identify more applications of such research in the later edition. Even more explicitly, there is a separate chapter on qualitative research.[36]

Also, areas such as biomedical research involving placebos in the context of randomised clinical trials (RCTs), and research involving Aboriginal peoples have been given an extended treatment. In laying out when placebos could be considered acceptable,[37] the first (and current) edition of the TCPS, was considered to be more

[35] Comments made here are based on the provisions of the forthcoming edition as at October 2009.

[36] Chapter 10 of TCPS (PRE 2008).

[37] Generally, a placebo control is considered appropriate when there is no proven treatment for the study condition. Where established treatment exists, placebos should not be used, except in extraordinary circumstances, in keeping with the principle of clinical equipoise. See Freedman 1987, 141.

restrictive than the ICH-GCP, which had been adopted by Health Canada (Sampson et al. 2009).[38] An initiative, the National Placebo Initiative, was then established in 2001 to find common ground on that specific issue. The forthcoming edition merges the provisions of the first edition with the guidelines.

Research involving Aboriginals had not been given extensive coverage in the current edition because, as was pointed out above, the communities had not been involved in extensive discussions. Since then, the CIHR had established an Aboriginal Ethics Working Group in 2004, which created the *CIHR Guidelines for Health Research Involving Aboriginal People* (CIHR 2007).[39] These guidelines, which came into effect in 2007, cover research funded by CIHR.[40] They are reflected in the extended chapter on Research Involving Aboriginal Peoples. These guidelines were developed following extensive discussions and engagement with aboriginal communities and researchers engaged in research with these communities.[41] Apart from these, there are other differences in content.[42] The content may still change as the policy remains under development.

The process of developing the second edition of the TCPS has been significantly different because of the presence and activity of the PRE. Instead of a transitory Working Group, the PRE is a permanent body which has a specific mandate to assist

[38] See also, National Placebo Working Committee 2004.

[39] See AREI PRE 2008.

[40] CIHR. Aboriginal Ethics Policy Development. http://www.cihr-irsc.gc.ca/e/29339.html. Accessed 14 Oct 2009.

[41] CIHR. Aboriginal Ethics Policy Development. http://www.cihr-irsc.gc.ca/e/29339.html. Accessed 14 Oct 2009.

[42] For example, distilling of ethical principles which numbered seven in the TCPS One (Respect for Human Dignity, Respect for Free and Informed Consent, Respect for Vulnerable Persons, Respect for Privacy and Confidentiality, Respect for Justice and Inclusiveness, Balancing Harms and Benefits, Minimizing Harm, Maximizing Benefit into three, namely: Concern for welfare; Respect for autonomy; and Respect for the equal moral status of all humans); Article 2.1 of TCPS Two: Change of definition of "research;" from systematic investigation which produces generalisable knowledge as stated in TCPS One p.1.1; Allowing for the use of deception in clearer terms (taking into consideration the concerns of researchers in the social sciences like psychologists); A more exhaustive list of types of research exempt from REB review (research using information exclusively from publicly available information, creative practices, public policy research, quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements. Article 6.4 - Composition – TCPS Two – community member must have relevant training and experience; Composition – TCPS Two – member knowledgeable in law (not risk manager or legal counsel, and not restricted to biomedical research as in TCPS One); Article 6.2 (see Application) Conflict of interest – senior administrators not to serve on REBs, A fuller section on conflict of interest in TCPS Two, Chapter Seven; Provisions on privacy and confidentiality in the context of internet research in TCPS Two, Article 10.3 has no equivalent in TCPS One; Ad hoc appeal boards not allowed in TCPS Two (Art. 1.11), but may be allowed under TCPS Two (Article 6.19, application); A fuller section on multi-centre research, including choice of model of REB; More details on research in public health emergencies, Article 6.21 in TCPS Two; More details on international research; Article 11.12 – New requirement for Clinical trial registries; and so on. See also PRE. What's New in the TCPS. http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/What's%20New%20in%20the%20TCPS.pdf. Accessed 12 Oct 2009.

the development of the TCPS. The concepts of democratic legitimacy, transparency, representation and community engagement may be argued to have been employed in some fashion in the work of the PRE. Comments are invited regularly from the general public and the research community on several areas that may require amendment. Several working committees have been established over the years to offer considered opinions on several areas, with comments from the research community. Responses to interpretation questions developed in the past several years, and the reports emanating from these committees, based on public consultations have been used extensively in revising the new version of the TCPS.[43] In the process of drafting the second edition, various consultations have taken place and many comments have been received by the PRE.[44]

It could be argued that the process of developing the second edition has the potential to be more democratic and encompass the necessary democratic values because of the existence of the PRE, which did not exist back in 1998. The PRE now serves as a middleman between the public and the research community and the Councils, replacing the Working Group. It may also be argued that this time will be different because the PRE advises the Councils, but has also been working with the public and the research community in the process of developing comprehensive guidelines based on consensus. Unlike the Working Group, it remains a more or less permanent advisory body that can take on board the opinions of members of the research community and the general public on a continuing basis. The PRE has been engaged in the process of revising the TCPS, and developing interpretations for nearly a decade now. Also, the mandate of the PRE is clear, possibly clearer than the mandate of the Working Group, which, at first, set out to revise the MRC Guidelines.[45]

Arguably, however, despite these positive arguments, these democratic concepts have been applied in a limited fashion and can be extended. First, in terms of the conflict of interest issues and the related issues of legitimacy, challenges clearly remain in this area. The PRE is a creation of the funding Agencies and reports to them. In fact, it could be argued that the Working Group may have had more independence than the PRE currently does, being beholden to its creator, the Councils. In this respect, several commentators have noted that it remains problematic for the funders of research to be the regulators of research, even as it puts in place guidelines which aim to address conflicts of interest in research involving humans (McDonald 2009, 20; Sampson et al. 2009). Downie summarises these concerns aptly:

> We must also be concerned about conflicts of interest and research funders. National funding councils currently set the standards for research ethics and are responsible for enforcement of these standards and yet their mandate is the promotion of research. The presidents

[43] What's New in the TCPS. http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/What's%20New%20in%20the%20TCPS.pdf. Accessed 12 Oct 2009, 2. For a list of these reports, see PRE 2009a, b, c.

[44] Some of these comments are publicly available online. See for example, Palys and Lowman 2009; Sherwin 2009; Halperin et al. 2009.

[45] See Baylis et al 1999. See also, McDonald 2009.

> of the three national funding councils recently named an interagency Panel on Research Ethics (PRE) with responsibility for interpreting and revising the TCPS. Many in the research ethics community called for this responsibility to be given to a group outside the councils rather than one appointed by and reporting to the presidents of the councils (Downie 2003, 14).

This is clearly not an optimal situation. It is, however, a situation that requires ongoing national discussion. Until a national solution can be found and that lacuna filled, it appears likely, unfortunately, that the Councils will continue to regulate research funded by them. However, in these circumstances and in the situation that the Councils will not remove the revision of the TCPS from the mandate of the PRE, the Councils must be prepared to take extra steps to show how this conflict of interest is being managed, including how much independence the PRE can exercise in this respect. Extra steps must be taken to show transparency at all stages of the processes.

In terms of accountability and representation, we raise the question, as we did in the context of the current edition: What is the composition of the PRE, and the various Working Committees that have made a significant input in the process of developing the second edition? The composition of the Working Committees varies. However, the PRE is composed of 12 members who serve on a voluntary basis.[46] They are experts and researchers drawn from various disciplines and institutions. There is greater public participation also, with the members of the public participating in the process of nominating the panel members. However, such public participation is clearly limited as the Councils have the final say, and it is not clear if the different perspectives (for instance, Aboriginal, Black, Third World, or Feminist perspectives) are a consideration. Unlike the Working Group, there appears to be a better gender balance, although this could stand for some improvement.[47] It is hoped that this allows for better representation of a diversity of views on the panel. Unfortunately, it is not clear, as some commentators have suggested, that there is specifically, a representation of past or current research participants on the PRE to represent the views of the very persons that the TCPS is established to protect.[48] This is an area worth considering as the PRE continues its work, both with respect to the PRE itself and the various working committees.

Further, it must be noted that several problems arise with respect to the seeming ad-hoc processes adopted in putting together the new edition. Hirtle summarises some of these concerns, which include the degree of transparency, credibility and legitimacy attached to the processes noting that:

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[46] The past and current members of the Panel are listed on the website. PRE. About Us: Panel Members Interagency Panel on Research Ethics. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/. Accessed 12 Oct 2009.

[47] There are currently four women on the Panel, not including the Executive Director of the Secretariat on Research Ethics. See PRE. About Us: Panel Members Interagency Panel on Research Ethics. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/. Accessed 12 Oct 2009. It will be recalled that the Feminist Network complained of the gross gender imbalance on the Working Group. See Baylis et al. 1997 and accompanying text.

[48] See McDonald 2009; Palys 1996a.

> An overarching concern related to governance of research is that while the Tri-Council Policy Statement is intended to be a living document open to review, there has been no formal and transparent review process but rather a multiplicity of ad hoc processes. A case-by-case approach may have the advantage of flexibility, but this may come at the cost of transparency, credibility and legitimacy. Should there be agreement on the need for a formal review process, the challenge will be to agree on what that process will be. Similar concerns over transparency, credibility and legitimacy also transpire from the lack of clear processes to establish new research ethics structures such as the Panel on Research Ethics. (Hirtle 2003, 151)

Others, like Palys in his comment on the second edition, for instance, allege that the PRE ignored some of the recommendations of some of its working committees (Palys and Lowman 2009, 17). Palys calls for further consultation on the draft second edition on the grounds that:

> PRE's strategy is that of an ethics deity imposing its own "right answers" rather than fulfilling its mandate to educate, promote discussion, respect disciplinary and methodological diversity, build consensus, and cultivate a culture of research ethics in Canada.
>
> 2) Draft TCPS-2 contains no annotations explaining PRE's rationale for the policy changes it proposes, as might be expected of a body that claims it operates according to the principles of "openness, transparency and accountability." (Palys and Lowman 2009, 20)

Still others, like Baylis, have also observed the conflicting ideas about how to formally incorporate previously existing guidance in different areas, such as stem cell research, use of placebos, or research involving aboriginal peoples into the second edition of the TCPS. Should this be by inclusion in the body of the TCPS; or by inclusion as an appendix to the TCPS; or by reference in the TCPS to the specific guidelines in question? (Baylis 2009). What is the status of these guidelines, after the second edition comes into force?

There are therefore concerns about the balance and diversity of perspectives with respect to the composition of the working committees and expert panels. These different committees and panels have had significant input into the revised edition, in a more or less makeshift fashion, raising legitimacy issues. On the other hand, there appear to be concerns that the recommendations of the working committees and expert panels are not being adopted. A different but related concern is how to incorporate other guidance into the TCPS. Such concerns raise questions of legitimacy, and about how standardized and stable the process of drafting the policy is. Going forward, a clearer and more transparent method of revision for the TCPS may be appropriate, as is the definition of the status of different guidance documents by the Councils.

In terms of community engagement, how broad have the consultations been? Are the different stakeholders being sufficiently consulted and adequate time being given for their input to be received? Since it first began work, the PRE has regularly called for comments from the public and the research community on different aspects of the TCPS. The PRE presented the draft second edition in December 2008, and has since engaged in regional consultations, visiting different institutions at the country, as well as national conferences, and receiving input (PRE 2009b).[49] The

[49] See also PRE. Conference Presentations. http://www.pre.ethics.gc.ca/eng/activities-activites/events-actualites/conferences/. Accessed 29 Sept 2009.

consultation period was to have ended in March 2009 but was extended to the end of June 2009, possibly to accommodate requests for more time to comment on the draft by persons and communities who believed that the 3 month period of comment initially provided was insufficient.[50] A final draft will be released to the public for final comments in December 2009 for a period of 60 days after which the final version will be prepared and presented to the Councils (PRE 2009c). There have, however, been complaints about the concentration of consultations in, and engagement with, academic institutions, with inadequate engagement with community-research partners. There have also been complaints that the Aboriginal community has not been sufficiently included in consultations with respect to the preparation of the second edition.[51]

Needless to say, it will be difficult, if not impossible, to accommodate every viewpoint in such a value-oriented policy as that contained in the draft second edition. But flexibility in consultation periods and broad inclusion in consultation processes will allow more feedback from the communities to be affected by the draft policy, the possibility of broader assessments of issues from sundry perspectives, high levels of awareness of the draft, broader support of the policy from those whom the draft may affect and the least negative repercussions later in the policy process.[52] There appears to be clear recognition that the engagement with the public is necessary to the success of the second edition (Beaudet et al. 2008). Hopefully, the PRE and the Councils will remain open to flexibility in allowing more time, if need be, for more consultations and in extending consultations to different interested communities. As yet, it is difficult to estimate how far the consultations undertaken, and comments received are influencing the direction of the document. However, it would certainly be beneficial for adequate consideration to be given to these comments in order to enhance not only the process, but also the moral support, acceptability and legitimacy of the resulting document.

As was clearly the case in the development of the current edition, the PRE, like the Working Group, will pass the draft second edition to the Councils. The Councils, as with the current edition, have the final say on the version of the edition that goes into effect. As such, the same issues that arose at the end of the process of making the TCPS are also likely to be present, with the Agencies able to make or to decide not to undertake any amendments without any consultations. Given the major accusation leveled against the process of the first edition that the Councils undertook a major revision without consultations, thus eliminating to a large extent the

[50] Several comments available online requested an extended period for comment. See for example, Palys and Lowman 2009, 21. See also, Sherry Ann Chapman, Letter to the PRE by Community-Partnerships for Health : RE: Extension of consultation time period and engagement strategy for community feedback. http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/CCPH-Letter-031809.pdf. Accessed 21 Sept 2009.

[51] Sherry Ann Chapman, Letter to the PRE by Community-Partnerships for Health : RE: Extension of consultation time period and engagement strategy for community feedback. http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/CCPH-Letter-031809.pdf. Accessed 21 Sept 2009, 2.

[52] Ibid.

democratic values that had earlier on been established, it can only be hoped that this will not be the case with this new edition. It makes little sense to engage in expensive consultations at the expense of the Canadian taxpayer, and then to undertake a revision process that does not take those consultations and comments into account. Apart from the financial resources expended, policymaking in which the democratic values discussed herein are not ensured risk losing essential support by the very entities that are required to apply it, thus jeopardizing its legitimacy and adequate implementation. Transparency and openness remain key in the success of this more recent process.

Conclusion

In 1998, the three major government funding Councils put in place the TCPS to regulate all research involving humans in Canada funded by them. In this paper, we have sought to examine the process of developing the TCPS, an historic and very important document in Canada's research ethics landscape and the application of the concepts of democratic legitimacy, transparency, representation, accountability and community engagement in that process. This exercise, important as it is, has received insufficient attention in the literature in the past. We have also considered the on-going process of putting in place a second edition of the TCPS.

Although process is quite different from substance, substance may be positively or adversely affected by the process of putting together the substance of important policies such as research ethics policy in democratic societies. As Hirtle rightly observes that, "Ensuring that the process for adopting rules is transparent, credible and equitable is crucial to promoting their legitimacy, authority and effectiveness" (Hirtle 2003, 141). It would appear from our discussion that there were several flaws in the process of developing the TCPS relating to the democratic values of democratic legitimacy, transparency, representation, accountability and community engagement. The TCPS, as previously discussed, remains the foremost ethics policy in Canada, and is widely used in research institutions. One could therefore think that the flaws in the process were perhaps not so severe as to damage the utility and effectiveness of the policy. One could also argue that the funding powers of the Agencies could also mean that, no matter how unacceptable the process, the policy would still have been effective and that the need for such a policy at the time of its creation would have outweighed other misgivings about the process. It is not debatable, however, that more could certainly have been done in terms of imbuing the process with democratic values, and this doubtless would have meant less need for revising the document afterwards, and more importantly, more respect being shown to the document (thus more protection of human subjects).

There are certainly lessons to be learnt for future policymaking efforts in the area of research ethics and in other important policy areas. Indeed, as we discuss in this paper, the work currently being done in terms of preparing a second edition of the TCPS could benefit from these lessons. Given where things stand at this stage of the

process, some of these lessons may appear to be belated, (for example, the Councils' conflict of interest in creating the TCPS), but others may still be timely (for instance, preparation of the final version and reflection of consultations). It can only be hoped that the PRE and the Councils will not repeat the mistakes of the past. Time will tell.

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Chapter 9
Human Research Ethics Guidelines in Australia

Colin Thomson, Kerry J. Breen, and Donald Chalmers

Introduction

This chapter describes the human research ethics guidelines that have been issued by national government agencies in Australia between 1966 and the present time, the identity, authority and composition of the issuing agencies, the processes that they adopted in guideline development and promulgation together with some reflections on those processes.

In the section "Human research ethics guidelines in Australia" we present a chronological history of guidelines that address all or part of human research and identify the national agencies that issued them. In the second section, we describe those agencies, their establishment, their authority and their membership and reflect on these. In the third section, we discuss some of the processes that those agencies used in developing, issuing and promulgating guidelines and in the fourth section we reflect on the strengths and weaknesses of those processes.

We have only briefly noted the issue of ethical guidelines for special areas of research. Most important of these are the guidelines in regard to health research involving Aboriginal and Torres Strait Islander peoples. The history of their development is important and complex and deserves to be told in detail and from an indigenous perspective.

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Human Research Ethics Guidelines in Australia

Australian activity in ethical review of human research began during the 1960s and was related closely to the federal government funding of medical research. Through the passage of the *Medical Research Endowment Fund Act 1937*, the Commonwealth Parliament had established the Medical Research Endowment Fund. Responsibility for the fund was vested in the Minister for Health, who could determine its use for medical research and in the training of persons in medical research, acting on the advice of the National Health and Medical Research Council (NHMRC), constituted in 1936, by an Order-in-Council.

In 1966, the NHMRC issued the *Statement on Human Experimentation (*the *Statement)* (NHMRC 1966) that expressly drew on the 1964 *Helsinki Declaration* of the World Medical Association (WMA 2000). It was amended in 1973 on advice from a subcommittee of the Council and in 1976 by the Medical Research Advisory Committee, at which time Supplementary Note 1 was added to make the requirement for review by an institutional ethics committee (IEC) explicit. The opening paragraphs were also amended to indicate that the *Statement* was applicable to all human subject research, encompassing medical, social and behavioural research. The paragraphs of the *Statement* addressed the following matters:

Scientific design
Advantages and risks
Prior laboratory research
Duty to research subjects
Qualifications of researchers
Novel procedures
Information and consent
Withdrawal from research
Discontinuance of research
Consultation with subjects
Dependancy
Medical ethics review committee review
NHMRC grant applications to have ethics committee approval

The *Statement* was revised and Supplementary Notes added in 1982 and in following years in the manner and on the matters indicated in Table 9.1.

All of these revisions and additions were issued by the NHMRC on the advice of the Medical Research Ethics Committee that had been formed in 1982.

In 1986, the NHMRC, together with the Menzies Foundation, convened a conference on “Research Priorities in Aboriginal Health”. That conference agreed to the subsequent convening of a National Workshop on Ethics of Research in Aboriginal Health that was held in 1987 and, in 1988, the NHMRC issued *Some*

Table 9.1 Changes to the statement on human experimention 1982–1992

1982	Statement revised, adding paragraphs on: protocol to state ethical issues; children and the mentally ill; fully informed research team members; payments to volunteers
	Supplementary notes revised:
	1. Institutional ethics committees
	Supplementary notes added:
	2. Children, the mentally ill
	3. Therapeutic trials
	4. In vitro fertilization and embryo transfer
1983	Supplementary notes added:
	5. Human fetus and human fetal tissue
1985	Supplementary notes revised:
	1. Institutional ethics committees
	Supplementary notes added:
	6. Epidemiological research
1987	Supplementary notes revised:
	2. Children and the mentally ill
	3. Clinical trials
	Supplementary notes added:
	7. Somatic cell gene therapy
1992	Supplementary notes revised:
	1. Institutional ethics committees
	2. Children and the mentally ill
	4. In vitro fertilization and embryo transfer

Advisory Notes on Ethical Matters in Aborignal Research (NHMRC 1988) that were arranged under the following headings:

The Process of Consultation
Social and Gender Issues
Communication and Consent
Community Benefit and Employment of Local People
Ownership and Publication of Materials
Exploitation of Community Resources

In 1991, the NHMRC issued interim *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (Interim Guidelines)* (NHMRC 1991), which superseded the *Advisory Notes*, and were arranged under the headings of Consultation, Community Involvement and Publication of Data. It is apparent from the text of this document that the Medical Research Ethics Committee of the NHMRC contributed to their development.[1]

[1] Some published versions of this document added the word "Interim" to the title, in recognition of the need for further consultation and development.

In May 1991, the Therapeutic Goods Administration (TGA), the federal government agency responsible for the admininstration of the Therapeutic Goods Act 1989 that governs the approval of new drugs or therapeutic devices, isssued guidelines on Clinical Trials of Drugs and, in December of that year, Guidelines for Good Clinical Research Practice. These were superseded in 2000 by *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)* (TGA 2000) that guides the conduct of clinical trials. In 1992, regulations under the Therapeutic Goods Act required that clinical trials of new drugs or devices could only proceed if favourable advice had been received from an institutional ethics committee that had notified its existence to the NHMRC (Therapeutic Goods Regulations 1990, 12 (1A), Schedule 5A).

In 1996, the NHMRC issued *Ethical guidelines on assisted reproductive technology* (NHMRC 1996a) which replaced Supplementary Note 4 to the *Statement*. Although these guidelines addressed the clinical use of assisted reproductive technology (ART), they also contained a section on research. They were developed by the Australian Health Ethics Committee (AHEC), a principal committee of the NHMRC established by the NHMRC Act (1992).

Following the recommendation in the *Report of the review of the functioning of institutional ethics committees* (NHMRC 1996b), the *Statement* was revised between 1996 and 1999 and issued in 1999 under the new title of the *National Statement on Ethical Conduct in Research Involving Humans* (*National Statement 1999*). These guidelines were developed by the AHEC. They were issued by the NHMRC with the endorsement of the Australian Vice-Chancellors' Committee (now Universities Australia), the Australian Research Council (ARC), the Australian Academy of the Humanities, the Australian Academy of Science, and the Academy of the Social Sciences in Australia and the support of the Academy of Technological Sciences and Engineering. The *National Statement 1999* was arranged in the following sections:

Preamble

1. Principles of Ethical Conduct
2. Human Research Ethics Committees
3. Multi-centre research
4. Research Involving Children and Young People
5. Research Involving Persons with an Intellectual or Mental Impairment
6. Research Involving Persons Highly Dependent on Medical Care
7. Research Involving Persons in Dependent or Unequal Relationships
8. Research Involving Collectivities
9. Research Involving Aboriginal and Torres Strait Islander Peoples
10. Research Involving Ionising Radiation
11. Research Involving Assisted Reproductive Technology
12. Clinical Trials
13. Innovative Therapy or Intervention
14. Epidemiological Research

15. Use of Human Tissue Samples
16. Human Genetic Research
17. Research Involving Deception of Participants, Concealment of Covert Observation
18. Privacy of Information
19. Intellectual Property

Consistent with its policy of revising guidelines after 5 years, the NHMRC commenced a revision of the *Interim Guidelines* in 2000 and, in 2003, issued *Values and Ethics: Ethical Guidelines for the Conduct of Aboriginal and Torres Strait Islander Health Research (Values and Ethics)* (NHRMC 2003). These were arranged under six values: Reciprocity, Respect, Equality, Responsibility, Survival and Protection and Spirit and Integrity. In 2005, these were supplemented by the issue of *Keeping Research on Track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics (Keeping Research on Track)* (NHMRC 2005).

In 2000, the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) published *Guidelines of Ethical Research in Indigenous Studies (AIATSIS Guidelines)* (AIATSIS 2000).

In 2004, following significant legislative change in Australia concerning ART, the AHEC revised the 1996 guidelines on ART and the NHMRC issued *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines)* (NHMRC 2004).

In the exercise of its policy of guideline revision, the NHMRC commenced a revision of the *National Statement 1999* in 2005. This revision was conducted jointly by the NHMRC, the ARC and the Australian Vice-Chancellors' Committee (now Universities Australia (UA)) who together issued the *National Statement on Ethical Conduct in Human Research* in 2007 (*National Statement*) (NHMRC 2007), which contains the present primary national human human research ethics guidelines. The *National Statement* (NHMRC 2007a) is arranged as follows:

A User Guide
Preamble
Purpose, scope and limits of this document
Section 1 Values and principles of ethical conduct
Section 2 Themes in research ethics: risk and benefit, consent
Chapter 2.1 Risk and benefit
Chapter 2.2 General requirements for consent
Chapter 2.3 Qualifying or waiving conditions for consent
Section 3 Ethical considerations specific to research methods or fields
Chapter 3.1 Qualitative methods
Chapter 3.2 Databanks
Chapter 3.3 Interventions and therapies, including clinical and non-clinical trials, and innovations

Chapter 3.4 Human tissue samples
Chapter 3.5 Human genetics
Chapter 3.6 Human stem cells
Section 4 Ethical consideration specific to participants
Chapter 4.1 Women who are pregnant and the human foetus
Chapter 4.2 Children and young people
Chapter 4.3 People in dependent or unequal relationships
Chapter 4.4 People highly dependent on medical care who may be unable to give consent
Chapter 4.5 People with a cognitive impairment, an intellectual disability, or a mental illness
Chapter 4.6 People who may be involved in illegal activities
Chapter 4.7 Aboriginal and Torres Strait Islander Peoples
Chapter 4.8 People in other countries
Section 5 Processes of research governance and ethical review
Chapter 5.1 Institutional responsibilities
Chapter 5.2 Responsibilities of HRECs, other ethical review bodies, and researchers
Chapter 5.3 Minimising duplication of ethical review
Chapter 5.4 Conflicts of interest
Chapter 5.5 Monitoring approved research
Chapter 5.6 Handling complaints
Chapter 5.7 Accountability

Finally, and again in response to national legislative changes, the AHEC revised some parts of the ART guidelines and the NHMRC issued these revised guidelines as *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines)* (NHMRC 2007a).

The National Agencies that Developed the Human Research Ethics Guidelines: Their Establishment, Authority and Membership

National Health and Medical Research Council

Before 1992

Human research ethics guidelines in Australia had their origins in medical and health research. Consequently, the central agency for human research ethics guidelines since 1996 has been the NHMRC and two of its committees. The NHMRC

was initially constituted by an Order-in-Council of the Federal Government to provide advice to the Minister for Health in relation to the expenditure of the Medical Research Endowment Fund. The terms of reference of the NHMRC in 1936 were:

- To advise Commonwealth and State governments on all matters of public health legislation and administration, on matters concerning the health of the public and on medical research.
- To advise the Commonwealth government as to the expenditure of money specifically appropriated as money to be spent on the advice of this Council.
- To advise the Commonwealth government as to the expenditure of money to be spent on medical research and as to projects of medical research generally.
- To advise Commonwealth and State government on the merits or reputed cures or methods of treatment which are from time to time brought forward for recognition (Commonwealth of Australia, Order-in-Council, 24 September 1936).

The development and issue of human research ethics guidelines by the NHMRC between 1966 and 1992 appears to have been in exercise of these broad terms of reference. Unchanged for 55 years, they did not include any reference to the ethics of human research or to a requirement for public consultation.

The membership of the NHMRC then comprised:

- The Commonwealth Director-General of Health (as Chair),
- 2 officers of the Commonwealth Department of Health,
- the heads of the departments of health of the Australian States,
- representatives from the federal Council of the British Medical Association (soon to be renamed the Australian Medical Association), the Royal Australasian College of Surgeons, the Royal Australasian College of Physicians, the Australian Council of the Royal College of Obstetricians and Gynaecologists, the Australian Dental Council, the 4 Australian universities having medical schools, and
- a prominent layman and laywoman. (Commonwealth of Australia, Order-in-Council, 24 September 1936)

It seems likely that the issue of the *Statement* was influenced by events overseas, particularly the issue by the World Medical Association of the Declaration of Helsinki in 1964 (WMA 1964).

In 1972, the NHMRC appointed the Ethics in Clinical Research Subcommittee to examine the need to revise the existing *Statement* and in 1976 this subcommittee reported to the Council recommending revisions.

The revision of the *Statement* in 1976 that stated that "institutions undertaking medical research on human subjects should have a medical ethics review committee" seems likely, again, to have been influenced by events overseas, including the enactment of the National Research Act of the United States in 1974 and the 1975 revision of the Declaration of Helsinki with its explicit requirement for prior ethics committee review of research.

In October 1982, the NHMRC adopted a report from a Working Party on Ethics in Medical Research and, in accordance with its recommendation, established the

Medical Research Ethics Committee (MREC) as a subcommittee of its Research Committee and gave to it the functions:

- to assist the Council by keeping under review and making recommendations to Council on ethical principles in human experimentation and
- to facilitate, keep under review and report to the Council on the work of institutional ethics committees and respond to questions raised by them.

The nine members of this committee comprised:

- A chair – in practice a professor of medicine
- 3 medical scientists
- 2 laywomen
- A non-medical scientist, and
- 2 lawyers. (NHMRC 1987)

The MREC was the source of advice to the NHMRC on changes and additions to the *Statement* between 1982 and 1992. It is also apparent from the text of the *Interim Guidelines* (NHMRC 1991), referred to above, that the MREC contributed to their development. The committee was disbanded in 1992 as a result of the passage of the *National Health and Medical Research Council Act 1992* (NHMRC Act) and the formation of the AHEC.

Between 1992 and 2006

In 1992, the Commonwealth Parliament passed the NHMRC Act which established the NHMRC as a statutory agency and also established the AHEC as a principal committee of the Council.

The NHMRC's general functions were identified in the legislation as:

(a) to inquire into, issue guidelines on, and advise the community on matters relating to:

  (i) The improvement of health; and
  (ii) the prevention, diagnosis and treatment of disease; and
  (iii) the provision of health care; and
  (iv) public health research and medical research; and
  (v) ethical issues relating to health; and

(b) to advise, and make recommendations to, the Commonwealth, the States and Territories on the matters referred to in paragraph (a); and
(c) to make recommendations to the Commonwealth on expenditure:

  (i) on public health research and training; and
  (ii) on medical research and training; including recommendations on the application of the Fund; and

(d) any functions incidental to any of the foregoing.

(2) Subject to the direction of the Minister, the Council has the general administration of this Act.

The specific function in relation to human research ethics guidelines was in section 8 of the Act, which provided:

> 8 (1) Without limiting any of the matters on which the Council may issue guidelines under subparagraph 7(1)(a)(v), the Council must issue guidelines under that subparagraph for the conduct of medical research involving humans.
> (2) The guidelines for the conduct of medical research involving humans must be issued precisely as developed by the Principal Committee known as the Australian Health Ethics Committee and provided to the Council for the purpose. (National Health and Medical Research Council Act. (Cwth) 1992, s. 8(2) (since amended))

Medical research was defined as "including the laboratory-based or clinical study, or group or community-based study of the causes, treatment and prevention of human diseases and also includes dental research" (NHMRC Act 1992, s. 4).

In this way, the Act contained the first formal grant of authority for any national agency to issue human research ethics guidelines, limited to those relating to medical research.

The functions of the Australian Health Ethics Committee were stated in the Act to be:

(a) to advise the Council on ethical issues relating to health; and
(b) to develop and give the Council guidelines for the conduct of medical research involving humans; and
(c) such other functions as the Minister from time to time determines. (NHMRC Act 1992 s. 35 (3))

The membership of the NHMRC during this period was prescribed as:

(a) the Chairperson;
(b) the Secretary to the Council;
(c) each person who is, or is acting as, the Chairperson of a Principal Committee and who is not a member of the Council because of the operation of any other paragraph;
(d) an officer of each State or Territory health instrumentality nominated by the Minister having administrative responsibility for the instrumentality concerned;
(e) an officer of the Department nominated by the Minister;
(f) a person:
    (i) nominated by the Aboriginal and Torres Strait Islander Commission; and
    (ii) having knowledge of the health needs of Aboriginal persons or Torres Strait Islanders;
(g) a person with expertise in health care training;

(h) a person with knowledge of professional medical standards and expertise in post-graduate medical training;
(i) a person with a background in, and knowledge of, the medical profession;
(j) a person with a background in, and knowledge of, the nursing profession;
(k) an eminent scientist:

  (i) who has knowledge of public health research and medical research issues; and
  (ii) who has no current connection with the Council;

(l) a person with a background in, and knowledge of, the trade union movement;
(m) a person with a background in, and knowledge of, business;
(n) a person with a background in, and knowledge of, consumer issues;
(o) a person with knowledge of the needs of users of social welfare services;
(p) a person with knowledge of environmental issues;
(q) a person with a background in, and knowledge of, public health issues;
(r) no more than 2 other persons with expertise relevant to the functions of the Council. (NHMRC Act 1992, s.20)

Although the Council had a formal role in the issuing of human research ethics guidelines, its membership is relevant because, while the Council could only issue research ethics guidelines precisely as developed by the AHEC, it was not prevented from refusing to issue guidelines. If, for example, the Council disagreed with such guidelines, it could decline to issue them and request AHEC to re-consider them. However, it is clear that the intention of the Act was that the primary work was to be done by the AHEC.

The membership of AHEC at this time was prescribed as:

(a) the Chairperson;
(b) a person with knowledge of the ethics of medical research;
(c) a person who has expertise in law;
(d) a person who has expertise in philosophy;
(e) a person who has expertise in religion;
(f) a person who has experience in medical research;
(g) a person who has experience in public health research;
(h) a person who has experience in social science research;
(i) a person who has experience in clinical medical practice;
(j) a person who has experience in nursing or allied health practices;
(k) a person with knowledge of the regulation of the medical profession;
(l) a person with understanding of health consumer issues;
(m) a person with understanding of the concerns of people with a disability;
(n) no more than 2 other persons with expertise relevant to the functions of the Committee. (NHMRC Act 1992, s.36)

The Act further required that the membership must include people who were members of the other principal committees. The appointments were to be made by the Minister who was required to consult with members of the Australian Health

Ministers Conference in relation to appointment of the Chair and of the category (b) member and, in relation to all the other categories, consider nominations from the following relevant professional bodies specified in regulations under the Act: Law Council of Australia; Academy of the Social Sciences in Australia; Australian Academy of Science; Australian Academy of the Humanities; Australian Catholic Bishops Conference; Australian Council of Churches; Australian Federation of Islamic Councils Inc.; Jewish Board of Deputies; Public Health Association of Australia Inc.; The Australian Medical Association Ltd; The Committee of Presidents of Medical Colleges; Australian Nursing Federation; Australian Council of Deans of Health Sciences; Royal College of Nursing, Australia; Australian Medical Council; The Committee of Presidents of Medical Colleges; Consumers' Health Forum of Australia Inc.; Disabled Peoples International (Australia) Limited; and National Council on Intellectual Disability Inc.

From 2006 to the Present

Amendments to the NHMRC Act in 2006 made by the *National Health and Medical Research Council Amendment Act, (Cwth) 2006* gave the Chief Executive Officer (CEO) the obligation to issue human research guidelines when they are provided to the CEO for that purpose by the Council. Although these amendments retain the requirement that the Council may only provide such guidelines precisely as developed by AHEC, they also state that "the Council is not obliged to provide particular guidelines referred to in subsection (2) to the CEO merely because the Australian Health Ethics Committee has provided the guidelines to it in accordance with this Division" (National Health and Medical Research Council Act. (Cwth) 1992, s.10(3)). Accordingly, although AHEC is given responsibility to "develop and give to the Council" (NHMRC Act 1992, s. 35(3)(b)) such guidelines, the Council may decide not to give those guidelines to the CEO to be issued.

Since 2006, according to its establishing statute, the NHMRC is formally comprised of the CEO, the Council, the committees and the staff.

The Act does not contain any qualifications for the CEO, only that the appointment is to be by the Minister. The membership of the Council is now prescribed as:

(a) the Chair;
(b) the chief medical officer for the Commonwealth;
(c) the chief medical officer for each State and Territory;
(d) a person with expertise in the health needs of Aboriginal persons and Torres Strait Islanders;
(e) a person with expertise in consumer issues;
(f) a person with expertise in business;
(g) at least 6, but no more than 11, persons with expertise in one or more of the following:

    (i) health care training;
    (ii) professional medical standards;

(iii) the medical profession and post-graduate medical training;
(iv) the nursing profession;
(v) public health research and medical research issues;
(vi) public health;
(vii) ethics relating to research involving humans; other appropriate expertise. (NHMRC Act 1992, s. 20(2))

The definition of medical research is unchanged and that of "public health research" is:

> *"public health research"* includes the study of the health of a community or population for purposes directed at improving or protecting the health of that community or population. (NHMRC Act 1992, s. 4)

Although the membership of AHEC is unchanged, the previous requirement for consultation and consideration of nominations from identified bodies before appointment have been replaced with the requirement that those appointments are to be made by the Minister "after consulting appropriately". (NHMRC Act 1992, s. 41(1))

National Bioethics Consultative Committee

For a short period of time, Australia had a separate National Bioethics Consultative Committee (NBCC). It was established in 1988 by the Australian Health Ministers Conference and given the following terms of reference:

To provide advice and undertake studies on matters as requested by the Australian Health Ministers Conference (AHMC) on the ethical, legal and social issues arising from:

- reproductive technology including human embryo experimentation and the bearing of children;
- biomedical and health related research;
- the application of scientific and medical technology; and
- the provision and delivery of health services.

This body did not issue any guidelines about ethics in human research. It was disbanded in 1992 and its work was assumed by AHEC under the 1992 NHMRC Act. In practical terms, AHEC can be seen to be a pragmatic merging of the roles and membership of the NBCC and the MREC.

Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS)

In 1989, the Commonwealth Parliament passed the *Australian Institute of Aboriginal and Torres Strait Islander Studies Act*, establishing the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS). This agency replaced the

Australian Institute of Aboriginal Studies formed by legislation in 1964. The functions of AIATSIS include "to assist in training persons, particularly Aboriginal persons and Torres Strait Islanders, as research workers in fields relevant to Aboriginal and Torres Strait Islander studies" (*Australian Institute of Aboriginal and Torres Strait Islander Studies Act* 1989, s.5(d)). It appears that it is this function that has been used to develop and publish guidelines on the ethics of indigenous research.

Australian Research Council (ARC)

Although it had operated as an agency in earlier years, in 2001, the Commonwealth Parliament passed the *Australian Research Council Act*, establishing the current ARC. The Act provides that the functions of the Chief Executive Officer (CEO), as assisted by the Council are:

(a) to make recommendations to the Minister under section 52 in relation to which proposals should be approved as deserving financial assistance under Division 1 of Part 7;
(b) to administer the regimes of financial assistance provided for in Divisions 1 and 2 of Part 7;
(c) to provide advice to the Minister on research matters;
(d) any other functions conferred on the CEO by this or any other Act. (*Australian Research Council Act* 2001, s.33B)

The ARC is comprised of the CEO, designated committees and the staff. There is no specification of any personnel qualifications in the Act establishing the ARC.

Universities Australia (UA)

Universities Australia (UA) was established in 2007 as the industry peak body representing the university sector. It represents Australia's 39 universities in the public interest, both nationally and internationally and succeeds the organisation previously known as the Australian Vice-Chancellors' Committee (AVCC) that was formed in May 1920 of Australia's then six universities. The aims of UA are to:

- advance and promote the benefits of Australian Universities to the nation;
- support Australian Universities in the performance of their roles;
- develop policy positions on higher education matters through discussing higher education issues, including teaching, research and research training;
- advance internationalisation of Australian Universities;
- provide information for and about Australian Universities;
- provide services and programs to Australian Universities including the negotiation of common purchasing arrangements;
- promote the welfare of students, staff and graduates of Australian Universities;

- facilitate opportunities for Australian Universities (in particular, their students, staff and graduates) to develop their knowledge and skills;
- study the problems and needs of Australian Universities and their relations with other education institutions, organisations and the community and to encourage and sponsor their study; and
- assist in the further development of Australian Universities.[2]

The UA is comprised of Australian universities represented by their vice-chancellors.

Some Reflections on Functions and Membership of National Agencies

This account of the functions and memberships of the national agencies that have been involved in the issue of human research ethics guidelines shows that the clarity of functions of the NHMRC have contributed to its being the leading agency in the activity. The only other body with comparable formal commitment to the subject appears to be AIATSIS.

In the functions of the ARC, there is no explicit function that relates to the ethics of human research. However, the function in paragraph (c) above appears to be broad enough to include advice in the form of guidelines.

For UA, there is no clear recognition of a role in relation to the ethics of human research. However, the breadth of its functions could support its involvement in the provision of guidelines on the subject.

The memberships of the NHMRC Council and the AHEC provide for some relevant expertise for the development of human research ethics guidelines. However, it is apparent that the scope of that expertise is confined (appropriately) to health and medical research. There is no assurance from the specified expertise that there will be adequate knowledge of the traditions and practices of human research in wider arenas such as social and behavioural research (Dodds et al. 1994).

What Processes Did Agencies Adopt for the Task of Developing Ethical Guidelines?

Prior to the 1992 NHMRC Act, there were no formal responsibilities relevant to the development and issuing of human research ethics guidelines. It appears from the report of the NHMRC Working Party on Ethics in Medical Research adopted by the Council in October 1982 that the NHMRC *Statement* had "wide acceptance" so that

[2] Universities Australia website, http://www.universititesaustralia.edu.au/content.asp?page=/about/index.htm. Accessed 3 Nov 2009.

the working party recommended retaining its format and making changes by the use of supplementary notes. There is no reference in the description of the revision to any consultation. Nonetheless, the recommended changes were prefaced with the following insightful observations:

In revising the NH & MRC Statement on Human Experimentation and preparing the Supplementary Notes we thought it important to strive for consistency. On the one hand we sought to avoid violating philosophical values which we thought were widely accepted in the Australian community, and on the other to avoid contradicting demonstrable biological facts. Throughout our discussions we tried to remember that ethics is not an exact science, that there are many issues to which the question "right or wrong?" cannot be given a simple answer, and that there are some matters that cannot be settled by consensus. When, therefore, our statements have indicated a belief that some activity is acceptable from an ethical standpoint, this will frequently mean not that it is clearly ethically right, rather that it is ethically defensible but may still be legitimately controverted. We recognised that judgments in these matters must always permit dissent. (NHMRC 1983, 5)

The work of the MREC between its establishment in 1982 and its replacement by the AHEC in 1992 drew mainly on the expertise of the members. However, it was the practice during those years to conduct annual 1 day workshops for institutional ethics committees and these provided opportunites for information and feedback about the *Statement* and its use. The reports of these workshops were drawn on when revisons of the *Statement* or Supplementary Notes were being conducted.

Statutory Consultation

Since the passing of the 1992 NHMRC Act, there have been statutory constraints on the process of developing and issuing guidelines, especially as to public consultation. Section 12 provided that before the NHMRC issued guidelines, it must consult "persons or bodies" in accordance with the steps set out in the section. Those steps were to publish a notice, in the specified manner and form, of the intention to issue guidelines, that invited persons or bodies to make submissions relating to the guidelines, in accordance with the procedures, and within the period, specified in the notice. The section required the Council to "have regard to any submissions received" and prepare a draft of the proposed guidelines and publish a second notice in the specified form, containing the draft and inviting persons or bodies to make submissions relating to it. The regulations specified a form for the notice and specified a minimum consultation period of 30 days.

These requirements were followed thoroughly in the revision of the *Statement* between 1996 and 1999. There were in fact three "rounds" of public consultation, the first to explore the opinions of users of the *Statemen*t as to the general form and style that a revision should take and the second and third that followed the required statutory sequence.

Late in the 1996–1999 process of revising the original *Statement*, AHEC invited a number of peak agencies to examine and thus possibly endorse or support the new *National Statement*, with the intent of legitimising its relevance to human research unrelated to medicine or health. One of these agencies was the ARC which at the time was part way through the process of developing its own ethical guidelines for researchers and institutions in receipt of ARC funding. These negotiations were successful to the extent that when issued, the *National Statement 1999* was "endorsed" by the ARC, the Australian Vice-Chancellors Committee (now Universities Australia), the Australian Academy of the Humanities, the Australian Academy of Science and the Academy of the Social Sciences in Australia, and "supported" by the Academy of Technological Sciences and Engineering.

This attempt to seek to establish a single national ethical guideline for all research involving humans was not without its difficulties. Tensions arose between members of AHEC who were concerned that negotiations with these peak agencies and academies could lead to a "watering down" of protections deemed essential in health research. The *National Statement 1999* had been subjected to two rounds of public and stakeholder consultation but neither round of consultation had deliberately included, as stakeholders, the general researcher membership of the peak agencies and academies that endorsed and supported the new document. This lack of consultation, together with a continuing clear primary focus on health research (by way of content and language), had the effect of creating considerable antipathy to the *National Statement* on the part of the large community of "non-health" researchers.

The statutory requirement for consultation was amended in 2000[3] and is now contained in section 13 of the NHMRC Act which, in relation to human research guidelines, provides:

Before:

(a) ….
(b) the Australian Health Ethics Committee provides human research guidelines to the Council for the purposes of subsection 10(2); the…Committee must:
(c) prepare a draft of the guidelines; and
(d) publish a notice, in the manner and form specified in the regulations:

    (i) containing a summary of the draft guidelines; and
    (ii) stating where copies of the draft guidelines can be obtained; and
    (iii) inviting persons or bodies to make submissions relating to the draft guidelines in accordance with the procedures, and within the period, specified in the notice; and

(e) have regard to any submissions received as a result of the invitation referred to in subparagraph (d)(iii). (NHMRC Act 1992, s.13)

[3] By the *Health Legislation Amendment Act (No. 2)* 2000, No. 6, Schedule 1.

The effect of the change to this section is to only require one round of consultation before guidelines are issued.

The current regulations referred to in this section provide:

6 Consultation about guidelines – manner and form of notice

(1) A notice under paragraph 13 (d) of the Act must be published:
  (a) in a daily newspaper that circulates throughout Australia; and
  (b) on an NHMRC website.

(2) A notice under paragraph 13 (d) must include the following:
  (a) the subject matter of the draft guidelines;
  (b) the last day, being a day at least 30 days after the notice is first published under sub-regulation (1), on which the Council or the Australian Health Ethics Committee will accept submissions relating to the draft guidelines;
  (c) the manner in which a submission is to be made.

Note A notice under paragraph 13 (d) of the Act must also include the information mentioned in that paragraph.

These provisions are a minimum standard and mere compliance can lead to a passive consultation process. Further, the requirement in section 13 that consultation about guidelines is consultation about a draft can lead to a perception that the consultation will exclude opinions that could have led to a fundamentally different draft.

In practice, in relation to human research guidelines, these risks have been addressed by a number of strategies. The first of these is to establish working parties that include members drawn from beyond the membership of the AHEC who can bring to the task a suitably wide range of perspectives. In the 2005–2007 revision of the *National Statement 1999* (NHMRC 1999), the primary working party established by the AHEC included representatives from the ARC and UA, and subcommittees were established in areas in which additional expertise was needed, such as qualitative methods research and the use of databases. Second, by the commencement of that process, the NHMRC had accumulated an extensive contact list of organisations that had an interest in human research and copies of the draft guidelines were specifically directed to those organisation with a request that a submission be provided. Thirdly, in relation to the methods that institutions used to address ethical review of research involving low risk, a workshop was convened to which representatives of a number of institutions were invited.

In some circumstances, the formality of the procedures prescribed in the legislation has been preceded by more informal but suitable processes. One example was in the development of the *Values and Ethics* (NHMRC 2003) guidelines between 2000 and 2003. The formal processes were preceded by extensive consultation with key individuals and organisations by a member of the AHEC who had extensive experience with and was respected by these people and their communities. Following that process, a meeting was convened of most of the key people who had been consulted in order to reach agreement on the revision process. The agreed process

included, in addition to the formal steps required under the Act, a 2 day workshop to clarify the key values that were to underpin the guidelines.

Having Regard to Submissions

The NHMRC's consideration of submissions was directly affected by the outcome and opinion of the 1996 Federal Court decision in *Tobacco Institute of Australia Ltd & Ors* v *National Health & Medical Research Council & Ors* ([1996] FCA 1150), in which the NHMRC was found not to have fulfilled its statutory duty to have regard to submissions related to guidelines about passive smoking. The judge said that:

> the obligation to have regard to submissions received required the NH&MRC, in preparing the draft recommendation, to take them into account and to give positive consideration to their contents as a fundamental element in its decision making. ([1996] FCA 1150 at 1161)

This obligation was clearly applicable to all the expert working parties that the NHMRC established and to the principal committees responsible for recommending guidelines to the Council. The process now followed is that all submissions are copied and copies provided to all working party members with the expectation that all members will read all submissions. In addition, staff and/or volunteer working party members summarize all submissions and strive to extract all of the key points and suggestions from each submission. Face to face meetings of working party members are held at which time the draft ethical guidelines are considered paragraph by paragraph and relevant comments made in submissions are debated by the working party. At times, a subgroup of a working party (colloquially called a "writing group") may undertake this detailed work but only on the understanding that the full working party will discuss the outcome of the subgroup's work and the submissions. The AHEC regularly reviews the progress of any working party it has established and members of the AHEC are also provided with copies of all public submissions. Guideline documents prepared by working parties are debated at AHEC meetings before being agreed to by the AHEC. The positive benefits and the significant impact of this public consultation process should not be underestimated. Analysis of the first draft of any proposed guideline and comparison with the final product will confirm this.

In the revision of the *Statement* between 1996 and 1999, all submissions were provided to members of the working parties and of the AHEC, with the expectation that they would all be read. Further, minutes were kept of the manner in which each submission was dealt with: whether the working party agreed or disagreed with it and how those decisions were reflected in the developing draft.

In the most recent revision process, between 2005 and 2007, in addition to following the same procedure as in 1996–1999, all submissions that were not confidential were published on the NHMRC website.

Promoting the Use of Guidelines

From 1982, the *Statement* (and succeeding NHMRC guidelines) required institutions conducting medical research involving human subjects to establish an institutional ethics committee (IEC). This establishment came to be one of the conditions for research funding eligibility for human research and, as a result, the practice of institutions notifying the existence of their IECs to the NHMRC developed. This was later formalized and is now referred to as registration of Human Research Ethics Committees (HRECs) and, at least since the *National Statement 1999*, these HRECs provide annual "compliance" reports to the NHMRC. These reports helped to maintain the relevance of the *National Statement 1999* and its successor guidelines, although the reports themselves did not collect data about the use of the guidelines.

Since the development of the *National Statement 1999*, the AHEC has undertaken considerable work to promulgate new or revised ethical guidelines through workshops in all capital cities and has held three bi-annual national conferences – in 2003, 2005 and 2007 – on health research ethics for researchers and members of HRECs. Both processes represent an opportunity for stakeholders to provide feedback to the AHEC on existing and proposed guidelines. This feedback then informs the subsequent work of the AHEC.

For the ethical review of clinical trials (which forms a large part of the workload of many HRECs), awareness of and compliance with ethical guidelines was reinforced for researchers and institutions in 1992 when new regulations under the Therapeutic Goods Act were issued. These required that clinical trials of new drugs or devices could only proceed if favourable advice had been received from an institutional ethics committee that had notified its existence to the NHMRC. Those regulations under the Therapeutic Goods Act were amended in 2000 to require that trials of new therapeutic goods were to be conducted in accordance with the *National Statement 1999*.[4]

Strategic Drafting

In its experience of working on the development of guidelines, the AHEC adopted some strategic responses to contested issues, of which two, accommodating differences and postponing determinations, we note here.

In the development of chapter 15 on use of Human Tissue Samples in the *National Statement 1999* (NHMRC 1999), the AHEC received widely competing submissions on the circumstances in which consent should be sought for the research use of human tissue previously collected from clinical investigations or held in tissue banks. There was strong research interest in reducing the need for consent so as

[4] Australian Government 1990. Therapeutic Goods Regulations 1990, 12 AD.

to facilitate research and, on the opposite side, forceful submissions asserting the right of individuals to control the use of "their" tissue as a protection against harm they may ensue or as a way of exercising their rights to any benefits, whether health or financial, that might flow from the research. The AHEC adopted an accommodating differences approach and drafted a provision (NHMRC 1999, 15.7) that required that consent should normally be obtained where the research use of such tissue "may lead to harm, benefit or injustice to a donor". It could be said that while this achieved a conceptual resolution of the differences, its expression left a wide scope for interpretation, rather than offering a helpful guideline.

The other approach of postponing a decision was adopted in two different ways in the guidelines on ART (NHMRC 1996a). In 1996, there was deep division within the Australian community about the status of the human embryo such that the guidelines, in addressing the questions of embryo research, stated that "At the present time these differences cannot be resolved" (NHMRC 1996a, 10). When these guidelines were revised in 2004, questions of the use of genetic technology associated with ART, sex selection and surrogacy were regarded as matters that, in the AHEC's opinion, required "further community debate and consideration by elected governments" (NHMRC 2004, 59). They were included in an Appendix to the 2004 guidelines with a summary of the contesting arguments.

Reflections on the Strengths and Weaknesses of the Australian System for Development and Issue of Human Research Ethics Guidelines

We readily admit that the following comments are likely to be biased as they come from people who have been deeply involved at a national level in the Australian system for ethical review of human research. Nevertheless, we have tried to be objective and reflect as honestly as we can on the strengths and weaknesses of the system as it has evolved.

Roles and Resources

The AHEC has made considerable efforts over time to keep itself informed of relevant developments of systems in other countries, most noticeably in Canada, the United Kingdom, the United States, and several European countries. It has participated actively in international conferences, including hosting the Fifth International Conference of National Bioethics Committees in Canberra in 2004 and has invited international experts to visit Australia. This has allowed the AHEC and NHMRC to compare Australia's processes with those of other nations.

Such comparison reveals that Canada is most similar to Australia in having issued national human research ethics guidelines designed to apply to all human

research and depending for their effect on federal research funding. The US research regulations have a clear focus on health and medical research, although they do govern other federally funded research. In most other developed countries, more attention has been directed to health and medical research than social and behavioural research.

An important difference from other nations emerges when the roles of national bodies other than those related to ethical guideline development are examined. The AHEC has responsibilities related to human research ethics and to the provision of advice to NHMRC, the Federal Health Minister and government on matters generally in health ethics. By contrast, most developed nations have established national bioethics committees but few have given those committees both the broad roles that the AHEC plays. Those national committees that do not have a role in relation to human research ethics, but only in bioethics, are frequently composed of persons with expertise in bioethics and not all such committees are bound to consult with the broader community in developing advice.

One view of the Australian position is that the national committee (AHEC) that emerged in 1992 out of the merger of NBCC and MREC has two important strengths: the breadth of backgrounds of its membership and the statutory requirement for consultation in guideline development. These facets make it more likely that positions developed by the AHEC will reflect a broad community consensus and will be better accepted by the Australian community. Another view is that the combination of responsibilities about human research ethics guidelines and health ethics advice in a part-time committee stretches available resources so that neither role is filled as well as it should be. The AHEC budget often cannot stretch to provide adequate resources for an engaged and pro-active consultation or for promulgating research ethics guidelines as well as resourcing adequate time to research and develop health ethics advice in sufficient depth.

Registration, Compliance and Complaints

The NHMRC administers a registration process for HRECs. Institutions intending to seek research funds from the NHMRC must undertake to have any human research reviewed by an HREC that is registered with the NHMRC. Legislation that governs the research use of unregistered therapeutic goods imposes a similar requirement.

To maintain registration, institutions and their HRECs submit an annual return assuring the NHMRC that they have adhered to the requirements of the *National Statement*. These returns are examined by NHMRC staff and the NHMRC Research Committee, responsible for recommendations of grants to institutions, is advised of the "compliance status" of each institution. This system creates the following potential problems. First, it makes the NHMRC both the issuer/creator of guidelines as well as the "policing body". Second, it raises but does not answer the question of whether the NHMRC has the power to take remedial action if non-compliance is

identified. Whether NHMRC has such power has never been tested, although refusing to pay research grant funds to non-compliant institutions would appear to have a contractual basis.

In our view, the enforcement role sits uncomfortably with NHMRC's and AHEC's role in promoting ethically good human research. The *National Statement* was purposefully developed as a document to promote deliberation and not an instrument to enforce compliance. In contrast to the regulations in the United States, the *National Statement* does not provide the precision necessary as a basis for formal and fair compliance interventions. These considerations expose the uncertainty in the scope of NHMRC's and the AHEC's responsibility in human research ethics beyond developing and issuing guidelines. However, to date, this uncertainty has not unduly influenced the form and expression of these guidelines.

The existence of a registration system of HRECs with the NHMRC has another consequence. It has at times raised the expectation that where institutional processes have failed to resolve a complaint about research conduct or review, the NHMRC might exercise a supervisory role and receive, investigate and resolve such matters. Such a function raises the same uncertainty about the scope of the human research ethics role and, at the same time, the questions about how available resources should be used.

Consultation, Deliberation and Promulgation

As described above, the issue of human research ethics guidelines has been preceded by consultation processes that, as a minimum, conform to the statutory design. This design is characteristic of its time – the 1990's – when a passive form of public engagement was regarded as sufficient, especially in relation to scientific or clinical practice guidelines where the community to be engaged was expert, articulate, organised, informed and accustomed to this type of communication. The use of the same passive methods for ethics guidelines can be questioned. Here, the community to be engaged frequently lacks, or believes it lacks, all the characteristics of a scientific community and, as a result is unlikely to see itself as equipped to initiate a submission. More pro-active methods have been used with effect in other countries and in Australia by other agencies, such as the Australian Law Reform Commission. These would better suit the development of ethics guidelines, but the resources needed to support them may not be available because they are needed to support the other roles of the AHEC.

The process of assessing, deliberating on and incorporating submissions into developing versions of guidelines is, we recognise, a complex and intricate interchange of opinion and experience. The wide range of AHEC membership means that its work is informed but not confined by the content of submissions, because individual committee members respond to each submission from their own perspective. The deliberation thus blends differing expert assessments of the relative weight and importance of the submissions with the content of the submissions themselves.

This process that depends on and uses the variety of committee opinion is as much an expression of community opinion as are the submissions.

The NHMRC, on the AHEC's initiative, has taken steps to inform HREC members and researchers when guidelines are issued or revised. This has been seen to be a natural and desirable initiative and valued by recipients. In the absence of other providers, the AHEC in the years from 2003 to 2007 (but not since) took on the role of providing training and education for HREC members. For this reason, advice was given to the appointing Minister of the value of appointing some AHEC members with HREC experience. However, since 2007,, these activities have largely ceased, for budgetary reasons, and the task of training HREC members and researchers in the application of ethical guidelines hopefully will be taken up by other agencies or entities. This is perhaps ironic because both the NHMRC *National Statement* and the *Australian Code for the Responsible Conduct of Research* (NHMRC/ARC/UA 2007b) require institutions to ensure that their researchers are adequately trained in research ethics.

Ownership of Guidelines

There is no doubt that a key task of the AHEC is to develop, revise and issue guidelines for the ethical conduct of health and medical research. The application of these guidelines to other types of human research has been deliberate and at times supported by other agencies that have seen the desirability of a single national document.

Through the broad membership of the joint agency working party and the wide stakeholder consultations, the *National Statement* appears to have been reasonably well received by researchers in disciplines outside of health and medicine. However, when questions arise during the life of this edition – as to interpretation or application – it is by no means clear whether such questions should be directed to and responded to by the AHEC or the NHMRC. These bodies simply lack the expertise and experience that would generate the confidence of a social or humanities researcher that meaningful advice was likely on inquiry.

Research Governance

Institutional establishment or use of HRECs is a condition for their receipt of NHMRC research funding and forms part of deeds of agreement that institutions sign to receive those funds. The membership requirements and responsibilities of those HRECs are provided in the *National Statement*. Until the latest revision of the *National Statement* and the revision of the complementary NHMRC document entitled the *Australian Code for the Responsible Conduct of Research* (NHMRC/ARC/UA 2007b), the importance of not only having effective human research ethics review in place but also an effective system of research governance in place had

been largely overlooked in Australia, especially in those hospitals that undertook research. This has been exposed starkly as recent initiatives to remove duplication of ethics review compel institutions to decide how to govern research when the ethical review is conducted elsewhere. Here again, as with research ethics, the NHMRC may not appear to be the best informed source of advice about how to establish such structures, even though its issued guidelines have promoted the need.

Some Historical Reflections and Changes to NHMRC Act in 2006

In the years since the formation of the AHEC in 1992, the committee appears to have achieved a perhaps enviable reputation as the national authority on both the principles and the practice of human research ethics. Although the AHEC was never a separate entity, but always only a principal committee of the NHMRC with obligations only to the Council of the NHMRC and to the federal Minister, it was referred to in the research community as if it was its own master.

One difficulty of this perception for the AHEC (and for the NHMRC) has been the expectation that the AHEC can (and should) not only issue guidelines, but also train researchers and HREC members in their use, assess annual institutional compliance with human research ethics standards, receive, investigate and resolve complaints about research ethics review and provide prompt, informal and expert advice about research ethics issues. To its credit and that of the staff who supported the committee, sufficient of this was in fact done so that the perception was maintained.

Changes to the NHMRC Act in 2006 have led to a more corporate vision of the NHMRC and to a more internally cohesive role for the AHEC. Issues of institutional research ethics compliance are now likely to be combined with financial accountability for research funding and, as noted above, the AHEC is likely to significantly confine its roles in promulgation and education. This appears to leave a space, perhaps even a vacuum, of activity in the promotion of human research ethics that is likely to be filled by other players. The significance of these changes for the nation is yet to be realised.

One of the strengths of the AHEC that we believe has been of great importance has been the statutory guarantee of a degree of independence from the NHMRC in the work of developing ethical guidelines for research. Another means of ensuring its independence (from politicisation) has been the need until 2006 for the Federal Minister of Health to consult with members of the Australian Health Ministers Conference in relation to appointment of the Chair and the member with knowledge of the ethics of medical research, and in relation to all the other categories, consider nominations from relevant professional bodies. The 2006 amendment to the *NHMRC Act 1992,* requiring, as it does, only that those appointments be made by the Minister " after consulting appropriately" appears to weaken this independence

from political considerations in appointments. Further, the specific powers given to the CEO appear to place the agenda and the public outcome of the work of the AHEC substantially within the CEO's power. While these constraints may have a sound organisational and accountability basis in government agencies that administer policy, they appear inappropriate for an entity charged with the development of ethical guidelines intended to reflect community opinion. It is concerning also that these changes were accepted without wide debate by key stakeholders. It is too early to determine if these changes will alter the broad community acceptance of the AHEC's status or alter the workings of the AHEC or the nature of the output of the AHEC's work, current and future.

Competing Interests The authors of the chapter have all had direct involvement in the development and issue of some of the guidelines and have drawn on their personal engagement as well as official records of this work.[5]

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[5] Nor have we have discussed our thoughts with Justice Robyn Layton QC who was the first chair of the Australian Health Ethics Committee.

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Chapter 10
Consultation, Deliberation and the Review of the *National Statement*

Eliza Goddard and Susan Dodds

Introduction

The *National Statement on Ethical Conduct in Human Research* (NHMRC 2007a, b) provides guidelines that set the Australian national standards for all research involving humans. Adherence to the *National Statement* requirements is a prerequisite for any researcher or institution wishing to have access to Commonwealth research funding. The research to which the guidelines apply (and hence the guidelines themselves) includes ethically contentious areas, and concerns about the *National Statement* guidelines frequently focus on these ethically contentious domains (such as criminological research, research on children and research into novel therapies). The law prescribing the *National Statement* (NHMRC Act 1992) requires that revisions to the *National Statement* must involve a process of public consultation. For these reasons the process of revision to the *National Statement* merits careful examination and assessment in the context of a deliberative democratic approach to public policymaking, given its importance for establishing the ethical framework for research involving humans, the significant public good (funding provided to universities, hospitals and public research organisations) that depends on adherence to its requirements, and the legislated requirement for public consultation in revisions to the *National Statement*.

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In 2003, the Australian Health and Ethics Committee (AHEC), a principal committee of the National Health and Medical Research Council (NHMRC), began a review of the *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC 1999). The review was jointly conducted with the Australian Research Council (ARC) and the Australian Vice Chancellors' Committee (AVCC, now Universities Australia (UA)). The review was overseen by a working committee, Chaired by Dr Christopher Cordner, and drawn from the membership of AHEC, the ARC and the AVCC. The review included a two-tiered public consultation process – involving the release of two consultation drafts, in January 2005 and January 2006, with requests for submissions to each. In 2007 the *National Statement on Ethical Conduct in Human Research* (NHMRC 2007a) was released and was greeted with considerable praise from the academic and medical community as a significant improvement to its antecedent.

In this chapter we review the consultation process used in the revision of the 1999 *National Statement* to assess whether the process met deliberative democratic ideals of inclusive *participation* in policy development (through consultation with all those affected by the policy), discursive *deliberation* based on that participation about policy arguments (through exploration of the reasons presented and addressed in the consultation process); and public *accountability* for policy decision-making (through a process of transparent justification).

In section "The Development of Human Research Ethics Guidelines in Australia", we examine the role of AHEC, and specifically the working committee formed to redraft the *National Statement*, in developing guidelines pertaining to human research ethics and the NHMRC's formal requirements for public consultation. In section "The Review of the 1999 *National Statement*", we describe the two public consultation rounds and submissions which made up the review of the 1999 *National Statement* and discuss the overall changes in the guidelines from this earlier *Statement* to the 2007 *National Statement*. In section "Research Involving Children and Young People" we examine a subset of submissions in detail – those that raised and defended critical ethical responses to the chapter on children and young people in research – and compare the changes in the chapter in each of the consultation drafts against these issues raised in the submissions. In the fourth and final section "Conclusions: Deliberation, Justification and Revision to the National Statement" we make an assessment of the strengths and weaknesses of the consultation process against the three ideals of deliberative democracy outlined above.

We focus on the revisions relating to research involving children and young people because this is an area that has raised substantive ethical tensions and because there were researchers and authors raising diverse concerns about the provisions of the *National Statement* in this area prior to, and throughout the revision process (Sanci et al. 2004; Spriggs and Gillam 2008). By tracing the way in which different contributors to the revisions framed their arguments about the changes relating to children in research in the *National Statement,* we will be able to get a better sense of the role of argumentation and deliberation in the processes leading to changes, so that we can establish the level of legitimacy that the resulting revisions are able to claim.

Our method is shaped by three matters that limit drawing strong conclusions from the evidence available: (1) public access to submissions to the *National Statement* Review does not extend to submissions made "in confidence", (2) access

to the deliberations of the AHEC *National Statement* working committee are not publicly available, and (3) the *National Statement* document does not provide reasons or arguments for the inclusion or exclusion of each guideline. The first and second of these matters limit our ability to accurately describe and assess the range of arguments presented to the working committee, and hence our ability to claim to know precisely which positions were extensively supported or rejected in submissions, and which positions that were presented in submissions were actively defended or challenged within the review committee discussion. Moreover, the minutes from the meetings indicating how the Committee responded to the arguments in submissions cannot be released without a successful Freedom of Information request because they contain notes on submissions that were submitted in confidence. Another factor which limits such conclusions is that the consultation drafts and the 2007 *National Statement* were not only a product of the written submissions; AHEC also sought advice from experts beyond the written submission process.

It is clear that the process followed for reviewing and redrafting the *National Statement* met, or exceeded, the consultation requirements spelled out in the Act (NHMRC Act 1992). However, that process only addresses some of the goals that we argue are central to democratic deliberation and legitimate public policy development. There are a number of points on which the process fell short. Specifically, participation in the process was narrow, as it primarily involved researchers and institutions, and did not reflect the broader public or research participants. Secondly, there are identifiable gaps and tensions between the emerging statement and the submissions, and these gaps are not explained or justified. Such tensions, in principle, need not indicate a lack of success in meeting requirements for democratic deliberation. However, given the limitations noted above regarding transparency of the process, we cannot judge. The limits placed on public access to the detailed reasoning that informed the final document suggests that the accountability requirement for effective public deliberation has not been met, at least, in spirit. Nonetheless, we have been able to identify indicators of careful responses to public submissions that raised clear arguments about the specific issue of consent by children and young people to participate in research. Our overall conclusion is that whilst the iterative AHEC consultation process elicited arguments that had an impact on the revised guidelines, the process itself lacked a level of transparent public accountability that would give the outcomes greater democratic legitimacy.

The Development of Human Research Ethics Guidelines in Australia

In Australia, the NHMRC is responsible for issuing guidelines pertaining to research involving humans. The Australian Health Ethics Committee AHEC, a principal committee of the NHMRC, is responsible for developing these guidelines. AHEC members are appointed by the Minister for Health, after "appropriate consultation", and AHEC's composition is specified in the NHMRC Act 1992. AHEC's membership includes people with expertise in philosophy, the ethics of medical research,

public health and social science research, clinical medical practice and nursing, disability, law, religion and health consumer issues.

AHEC's functions are to advise the NHMRC Council on ethical issues relating to health and to develop and give the Council human research guidelines (NHMRC Act, 35(3)).[1] For the revisions to the 1999 *National Statement* guidelines, a working Committee comprising a subset of AHEC members and members nominated by the two other authoring bodies of the *National Statement*, the ARC and AVCC, was given the task of drafting the revisions and considering submissions to the consultations. The guidelines are required to be issued by the NHMRC precisely as developed by AHEC (section 10(2)) and are to be laid before each House of Parliament within 15 days (section 10(4)). So, whilst AHEC is part of the NHMRC, it acts independently in the development of human research ethics guidelines. The NHMRC and ARC give "teeth" to AHEC's guidelines by being able to withhold research funding from any institution that does not follow the *National Statement's* requirements for the establishment and support of a Human Research Ethics Committee (HREC) (see Thomson, Breen and Chalmers, this volume, Chap. 9, for further discussion of the role of AHEC and the history of research ethics guidelines in Australia).

Formal Requirements for Public Consultation

In the production of its recommendations, including revision to guidelines, the NHMRC (and its committees) is formally required to engage in public consultation. The NHMRC Act sets out the relevant consultation process for the development of guidelines (section 13). Firstly, the intention to develop a regulatory recommendation or engage in a prescribed activity (in this case the review of human research guidelines) must be advertised and persons and bodies are invited to make submissions (sections 12(a) and (b)). A draft is to be prepared, and a notice published containing "a summary of the draft guidelines; stating where copies of the draft guidelines can be obtained; and inviting persons or bodies to make submissions relating to the draft guidelines in accordance with the procedures, and within the period, specified in the notice" (section 13 (c) & (d)). In the case of the development of the 2007 *National Statement* AHEC issued two consultation drafts and public submissions were invited in response to each.[2] As part of the public consultation process the NHMRC (or AHEC in this case) must have "regard" to any submissions

[1] Other functions listed include: any other functions conferred to the Committee in writing by the Minister after consulting the CEO; and any other functions conferred on the Committee by this Act, the regulations or any other law.

[2] Thomson et al, this volume, Chap. 9, note that whilst previously two rounds of consultation had been a statutory requirement, this had been amended in 2000 to requiring only one round of consultation. Despite this, the review of the 1999 *National Statement* went through two rounds of public consultation.

received (13(e)). Chalmers notes that the requirement for regard was inserted "to ensure that the guidelines were a product of the public consultation process rather than the individual, and possibly medically biased, views of the Council of the NHMRC itself" (Chalmers 2001, 29).

The NHMRC's policy document, *Public Consultation–procedures for making submissions* sets out a procedural understanding of "due consideration": "All submissions will be considered. The committees are obliged to report to Council on the consultation process, including showing how they addressed the comments that submitters have made" (NHMRC n.d). NHMRC staff note that in practice this means that every member of a working committee charged with considering public submissions is given a complete copy of all of the submissions received as well as any summaries of submissions that were used to assist the review process.[3] In this way, each member can read and consider each submission in its entirety and within context. Thomson et al (this volume, Chap. 9) note the adoption of these practices was a result of the outcome of the 1996 Federal Court decision in *Tobacco Institute of Australia Ltd & Ors. v NHMRC & Ors.* [1996], which considered the specific terms of section 12 of the NHMRC Act and placed additional responsibilities on the NHMRC in relation to any submissions received, including the requirement to record detailed minutes of all committee discussion of submissions. It is clear that the level of public consultation required by the NHMRC is for substantive consideration of arguments received from the public in the course of committee decision-making which includes accountability for the policy decisions made after consideration of public submissions through the retention of a record of account of the ways in which arguments have been addressed or dismissed.

Review of Human Research Ethics Guidelines

Human research ethics guidelines in Australia are subject to periodic review.[4] The release of the 2007 *National Statement on Ethical Conduct in Human Research* continued the process of refinement, and development, of human research ethics guidelines in Australia since the 1992 NHMRC *Statement on Human Experimentation*. Over the intervening years the scope of research falling within the remit of the *National Statement* expanded to include, first, *all health research*

[3] Correspondence with NHMRC Secretariat, email August 2009.

[4] Following the release of the 2007 *National Statement*, AHEC introduced a process of "rolling review" for revising guidelines contained in the *National Statement*. This involves updating parts of the *National Statement* as needed, in contrast to the practice of reviewing the entire document every five years. This process allows for updates and revisions as needed, so as to address changes in research practice or specific sections of the S*tatement* in a timely fashion. In 2013, AHEC established a sub-group, including representatives from the ARC and UA, to make an appraisal of the *National Statement* and to develop a strategy for its ongoing review. We note that no amendments have been made to the chapter 'Research involving children and young people' since the release of the 2007 *National Statement* and the production of this chapter.

involving human participants, and later, to *all research* involving human participants, including social science research. Further, the NHMRC extended the authority of the *National Statement* by seeking, in 1999, the endorsement of the *National Statement* by the AVCC and ARC, the Australian Academies of the Humanities, Science and the Social Sciences (and support of the Australian Academy of the Technological Sciences and Engineering). Finally, as the scope of research covered by the *National Statement* expanded, so too did the range of stakeholders to whom the *National Statement* was addressed. The 2007 *National Statement* is directed to researchers, research institutions, funding bodies and the HRECs responsible for reviewing and approving the conduct of research. (see Dodds 2000; Dodds et al. 1995; Thomson et al. this volume, Chap. 9).

Issues Shaping the Review Process

The Preamble to the 2007 *National Statement* refers to the focus and intent of the review undertaken in its development: "[t]he National Statement has been extended to address many issues not discussed in the previous version, or discussed in less detail. This is in response to requests for clearer guidance for those conducting research and those involved in its ethical review." (NHMRC 2007a, 3–4). What were some of the issues driving the changes to the *National Statement* between 1999 and 2005? What issues were recognized as having not been discussed in 1999 or which generated "requests for clearer guidance"? Warwick Anderson, Christopher Cordner and Kerry Breen raise a set of general concerns in an editorial in *The Medical Journal of Australia* (2006). That editorial lists weaknesses in relation to the 1999 *National Statement* that have been identified in various reports and articles, including:

> under-resourcing of overworked HRECs [ALRC/AHEC 2003], deficiencies in transparency and accountability of HRECs [ALRC/AHEC 2003], absence of explicit application of the guidelines to the private sector [ALRC/AHEC 2003], the failure of institutions and HRECs to accommodate the vast increase in multicentre research [Roberts et al. 2004] and the 'one size fits all' process of ethical review [Israel 2004] (Anderson et al. 2006, 261).

Earlier criticisms of the 1999 *National Statement* included the assumed, and continued use of, a medical paradigm of research, despite its endorsement by the ARC and the Academies of Humanities and Social Sciences (see Dodds 2000, 2002; Israel 2004, 10). One area of concern for researchers and for HRECs in universities was the poor fit between the *National Statement's* narrow (medical) approach to research involving children and young people and the vast array of research involving children and young people that is undertaken in universites. Examples include: research on teaching practices in schools, where students are involved in research incidentally; non-invasive survey research on school children; observational studies of children's activities in public spaces; research evaluating educational or social interventions involving children or young people; and, interviews with homeless

young people. Chapter Four of the 1999 *National Statement*, on children and young people in research, still drew on a paradigm of research as clinical experimentation in a medical context, rather than reflecting the diversity of research topics, methods and approaches used in research involving children and young people. While there is a set of important ethical issues to be addressed about the inclusion of children and young people in risky medical research, it is not clear that the same ethical issues apply to observational research of children in public spaces, or educational research that is undertaken on pedagogy in schools, where the research is non-invasive, the direct risks to participants may be very low, and where the aim of the research is not to test different clinical treatments on patients, but to understand, for example, developmental social dynamics. Further, within medical research there were questions raised about the 1999 *National Statement* requirement that all research involving children and young people must not be "contrary to the child's or young person's best interests". Such a requirement would, presumably, prevent research activity that posed very low risks to a child or young person but which might provide important information about children and young people not obtainable in other ways.

One set of areas for debate about children and young people in research address the appropriate balance between the values of respect for autonomy and paternalistic protection of the vulnerable. This tension is manifest in debate about the capacity of children (or older children) to consent to participation in research (Sanci et al. 2004), concern over the blanket requirement for parental or legal guardian consent in all cases of research involving children and young people, and, whether children and young people may refuse to participate in research (notwithstanding consent by their parent or guardian).

Given the significance of the range of issues raised (the demand for clearer guidance to HRECs and researchers, recognition of the need to better attend to the range of research topics and methodologies, and concerns about children's involvement in research) and their presence in debate among researchers and within HRECs prior to the review, it is reasonable to expect that they would be significantly reflected in the changes to the *National Statement*. This paper attempts to track that influence, with a specific focus on the involvement of children and young people in research.

The Review of the 1999 *National Statement*

In September 2003 the AHEC established a working committee to review the 1999 *National Statement on Ethical Conduct in Research Involving Humans*, which consisted of "members from AHEC, the ARC and the AVCC" (NHMRC 2007a, 85). Within AHEC, three groups were involved in the review process at different levels of detail: there was AHEC, which had oversight and final authority over the review,

a sixteen member working committee[5] and a smaller subset of the working committee, a writing group. The working committee was split into a number of groups focussed on different issues, all of which reported back to the working committee as a whole. The smaller writing group was composed of 4–5 individuals and was responsible for taking these comments and drafting the sections and chapters.

Timeline for the Review of the 1999 National Statement *and Release of the 2007* National Statement

In preparing the first consultation draft for public review, the working committee used the 1999 *National Statement* as the base document, however it was significantly reworked in terms of its structure and its scope was clarified (see below). At the outset, the working committee also sought some limited, targeted consultation with key stakeholders – researchers with specific expertise and institutional HRECs with particular experience in ethical oversight of some areas of research, who were given relevant sections from the *National Statement* (NHMRC 1999) and asked to give input.[6] In January 2005 (and in accordance with the NHMRC Act Section 13(1) b) AHEC released the *Review of the National Statement on ethical conduct in research involving humans – first consultation draft* (NHMRC 2005) for public consultation lasting 3 months until March 2005. The draft was available on the NHMRC website and hard copies were distributed via the NHMRC mailing list and advertised though the AVCC and ARC. Whilst the first consultation draft was accompanied by an invitation to contribute to the document, there was no direct request for comment on any specific parts of the consultation draft.

Submissions in response to the first consultation draft (NHMRC 2005) were received by email and post, as text and handwritten. The working committee considered these submissions and a second draft was prepared (NHMRC 2007a, 86). In January 2006, AHEC released the *Draft of the National Statement on ethical conduct in human research – second consultation* (NHMRC 2006a, b, c) and undertook a second round of public consultation, again lasting 3 months, from January– March 2006. The second consultation draft was circulated in a manner similar to the first and was accompanied by a letter from the Chair of the working committee, Dr Chris Cordner (NHMRC 2006c). This letter details changes made by the committee in the second consultation draft and lists specific areas on which they sought comment from stakeholders. Electronic submissions were strongly encouraged. Those who made a submission were required to complete a submission form which asked for information on authorship and whether the author wished the submission to remain confidential, amongst other details. Submissions without this form attached would

[5] For a full list of members of the working committee, see *National Statement on Ethical Conduct in Human Research* (NHMRC 2007a: 97).

[6] Meeting with NHMRC Secretariat, August 2009.

Table 10.1 Timeline of the review process of the 1999 *National Statement* and release of the 2007 *National Statement*

September 2003	AHEC establishes working committee to review the *National Statement on Ethical Conduct in Research Involving Humans*
January 2005	AHEC releases *Review of the National Statement on Ethical Conduct in Research Involving Humans – first consultation draft* for 3 months of public consultation
January 2006	AHEC releases *Draft of the National Statement on Ethical Conduct in Human Research – second consultation* for 3 months of public consultation
April 2007	NHMRC releases the revised *National Statement on Ethical Conduct in Human Research*
January 2008	Researchers, Institutions and HRECs to be compliant with the *National Statement*

not be accepted. A template for comments was prepared and could be accessed on the NHMRC website (NHMRC 2006b, i).

The working committee then considered submissions in response to the second consultation draft and completed the writing of the final draft. "This agreed version was then presented to the Council of the NHMRC (at its 164th Session in March 2007) for consideration. At that session the Council agreed to advise the CEO that the final draft should be issued" (NHMRC 2007a, 86). Despite the review of the *National Statement* having extended considerably beyond the triennium of AHEC membership that launched the review, the *National Statement on Ethical Conduct in Human Research* was finally released in April 2007, (ibid.). Researchers, Institutions and HRECs were to be compliant with the *National Statement* from 1 January 2008 (see Table 10.1).

Public Submissions to the Consultation Drafts

In response to the first and second consultation drafts, the working committee received a total of 362 submissions. Submissions were received in two categories – from organisations and from private individuals. Forty-seven organisations, or private individuals, provided a submission to both consultation rounds.[7]

In response to the first consultation draft (NHMRC 2005), the working committee received 178 submissions (NHMRC 2007a, 86). Of the total number of submissions received, 104 were made publicly available: 74 from organisations and 30 from private individuals.[8] The bulk of these submissions were received from groups

[7] The NHMRC made available to our research team the non-confidential submissions to the first and second consultation drafts of the *National Statement*.

[8] An analysis of the 74 publicly available submissions from *organisations* by stakeholder shows that: 22 were received from universities/university faculties; 17 from professional bodies (professional bodies includes peak bodies and learned bodies); 9 from research centres/institutes (often

Table 10.2 Analysis of submissions made to the first and second consultation drafts

Submissions	First consultation draft	Second consultation draft
Total number of submissions	178	184
Publically available	104	147
Organisations	74	106
Private Individuals	30	41

or individuals with government institutional affiliation - universities; research centres; hospitals and government departments. Of the 104 publicly available submissions, only a small proportion were from non-institutionally aligned individuals and non-government organisations, some of which represent research participant groups, such as consumer groups, peak bodies and the like – for example, the Australian Privacy Foundation, the Humanist Society of Victoria and the Australian Injecting & Illicit Drug Users League. Some of these organisations are lobby groups, as well as bodies which act on behalf of research participants, or both. As a process of public consultation, it is safe to conclude based on this data that the publics who participated effectively in the process were overwhelmingly members of various research communities (hospital, research institutes and university) and that participant and lay public views were underrepresented in the consultation. Whilst it is clear that the bulk of submissions were received from those with institutional affiliation or experience, it is reasonable to assume that of those 74 submissions made in confidence, a number may have been from research participants who wished to protect their privacy through confidential submissions.

In response to the second consultation draft, the working party received 184 submissions (NHMRC 2007a, 86). These were again received in two categories – from organisations and from private individuals. 147 of these submissions were made publically available[9]: 106 from organisations and 41 from private individuals.[10] A larger proportion of submissions in response to the second consultation draft were from non-government organisations, with an increase in submissions from lobby groups with an interest in "right to life" issues and advocacy groups

within universities); 8 from hospitals/health services; 7 from NGO's (which includes consumer groups, advocacy groups, not for profits and community groups); 6 from government departments and agencies; and, 3 from churches/religious organisations (2 were unknown). Of the 30 publicly available submissions received from *private individuals*: 25 were received from persons with institutional – university, hospital or research centre – affiliations; 3 listed no affiliation; and 2 were anonymous.

[9] Submissions made to the second consultation draft that were not confidential were made available on the NHMRC website. This website is no longer available.

[10] An analysis of the 106 publicly available submissions from *organisations* by stakeholder shows that: 21 were received from universities/university faculties; 20 from professional bodies; 18 from government departments and agencies; 17 from NGO's (which includes consumer groups, advocacy groups, not for profits and community groups); 13 from research centres/institutes; 12 from hospitals/health services; and, 5 from churches/religious organisations. Of the 41 publicly available submissions received from *private individuals*: 27 were received from persons with institutional – university, hospital or research centre – affiliations; and, 14 listed no affiliation.

concerned with issues related to fertility and motherhood.[11] Despite this growth, the voices of participants and lay publics remained relatively quiet in comparison with those of researchers, clinicians and research organisations (see Table 10.2).

Public consultation was not limited to the request for submissions; the working committee also consulted key stakeholders (including researchers, health consumer groups and institutions) throughout the redrafting process on a number of issues (NHMRC 2007a, 86), including consultation with a "range of individuals and groups for advice on specific areas of research" (NHMRC 2006c, 1). Workshops were also held to "develop models for devolving review of low risk research, to determine the methods of streamlining ethical review" (NHMRC 2007a, 86).

The 1999 National Statement *and 2007* National Statement *Compared – Structure and Scope*

In order to get a sense of the scope of the changes to which the submissions (and stakeholder advice) gave rise, we provide a brief summary of the numerous changes from the 1999 *National Statement* to the 2007 *National Statement*, followed by a summary of the main issues raised in the publicly available submissions.

The format of the 2007 *National Statement* is closely based on the 1999 *National Statement*. Both commence with statements of broad ethical principles. Much of the material covered in the 19 chapters of the 1999 *National Statement* is retained in the 2007 *National Statement* and rearranged under 5 sections, each of which contain chapters.[12]

The 2007 *National Statement* includes new guidelines pertaining to: risk; research methods, including qualitative research methods, databanks, and human stem cells; and to types of participants, including: women who are pregnant and the human foetus, people who may be involved in illegal activities and people in other countries. Significant revisions have been made to guidelines on: consent, circumstances where consent may be qualified or waived, and specific participant groups including children and young people and Aboriginal and Torres Strait Islander Peoples (NHMRC 2007b, 2). Chapters on research involving ionizing radiation and research involving assisted reproductive technology have been removed as they subsequently had been covered by other guidelines, and the chapters on research involving collectivities and epidemiological research have been incorporated in other chapters.

A more significant difference between the *National Statements* relates to identifying when research requires HREC review. The 1999 *National Statement* states:

[11] The increased number of submissions from groups concerned with fertility and motherhood issues may have been in light of legislative review of reproductive cloning and embryo research (Australian Government 2005).

[12] The 2007 *National Statement on Ethical Conduct in Human Research* is 107 pages long and consists of a Preamble, 5 sections (each with a number of sub-sections/chapters), and an Appendix, Glossary and Index. The 1999 *National Statement on Ethical Conduct in Research Involving Humans* is 68 pages long and consists of a Preamble, 19 chapters and 3 Appendices.

> Where activity involves human participation or definable human involvement and has a purpose of establishing facts, principles or knowledge or of obtaining or confirming knowledge, the features of human involvement will be the focus of deciding whether it is research and so subject to review by an HREC.
>
> Where that involvement has a potential for infringing basic ethical principles, at least respect for humans, beneficence and justice, review by an HREC is warranted. (NHMRC 1999, 7–8).

By contrast, the 2007 *National Statement* specifies more clearly when and how research may be subject to ethical review. In addition, section 5 makes provision for institutions to establish different levels of ethical review for research with different levels of risk, namely: "negligible risk" – no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience; "low risk" – the only foreseeable risk is discomfort; and "more than low risk" – the foreseeable risk is more than discomfort. All research that involves more than low risk requires HREC review (NHMRC 2007a, 5.1.6(a)). In addition, some specific research, including interventions and therapies, research involving human genetics and stem cells, as well as research involving participants who may be vulnerable in a research context, including: women who are pregnant and the human foetus, people who are highly dependent on medical care or who have a cognitive impairment, Aboriginal and Torres Strait Islanders, as well as some people who may be involved in illegal activities, requires HREC review (NHMRC 2007a, 5.1.6(b)). For research that carries only a low risk, and does not fall under the categories listed above, institutions may establish their own levels of critical review (NHMRC 2007a, 5.1.7). Research that carries negligible risk is exempt from ethical review.[13]

In contrast to the 1999 *National Statement*, the structure of the 2007 *National Statement* is more process-driven. Each chapter is structured around the four guiding ethical principles: research merit and integrity, balancing benefits and risks, justice and respect for human beings. Researchers and HRECs are drawn through a process of considering the applicability of these guiding principles to the particular focus area of the chapter. The 1999 *National Statement* is more rule-driven, focussing on matters that HRECs needs to attend to in their decision-making. The 2007 *National Statement* identifies of three levels of review: by the researcher(s), the HREC(s) and the institution(s). Stakeholders and the drafters alike note that the added flexibility of the revised 2007 *National Statement* provides more opportunity for consideration of the nuances of particular research contexts in determining how the four guiding principles apply to concrete cases (Spriggs and Gillam 2008; Cordner and Thomson 2007).

[13] And meets the requirements as listed in 5.1.22 and 5.1.23 (NHMRC 2007a).

Issues Raised in the Publicly Available Submissions

The length of submissions varied from two paragraphs to over twenty pages, including supplementary documents. The content of the submissions ranged from procedural – suggestions on wording of certain guidelines – to substantive discussion of concepts. Some also commented on the format and scope of the document. Some submissions simply stated their position whilst others provided reasons for their stated positions. Some limited their comments to endorsing the draft, whilst others welcomed the opportunity for review and made significant numbers of comments, in some cases with pages of suggestions for rewriting sections. There were also outliers to the whole process, ranging from those who argued that the *National Statement* should not simply be revised but rewritten in its entirety, to those that expressed the view that applying institutional process to ensure ethical research is inappropriate and will not encourage ethical research nor facilitate an awareness of ethical research.

Taken as a whole, submissions commented on all sections of the consultation drafts. Key issues raised by the submissions concerned: (1) the definition of research and participants of research and of types of research; (2) the definition of the ethical principles and how they pertain to governing research, as well the relationship of these principles to one another; (3) the status and role of the document – as standards or guidelines; (4) consent – how it should be obtained and in what form; when and how it can withdrawn; for how long, i.e. future use of data for research, as well as consent as related to different research methods and participants; (5) confidentiality and privacy; (6) risk in research and how this is to be quantified, including low risk research and review; (7) commercialisation of research and payments to research participants and disclosure of funding sources; (8) requirements to publish research and inform participants (and relations) of results of research; (9) the roles and responsibilities of HRECs, including concerns about ethics creep (HRECs judging research merit and legal issues) and the composition of HRECs; complaint handling procedures, recording of decisions and conflicts of interest; and (10) multiple review of research.

In order to focus our review of the effect of submissions on the outcomes of the review through the iterated drafts, we will narrow our concerns to the chapter concerning children and young people's participation in research. Prior to 2007 the *National Statement* restricted children's involvement in research to cases where the research was important to the health and well-being of children, where the involvement of children was indispensible to the research and where the research was not contrary to the best interests of each child-participant.

Research involving children has raised substantive ethical concern throughout the twentieth century, due to notorious examples of research conducted on children in institutional care and because of the presumption that children's vulnerability merits special protection, either by excluding children from research or requiring parental consent (Grodin and Glanz 2004). At the same time, the presumption that children ought not to be used as experimental subjects has meant that treatments

prescribed for children have not been assessed through the same clinical trials that would apply to treatments for adults and so there are reasons for wanting to consider whether approaches that allow children to participate in appropriate trials could be developed to improve knowledge about the effectiveness and safety of treatments offered to children (Arnold et al. 1995). Similarly, the rise of research involving children in education, psychology, social work, criminology and physical exercise has put pressure on the existing presumptions against involving a child unless participation is in the child's best interests, and has generated demand for revision of requirements thought to be overly paternalistic (Israel 2004, 38). These debates presented challenges to researchers and HRECs in Australia prior to the review of the 1999 *National Statement* and they produced significant submissions during the consultation process.

In the following section we ask: To what degree is it possible to attribute the changes to the *National Statement* in the chapter on children and young people to the submissions received during the review of the *National Statement*? What was the nature of the impact of the submissions? In order to address these questions we compare the changes in the guidelines concerning children and young people's participation in research between the 1999 *National Statement*, the two consultation drafts and the 2007 *National Statement*, against issues raised in the submissions. We will argue that the public submissions did have an impact on the changes made by the working committee to the guidelines, and, in many cases, this impact was significant and substantial. We conclude that the two-tier consultation process contributed to a more detailed, nuanced set of guidelines than one round of consultation would have achieved. However, we raise some questions about the degree to which democratic and deliberative ideals are reflected in the outcome of the review. In the following section we make an assessment of this impact in terms of three ideals of deliberative democracy: *participation*, *deliberation* and *accountability*.

Research Involving Children and Young People

The chapter on research involving children and young people contained in the 1999 *National Statement* (NHMRC 1999, 4) is one page long and consists of four brief guidelines. These establish principles relating to (1) the conditions under which research involving children and young people can be conducted – which include the fit of the research question and method, they must be in the best interests of the child or young person, their participation must be indispensible, the method appropriate and provide for the safety (physical, emotional and psychology) of the child or young person (4.1 (a)–(d)); (2) from whom consent must be obtained – the child (when sufficient competence), and the parents or organisation/person required by law (4.2 (a)–(c)); (3) limits on the authority of HRECs to approve research involving children and young people – research must not be "contrary to the child or young person's best interests" (4.3); and (4) respect for a child's or young person's refusal to participate (4.4).

In contrast, the chapter on research relating to children and young people in the 2007 *National Statement* is considerably longer, more detailed and nuanced than its 1999 counterpart. It is three pages long, contains 14 guidelines (4.2.1–4.2.14), some with a number of sub-clauses, and includes a detailed introduction. Whilst the revised chapter retains the original four principles (contained in the four guidelines listed above) of the earlier version, two of these are significantly revised – from whom to obtain consent (4.2) and respect for a child's refusal to participate (4.4). Additional guidelines are included which cover: (a) the need for researchers to explain how a child/young person's capacity to consent, with attention paid to vulnerability, will be assessed, and how discussions with the child or young person will proceed; (b) approval of research to which *only* the child or young person consents; (c) standing parental consent; and (d) protection of the safety and welfare of children or young people in research. Further elaboration in the chapter includes an introduction justifying research involving children, which both describes a broader range of research that may be conducted involving children and young people and recognises the specific ethical issues and problems raised by such research. Most significantly, the revised chapter provides a different approach to assessing a child or young person's consent to research – in terms of graduated stages of capacity to consent by level of maturity and information on assessing *capacity to consent*, including recognition of children's and young people's vulnerability through immaturity. The introduction states that:

> [r]esearchers must respect the developing capacity of children and young people to be involved in the decisions about participation in research. The child or young person's particular level of maturity has implications for whether his or her consent is necessary and/or sufficient to authorise participation (NHMRC 2007a, 4.2).

The 2007 *National Statement* sets out four levels of maturity and corresponding decisional capacity to be considered in assessing ability to contribute to consent decisions. These include:

(a) infants, who are unable to take part in discussion about the research and its effects;
(b) young children, who are able to understand some relevant information and take part in limited discussion about the research, but whose consent is not required;
(c) young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research; and
(d) young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian. (NHMRC 2007a, 4.2).

Within this model, a child's capacity to consent is linked to a child's ability to understand information and the concept of "vulnerability" is introduced as a way of assessing whether they may be subject to unacceptable risk through their involvement in the research and hence whether there is a requirement for parental consent either alone, or as a supplement to the child's consent. There is no attempt to attach fixed ages to each level. This new material on the levels of maturity and consent shape the interpretation of the guidelines that follow in the chapter – for example, researchers are required to specify how they will judge a child's vulnerability and

capacity to consent, and describe the form of discussions with children at their level of comprehension (NHMRC 2007a, 4.2.2(a) & (b)), as well as additional guidelines that require recognition of the developmental level of children in the provision of information about research participation and outcomes (NHMRC 2007a, 4.2.6).

Overview of the Consultation Drafts and Submissions

As discussed above, AHEC released two consultation drafts for public comment. Over both consultation rounds, the working committee received close to 100 submissions commenting on the chapter on children and young people in research.

Prior to the release of the first consultation draft, AHEC sought expert stakeholder advice on the chapter on children and young people (NHMRC 2005, 3.2, 36–7). The first consultation draft is presented in the new format adopted for the *National Statement*, which structures the guidelines of the chapter according to the four[14] guiding ethical principles (as noted above). It begins with an introduction that addresses the particular ethical issues raised by the inclusion of children and young people in research and notes "these considerations … assume special prominence in health care research" (NHMRC 2005, 36). The chapter contains eight guidelines that draw on and expand (with minor revision) the guidelines of the 1999 *National Statement*. The first consultation draft chapter includes two new guidelines. The first allows for HREC approval of research to which only the child or young person consents (NHMRC 2005, 3.2.6). The second requires explicit justification to the HREC in cases where researchers do not propose to obtain consent from a child or young person for participation in research (NHMRC 2005, 3.2.5). It also clarifies that consent should be obtained by *both* parents and the child and not just *the* parents (NHMRC 2005, 3.2.4(a)&(b)).

26 per cent (27 of 104) of the publicly available submissions received in response to the first consultation draft commented on issues arising from the chapter on children and young people in research.[15] Almost all guidelines of this chapter received some comment.[16] Those that received the most comment concerned the amended guidelines on consent (NHMRC 2005, 3.2.4(a)&(b) – 19 comments), the additional guidelines concerning minimal risk (NHMRC 2005, 3.2.6 – eight comments) and the requirement for researchers to justify the inclusion of young people in research without their consent (NHMRC 2005, 3.2.5 – nine comments). The introduction; the guideline concerning when a child should not be included in research (NHMRC

[14] In the first consultation draft only three guiding principles are used: research merit and integrity; balancing benefits and risks; and respect for human beings. By the second consultation draft the guiding principle of justice is added as a subheading and "balancing risks and benefits" is now termed "beneficence".

[15] Of these, 30% (22 of 74) were from organisations and 17% (5 of 30) were from private individuals.

[16] Clauses 3.2.2 and 3.2.3 received little or no comment.

2005, 3.2.7); and, the guideline concerning a child's refusal to participate (NHMRC 2005, 3.2.8), each received three comments.

In the second consultation draft, the chapter was further revised (NHMRC 2006a, 4.2). It was expanded to three pages, with an introduction and ten guidelines, many of which contain a number of sub-clauses. The chapter is more detailed than the previous version. The original eight guidelines in the first consultation draft are retained, some with only small revision, others are more substantially altered. Significant changes address: (1) from whom to obtain consent (NHMRC 2006a, 4.2.4) and the conditions under which approval for research can be granted to which only the child or young person consents (NHMRC 2006a, 4.2.5); (2) circumstances under which a researcher should respect a child or young person's right to refuse to participate (NHMRC 2006a, 4.2.10); and (3) circumstances when researchers do not need to obtain the consent of a child or young person. New guidelines are also included relating to 'standing' and parental consent (NHMRC 2006a, 4.2.8). The introduction is revised to specifically note the ethical concerns surrounding research involving children and young people that arise in educational and health research.

46 per cent (67 of 147) of the publicly available submissions received in response to the second consultation draft commented on issues arising from the chapter on children and young people in research, an increase in the number of submissions on this chapter compared with the first consultation draft.[17] Of these submissions, 19 had previously made submissions to the first consultation draft and 12 of these commented on issues related to the chapter on research involving children and young people.

A letter from the Chair of the working committee, Chris Cordner, accompanied the call for public submissions to the second consultation draft, seeking specific feedback on several issues, including: "What are your views on the guidelines for children's and parents' consent for research involving children and young people in Chapter 4.2?" (NHMRC 2006c, 2). The higher volume of submissions commenting on this chapter in the second consultation draft is attributable to this request.[18]

All sections of the chapter on children and young people in research received some comment in response to the second consultation draft. Those guidelines that received the most comment concerned the new guideline on standing parental consent (NHMRC 2006a, 4.2.8 – 24 comments) and the revised guideline on refusal to participate (NHMRC 2006a, 4.2.10 – 28 comments). Submissions also commented on the revisions to consent from a young person only (NHMRC 2006a, 4.2.5 – 21 comments). There were also a considerable number of submissions that made general comments, or comments related to the introduction to the chapter on children and young people in research (23 comments). The revised guideline concerning

[17] Of these, half (50%, 53 of 106) were from organisations, and just over a third (34%, 14 of 41) were from private individuals.

[18] Included in the letter there was an additional request concerning the merit of combining chapters, which included the chapter on children and young people (NHMRC 2006c, 2). About 12 submissions gave limited comment in the respect.

from whom to obtain consent (NHMRC 2006a, 4.2.4(b)) also received some comment (eight comments), however not as much as in the first consultation draft.[19]

With the final release of the *National Statement* (NHMRC 2007a) the chapter on children and young people in research was again revised. The guidelines in the final version of the *Statement* comprise 14 guidelines, incorporating the ten guidelines from the second consultation draft (with some revision) and four new guidelines. The introduction is now four paragraphs and contains the material on levels of maturity and vulnerability discussed above. New guidelines are added reflecting this new material, and additional guidelines are added to those on standing parental consent. Guidelines relating to refusal to participate and research to which only the young person consents are also modified.

Relationship Between the Changes to the Statement and the Submissions

In the preceding section we outlined the major changes to the chapter on children's and young people's participation in research between the 1999 *National Statement*, the two consultation drafts issued as part of the Review of the *National Statement* and the 2007 *National Statement* and outlined the broad areas of submissions relating to this chapter. We now turn to the specific comments presented in the submissions to explore whether and how the content of submissions is reflected in the changes. We focus on submissions concerned with: assessing capacity to consent and requirements for parental consent; research to which only the child or young person consents; research to which the child or young person does not consent; provisions for "standing parental consent"; and, respecting a child or young person's refusal to participate.

Capacity to Consent and Requirements for Parental Consent

The 1999 *National Statement* states that consent to a child's or young person's participation in research must be obtained from: "(a) the child or young person whenever he or she has sufficient *competence* [our emphasis] to make this decision; and either (b) *the* [our emphasis] parents/guardian in all but exceptional circumstances; or (c) any organisation or person required by law" (NHMRC 1999, 4.2 (a)–(c)). This guideline is revised in the first consultation draft – consent should be obtained from: "(a) the child or young person whenever he or she has the *capacity* [our emphasis] to make this decision; and (b) *both* [our emphasis] parents or where applicable the guardian and any organization or person required by law" (NHMRC 2005, 3.2.4 (a)–(b)). In the second consultation draft, sub-clause (b) is again revised

[19] In addition, section 4.2.1 received 7 comments, 4.2.7 – 5 comments; 4.2.9 – 4 comments; 4.2.2 – 3 comments and 4.2.3 – 2 comments.

and consent is required of only "*one* [our emphasis] parent, except when, in the opinion of the … HREC … the risks involved … require the consent of both parents" (NHMRC 2006a, 4.2.4 (a)–(b) (i)–(ii)). This guideline remains unchanged from the second consultation draft in the 2007 chapter (NHMRC 2007a, 4.2.7).

The two consultation drafts and the 2007 *National Statement* significantly expand on the 1999 *National Statement* concerning the assessment of children's and young people's capacity to consent, with the 2007 *National Statement* setting out levels of maturity which recognize vulnerability due to immaturity when assessing capacity to consent, allowing for a range in the ability to consent from an inability to be involved, that is, infants, to a recognition of young people being mature enough to give full consent requiring no additional parental consent.

Not surprisingly, this guideline received considerable attention in the consultation rounds. In the first round of consultation, comments in the submissions were addressed to the two sub-clauses concerned with a child or young person's decisional capacity to consent (NHMRC 2005, 3.2.4(a)) and requirements for parental consent in addition to the child or young person's consent (NHMRC 2005, 3.2.4(b)).

Comments directed to 3.2.4(a) raised concerns related to *assessing and determining a child's capacity to consent*. These ranged from criticisms that the subclause is "too vague in its formulation" (#70; #35),[20] that it left uncertainty as to when a child has the capacity to consent and the researcher's role in making this assessment (#152), and that further guidance is needed in cases where it would not be necessary to seek parental consent (#117). A number of submissions requested further clarification about determining a child's capacity to consent (#59), including clarification of the age of a child or young person that determines whether parental consent is required (#135) and requests for definitions of a child and young person (#107). Another asked whether *formal* assessment is required to determine a child's or young person's capacity to consent (see #127 and #150). Quite a few submissions made suggestions including the importance that material used to gain consent be age/developmentally appropriate so that the child or young person could meaningfully make a decision (#95; #127). Others suggested that there could be circumstances when a child's capacity to understand relevant information fell below the level required for meaningful consent and suggested that the concept of children's "assent" to research could be drawn on in these cases (#104, #127).

Comments directed to guideline 3.2.4(b) raised concerns about the requirement that *consent must be sought from both parents*, in addition to the child or young person where she or he has the capacity to consent. Concerns raised in the submissions related to the requirement for parental consent by both parents as well as the requirement for any parental consent in some cases. Argument was heavily weighted against the requirement for both parents to consent and several submissions raised issues arising from working with mature minors. Issues raised ranged from the unavailability of both parents (#95, #127), a failure to acknowledge diverse family arrangements (#30) and disagreement amongst parents and carers (#107), as well as

[20] The numbering of the submissions are those assigned by the NHMRC on the original website for each of the rounds of public consultation.

of exposing young children and minors to risk if consent was sought from either one or both parents (#97, #138). The reasons in these submissions are most aptly summarized by submission #90 which states: "It may be that gaining parental consent for people under 18 is neither practical nor appropriate and in some cases, gaining parental consent can actually impede research." Only one submission argued that consent provisions should be more stringent, arguing that consent from young children and both parents should be obligatory (#64). Quite a number of submissions suggested that a weakness of the guidelines was that they did not distinguish between those young adults who have the capacity to consent from younger children who are not capable of giving consent and suggested that the guidelines should adopt a mature minor principle (applying the principle to street kids for example, #61). One reason given for the importance of adopting a mature minor principle was that, without such a principle, the burden of consent may impede some research that poses low risk to children (#48, #80) and "some types of research may be seriously and unreasonably curtailed" (#78).

We can see in the changes made to this guideline in the second consultation draft that the submissions received in respect to the first consultation draft influenced the working committee in their revision of this guideline. The majority of submissions received favoured not requiring consent from both parents and many provided reasons for this view, ranging from the inappropriateness of requiring both parents to consent to the possibility that requiring consent from both parents might endanger research participants. This change would generally satisfy those who argued that in many cases obtaining the consent of both parents is impractical (inappropriate or risky to the child or young person), although it would not satisfy those who thought that there should be more clarity about how to determine children's capacity to make a decision to consent.[21]

There was less comment on this guideline in submissions made to the second consultation draft. Not surprisingly, a number of submissions applauded the change to requiring only one parent's consent. Others restated the request for more information on capacity to consent (#56, #164) and the appropriate form of provision of information to children and young people (#73, #164). A number of submissions

[21] The terminological shift from "competence to consent" in the 1999 *National Statement* to "capacity to consent" in the first consultation draft (and retained thereon) was not due to the impact of the public submissions, as it occurred prior to the release of the first consultation draft. This could mean that the *National Statement* consultation draft was more concerned with children's *decisional capacity* (understood as the effective ability to make a specific decision), whereas the *National Statement* had previously been concerned with children's *mental competence* (which may be said to obtain when a person has a relatively intact and robust set of mental abilities that justify a presumption of decisional capacity); however, it may simply reflect a change in word preference for synonyms (Charland 2008). While it is more likely that a child or young person will have (in specific domains) decisional capacity than (global) mental competence, the *National Statement* does not elaborate what significance should be given to the change in terminology. It is worth noting that around the time of the review of the *National Statement,* the bioethics literature was shifting in its recognition of relational autonomy and relative competence to consent based on decision-specific capacity (See for example Berghmans et al. 2004; Beauchamp and Childress 2009).

requested definitions of children and young people with associated age brackets. At least three submissions raised the distinction between a child's ability to "assent" and capacity to "consent" to participation in research.

The inclusion of material in the introduction to the 2007 *National Statement* about levels of maturity, and subsequent reference through the chapter, shows that the working committee responded to the requests for more guidance on informing, assessing and demonstrating capacity for consent of children and young people in research. The information pertaining to levels of maturity responds to those submissions to the first consultation draft, and repeated by submissions to the second consultation draft, that called for further guidance on consent and capacity, as well as those who requested explicit recognition of a mature minor principle.

It is evident from the changes to the document and the details of the submissions that the working party revised the sections on capacity for consent and the requirements for parental consent, that is, a position between those who advocated that parental consent must always be sought for the inclusion of children and young people in research and those that requested specific age levels for consent by young people. Ethicists who had been vocal in criticism of the earlier guideline welcomed the material on levels of maturity (e.g. Spriggs and Gillam 2008, 360).[22]

Conditions Under Which Research Can Take Place with Only the Child's or Young Person's Consent

Related to the issues raised above about assessing a child's or young person's capacity to consent and requirements for parental consent, concerns were raised in the public submissions about the conditions under which research can take place to which only the child or young person consents. The first consultation draft allows for HREC approval of research to which only the child or young person consents if she or has the capacity to consent and the research is "minimal risk" (NHMRC 2005, 3.2.6).[23] This guideline is revised in the second consultation draft to include conditions for allowing HREC approval of research to which only the child or young person consents, beyond research involving "no more than low risk", to include cases where the young person is estranged from their parents or it would be contrary to the child or young person's best interests to obtain parental consent (NHMRC 2006a, 4.2.5 (a)–(b) (i)–(iii)). In the 2007 chapter the section is again revised with the inclusion of material on levels of maturity and recognition of vulnerability. A review body may approve research to which only the child or young

[22] Spriggs and Gillam note, however, that the change from "competency" to consent to "capacity" to consent, is confusing because there is no explanation for the shift. They further argue that the inclusion of "vulnerability", whilst a move in the right direction, "is likely to cause confusion" and also requires further explanation (Spriggs and Gillam 2008, 362).

[23] The first consultation draft uses the term "minimal risk", this is replaced in the second consultation draft with "neglible", "low" and "more than low" risk. The change in terminology reflects a revision on how risk is understood in the second consultation draft which is further revised in the 2007 *National Statement*.

person consents if the research involves no more than low risk and "he or she is mature enough to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects" (NHMRC 2007a, 4.2.9 (a)). Further, the chapter stipulates that research involving children or young people must benefit the research population (i.e. children and young people) and extra material is inserted stating that the researcher must protect the child or young person's safety (NHMRC 2007a, 4.2.9 (c)–(d) (i)–(ii)).

Several submissions to the first consultation draft commented on the inclusion of the new guideline concerning accepting a child or young person's consent alone in the case of minimal risk (NHMRC 2005, 3.2.6). These ranged from concerns about the nature of the principle being supported (that the circumstances justifying research without parental consent are unclear or depend on subjective considerations about minimal risk (#79B; #80)), to questions about whether it creates risks to privacy or legal liability (#104). Submissions echoed calls for more guidance on assessing the capacity to consent, for example, by advising on ages of children and young people who are able to consent and the types of research where parental consent is not required (#80). Opinion was divided. There were those who objected to the guideline and who argued against the acceptability of conducting research without the consent of parents, where the child or young person was able to consent, however minimal the risk (#3, #35, #118). On the other side were those who welcomed the inclusion of the guideline (#48, #26).

The inclusion of clauses under this guideline in the second consultation draft which set out additional conditions under which children and young people may participate in research to which only they consent recognizes issues raised in those submissions which argued that in many cases obtaining the consent of both parents is impractical, inappropriate or risky, echoing concerns raised in submissions to the guideline on assessing capacity to consent and whether consent is requirements for parental consent, as discussed above. The revised guideline also seeks to provide clarification of those circumstances when consent is not required, although it does not provide further clarity about how to determine a child or young person's capacity to make a decision to consent.

Twenty-one submissions to the second consultation draft commented on the changes to this guideline (NHMRC 2006a, 4.2.5). Several of these applauded the inclusion of additional conditions permitting research to which only the child or young person consents, which appeared to go some way toward accepting the "mature minor" principle (# 66, #164). Others still had concerns about how "capacity", "best interests" and "low risk" were to be assessed (#21, #35, #78, #118), as well as the concern that HRECs would be taking the role of parents in deciding what research was appropriate for children (#56). Even where the inclusion of this guideline was welcomed, there was concern to ensure that the matter was handled appropriately in relation to different cultural expectations (#78, #155).

The recognition of (four) levels of maturity and the need to assess decisional capacity to consent to research participation with recognition of vulnerability through immaturity in the 2007 *National Statement*, suggests that the Working Committee wished to take the support found in the submissions to the second

consultation draft for loosening of conditions under which a child or young person might participate in research without parental consent one step further to satisfy those who had been calling for more guidance concerning the assessment of capacity to consent. It is interesting that the material on levels of maturity first appears in the introduction to the chapter on children and young people in 2007 *National Statement*, and is only referred to inferentially in the guidelines that follow. This suggests that the new introductory material was a relatively late inclusion and is intended to provide over-arching guidance to HRECs and researchers on assessing capacity to consent.

Including Children or Young People in Research Without Their Consent

In the first consultation draft a new guideline is included that requires researchers to justify not obtaining a child's consent to research: "Researchers must justify any decision not to obtain consent from the child or young person for participation in research" (NHMRC 2005, 3.2.5). The inclusion of this guideline, confirms, by implication, that some valuable and ethically defensible research involving children or young people can only be done in the absence of the child's consent, for example research involving infants or toddlers (NHMRC 2005, 3.2.5). In the second consultation draft this guideline is revised: "The justification for a decision that a child or young person does not have the capacity to consent should always be explicitly stated, even if it is as obvious as the fact that the child is an infant" (NHMRC 2006a, 4.2.7). In the 2007 chapter this guideline is removed, and the most likely reason was that the introduction of the material on levels of maturity in the revised *National Statement* made the guideline superfluous.

Submissions to the first consultation draft commenting on guideline 3.2.5, and the question of whether research could be conducted on children or young people without their consent, ranged from the view that the conditions justifying research without the child's consent were unclear (#3), ambiguous (#118) and require further elucidation (#127) to the claim that it is ethically indefensible for it may provide "a justification for not obtaining consent or seeking assent" (#35) and that the guideline is too weak and potentially allows for researchers to undermine the family unit (#64).

Five publicly available submissions to the second consultation draft commented on the reformulation of the guideline (#49, #116, #147, #152, and #164). Several of these questioned whether the revisions to the guidelines adequately respected children and their varying capacities for involvement in decision-making (#164) and whether this guideline might be interpreted as allowing the default to become not to seek children's assent (#49) or whether it was unclear who was responsible for stating the justification (#147). Two submissions suggested that the phrase "even if it is as obvious as the fact that the child is an infant" was either awkward or introduced and unnecessary requirement on researchers (#116, #152).

In light of the submissions and the omission of the guideline in the revised 2007 *National Statement*, it appears that in the Working Committee discussion of

circumstances when neither consent nor assent to participate is required from a child was tied to the discussion about capacity to consent and the ideas of levels of maturity discussed above; that is, the committee recognised that the inclusion of material related to levels of maturity and assessing decisional capacity would cover circumstances where children and young people could be included in research without their consent or assent.

Provisions for "Standing Parental Consent"

A significant addition in the 2007 *National Statement* is the introduction of the concept of "standing parental consent", which appears to have come from consideration of educational research and social research undertaken through schools, sporting or other extra curricular organisations. Guidelines relating to standing consent are introduced in the second consultation draft.

> Schools may arrange for standing consent to be given for a child's participation in research that is:
>
> (a) for the benefit of children;
> (b) not undertaken for profit; and
> (c) comprises no more than overt observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or surveys on subject matters not involving sensitive personal information or family relationships.
>
> Parental consent for each specific project of this kind is not needed; notification to parents of each project is enough (NHMRC 2006a, 4.2.8).

In the 2007 *Statement*, this guideline (now NHMRC 2007a, 4.2.11) is modified by removing the sub-clause restricting standing consent to research not undertaken for profit. Two additional guidelines are also added. The first provides a description of "standing parental consent", and explains the conditions under which parents should be notified of projects to which that consent applies, as well as their right to withdraw their consent.

> 'Standing parental consent' enables parents to give standing consent (for example at the beginning of each school year) to their child's involvement in certain types of research in the school setting during that year. Under standing consent, parents are notified of each project, but are not required to give further consent for each project. They should be reminded with each notification that they may withdraw their consent for that project, and also may withdraw their standing consent at any time (NHMRC 2007a, 4.2.10).

The second additional guideline stipulates that explicit parental consent is required for all other types of research (that is, research for the benefit of children and which comprises more than obvert observation or coded questionnaires or surveys), except when the research satisfies the conditions under which HRECs and ethical review bodies may approve research to which only the young person consents (as outlined earlier in the section) (NHMRC 2007a, 4.2.12).

Of the publically available submissions to the first consultation draft, a small number raised issues relating to research in education and involving observational methods including clarification of methods for obtaining parental consent for

research conducted in schools (#138), as well as suggestions of the types of persons and research that may fall under this (for example, the usual carers of children to permit some forms of observation and survey (#30)). These issues were echoed in general comments raised in the submissions that the chapter (and introduction) should extend the range of examples of research with which children are involved, to include examples from non-medical research (#35, #127), including educational, marketing, creative arts, physical activity and social research (#150). Submissions which commented on the guideline pertaining to children's inclusion in research (NHMRC 2005, 3.2.1) questioned whether the advance in knowledge about matters relevant to children and young people, and where children's or young people's participation was necessary for the conduct of the research, are the only legitimate grounds for inclusion of children or young people in research (#95, #156).

The inclusion of guidelines related to standing parental consent and educational research in the second consultation indicates a responsiveness to suggestions in the submissions made to the first consultation draft, as well as to arguments that some types of research would be hindered by a requirement of always obtaining consent from children or young people or their parents or guardians. In the introduction to the second consultation draft, educational research is noted with health research as areas of significance in research involving children (NHMRC 2006a, 56). These new provisions could be viewed as recognising the value of educational research where a child's participation is incidental to observation of teaching practices. These provisions could also be understood as seeking to reduce the burden on schools and parents in managing the paperwork associated with consent to this research while still allowing parents to either consent (as standing consent to participation) or withhold consent, on the basis of adequate information about the research in which their child is involved. It is worth noting that guideline 4.2.5 (NHMRC 2006a) sets out the conditions under which research can take place with only the child's or young person's consent by reference to "no more than low risk" and, guideline 4.2.8 (NHMRC 2006a) uses the following language to indicate low or minimal risk – "no more than overt observation …not involving sensitive personal information and family matters." It is unclear whether there are other areas of low or minimal risk research that might fit into guideline 4.2.8 (NHMRC 2006a). This apparent ambiguity raises the question as to whether sufficient guidance is provided to HRECs.

The inclusion of the guideline relating to standing parental consent (NHMRC 2006a, 4.2.8) received mixed comment in the second round of consultation. A number of submissions expressed serious concerns related to the inclusion of standing parental consent (#4; #86; #90) and some argued that the working committee reconsider the inclusion of this guideline (#30, #171). In contrast a number of submissions welcomed the inclusion of this guideline (#14, #15, #99, #123, #140). Nonetheless, most of these submissions include issues of concern or reservations, and some offered suggestions for revisions.

Concerns about "standing parental consent" included objections to the concept *per se*– for example, that it diminishes the authority of informed consent of parents and child participants (#4) and the possible impact of the guideline on vulnerable

groups (#86). Others asked for more clarification of the concept (#156), including a definition of standing parental consent (#176). Yet others argued that children should be allowed to withdraw participation (#99) and parents should be given the opportunity to object (#112).

Several submissions argued that the types and scope of research covered by the guideline were too broad (#56; #70; #90), whilst one argued "overt observation" was too limited (#123) and another that they were happy with the types and scope of research covered by the guideline (#15). Other submissions queried how the examples covered by the guideline, that is "obvert observation in school classrooms or anonymous or coded (potentially identifiable) questionnaires or survey," related the ideas of "minimal risk" and "low risk" research (as well as consent) discussed in other parts of the *National Statement* (#56; #116). Some asked for more clarification (#140; #159), whilst others were concerned about possible contradictions with guidelines in other chapters of the *National Statement* (#86; #20). Still others were concerned about their relation to ethical standards and guidelines of schools and education authorities (#14; #49; #147), as well as international guidelines, such as the United Nations Declaration of the Rights of the Child (#90).

There was also division expressed in the submissions to the guidance that "parental consent for each specific project of this kind is not needed". Whilst a number of submissions supported this statement, a number also asked for additional information about notification and withdrawal (#15; #30), several submissions emphatically stated that parental consent must be sought for each specific project (#32).

In the 2007 *National Statement* the spirit of the second consultation draft guideline (NHMRC 2006a, 4.2.8; now NHMRC 2007a, 4.2.11) remains largely unchanged, which shows that the working committee did not change their position regarding standing parental consent following the second consultations process (although they may have debated this issues extensively behind closed doors). As such, the committee's formulation of the guideline did not accept the view of those submissions that argued against this position.

However, the inclusion of material containing further information about the meaning of standing parental consent, the requirement for parental notification of projects, information relating to withdrawal of consent, and the responsibilities of schools, shows a responsiveness by the working committee to the submissions which asked for further clarification of standing parental consent and provision of information to parents, as well as some responsiveness to the concerns of those against standing parental consent. For example, whilst permission need not be obtained for each research activity, schools should remind parents of their standing consent and researchers and institutions be informed of the conditions under which consent would need to be sought again. This again charts a nuanced response to the submissions favouring standing consent and those that wished to ensure parents had control over their child's participation in each research proposal.

The inclusion of the guideline which explicitly states that for any other research, specific parental consent must be obtained (NHMRC 2007a, 4.2.12) demonstrates a willingness by the working committee to accommodate the concerns raised about the scope of standing parental consent. Similarly the reference to, and inclusion of,

new guidelines concerning research that an HREC might approve to which only the young person consents, shows an attempt by the working committee to deal with concerns about the consistency of guidelines pertaining to standing parental consent with guidelines about consent and "no more than low risk" research (NHMRC 2007a, 4.2.8 and 4.2.9).

Respecting a Child or Young Person's Refusal to Participate in Research

In the 1999 *National Statement* a child or young person's refusal to participate in research is absolute (NHMRC 1999, 4.4). This guideline remains unaltered in the first consultation draft: "A child's or young person's refusal to participate in a research project must be respected" (NHMRC 2005, 3.2.8). However, it is altered in the second consultation draft.

> A child or young person's refusal to participate should be respected, except:
>
> (a) where there is standing parental consent for the research, refusal to participate should be respected only of there is reason to believe participation in the research is contrary to the child's best interests: or
> (b) and where in the case of the very young, the child's refusal may be overridden by the parent's judgement as to what is in the child's best interest. (NHMRC 2006a, 4.2.10).

The change allows for exceptions – when the child's refusal to participate can override standing parental consent for the research and when the parents' judgment can override the child or young person's refusal to participate. The guideline is again altered in the revised 2007 *National Statement* through the introduction of assessing consent in terms of levels of maturity.

> A child or young person's refusal to participate in research should be respected wherever he or she has the capacity to give consent to that same research (see levels of maturity (c) and (d) in the Introduction to this chapter). Where a child or young person lacks this capacity, his or her refusal may be overridden by the parents' judgement as to what is in the child's best interest. (NHMRC 2007a, 4.2.14).

This has the effect of clarifying when refusal should be respected, and when parents can override a child's refusal. The guideline limiting a child's ability to refuse consent where there is standing parental consent has been removed.

Three publicly available submissions to the first consultation draft (#127, #99, #156) commented on the guideline. One submission reinforced the existing guideline – "personal refusal must be respected" (#156), another suggested making it explicit that a child's refusal is the determining factor (#99), whilst a third argued for the inclusion of a qualifying statement in order to recognise that "in the case of very young or incapacitated children, the researcher may need to utilize the parents' knowledge of the child's best interests to determine if the child should refuse" (#127). It is this latter submission (or perhaps similar arguments presented outside

the public submissions) that appears to have influenced the working committee to revise the guideline.[24]

The revision of this guideline in the second consultation draft suggests that there has been a cause for reconsideration by the working committee about a presumption evident in earlier versions of the *National Statement* – that young children may lack the capacity to judge their own best interests. However, this formulation has changed the emphasis from the 1999 *National Statement*, which appeared to presume that participation in research was, *prima facie*, against a child's best interests. In the second consultation draft there appears to be acknowledgement that, at least sometimes, participation in research (including risky research) may be in a child's best interests, for example, where no known safe or effective treatment is available.

Several submissions to the second consultation draft addressed the sub-clause concerning overriding a child's dissent or refusal to participate (NHMRC 2006a, 4.2.10(b)). Some were concerned because the new sub-clause meant that parents (and standing parental consent) could overrule a child's or young person's refusal to participate. In contrast, other submissions noted the amendments to this sub-clause were welcome and provided respect for children and young people. Some submissions noted that a child or young person should not be required to provide a reason when refusing to participate. Others claimed that there were inconsistencies between different guidelines relating to respect for young people's consent and refusal to participate (#49, #78). [25]

In the revised 2007 *National Statement*, recognition of refusal to participate (NHMRC 2007a, 4.2.14) is informed by the new material on levels of maturity, as spelt out in the introduction to the chapter on research involving children and young people. The guideline retains the provision that allows a parent's judgement to overrule a child's right to refuse to participate, where the child lacks the capacity to refuse and the parent judges that participation is in the child's best interests (NHMRC 2006a, 4.2.10(b)), but removes the clause that standing parental consent can overrule a child or young person's refusal to participate (NHMRC 2006a, 4.2.10(a)).

By omitting the sub-clause that standing parental consent can overrule a child's or young person's refusal to participate, the working committee appears to be responding to the arguments in submissions. Again, we see the working committee attempting to negotiate between opposing views: that children's refusal should be respected and that parents (and others) should be able to overrule this in certain circumstances. By introducing levels of maturity the working committee attempts to mediate between these positions and justify the "middle ground" response.

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[24] Submission #127 notes that "[t]here is no consideration of what 'refusal' consists of in the case of infants, toddlers and children with severe intellectual impairment. The researcher may need to seek guidance from the parent/guardian and their knowledge of the child's best interests to determine the child's wishes to refuse". The author suggests some examples of a reworded clause, as well as the inclusion of a qualifying statement guiding the researcher to seek guidance from parents about the child's interests and wishes.

[25] NHMRC 2006a, 1.10, 4.2.4 and 4.2.10.

Summary – Evidence from the Submissions and Changes to the National Statement

We have shown that the public submissions had an impact on the revised 2007 *National Statement* and, in many cases, the working committee developed a thoughtful and nuanced response to opposing views in the submissions. In light of this, we have shown that: (1) there is evidence of impact; (2) this impact resulted in a more subtle and nuanced document; and (3) the two-fold consultation process resulted in a revised *National Statement* that was responsive to the submissions. These conclusions support the democratic legitimacy of the revisions.

It appears, however, that some of the more significant changes relating to the involvement of children and young people in research, specifically the formulation of levels of maturity, and of vulnerability through immaturity, did not arise from the public submissions. Perhaps they came from stakeholder advice, or if they did arise in submissions, these were confidential. The 2007 *National Statement* is recognised by both researchers and its drafters as more flexible, and there is considerably more nuanced information provided. However, in light of repeated requests for clearer guidance before and throughout the review process, some researchers view the final document as containing limited guidance for HREC members and greater ambiguity for researchers (Spriggs and Gillam 2008).

Conclusions: Deliberation, Justification and Revision to the *National Statement*

The revised *National Statement on Ethical Conduct in Human Research* (NHMRC 2007a) merits particular attention on democratic grounds because (1) the guidelines set the national standards for all research involving humans in Australia; (2) adherence to the *National Statement* requirements is a prerequisite for any researcher or institution that wishes to have access to public (Commonwealth) research funding; and (3) the research to which the guidelines apply (and hence the guidelines themselves) include ethically contentious areas and concerns about the *National Statement* guidelines frequently focus on these ethically contentious domains (such as criminological research, research on children and research into novel therapies). Furthermore, because the NHMRC is a public body that (through AHEC) develops research ethics guidelines, provides advice to the medical profession and government on health and medical matters and funds health and medical research, it is open to public scrutiny and accountability. Finally, the *NHMRC Act* and NHMRC policy have created substantive requirements for public consultation. It is worth questioning whether, in practice, that public consultation process yields democratically defensible policy outcomes.

Based on our review of the process of the review and revision of the *National Statement on Ethical Conduct in Human Research* between 2003–2007 it is possible

to make the following conclusions concerning *participation*, *deliberation* and *accountability*.

First, while the AHEC working committee responsible for the review of the *National Statement* conducted an extensive public consultation process, relatively few members of the wider public participated in the review process, as far as can be determined by the publically available submissions. While confidential submissions to the review may have included more submissions from individuals, for example, who have been participants in research, there is little evidence of engagement with the wider "lay public" in the consultation process, based on the publicly available submissions. Given that this wider public benefits from research advances that may translate into better health, health care or access to medical advances, it is perhaps surprising that relatively few members of the "lay public" engaged with the process. This is even more noticeable if one considers that, in Australia, university and hospital based research (excluding pharmaceutical research) and health care are primarily funded through taxation paid by that wider public.

Some explanations may be available to account for this limited participation. First, Australians appear to have a high level of trust in both researchers and the allocation of research funding, and (so far) have not had much reason to question the ethical conduct of researchers (Critchley 2008; Cormick 2003). They may, therefore, trust that the AHEC guidelines and HREC processes in place are adequate and not a threat to Australians generally, or to particular individuals who may be approached to participate in research. Second, the manner in which the review was advertised – to stakeholders who engage with the NHMRC regularly, on the NHMRC website and in newspapers, as well as the format sought for contributions – using a *pro forma* document in response to draft text and not issues, did not reach or engage a wide range of stakeholders and may have been too technical or alienating to support inclusive participation. Moreover, the prime stakeholders in the research participation that we have considered are children and young people, making it particularly difficult to secure their involvement in the process. Third, it could be that the revisions to the *National Statement* were seen as largely affecting institutional and HREC arrangements and hence did not directly affect potential or actual research participants, and one would expect institutional and researcher involvement to be much greater than that of participants. However, as we have shown, several of the changes in the 2007 *National Statement* directly affect participants and their involvement in research and the consultation raised some contentious issues about participation in research (especially children's and young people's involvement). On this account, it is reasonable to conclude that the consultation process was not successful in securing the inclusion of voices from the wider public and people who may be directly affected by the policy development.

It is also worth considering a criticism raised by Thomson et al (this volume, Chap. 9) that the requirements for consultation and giving due consideration to public input lead to a *passive* consultation process. That is, that the form and purpose of the consultation under section 13 of the NHMRC Act emphases the role of considering each submission as a comment on draft guidelines. This raises the potential that drafters fail to consider those opinions that comment on the approach

taken in framing the guidelines as being significant, or fail to engage with submissions that present substantially different approaches. Due attention to submissions from the public consultation process requires consideration and judgement to inform an legitimate outcome. Thomson et al urge the consideration of more proactive methods for calling for public consultation. On our account consultation processes that engaged more effectively a range of publics and positions in developing guidelines in contentious areas would better support the legitimacy of the resulting guidelines, better respect the publics affected by research and demonstrate greater accountability for the process of developing research ethics policy.

A further matter to consider is the influence of *deliberation* informing the review and revision to the *National Statement*. Here there is evidence that allows us to infer that the working committee and writing group drew extensively on arguments made in the submissions to make substantial changes between the first and second consultation drafts and between the second consultation draft and final *National Statement*. It is clear that the arguments made in response to the chapter on research involving children and young people influenced the working committee, which reconsidered its position and revised the guidelines in the *National Statement* accordingly. This demonstrates that the process did allow for the uptake of the submissions and that this uptake was not just an unreasoned assimilation of the views in the submissions, but in many cases a thoughtful approach by members of the working committee to mediate between conflicting views on contentious matters.

What we cannot assess, given the limited publicly available evidence, is whether the arguments presented for the changes made in the submissions were the *most persuasive* influences on the working committee in making revisions, nor whether there were more persuasive arguments presented in confidential submissions, in consultations directly with expert stakeholders or in the working committee deliberations that lead to the revisions. The inability to track the influence of submissions, consultations and working committee deliberations raises concern, given that transparency and accountability are among the hallmarks of legitimate public policy. Nonetheless, it is clear that AHEC members responded to the commentary received on the consultation drafts and felt a need to reconsider significant issues. This indicates a clear commitment to a genuine process of public consultation and deliberation, rather than a minimalist process of "mere consultation", i.e. calling for input from the public, but not being concerned to have that input shape the outcome of the process. One could argue that this is evidence of the effectiveness, in this case, of the NHMRC requirement that committee members give "due consideration" to submissions in response to consultation. The process allowed views other than those of clinicians, researchers or members of AHEC to contribute to the development of the guidelines. Which, according to Chalmers (2001), was part of the purpose of the pubic consultation process.

Also worth noting, is that the varied expertise of AHEC membership means the work of processing, deliberating and incorporating submissions into developing versions of the guidelines, whilst informed by the submissions, is not confined to them, as committee members bring their own experiences and perspectives to the process. As Thomson et al (this volume, Chap. 9) note, the deliberation by the

committee members involves an assessment of the relative weight and importance of the submissions, by members of the working committee drawing on their various relevant expertise and backgrounds. They note, deliberation by a diverse group is itself a reflection of community opinion, as much as are the submissions.

However, whilst we have been able to identify indicators of careful response to public submissions raising clear arguments about children's and young people's consent to research and show that AHEC consultation elicited arguments that had an impact on the revised guidelines, the process itself lacked a level of public accountability that would give the outcomes greater democratic legitimacy. Access to many submissions to the review and the record of the deliberations of the working committee remain confidential (as these contain information and reference to confidential submissions), even though there are requirements for "due consideration" set out for the consideration of public submissions by AHEC, including a detailed record in the minutes of how the submissions were considered by the working committee through the revision process. Whilst one can access information concerning the deliberations of the working committee through Freedom of Information requests (see Chalmers 2001), this requirement inhibits critical public scrutiny of how decisions were made and on what basis. Given the status of the NHMRC (of which AHEC is a committee) as a significant funder of research, and as the body that develops recommendations on health to government and the health professions, it is particularly important that decisions about research ethics guidelines should be publicly defensible. Greater public accountability for the decision-making process involved in revising the *National Statement* would be one way of enhancing the process.

Finally, one can ask whether the process met the expectations of *transparency* and *accountability* through a process of public justification. The principles and guidance that guidelines, like the *National Statement,* offer is presented without justification or argument. The changes in the 2007 *National Statement* are in this sense the conclusion to the argument, not the reasoning process that led to that conclusion. By comparison, the report of the Lockhart review into Human Cloning provides a full defense of the recommendations of that review and explicitly presents information from the submissions that were relevant to the argument (see Dodds and Ankeny, Chap. 7 of this volume). In addition to the revised *National Statement,* a fuller justification could have been provided as part of a separate public report on the consultation and revision process that would demonstrate how the AHEC working committee and writing group dealt with the substantive arguments presented in the process of review. A formal report on the deliberative process and reasoning of the working committee would provide greater accountability and evidence that the policy outcome reflected the quality of the reasoning revealed through the deliberative process.

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Part IV
Deliberating About Emerging Health Policy

Chapter 11
Three Approaches to Chronic Fatigue Syndrome in the United Kingdom, Australia, and Canada: Lessons for Democratic Policy

Rachel A. Ankeny and Fiona J. Mackenzie

Introduction

We live an era of rapid growth in both knowledge and technologies in the medicine, which in turn generates new and difficult questions that need to be tackled by clinicians, policymakers, and bioethicists. Some policies are instantiated in formal regulations or laws which govern what types of care can be provided, and to whom. Other policy decisions take the form of what can be described as informal governance mechanisms: although these are often less overtly binding than more formal regulations or laws, they can have considerable effects on patients and on the practice of medicine. These types of policies have particular impacts on whether patients can access various forms of care for disease conditions that are emerging or in evolution in terms of their characterization.

A key starting point for the provision of good care is diagnosis, but many diagnostic categories are far from straightforward despite continued investigations into the bases of various disease conditions. Furthermore, different types of evidence are recognized as contributing to the definition of disease conditions and the standards of practice associated with them, particularly for controversial or novel disease conditions. Expertise is no longer limited to clinicians or medical scientists, as inputs from patients are increasingly included in debates over disease definitions and in association with appropriate diagnosis and treatment for certain diseases. Decisions about diagnostic categories through clinical practice guidelines (CPGs) represent a central type of informal policymaking which affect the scope of publicly-regulated health services and directions for future research. CPGs are typically formulated by

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medical professionals but increasingly involve inputs from the public, particularly those affected by the disease condition.

In this paper we examine the development of CPGs for chronic fatigue syndrome (CFS) in three different national contexts, in order to examine diverse approaches to the development of such guidelines. This case study is ideal for the purposes of assessing the processes associated with the establishment of CPGs because the three countries in which the policies were developed—the United Kingdom, Canada, and Australia—are similar in terms of their overall socialized health systems and other factors related to the public provision of medical case, and because the processes surrounding the formulation of the CPGs occurred in roughly the same time period but with distinct and contrasting outcomes.

Our methodology depends primarily on analysis of published literature including research papers and accounts of the policy development, as well as working papers and similar from each of the processes. With approval from the University of Sydney Human Research Ethics Committee, we also did interviews with some key actors involved the Australian policy process as well as gaining access to published (particularly in the more ephemeral "grey" literature such as advocacy group documents and internet postings) and unpublished materials relating to all three processes in their personal archives, and to the formal public submissions to the Australian process. Our analysis is based on an extremely useful tripartite framework for analysis of policy in action, proposed by Heather Elliott and Jennie Popay (2000) in their qualitative research on evidence-based policymaking in the UK National Health Service (NHS), which distinguishes between problem-solving, interactive, and dialogical approaches.

In brief, the problem-solving model (see Weiss 1979) emphasizes the role of research in policymaking as the main—if not the sole—relevant source of evidence. Once a policy problem is identified, the solution is sought through research (whether it be drawing on an existing corpus or facilitating ongoing or even new research), and then information is translated from the research context into the policy domain. Policymakers work on the assumption that knowledge exists that can answer the question (or that such evidence can be relatively easily generated). Although this process might be the most ideal, a key criticism of this model is that it does not reflect the realities of policymaking in that it assumes availability of relevant research at the time at which the policy needs to be made as well as the potential for relatively straightforward translation of research into policy.

In partial response to recognized limitations of this type of process, the interactive model considers research to be one of several sources of knowledge and information (together for instance with experiences of those affected by the problem under investigation) on which policymakers can draw in an iterative manner (Weiss 1979). However some critics point out that this model still assumes priority for the data and information derived from research over patient knowledge and experiences. The dialogical model (Giddens 1987) takes a more extreme approach, viewing knowledge as constructed via interaction, social knowledge as contestable, and lay persons' understandings and experiences as central to the construction of knowledge for applications in policy. As we will highlight below, this conception

changes the policymaking process into one of deeper and ongoing communication between a range of actors, but particularly policymakers, clinicians, researchers, and patients.

We utilize these three models to analyze policy discussions regarding CPGs for CFS in recent years in three locales—the United Kingdom, Australia, and Canada. We believe this framework allows a clearer articulation of the range of potential approaches to CPGs and the resulting divergent outputs. Although of course other models of policymaking exist, particularly in public health (for a summary, see Bowen 2005), they are difficult to map onto the processes associated with articulating CPGs because CPGs are very specific types of informal governance mechanisms that are more indirect in their effects than more formalized and binding public health policies for which impacts may be more typical or obvious. We argue that the CPGs formulated for CFS in the United Kingdom, Australia, and Canada reflect contrasting modes of policy development, and that the differential levels of acceptance of these guidelines by a range of relevant parties provide guidance as to which mode of policy development is likely to be most effective and acceptable particularly in the domain of controversial or contested domains within medicine.

Background: Clinical Practice Guidelines

CPGs evolved in parallel with the rise of evidence-based medicine (EBM) in the 1990s. According to their canonical definition, CPGs are viewed as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field and Lohr 1990, 38). The original purpose of CPGs was to eliminate variations in care by providing a solid basis for best practice (Chassin 1990; Grimshaw 1995; Pare and Freed 1995; Wensing et al. 1998; Gundersen 2000). Second, CPGs provide a clearer basis for translation of research into clinical practice. However, more subjective factors influence the adoption and use of CPGs, as physicians are more likely to follow them if they are uncontroversial (Gundersen 2000) and if developed by a trustworthy source, such as a professional medical association or college.

Of course CPGs can be ineffective if not properly constructed or implemented, and there is a sizeable literature detailing the advantages and disadvantages of CPGs (e.g., Gundersen 2000). Although it may seem obvious that evidence from randomized controlled trials should serve as the main basis for CPGs where it is available, authors of CPGs "often have to resort to less rigorous evidence or clinical opinion or both, owing to the limited availability of high-quality evidence" (McCormack 2002, 168). Some authors argue that "CPGs should be judged more on the basis of the wisdom of their recommendations than on the explicit processes of their creation" (Lewis 2001, 180). Nonetheless many agree that "there are too many CPGs, and many are of dubious quality" (Anonymous 2001, 141, commenting on the results published in Graham et al. 2001).

What Is Chronic Fatigue Syndrome?

Chronic fatigue syndrome (CFS) has long been an illness surrounded with uncertainty and controversy. Its main presentation is fatigue after exertion over a period lasting at least 6 months, but patients also can suffer from an array of complaints in diverse systems of the body; the range of severity is as wide as the range of symptoms. The condition has been associated with several other syndromes and sometimes equated to with them, most notably myalgic encephalitis (ME) and fibromyalgia, as well as other illnesses of inexact definition such as multiple chemical sensitivity (MCS) and irritable bowel syndrome (IBS). Definitive evidence as to the cause or basis of CFS has remained elusive. Without such causal explanations, accurate diagnoses and effective treatments often have been difficult to obtain, and in turn the illness has been perceived by many as being illegitimate because of difficulties in proving the existence of a particular disease given the lack of traditional forms of clinical evidence for it. These issues severely impact on the lives of patients and carers with these diseases, and on the care that is thought to be appropriate to be made available for patients.

Although CFS constitutes a relatively 'grey area' of medical diagnostics in contemporary terms, patients with similar symptoms have been described for at least two centuries, a history which serves as both a help and a hindrance to stakeholders. When 'neurasthenia' was proposed as a diagnostic category in the late nineteenth century by neurologist George Beard, it was a disease term couched in the language of science and served to explain many difficult clinical cases that could not easily be grouped under other existing diagnostic categories. It thus was widely accepted by medical professionals and the broader society in the Anglo-American world, and became very popular in a short period of time (for histories relating to CFS and its precursors, see e.g. Aronowitz 1998, 2001; Shorter 2008).

Historical clinical descriptions of neurasthenia are extremely similar to those of modern-day CFS. Perhaps unsurprisingly then, the two illness categories have had parallel trajectories in terms of acceptance and controversy. The diagnosis of neurasthenia was the subject of heated debate by the turn of the twentieth century. By 1930 it had almost fully been phased out as the syndrome came to be subsumed within various psychiatric diagnoses. The disease category of neurasthenia ultimately was eliminated due to the lack of detectable 'organic lesions,' absence of sound scientific grounding for its somatic basis, and ultimately due to its unconvincingly vague nature, which even much earlier had been described as "a mob of incoherent symptoms borrowed from the most diverse disorders" (Clarke 1886).

After several decades of medical obscurity, the illness of chronic post-exertional fatigue re-emerged along two separate paths that would later converge. ME was defined in 1956 on the basis of several outbreaks of an illness which had first been linked with polio in 1934. The link to polio was discovered to have been created largely by hype, and the diagnosis of ME was drawn into question. However the initial and widely agreed-upon viral etiology of the condition enabled it to be taken seriously enough to be granted inclusion (admittedly tenuous in nature) in the

lexicon of Western medical diagnoses (Aronowitz 1998). Similarly, in the 1980s the Epstein-Barr virus (EBV) was used, based on circumstantial evidence, to explain an emerging "lingering viral-like illness, manifesting as fatigue and otherwise largely subjective symptoms" (Aronowitz 1998, 24). While some clinicians and medical journals granted it credence, failure to produce a solid scientific grounding for this circumstantial evidence in subsequent years generated skepticism about 'chronic Epstein-Barr infection' and suggestions of non-somatic origins for patient complaints emerged early, particularly relating to psychiatric issues (e.g., Kruesi et al. 1989; Manu et al. 1988a).

By 1988, the skeptics seemed to win a temporary victory in the debates, with the release of a case definition by the US Centers for Disease Control (CDC) in which the illness was officially renamed as 'chronic fatigue syndrome' (Holmes et al. 1988). CFS advocates claim this definition virtually denied the existence of any physical symptoms. Interestingly, the CDC criteria also were not widely accepted by physicians, since they were taken as allowing patients, rather than doctors, to define the disease. Around the same time, publication of a series of studies that were claimed to show psychiatric causality for CFS (e.g., Manu et al. 1988b; Swartz 1988) and the media began to use labels such as 'yuppie flu' and 'Hollywood blahs' (e.g., Holland 1988; Amory 1989) to describe the illness. However, the theories and methodologies of those who proposed a psychiatric basis for the disorder proved no more conclusive than earlier attempts to prove the link with EBV (Aronowitz 1998). By this stage, the debate surrounding CFS had led activists and patient groups associated with other controversial illnesses including ME to join with those associated with CFS in a common bid for legitimacy. High stakes for patients and practitioners together with continued clinical uncertainties produced a passionate and loaded debate regarding these types of illnesses.

This brief history of CFS and the conceptual issues underlying it indicate that at this point in time, any resolution was not likely to be straightforward, particularly with lack of consensus among various invested participants about what counts as scientific evidence and who should contribute to its construction. What is also clear is that the discourses surrounding the disease condition (and those closely related to it) reveal different priorities and perceptions, evidenced for instance by frequent references to the same historical events or research findings by opposing sides to support contradictory arguments (Aronowitz 1998). The camp that rejected the existence of CFS-related syndromes altogether emphasized that many different factors contribute to the 'vagueness' and uncertainty of these syndromes, as well as underscoring the overlaps with recognized psychiatric illnesses. Most CFS advocates argued that there was biological evidence for somatic etiology, and fought vehemently against its 'psychiatric association.' Debates about mental versus physical causation are in fact the most common argument seen in the literature and debates about CFS, heated by a widely-held belief that "the division between organic and psychological" equates with "a division between real and unreal illnesses" (Wessely 1994), and further fuelled by stigmatization of sufferers as 'mental' patients. The skepticism of some in the medical community appears to have been related to the vague nature of the illness definition, the unconventional

doctor–patient relationships developed through the activism and intense involvement of lay advocates, and the social and symptomatic construction of CFS in the absence of more traditional forms of scientific evidence.

In turn, members of the CFS patient community viewed this skepticism in terms of what it meant for them, namely that they were disbelieved and viewed as malingerers not suffering from something 'real': thus medical scientists were thought to have become "overly reliant on objective tests while denigrating the patient's experience," equating the "'not known' with the 'not real'" (Aronowitz 1998, 33). Some went further to claim this phenomenon as dangerous, citing cases of patients that remained undiagnosed despite the presence of debilitating and even life-threatening illnesses. It is undeniable that patients with this condition suffered directly not only from the condition itself but also indirectly through community and professional attitudes that took the medical profession's word as final and related to the 'patients' accordingly, often stigmatizing them.

On the practical level, all of this uncertainty and disagreement during this period in the late 1980s and early 1990s resulted in "widespread ignorance and mismanagement of chronic fatigue symptoms" (National Task Force 1994), and led to frequent calls for more standardized measures and objectivity in diagnosis. It became clearly recognized in many parts of the world that the best way to approach this issue would be to establish standard case definitions or CPGs, which would "reduce the expensive problem of patients being sent to many specialists before being diagnosed, and [would] allow patients to receive appropriate treatments in a timely fashion." (National ME/FM Action Network 2002, quoting comments from Bruce Carruthers, lead author of the Canadian guidelines to be discussed below). The main issue was precisely how to do this when there were such diverse points of view on all aspects of the illness, and limited conclusive and agreed-upon empirical evidence to resolve these differences and on which to formulate a useful and appropriate set of guidelines.

The United Kingdom and the 'Problem Solving' Model

Of the many reviews and policy discussions on CFS that emerged in the United Kingdom since the mid-1990s, the report produced in 1996 by the Joint Colleges is considered the main set of 'guidelines' for practitioners. A National Task Force Report (also known as the 'Westcare Report') had been produced in 1994 noted that progress in understanding syndromes related to chronic fatigue had been impeded by the use of different definitions of CFS as well as heterogeneous study groups, hence making it difficult to consistently compare and synthesize research findings. Hence the UK Chief Medical Officer requested a report from the Academy of Medical Royal Colleges (which then formed a joint working group drawn from the Royal Colleges of Physicians, Psychiatrists, and General Practitioners) "to advise on matters such as diagnosis, clinical practice, aetiology (causes), and service provision for this condition" (Sleator 1998, 18). The working group, headed by Simon

Wessely, utilized what can be viewed as the 'problem solving' model in their formulation of CPGs. As stated by Wessely on behalf of the working group in their final report:

> it is the aim and policy of both the medical professions and of government that health and medical care in Britain should become increasingly 'knowledge based.' The need for such an approach, in which diagnosis and treatment are based on sound research evidence, should apply equally to the difficult problems posed by CFS as to other areas of health care.

The UK document was explicitly not a consensus document. During the process of formulating the document, the working group did not make any attempts to foster or engage public opinion or patient experiences. In addition, it was reported by a patient advocacy group (known as the '25 % ME Group,' due to its focus on the severe form of the condition which affects 25 % of those with ME) that the working group refused to collaborate with the National Task Force, upon whose report they claimed to be building to produce the 1996 document. Moreover, the working group actually opposed some of the 1994 report's statements, most notably the claim that ME was a major sub-group of CFS (to be discussed in more detail below). There were no calls for external inputs to the report and both the working group and the government consistently dismissed criticisms or reactions from the public, including scientists, clinicians, and sufferers; a petition with 12,000 signatures calling for the report's withdrawal was presented to the House of Lords in late November of 1997 and subsequently rejected (Montague and Hooper 2001).

Some key points of note in the UK Joint College 1996 report include that it focuses on psychiatric explanations of etiology, diagnosis, and treatment of CFS, and recommends against other forms of investigations of the condition. It also endorsed the Oxford 1991 case definition (Sharpe et al. 1991) which was an update of the CDC's 1994 definition which claimed no physical basis for the symptoms of CFS and emphasized psychiatric components. It denied the existence altogether of ME, in contradiction to the World Health Organization's definition relating to these conditions (WHO ICD-10 G93.3). Most notably, it actually advised against the development of CPGs, instead providing a definition for CFS itself.

The broader context against which the UK recommendations were produced is extremely relevant when considering the model of policymaking adopted and the conclusions generated. In the early 1990s, many countries began to take a more evidence-based approach to health care, and the move toward standardized CPGs occurred in tandem with the rise of EBM and its use for assessing health care interventions. Policy in turn was directly influenced by these trends, particularly in the United Kingdom "where there were concerted moves to ground policymaking as well as practice on evidence" (Elliott and Popay 2000, 461). In addition, some have claimed that the UK government deliberately produced a report that was both biased toward psychiatric approaches and recommended against somatic research into CFS in order to save money on pensions as well as research and to pacify the insurance industry. A UK parliamentary group in 2006 pointed to potential conflicts of interest relating to this due to existing consultancy relationships between the Department for Work and Pensions and the insurance industry (UK Parliamentary Group 2006).

Australia Trials (and Abandons?) the Dialogical Model

In 1993, the Australian Commonwealth Minister of Health established a CFS Review Committee to "make recommendations on diagnostic and management regimens that the medical profession would regard as appropriate for sufferers of CFS" (see Loblay et al. 1994). The Committee approached the Royal Australian College of Physicians (RACP) who in turn passed this task to the Australasian Society of Clinical Immunology and Allergy (ASCIA), which then published a working paper and a survey for specialists (Loblay et al. 1994). The resulting report which came to be known informally as the Watson Report (after its chair) was provided to the Ministerial Review Committee at around the same time as the UK's National Task Force Report, and put forward recommendations calling for more in-depth analysis of CFS CPGs. An Australian working group to produce CPGs for CFS was set up in February 1996, 8 months before the controversial UK joint colleges report was issued. The Australian CPGs were not actually completed for nearly 6 years, and were only finally published in 2002 (Toulkidis et al. 2002).

By the time the Australian working group was established, they were aware that what the UK Joint Colleges working group was about to publish were in fact not formal CPGs, and this fact appears to have shaped the distinct approach utilized in Australia as compared to that taken in the United Kingdom as well as their initial intentions to produce CPGs. Criticisms to the 1996 UK Joint Colleges report mounted at this time, focused on inadequacies in content and evidence evaluation, working group bias, and the overall limited usefulness of the document. The Australian working group appears to have explicitly attempted to focus attention on these factors and preemptively address them in order to achieve better results from their process, for instance by performing a more thorough literature review, emphasizing the goal of generating a useful document by formulating more explicit CPGs, and by accepting the existing WHO definitions. The criticisms regarding bias and a lack of consultation in the United Kingdom also were addressed in the Australian process by convening a more inclusive and diverse working group and including community consultation. Australia's drawn-out attempts to produce a definitive CPG document on CFS had consistently involved different levels of consultation since as early as 1993 with the CFS Review Committee described above.

However as in the United Kingdom, the rise of EBM and the concurrent trend toward evidence-based CPGs was a strong influence on the Australian policy process, and so the Australians took on the dual task of calling for submissions from the public and carrying out a thorough review of the research evidence using the evidence hierarchy principles favored within the EBM approach. Whereas the latter part of this dual approach resembles the problem-solving model utilized in the United Kingdom, the Australian group also attempted to utilize the dialogical model by opening up the policy process to outside inputs via an extended process of communication between a range of actors. As noted by Elliott and Popay (2000, 467), the choice of a dialogical process is usually guided by concerns "to develop a negotiated and locally sensitive understanding of health need." The Commonwealth

Department of Health committed to addressing the 1994 recommendations made by the Watson Group, including that they conduct a survey of general practitioners (and re-survey based on findings about the cost implications of various proposals), hold a consensus conference and publish based on it so that results were publicly accessible, and prepare a consensus document to be used for education of medical practitioners and students. They also unofficially recommended conducting consumer surveys in parallel (this recommendation could not be made officially as it fell outside of their explicit terms of reference).

Initially, following the release of the Watson Report's recommendations, members from the RACP and ASCIA met to discuss fulfilling one of the recommendations and forming a consensus position on the diagnosis and management of CFS. However, the release of the National Health and Medical Research Council (NHMRC)'s 'guidelines for guidelines' in 1995 changed this course of action, and in February 1996 the Department of Health funded the RACP to lead a working group to produce evidence-based CPGs instead. The Commonwealth had expressed concern that a consensus conference "would result in an outcome that is not representative of the medical profession" (RACP I109, April 1996), and the new working group seemed eager to please the Commonwealth: "We wish to develop the Guidelines in accordance with NHMRC protocols in order to obtain their endorsement" (RACP I90, October 1998).[1] Their choice of methodologies seems to have been at least partially driven by the desire for official backing to ensure the status of the guidelines: in the policy process documentation, there is considerable focus placed on the need to obtain NHMRC endorsement for the draft, as well as on gaining its approval for a key part of their process relating to asking general practitioners to participate in before-and-after focus group testing of draft CPGs as part of continuing medical education programs. These requirements may well have been a large part of what led the process to drift away from the working group's original intention of following a more dialogical model, inasmuch as research and general practitioner opinions became the main foci.

Canada Goes 'Interactive'

In contrast, the thrust of the processes relating to CFS CPG development in Canada from start to finish was consensus generation. The CPG development panel was selected via a nomination process, covering what were claimed to be the five broad categories of stakeholder groups (government, university, clinicians, industry, and advocacy), and included international involvement. Although the document produced (Carruthers et al. 2003) was evidence-based, there was a more inclusive approach taken than in the United Kingdom or Australia, with a wider range of

[1] These (and subsequent references to RACP documents) refer to submission numbers from documents made available to us via the archival files of a participant in the RACP working group, Dr Rob Loblay, to whom we are extremely grateful for assistance.

levels of evidence considered, such as accepting expert opinion and background information, or even case series, as relevant. The panel noted that while data on a biological basis for CFS had not been established, the idea still needed to be openly considered. Three generations of drafts were followed by a capstone consensus workshop before the final document was produced. This approach clearly is based on an interactive model where research and traditional forms of evidence are only one of several knowledge sources together with knowledge, experiences, and inputs from a range of actors which are incorporated in the policy process in an iterative manner.

The Canadian document begins with an extensive overview of how it differs from the Australian and UK guidelines, which it describes as having "received considerable criticism." It seems apparent that the failures of its foreign counterparts were major and conscious influences on the Canadian process, as these other efforts were noted to have not been properly designed for the clinical setting (National ME/FM Action Network 2002). In contrast to the other policy documents, the Canadian guidelines criticize psychological and psychiatric explanations, stating instead that ME/CFS manifests symptoms predominantly based on neurological, immunological, and endocrinological dysfunction, express support for further research on the biochemistry and biology of the illness, and endorse the name of the illness as listed in the WHO definition. In addition, there is clear evidence in the policy documents of respect for patients and their experiences, such as in the statement that "most patients are well motivated to improve their condition and have lost much more than they could possibly ever gain from becoming ill" (46).

Responses to the Three Documents

The UK document was extensively criticized soon after its release by numerous parties particularly in grey literature such as correspondence and internet-based activism for a range of reasons: the most frequent and vociferous attacks were on the methodology utilized, and the low quality of the review and analysis of the existing literature and evidence. The report also was condemned for being issued in an isolated context and being heavily biased, especially given that it involved no public consultation and appeared to reflect a poor understanding of CFS patient experiences and the special needs of CFS sufferers. A particular concern was the clear bias toward psychiatric factors in terms of management and causation, and against organic or somatic causal factors. In addition, the report was faulted for sloppiness in the interchangeable use of different terminology without clarification, poor understanding with regard to fatigue symptoms, inaccurate and misleading epidemiological reporting, failure to consider the range of symptoms and severity of illness, and frequent mischaracterization of available evidence. In short, the report was thought to provide inadequate guidance to be of any use for doctors or patients, in no small part because of the lack of inclusion of actual CPGs.

A few commentators wrote in support of the document and defended these criticisms, noting that the evidence was comprehensively reviewed and that "the report is well balanced, unemotional and does not try to give a definitive answer as to whether the basis of CFS is psychiatric or physical, but rather tries to give priority to the plight of the patients who suffer from it, and looks for an agreed way to treat them" (archival submissions). The ME/CFS Charities Alliance's response perhaps surprisingly endorsed a number of parts of the report, and (perhaps worst of all for many patients) agreed with the endorsement of cognitive behavior therapy (ME/CFS Charities Alliance 1996). In response to the report, there were calls for the government to establish a broader panel including scientists from a variety of fields and patient groups to discuss the broad spectrum of CFS along with explicit management plans.

The Australian process also met with numerous complaints (much of which did not occur in published fora but in correspondence held in archives made available to us in the course of this research) particularly relating to the lack of explicit incorporation of public submissions into the process and final CPG document including those detailing clinician and patient knowledge and experiences, the make-up of the working group (inasmuch as it was claimed to not be representational enough), the sheer length of time the process took (more than 6 years), inconsistent use of evidence, and production of what was thought by some to be a poor-quality literature review. Complaints about content included a perceived bias toward psychiatric factors and away from biological factors and confusing usage of terminology relating to fatigue (both of which also were criticisms of the UK process). There is some evidence of support for the Australian process; for example, a medical journal praised the methodology and the thorough literature review as well as the consultation process (archival documents).

In contrast, the response to the Canadian process was generally positive, and at times even glowing, oftentimes through explicit contrast to the UK and Australian processes and resulting documents. Not surprisingly, the main criticisms of the Canadian guidelines arose from researchers working on psychiatric approaches to CFS, who claimed that the guidelines should be viewed only as clinical criteria and not as criteria to judge fruitful future research directions. However numerous supporters including clinicians and patient advocates noted that the Canadian document explicitly avoided psychiatric explanations, and in turn did not endorse cognitive behavioral therapy. Patient groups from the United Kingdom and the United States registered their support for the Canadian CPGs and called for their worldwide adoption, noting for instance that "the guidelines respect and empower the patient" (Bryant 2005).

Similarly, an Australian ME/CFS patient group explicitly outlined its reasons for supporting the Canadian guidelines over the Australian ones: a clearer and fuller definition of the spectrum of the disease which was not just focused on fatigue; lack of psychiatric bias; recognition of problems with various studies and certain levels of evidence; inclusion of patient reports and clinical experiences where research evidence was lacking; and development of a new (and more useful) clinical case definition. The ME/CFS Society SA (Australia) also praised the Canadian guidelines,

noting that "[t]he definition provides a flexible conceptual framework that more adequately reflects the complexity of symptoms of a given patient's pathogenesis and should establish ME/CFS as a distinct medical entity" (ME/CFS Australia [SA] 2003).

What Can We Learn About Policy Development from These Processes?

Based on responses to the three documents and the processes which produced them, the obvious question is: what went wrong in the United Kingdom and Australia, and why did the Canadian process and the resulting CPGs seem to generate much more positive response and uptake? On the surface, a skeptic might conclude that these diverse reactions were simply the result of telling people (particularly patients and those clinicians working closely with those with CFS) what they wanted to hear in the Canadian process, and sticking more closely to the available evidence in the United Kingdom and Australia, despite the fact that it revealed information about CFS that went against popular views held amongst patients and their advocates. But a deeper and more useful interpretation can be obtained by focusing on the types of policy processes instantiated in each instance, and how they measure up against the ideals of each type of policy model.

The problem-solving model clearly has limitations particularly in areas where the types of evidence privileged in an EBM approach do not map well onto the existing evidence base. Elliott and Popay (2000) summarize key criticisms of EBM as they apply to its use within policymaking processes: it is "too closely identified with randomized control trials, marginalizing research using other designs" (462). Even more importantly, EBM does not address how to weigh or integrate the types of value judgments which are required when writing policy, nor are there standardized methodologies for how to integrate evidence based on research, clinical practice, and patient experiences. Finally, EBM alone does not provide guidance on how make evidence transferable to practice, or in this case to CPGs.

Given such potential problems with producing a strictly research evidence-based policy document, it is not surprising that the UK working group's attempt to do so met with such strong opposition. In their work on the NHS, Elliott and Popay (2000) found that amongst policymakers studied "[i]t was generally felt that research could clarify and contribute to decision making but not provide answers" (465), a lesson that could have been of considerable benefit to those participating in the CFS policy process in the United Kingdom. Hence they concluded that "[r]esearch was more likely to impact on policy in indirect ways" (462) with the influence of external factors and inputs and policymakers' experiential knowledge playing critical roles, regardless of what model of evidence usage was initially adopted.

Elliott and Popay (2000) found that while true dialogue and joint interpretation as emphasized in the dialogical model are often an ideal to which makers aspire,

they are were difficult to achieve and rarely occur in actual policymaking processes. They provide an account of a policymaker in their research who was afraid of becoming "too close" to the "users' perspectives" and acting as their advocates rather than "taking their views into account as part of the whole" (466). And the pressures to do so are undeniable: it is clear from the documentation of the Australian policymaking process that the patient groups and individuals often believed that their views should be directly incorporated into the guidelines rather than serving merely as indirect inputs. Much of the anger generated throughout the process appears to have been in reaction to such demands not being met, and weighing up responses and inputs to the CFS guideline documents, rather than taking them at face-value, which resulted in the expectations of those involved from within the CFS community not being met.

The nature of and ground rules for broader public consultation as part of the dialogical model for policymaking impact on the development of such expectations (and the resultant backlash that may occur should they not be met). If not done 'correctly,' consultation can leave participants feeling fed-up, disappointed, and angry, rather than viewing themselves as having been heard (even if their opinions are not fully endorsed) and as respected contributors to the policymaking process. Unfortunately although one of the main goals initially in the Australian process was "to ensure appropriate consumer input at all stages" (RACP I7, Nov 1996), this key tenet was transformed as the process proceeded, with later suggestions that consumer views be omitted altogether from the guidelines since the target audience was general practitioners (RACP I57, Apr 2000). In addition, many inadequacies in the submission process were reported by those who contributed (RACP S25, 1997; C11, 1996; S30, 1998; F9, 1998, F24, 2002), especially extremely short submission times (RACP S68b, S68d, S68i, I105).

It is clear that so-called dialogue in fact can be "experienced as confrontational or fraught" (Elliott and Popay 2000, 467): perhaps it is inevitable in such controversial domains that interpretations will clash and complete consensus will never be reached, particularly given differences in perspectives and priorities. As Charles Collins et al. (1999) note: "[t]he same feature of the [policy] context can mean different things to different groups and individuals… Depending on the degree of consciousness expressed by such groups, these interpretations will be consistent with their own group interests" (80). Along these lines, the working group for the Australian CFS CPGs found dialogue highly problematic as they attempted to juggle two opposing models. Whilst they purported to be fervently incorporating views and input from all sectors and carrying out widespread submission processes multiple times, in reality they came to believe that they were compelled to produce an evidence-based document according to the (recently issued) NHMRC guidelines for guidelines (2005).

Although comments and suggestions from researchers may appear to be part of the dialogue, as they are backed by their scientific studies, Elliott and Popay (2000) found that such perspectives "[were] only acceptable in the context of in depth knowledge of the [phenomenon under exploration] and an understanding of the constraints policymakers operated under" (466). So whilst such data might

theoretically be valued in terms of the traditional evidence hierarchy, it often comes to be considered as only peripheral to the review of research evidence, providing "an independent view point on what [the policymakers] already knew" (466). When it was suggested by a specialist practitioner during the Australian submission process that where no clear evidence exists, the working group might consider using consensus-based clinical opinion documented via focus groups, a working group member simply commented that they were "not in the business of conducting research" (S68g). Hence in the Australian context, inputs coming from patient and advocacy groups, and even CFS-friendly clinicians and researchers, were relegated to the category of level IV evidence and often dismissed against the backdrop of other available evidence sources, resulting in a fallback to a form of the problem-solving model.

Highlighting the difficulty in integrating the goals of both the problem-solving and dialogical models, Elliott and Popay (2000) explain that "the thorough strategies developed to incorporate users' views into the project was fuelled by concerns that the project was credible among an articulate and well organized group of service users in addition to commitment to user involvement" (466) in one of their case studies. However it was often the case that recommendations developed in this way were not consistent with "what the research said." These problems are clearly in evidence in the Australia policymaking processes, particularly given the shift from one model to another partway through the process.

An interactive, consensus-driven approach such as that used by the team producing the Canadian CPGs seems to be more appropriate than the approaches taken in the United Kingdom and Australia in situations where there is limited, conclusive research evidence, as is the case in many highly contested medical domains. Elliott and Popay (2000) found that the interactive model of utilizing available research evidence as well as a wide range of other inputs, and integrating these inputs in diverse ways, was the most productive approach to policy development. Research data undoubtedly are important, but "are open to multiple interpretations, which are shaped by the personal and professional values of the interpreter and by the…contexts within which research findings are to be applied" (467). These conclusions clearly apply in the Canadian CFS CPG policymaking context: conventional evidence was taken seriously among other inputs, but most importantly considerable emphasis was put on a refined process of policymaking which engaged and enlisted diverse stakeholders with a range of values in an interactive manner, leading in turn to outcomes that were much more widely acceptable and endorsed.

Even if it is clear from this case study that the interactive, consensus-driven approach produced the most widely-accepted outcomes, the question remains as to whether this necessarily promoted the most democratic or justifiable process or outcomes, particularly for those affected by CFS and those who care for them. It is undeniable that the interactive model utilized in the Canadian process shares many features of the deliberative democratic approaches, notably the emphasis on including not just expert opinions but also public reason and debate when developing policy recommendations and justifying policy outcomes. What seems to be the main cause for many of the controversies as described in this case study is whether this

type of example in fact represents a type of policy decision, or is merely a scientific issue to be decided by experts. As outlined in this essay, we view this example as an exemplar of decision-making in controversial areas in medicine where uncertainties exist, resources need to be allocated, and best practice has yet to be established. A broader exploration of these types of cases likely will reveal that many instances in medicine fall into this category, and are as much about social policy decisions as they are about the supposed 'facts' about sickness and health.

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Chapter 12
Seeking Community Views on Allocation of Scarce Resources in a Pandemic in Australia: Two Methods, Two Answers

Jackie M. Street, Helen Marshall, Annette J. Braunack-Mayer, Wendy A. Rogers, Philip Ryan, and FluViews Team

Introduction

Limited resources linked to unlimited demand for health care means that ranking of competing demands, with associated funding decisions, is essential in any health care system. Such decisions may have social and political consequences: the former will impact the community directly and the latter will ensure that political attention is focussed on the area. Both may be used to justify the collection of community views with respect to allocation of scarce resources in a pandemic. However, some might argue that allocation of scarce resources in this scenario should be based solely on expert evaluation of evidence. That is, evidence should be used to prioritise the needs of sub-groups in the population and to evaluate the efficacy of specific health resources in addressing those needs. The objectives in resource allocation in a pandemic might include (i) maximising community benefit, (ii) equitable allocation of resources, (iii) protection of vulnerable groups, and (iv) fulfilment of obligations for reciprocity towards those who might put themselves at risk to provide care. Examining these objectives, it appears likely that interpretations of benefit, equity and the bounds of reciprocity will differ across the citizenry and that it will be important to consider community opinion and values in making these decisions.

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In doing so we would address instrumental goals (Abelson et al. 2007): we would focus on collecting community views in order to build policy that better reflects community preferences and values and is therefore more acceptable and workable. However, community views might be elicited for other reasons such as to support democratic or process oriented goals (Abelson et al. 2007). This orientation, which values citizen involvement in decision-making for its own sake, emerges from a number of areas including deliberative democratic theory (Smith and Wales 2000), the rise of literate active citizen groups and the increased demands for public accountability for public funding. In this case the focus is on democratic decision-making, fair and transparent process and participant empowerment. Alternatively capacity building goals (Abelson et al. 2007) may focus attention on improving community health literacy and enhancing the ability for citizens to engage in debate in areas of complex health policy.

Surveys are a widely used method for meeting instrumental goals: to elicit public views to inform policy decision-making or to provide public commentary or response on past decisions. A legitimate concern in gauging community views in this way is that the level of knowledge in the community about some of the more complex areas of healthcare planning and policy may be low. This may be particularly the case with emerging health technologies, new health threats or complex health policy areas. This methodological weakness may also apply to qualitative methods such as focus groups or interviews. The concern is that the community perspective, accessed through any of these methods, prior to a projected health emergency such as a pandemic, or before a new technology is rolled out, may change when the emergency occurs or technology is used and there is more interest in and access to information. In addition, policymakers might question the validity of citizen-driven decisions when the citizens have limited access to information to adequately inform those decisions. For this reason, deliberative process has been proposed as an anticipatory tool which can gauge the views of the community in policy areas that may generate future issues but where there is little current public debate (Warren 2009). Deliberative methods involve prolonged engagement with community members and provision of detailed information which the participants may draw upon in their decision-making. However, these methods also suffer from drawbacks, in particular with respect to how representative the views presented in small forums are of the population at large. These issues may limit the acceptability of deliberative methods to policymakers seeking to use community views to inform policy decisions.

Which method should a policy maker use in collecting community views to inform policy and how will the choice of method affect the findings? Very few studies compare different methods for gauging public perspectives on a single issue. This chapter uses a case study to examine the relationship between the choice of goals and methods and the resultant outcomes. We compared community views in South Australia on the allocation of scarce resources in a pandemic using two different methods: first, a cross-sectional survey of nearly 2000 citizens using com-

puter assisted telephone interviews; and second a deliberative inclusive forum which used stratified random sampling to select a small number of citizens. The first method offered a snapshot of community views in a policy area which, at the time before the 2009 H1N1 pandemic, was not topical and on which the general public was not well informed. The second method allowed for engagement with citizens in an informed deliberative process, also prior to the 2009 pandemic.

Pandemic Influenza as a Case Study

The importance of planning for a pandemic was reinforced by the emergence in 2009 of a novel influenza A (subtype H1N1) virus. National plans (Department of Health and Ageing 2008a), developed in response to an emergent virulent Avian Influenza A (H5N1) and the 2003 SARS outbreak, were implemented during the first wave of the 2009 pandemic. Prior to 2009, the Australian Commonwealth Government as part of its pandemic planning had stockpiled nearly 9 million courses of antiviral drugs (Department of Health and Ageing 2009a) which fortunately proved an effective treatment for pandemic-strain H1N1 viral infections. In addition, a specific vaccine against a candidate strain of H5N1 was developed (Department of Health and Ageing 2008b) and an agreement to develop and produce pandemic viral vaccines as required was contracted with a private company (Department of Health and Ageing 2009a). Therefore with the emergence of the novel H1N1 sub-type in March–April of 2009, the Australian Prime Minister was able to reassure the Australian public that it was "the best prepared country in the world to deal with the threat of swine flu" (The Daily Telegraph 2009). Ultimately Australia was the first country to develop, test and deliver a pandemic vaccine (Greenberg et al. 2009; Nolan et al. 2010).

Despite this preparation, gaps in pandemic planning persisted, some of which became apparent during the 2009 H1N1 pandemic. The mildness of the virus caught policymakers by surprise and in Australia a new 'protect' phase (Department of Health and Ageing 2009b) was devised to cater to this turn of events. Planning had been primarily carried out with little consultation with stakeholders, such as healthcare personnel, who were involved in implementing the plans, or the public, who were impacted by the plans in their daily lives. Some key issues had been only sketched out. In particular, the groups allocated as priority for access to antiviral drugs and vaccine in pandemic had only notionally been described (Department of Health and Ageing 2008a). Even now it is not clear how decisions about allocation of scarce resources will be made should such resources be in short supply in a severe pandemic. Some of the gaps exposed in the 2009 pandemic were foreshadowed by the findings of the deliberative forums described later in the chapter.

Telephone Survey

A detailed description of the methods used for the telephone survey has been published elsewhere (Marshall et al. 2009). This was a cross-sectional study using a computer assisted telephone survey of 1975 citizens (participation rate 67.2 %) aged 18–94 with a mean age of 53 years. The participants were randomly selected from the South Australian electronic white pages telephone listings and the interviews conducted in April–May, 2007. This survey was part of the Health Monitor program through HealthSA. The survey was 15 min long and consisted of 36 questions.

The study was conducted to assess both knowledge of pandemic influenza (PI) and community attitudes towards the proposed implementation of strategies such as home isolation and vaccination to prevent spread of infection. Open-ended questions were asked where possible. The survey data were weighted to the age, gender, and geographical area profile of the population of South Australia and the probability of selection within a household. Participants were asked the meaning of 'pandemic influenza' and following this question a comment to explain PI was included:

> *An influenza pandemic occurs when a new influenza virus appears and the human population has no or poor immunity to the new virus. This causes a rapid spread of the virus to people around the world and has the potential to cause large numbers of deaths and serious illness.*

No other information was provided. Two of the questions posed to the participants were:

> *If supplies of the vaccine were limited who would you consider a priority for vaccination?*
> *Do you believe enough is being done to prepare for a pandemic?*

Participants were not provided with any prompts and the responses were self nominated. Data was analysed using Stata with routines specifically designed to analyse clustered weighted survey data (Stata 2005). Statistical tests were 2-tailed with a significance level of 5 %. The study was approved by the Children, Youth and Women's Health Service research ethics committee.

Deliberative Forum

A deliberative forum, in the style of a citizens' jury, was convened in Adelaide, over one day, in February 2008. The forum deliberated on the question:

Who should be given the scarce antiviral drugs and vaccine in an influenza pandemic?

A detailed description of the methods used in this research have been published elsewhere (Rogers et al. 2009; Braunack-Mayer et al. 2010).

The research was guided by a reference group of policymakers and academics from communicable disease control, epidemiology, health promotion, public health economics, health ethics and public policymaking. Participants were recruited by

the same market research company as for the survey, from a database of citizens, recruited through an annual face-to-face community survey.[1] Potential forum members (N = 14) were selected using random sampling stratified with respect to gender, age, employment and household income. Withdrawal of five of the participants, at late notice, meant that the forum, with 9 participants, was older and more female than anticipated. All participants attended a pre-forum evening dinner and received an honorarium of $100 and travel expenses.

Information Modules

Evidence concerning the efficacy and effectiveness of antiviral drugs and vaccines in the event of an influenza pandemic was collected from a systematic review of the peer-reviewed and grey literature. Information modules were prepared in simple language in relevant areas such as evidence for safety, effectiveness and efficacy of vaccines and antiviral drugs, and the ethical and logistical issues associated with provision of vaccine and antiviral drugs at a population level in a pandemic.

Forum Process and Structure

Participants were seated around a single rectangular table. Specialist experts sat at the table when delivering information, otherwise they sat at the back of the room. Material was recorded on an electronic whiteboard and deliberations were recorded using immediate transcription with backup voice recording.

The day, which was guided by an independent facilitator, allowed the jury to interact with specialist witnesses. The forum worked as individuals, small groups and as a whole to deliberate the question and deliver their verdict. Forum members were advised that they were seen as experts in relation to their own experience and as citizen representatives.

Assumptions Made by the Forum

The jurors were told that there were initial reserves of antiviral drugs and vaccines (when made available) to treat only 10 % of the population or provide preventive prophylaxis for 5 %. The forum understood that antiviral drugs would initially be provided to ill persons and their contacts in an effort to contain the pandemic. It was assumed that the period of containment had passed rapidly so that a significant drug stockpile remained. It was assumed that the vaccine would not be available

[1] Participants in the South Australian Health Omnibus Survey (HOS) are aged over 15 and are selected using a random pattern of street addresses across a random pattern of suburbs and are weighted by age, gender and geographic location to accurately reflect the South Australian population. First contact is by letter with an opt-out clause. The HOS had a 70 % participation rate.

for 3–6 months after the recognition of a new pandemic virus. The forum also assumed that unlike the first wave of the 2009 pandemic H1N1 influenza, the virus would be highly virulent and cause large numbers of cases and a high clinical case-fatality rate.

Findings from the forum included flip chart and electronic whiteboard recordings from small group and summary sessions and the anonymised transcripts from the deliberation. Evaluation of the forum was carried out through a telephone survey of all participants which asked them about their views on process and outcomes. The study was approved by the Human Research Ethics Committee of the University of Adelaide.

Findings

Survey

The South Australian survey respondents were asked for their opinion on whom should be immunised first using the scarce vaccine supplies in a pandemic. Of the respondents canvassed by the telephone survey, most placed children (49.7 %; CI: 47.0–52.3) or the elderly (23.3 %; CI: 21.2–25.7) at the top of the priority list (see Table 12.1).

A gender difference in this response was observed ($\chi^2 = 25.1$ $P < .001$) with men more supportive of emergency service workers (i.e. ambulance, emergency management, fire and rescue services) receiving priority for vaccination (63.0 %; 95 % CI: 56.1, 69.4) than women (37.0 %; 95 % CI: 30.6, 43.8). Women were more likely to consider vulnerable groups such as children, the elderly, or sick people as priorities for vaccination (53.9 %; 95 % CI: 50.9, 56.9) than were men (46.1 %; 95 % CI: 43.1, 49.1).

Table 12.1 First choice for priority of vaccination during a flu pandemic: a comparison of surveys conducted in South Australia and Ireland – see Discussion section

Rank	South Australia 2007[a]	%	Ireland 2006[b]	%
1	Children	49.7	Health care workers e.g. Doctors, nurses	62
2	Elderly	23.3	Highest risk groups e.g. Children, elderly	29
3	Hospital workers	8.7	Key Government decision-makers	3
4	Sick people	5.3	Essential service workers e.g. Gardai (police), electricians	2
5	Doctors	2.0	Politicians	2
6	Emergency workers	2.0	Healthy people	1
7	Parents	1.0		

[a]n = 1975, Base: all adults aged 18+, self nominated categories, engaging more than 1 % of total responses

[b]n = 1005, Base: all adults aged 15+, ranked from a supplied list, engaging more than 1 % of total first choice responses

Vaccine and antiviral drug production workers, workers in essential services such as electricity or water supply and the military did not feature in the list compiled from survey respondents. Health care workers such as hospital workers and doctors, made the top of the priority list for 10.7 % of the survey respondents.

Less than a third 32 % (95 % CI: 29.5, 34.6) of the survey participants believed that enough was being done to prepare for a pandemic with nearly half 44.7 % (95 % CI: 42.1, 47.4) unsure.

Deliberative Forum

The initial list of potential recipients identified by the forum was broad and eclectic and included groups providing services in high demand in a pandemic such as health care workers and funeral organisations, groups that were essential to the continued maintenance of societal function such as water and electricity workers and vulnerable populations such as asylum seekers and prisoners. Several participants included people aged 2–30 years for a number of reasons: they were seen as an important conduit for influenza transmission, as important for the survival of society and as a vulnerable population group.

The constraints of the limited stockpiles were quickly reached and the forum discarded specific vulnerable groups from their final list (see Table 12.2) in favour of groups that would be necessary to maintain medical services, vaccine and antiviral drug development and production, and essential services. They removed groups such as the clergy and funeral organisations whose roles might potentially be covered by others in the population but included the military because of their multiskilled workforce trained in disaster and emergency response.

In prioritising the list, the forum participants focussed on preservation of society in a time of crisis. Although the questions were posed separately, most of the participants did not distinguish between antiviral drugs and vaccine and felt distribution patterns should be similar for both.

If forced to choose between preserving society in the long run and saving the most lives the forum indicated that it would choose to preserve society. In particular,

Table 12.2 Priority list for vaccine and antiviral drugs decided by deliberative forum – Adelaide, South Australia

Sector (ranked)	Rationale
1st Health care workers	Maintenance of health services for all to reduce mortality
2nd Vaccine and antiviral drug production workers	Ensuring timely supply of vaccines and antiviral drugs
Equal 3rd Essential services	Maintenance of infrastructure to assure functioning of society
Equal 3rd Military	Back-up role in maintenance of infrastructure to assure functioning of society

the forum wished to uphold the Australian life style and ensure personal independent living through continued access to essential services.

The South Australian forum participants were aware of the potential in a severe influenza pandemic for loss of essential services such as sewage, water and power and that health services would be under severe stress. The potential impact on society of such circumstances became apparent in the deliberative process. The forum participants were also aware of the value of vaccine development and continued production of antiviral drugs. Their response was to prioritise workers in these areas. The most surprising choice of the forum was to include the military in the priority list. However, this is explicable in the light of the forum's aim to support and preserve society in potentially catastrophic conditions, and when it is placed in the context of Australian experiences with the role of the Australian military. In recent years, the Australian military has been involved in a number of humanitarian and international policing roles including the public health and medical response to the 2004 Aceh Tsunami (Pearce et al. 2006), a policing role in the 2003 Australian-led Regional Assistance Mission to Solomon Islands (Hegarty 2001) and nation building in East Timor (Blaxland 2002). The forum saw the military as a flexible resource, able to provide an effective response in a time of extreme stress.

Discussion

These two studies suggest that asking the community their views on an issue of allocation of scarce resources with different methods may provide very different answers to the same question. It is clear that the forum participants placed greater importance on the preservation of society and societal functions and expressed less concern about protection of specific vulnerable groups. In contrast, the survey participants emphasised vulnerable populations, particularly the elderly and the young. In this discussion we will examine how the characteristics of the two methods might have affected findings in each case. We will also explore how the choice of method might impact the acceptability and applicability of the findings in the policy context. Finally, we will compare the findings from the studies described in this paper with similar studies carried out elsewhere.

Method Characteristics Which Affected Participant Decision-Making

Level of Understanding

Although we do not know how much consideration individual survey participants gave to the question, we do know that the level of knowledge of pandemic influenza shown by many of the survey respondents was low. It would therefore be reasonable

to suppose that the decision-making of this group, as a group, was less informed than in the forum and, for many survey participants, was based on the minimal information provided during the survey. The forum clearly had an advantage over the survey in terms of resources available to support decision-making since participants had access to written and verbal information, were able to actively question expert witnesses in real time and had access to material resources such as whiteboards to assist collective decision-making.

Opportunity to Consider the Options

The survey participants lacked not only the information available to the forum participants but also the opportunity to discuss their opinions with others, to weigh the advantages and disadvantages of different choices, and to engage in a structured decision-making process. A structured decision-making process and transcription of the deliberation with subsequent analysis, such as occurred in the deliberative forum, permits documentation of the decision-making process and the underlying reasons for the decisions. The underlying reasons for the participants' choices were not explored in the survey but the attitudes described may reflect Australian public health messages about which population subgroups would benefit most from the seasonal influenza vaccination (Fiore and Neuzil 2009). It is possible that these messages influenced survey participants in their choices. Alternatively the choice may reflect consideration of and concern for vulnerable groups in society more generally.

Timing of Community Involvement

Given that political context and timing may be important influences on public response, it is worth noting that the two data collection processes described were held in the same state of Australia during a similar time period when interest in pandemic influenza was low and the level of transparency of government decision-making in the area could be considered low to moderate. That is, the data collection in both cases occurred early in the decision-making process at a 'stage when value judgments might be important' (Rowe and Frewer 2000, 14). This may influence the response in that survey participants may perceive the question to be of little interest and not applicable personally to them. Such a response may change if the question was asked during a severe pandemic. In contrast, in the deliberative forum the participants were guided through the events which would unfold in a pandemic and therefore were more immersed in the scenario. It is still possible that they did not perceive that they would be personally affected but it is much less likely and the responses from the participants in the forum suggested that they did see themselves to be at risk. For example, participants in discussing whether scarce antiviral drugs should be reserved for essential services, related their judgment back to their own personal risk in the circumstances.

Participant 1: Not so much. I wouldn't pick the essential services people because they are at risk, I would pick them because without power, water what have you, society wouldn't function.

Participant 2: We would be at more risk. They are the things that make our living go on in sickness and health.

Method Characteristics Which Affected Acceptability to Policymakers

Representativeness

Both methods of community engagement described in this chapter randomly selected participants to fill categories so that the groups reflected population demographics. However a forum of nine people is obviously not statistically representative whereas the survey did include sufficient randomly selected participants to fulfil this criterion. The forum could be considered to be 'logically' representative in that one can use some process of logical deduction to draw conclusions from the forum. If we use the analogy of decision-making in the courts, and are willing to accept a court decision made by a jury of 12 members of the community as binding, we could argue that the forum is 'representative' but we would also have to accept that another jury or another forum may make a different decision. Unlike a court jury or the survey findings, the deliberative forum provided a rationale for their decision and therefore, as 'observers' we are able to examine that decision-making and decide if we think the rationale is acceptable and therefore representative of our own possible decision under similar circumstances. The findings of the deliberative forum described in this exercise were not widely broadcast but, if this did occur, public discussion could be elicited through print and on-line media such that the 'representative' nature of the findings could be tested in the public arena.

Smith and Wales (2000) suggest that when community involvement is limited to such a small number, inclusiveness and not representativeness should be the criteria of analysis, since such a small sample could never "accurately mirror all the standpoints and views present in the wider community" (Smith and Wales 2000, 56). That is, the participants are not chosen to represent categories of society but rather so that the forum might be inclusive of a range of experience and perspective to be found in the community (Street et al. 2014).

Generalisability

Similarly if we are willing to accept a court decision made by a jury of 12 members of the community as binding and, through this, generalisable to other situations, then we can similarly regard our forum as generalisable. However, if we treat the deliberative forum as a data collection and analysis exercise that merely informs

policymaking, then generalisability is a more difficult issue. The best that we can say is that a deliberative forum tells us about how an informed and engaged public might interpret and make decisions about a particular issue. Thus, if the methods adopted with the forum were used in a publicity campaign aimed at the general population, then public acceptance of the allocation choices would possibly be similar. Without such a campaign the outcomes of the forum may be of little value since an uninformed public could allocate the resources differently. The survey on the other hand could be considered to be generalisable to the South Australian population as a whole at least at the collection time point.

Transparency and Rigour

Both forum and survey were conducted independent of external influence from a sponsoring organisation, although in the case of the forum, representatives of the funding partners (South Australian Department of Health) sat on the reference group. Participants in both had full control over their choices as to who should be considered a priority for receiving scarce drug supplies in a pandemic.

Transparency in community engagement, as described by Rowe and Frewer (2000), should be such that the broader public can judge the independence and validity of the engagement process. Transparency, in this context, was low for both methods, since details about the participation process, and the subsequent findings in each case, were not revealed, except in the academic literature following a peer review process and journal publication. The peer review process does permit explicit judgment of independence and validity and in this context both methods could be considered to have high transparency. Dissemination without peer review is generally discouraged in academic circles, but this approach runs contrary to deliberative democratic theory which suggests that details about the forums should be publicised at all steps in the process. Suppression of details about the forum, until a publication had passed muster at peer review, was endorsed by the policy partners but it could be criticised, in that, such an approach prevents broader public engagement and debate which might be expected to ensue if engagement exercises were more broadly advertised.

Cost

A costing for the two methods (2008 figures) is shown in Tables 12.3a and 12.3b. Costs will vary depending on the facilities available to the researchers and the level of amenities used but the deliberative forum was clearly considerably more expensive than the survey. However, if the evidence collected for the forum had been otherwise available (for example, already collated for another purpose) the cost would be similar to that of a survey.

Table 12.3a A summary of the principal cost items for a deliberative forum ($Au, 2008 figures)

Item	Unit cost	Number of units	Total
Recruitment by market research company	250	12	3000
Honorariums (100/day)	100	12	1200
Evening meal	75	18	1350
Evidence review and preparation of modules (salary + oncosts/month)	6700	6	40,200
Preparation for jury (12 weeks/1 day of casual admin support)	2500	1	2500
Reporter for instantaneous transcription	800	1	800
Venue	0	1	0
Refreshments (all costs/day)	1500	1	1500
Data analysis (salary + oncosts/month)	6700	1	6700
Facilitator	1200	1	1200
Expenses for jurors	35	12	420
Papers (15 papers at 25/paper)	25	15	375
Total			59,245

Table 12.3b A summary of the principal cost items for a survey ($Au, 2008 figures)

Preparation and pilot of survey (Salary cost/h)	100	10	1000
Survey implementation through a state-based survey instrument including recruitment, telephone interview, data preparation (cost/question)	1200	17	20,400
Data analysis (salary cost/h)	100	40	4000
Total			25,400

Theoretical Frameworks

The two methods used in this example are drawn from very different theoretical frameworks. Surveys arise from a positivist understanding of the world where social phenomena can be measured and categorised and where meanings are not problematic. Surveys can provide useful descriptive data which cannot be efficiently collected by any other method. Deliberative forums, in contrast emerge from deliberative democratic theory which contends the transformative nature of informed debate and argument in decision-making. In this framework, new meanings may be constructed in the space between the evidence presented and the experience of the citizen participants. However, the deliberative forum described in this chapter took place in a team project negotiated between academic researchers and policymakers. Some members of the team approached the project from a constructivist framework with capacity building and/or democratic empowerment goals foremost whereas some worked from a positivist framework and focussed solely on instrumental goals. The constraints of time and money meant that not all these goals could be

met: choices were made which compromised democratic process in order to deliver outcomes which would be most useful for policymaking.

Outcomes

Influence in the Policy Sphere

The deliberative forums took place while pandemic plans were still undergoing review, thereby allowing feedback of the outcomes to policymakers: policymakers sat on the steering committee; the findings were provided to the state Pandemic Influenza Health Steering Committee on a regular basis; and a summary of the findings were submitted to the Pandemic Influenza Sub-committee of the Coalition of Australian Governments (COAG). No explicit effort was made to feedback the findings of the survey to policymakers but the findings were reported at the annual National Immunisation Conference (as were the findings of the deliberative forum) which is attended by policymakers working in the infectious disease area. However, we do not know what effect, if any, the findings of the forum or the survey had on policy development.

Comparing the Two Methods with Other Data Collection Exercises

In comparing the outcomes from these two methods with the limited number of community engagement exercises on the same question in other countries, research method appears to be a major contributor to differences in the findings. The choices made by the deliberative forum are similar to those made by participants in another deliberative engagement exercise, the Public Engagement Pilot Project on Pandemic Influenza (PEPPPI) project (HHS USA 2005), which was staged in four states in the United States (see Table 12.4). Participants in the PEPPPI project supported the goal of 'assuring the functioning of society as first priority in provision of vaccine', followed by 'reducing the individual death and hospitalization due to influenza'. The other possible options: 'prioritise young people', 'use a lottery system' or a 'first come first served' approach had little support. A similar exercise in Canada (Pan-Canadian Public Health Network 2007) on the allocation of antiviral stockpiles also supported the goal of "keeping society functioning" over "minimize serious illness and death". Support for "minimize government's role" with highest priority given to health care workers was not because they were at greater risk (although for some participants this was a factor) but because they played an important role in "keeping society functioning and containing the spread". This is similar to the findings of the forum described in this chapter.

Participants in a large survey in Ireland (Irish Council of Bioethics 2006), ranked health care workers as first priority (Table 12.1) which on the surface seems to be more similar to the finding of the deliberative forum than the South Australian

Table 12.4 Recommendations of the PEPPPI Project (Citizens and Stakeholders) – United States of priority groups to receive scarce pharmaceuticals in a pandemic

Sectors targeted	Rationale (ranked)
Vaccine supply workers	Assure functioning of society
Emergency response and lifesaving services	
Critical services such as police, key government decision-makers, homeland security, food distribution, telecom workers	
Protect those more likely or most likely to die from a new influenza strain	Reduce individual deaths and hospitalizations due to influenza
Healthy persons 2–64 years old not in other groups	

survey. Second choice was the elderly and children. However, when the Irish citizens were asked the reason for their choice most chose "treat everyone equally as possible" (43 %) over "give priority to sick and frail" (27 %) or "save the most lives" (23 %) (Irish Council of Bioethics 2006). Only 5 % of the Irish respondents selected "preserve essential services" as their top priority. This suggests their choice of health care workers was to permit continued treatment of all, including the survey participants themselves, rather than preservation of the structure of society. This places the outcomes of the Irish survey more in keeping with the South Australian survey, which also did not envisage that a pandemic might pose a threat to social function, in contrast to both the PEPPPI project and the South Australian forum which did.

What Did the Findings Add to the Policymaking Process?

The South Australian forum priorities fit closely with Australian Government priorities listed in the Australian Health Management Plan for Pandemic Influenza (AHMPPI) (Department of Health and Ageing 2008a) for a severe pandemic: the AHMPPI would prioritise pre- and post prophylaxis for health care workers and some other occupational groups but also includes 'treatment of cases as clinically appropriate'. This might include the survey participants' choice of the young or the elderly if these groups were found to be particularly vulnerable to a specific strain but the plan does not include these groups without such a proviso. In a severe pandemic the AHMPPI contains provision for 'the need to maintain functioning of critical infrastructure' which fits closely with the choices of the South Australian forum.

A study by Uscher-Pines et al. (2006) which looked at national preparedness plans around the globe found that essential service workers and health care workers were the second and third most prioritised groups with the armed forces seventh and vaccine manufacturers tenth. The most prioritised group in national preparedness plans is high risk individuals, who did not feature on the lists from either the South Australian survey or the deliberative forum. The highest priority groups in the South

Australian survey, the elderly and children, are fourth and fifth of the most prioritised groups globally.

Both methods are important for policymakers since the survey provided an indication of the degree of understanding in the population and the way in which a variably informed public may view decisions about resource allocation in a pandemic. In contrast, the forum provided informed community perspectives and highlighted areas in which citizens can contribute to our understanding of the values which citizens may hold in a situation of resource allocation in an emergency. It is noteworthy that a well-informed public, as represented by the forum, might be more likely to accept resource allocation as described in the AHMPPI, compared to a public who have been shielded from discussion about worst case scenarios. In this case study of pandemic planning in a pre-pandemic era, both of these methods proved valuable by providing insight into community understanding and values for decision-making about scarce antiviral drugs and vaccine. Using a variety of methods to engage the public may help to shape more effective and efficient policy and practice.

Using Participatory Methods for Policymaking

The deliberative forum described in this study differed from citizens' jury models which focus on capacity building or democratic goals: the citizens were not involved in the development of the materials or the selection of the witnesses; the forum was smaller and there was a tight time frame. These modifications were in response to our instrumental goals which focussed on the best way to collect views about allocation of scarce pharmaceuticals in a pandemic such that these views reflected an informed public opinion which might be used to inform policymaking. Within a limited budget, we wished to gauge community perspectives on a number of different aspects of the Australian Pandemic Influenza Management plan and were therefore constrained with respect to time and funding available to explore each area.

In addition, although our evaluation suggested that individuals participating in the forum felt empowered by their participation, our primary objective in conducting the exercise was not to fulfil the democratic goals of empowerment and citizen participation but rather the instrumental goals of health technology assessment and informing policy (Abelson et al. 2007). Both the survey and the forum fulfil the objective of community consultation but provide different information about community perspectives. This clear difference in outcomes raises concerns about the danger in policy development of 'cherry-picking' preferred results through the selection of methods which will provide those results.

It is worth noting that, although we presented the participants in our forum with a comprehensive summary of the relevant information from the published literature, some information available to policymakers may not be in the public realm and therefore the information used in deliberative methods may be incomplete. This may impact on the quality of the decision-making. Similarly some information will be dependent on the nature of the pandemic virus and therefore information can

never be complete in a pre-pandemic period and as has been shown with the 2009 H1N1 pandemic, uncertainty may persist well into the pandemic period (Roxon 2009).

Conclusion

These studies support the view that although surveys may elicit wide acceptance from the public and policymakers because of high representativeness, the quality of the decisions elicited is compromised by the inability of most citizens to access crucial information which would be readily available to a government decision-maker. Deliberative forums potentially provide higher quality information about decision-making but may struggle for acceptance by policymakers and politicians because of the small number of participants, with concerns about generalisability of the results. Our work would support the contention of Rowe and Frewer (2000) that a combination of several methods with different strengths can provide a more complete picture of community views and therefore a solid base on which to build effective policy.

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Chapter 13
Assessing Deliberative Design of Public Input on British Columbia Biobanks

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Introduction

This chapter describes a series of deliberative engagements on biobanks to demonstrate that it is possible and desirable to seek informed deliberative input of diverse publics into policy. We propose that deliberative engagement increases the legitimacy and sustainability of policies on biobanking. The approach described here does not attempt to represent a population, but to better represent the diversity of interests in various constitutions of 'the public' (Burgess 2004). Deliberation in these 'mini-publics' with the goal of informing policymakers may enhance the range of views or interests considered and highlight the convergences and divergences of opinion about policy through informed deliberation that would be difficult to achieve on a larger scale (Goodin and Dryzek 2006; but see Ackerman and Fishkin 2004). As a result of the give and take of considering other perspectives, hearing different modes of presenting life experiences and information, and assessing justifications provided for different perspectives, the group decisions are more likely to be sustained by the participants than top of the head perspectives given without deliberation. Further, the issues raised by the deliberation may anticipate responses and public concerns, directing policymakers and researcher to further investigate these aspects of policy (cf., Warren 2009).

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Calls for public governance of science have become increasingly popular over the past decade (Dietrich and Schibeci 2003; Fukuyama and Furger 2007; House of Lords 2000; Walmsley 2009). Public engagement generally seeks to democratize science policymaking by expanding typically expert or stakeholder driven conversations regarding the governance of science to include lay citizens (Rowe and Frewer 2005). Methods described in this paper were inspired by examples of such public engagement events including: the 2004 BC Citizens' Assembly; 2001 Canadian Public Consultation on Xenotransplantation; 2002 UK GM Nation; Danish Board of Technology's 2005 Citizen Jury assessment of transgenic crops; UK government's Nanotechnology Engagement Group; New Zealand Bioethics Council's 2007 Who gets born? Pre-birth testing deliberative dialogue; and CaliforniaSpeaks 2007 (for more on these events see Walmsley 2009).

There are many critiques of public consultation and deliberative engagement. Legal challenges (cf., Means 2002) and some critical debate about deliberative democracy have focused on the definition of reason as problematic (Mouffe 2002; Reardon 2007; Fung 2006). Since many policy decisions, whether in health or other areas, cannot simply be derived from the application of human rights or ethical values, it is inevitable that they include trade-offs between different interests. What constitutes 'acceptable' trade-offs is notoriously complicated, as indicated by the literature on risk and risk perception. Although knowledge does influence risk perception, the view that public fears about risks can be alleviated by providing technical knowledge has been discredited. Further, social science studies of science and technology have demonstrated that publics can understand complex issues sufficiently to have meaningful discussions (Kerr et al. 1998). Many public engagements are not adequately informed (See, for example, Niemeyer 2004; Rowe and Frewer 2005, and Sunstein 2002). It is also recognized that public events are typically not subjected to extensive evaluation due to monetary and other constrains (Office of Science and Technology and the Wellcome Trust 2001). Many commentators argue that it is both necessary and desirable to submit deliberative engagement methods to explicit justifications and assessment to ensure effectiveness (Rowe et al. 2005). Some (e.g., Einsiedel 2002) have called for evaluations of concepts that are of particular significance to the field of public engagement such as sampling for representativeness (Office of Science and Technology and the Wellcome Trust 2001).

BC Biobank Deliberative Engagements

Biobanks, or tissue and data repositories organized to facilitate research, have become a dominant biotechnology and a global focus of ethical and legal reflection. Computational technologies, genetic and genomic research, the history of use of cohorts to study population health, and the advent of electronic health records are among the contributing factors to the prominence of biobanks as a research resource.

Several other factors combine to establish strong 'public interest' in biobanks. Some biobanks depend on previously collected tissues and data that were stored for

clinical purposes, but with new technologies present attractive research resources. Large numbers of samples and data are required for biobanks to be useful, making it important that there is efficient access to a large number of well 'annotated' samples. The size and infrastructure required to support biobanks typically draws on public resources, representing lost opportunity costs in order to invest in biobanks as a research resource. Biobank research is likely to influence the kind of social policies and health interventions developed in the near and intermediate future. Those who have strong concerns about biobanks usually focus on how biobanks can be used to reinforce existing social categories, contributing to sustaining related social inequities such as those related to disability and race. The investment and influence of biobanks on the future of society together justify an emphasis on assessing the range and nature of different interests that could be served or undermined.

Donors might also have a strong interest in biobanks. It may appear that due to the size of biobanks individual donations, or their withdrawal, have little effect on the biobanks and associated research. But it is only through the collective investment in biobanks that the resource develops value for research. As David Winickoff has articulated, the collective investment creates a resource in which each donor has an interest (Winickoff 2007). Further, trust in the governance of the biobank and the fact that any member of the public could be recruited suggests that if the resource is to be socially sustainable it will need to engage with public interests.

The design of the deliberative event was the result of several graduate seminars and the activities of a research group leading to a small international workshop in 2006. Following the workshop the research team revised the design and received further comment from the invited participants. The design has undergone subsequent revisions for events mentioned below, but the design generally follows this discussion.

The design and implementation of two deliberative engagements in BC, with additional use of the approach at the Mayo Clinic in Rochester Minnesota and the Office of Population Health Genomics in Western Australia, occurred from 2006 to 2009. The design of the first deliberation was produced through graduate seminars, interdisciplinary collaboration, a small international workshop and months of refinement. The primary objectives of the design were to

- form a group of participants that reflected the diversity of perspectives of the population of BC on issue of biobanking
- to inform the participants of the technical and contextual issues and opinions related to biobanks
- to avoid stakeholder capture, ensure respectful listening and participation by all participants
- stimulate critical appraisal of claims of experts, stakeholders and participants
- encourage the development of group decisions about what might be appropriate policy and identify areas of persistent disagreement.

These objectives are captured in Abelson et al.'s (2003) criteria for assessing public engagements:

1. Representation
2. Structure of process or procedures
3. Information used in process
4. Outcomes and decisions arising

These categories will serve as the structure for our description of the deliberative engagement of publics on the topic of biobanks.

Representation: Constructing the 'Public'

Social science researchers typically use stratified random sampling methods to produce a group of participants that represent a series of subpopulations. However, there is a great deal of disagreement concerning what 'representative' means and how one can achieve it. Typical filters for gender, age, or recruiting from student populations often produce samples that over represent highly educated respondents from higher socioeconomic groups or dominant voices (Einsiedel 2002). It is also important to note that one can only filter for interests that are known to researchers. There is no guarantee that randomly sampled participants will encompass the full range of interests and values relevant to biobanking. Recruiting specifically for diversity of interests will ensure that we have included a wide range of participants who can draw on distinct life experiences, values, and styles of reasoning when contributing to both large and small group deliberations. We demonstrate here how the representativeness of sampling approaches can be based on the key objectives of a deliberative event. We explicitly consider tradeoffs in potential sampling methods and the ways in which these tradeoffs may impact on our ability to achieve key event objectives as part of our analysis.

Our team considered all elements of the event's design, including recruitment and deliberative processes (i.e., speakers, information, moderation), after key objectives for deliberative engagement were determined. Consistent with the advice of decision analysis experts that it is important to carefully consider value tradeoffs among key objectives when making recruitment decisions and designing engagement (Keeney 1992; Keeney and McDaniels 1992), we assessed several types of recruitment strategies before selecting our approach to recruitment.[1]

Recruitment design was driven by practical considerations (expense and time) and concerns to enhance the diversity of experiences deliberated by the participants. One proxy for diversity in communication styles and life experiences that might influence the discussion of biobanks was geographic location, particularly urban and rural locales. The Province BC is divided into five health regions, providing a convenient way to structure the sample by recruiting from each region. Another consideration related to diversity was how to increase participation by people who

[1] A detailed account of the rationale and decision making process of designing recruitment is provided in Longstaff and Burgess 2010.

would be absent from other public consultations due to self-selection leading to deficits of representation due to strong representation of those with vested interests (Burgess and Tansey 2008). Selecting participants for their unique location regarding discursive styles and life experiences can introduce novel perspectives to group deliberations that might otherwise be lost (i.e., First Nations, people with disabilities, those with particular religious perspectives). Certainly many classic demographic categories are likely to be a basis for variation (e.g., age, gender, and ethnicity). In order to give those without strong background or positions related to biobanks the opportunity to consider different views and develop their own it was important to avoid domination by those with pre-deliberation vested interests and positions.[2] Further, recruiting non stakeholders may produce a more heterogeneous sample than recruiting participants based on representing and balancing identifiable vested interests. Representing stakeholder views is considered under the information and process, below.

Ultimately, event participants were random digit dialed and recruited to fill stratification for ethnicity, religion, occupational group, sex, and a series of additional filters using the 2001 Canadian Census for the province (see Table 13.1). A minimum of two participants were also recruited from each of the province's five geographic health regions. Ultimately 1505 unique households were contacted through 1796 phone calls to complete an oversample of 34. Twenty-three members of this group registered for the first meeting and 21 completed the second weekend.

Constructing a diverse sample does not establish that we achieved diversity in deliberations. Ultimately, analysis of event findings is necessary to determine if deliberations represented a broad range of perspectives.[3]

Structuring the Deliberative Process

Deliberative democracy requires that participants are informed, try to understand the perspectives of others, demand and provide 'warrants' for their positions, and are willing to attempt to find a policy or other conclusion that they agree is fair (Gastil and Levine 2005). Combining Chambers' (2003) and Dryzek's (2000) accounts, we attempted to reflect five general objectives of deliberative democracy:

1. Augment legitimacy through accountability and participation
2. Encourage a public-spirited perspective on policies issues through cooperation
3. Promote mutual respect between parties through inclusion

[2] For more on the challenges of representation and expertise please see MacLean and Burgess 2010.

[3] The event and deliberative conclusions are also described in Avard, et al. (2009), and in Burgess et al. 2008.

Table 13.1 Demographics of participants for 2007 event[a]

Gender	Female	12	Income (21 responses)	Less than $25,000	1
	Male	10		$25,000–$49,999	3
Health Region	Fraser	7		$50,000–$74,999	3
	Interior	2		$75,000–$99,999	1
	Northern	2		$100,000–$149,999	3
	Vancouver Coastal	9		$150,000 and over	0
	Vancouver Island	2		Undisclosed	10
Employment (20 responses)	Business – Finance – Administration	3	Chronic illness/ disability	Yes	4
	Chemical Engineering	1		No	18[a]
	Social – Education – Gov't – Religion – Health	4	Risk of inherited disease	Yes	8
	Trades – Transportation – Equipment	3		No	14[a]
	Unable to work	2	Religion	Atheist	1
	Looking for work	1		Buddhist	1
	Retired	5		Catholic	4[a]
	Other	1		Christian	6
Ethno-cultural	Caucasian	2		Muslim	1
	Chinese	3		Protestant	1
	Pakistan	1		Sikh	2
	Indian	3		Theist, no religion	1
	Anglo	1		None or other	5
	Ukrainian	1	Number of children (17 responses)	None	6
	First nations	2		1	4
	German	1		2	3
	Filipino	1		More than 2	4
	Other	7	Age (18 responses)	Under 30	3
Education	More than high school	20		30–45	5
	Less than high school	2		45–60	4
				Over – 60	6

[a]These demographics include one person who only participated in the first weekend's deliberation

4. Enhance quality of decisions and opinions through substantive and informed debates
5. Allow the contestation of (notably dominant) discourses through the public sphere.

The process was to draw participants' attention beyond their own interests toward a "civic-mindedness" that could move toward agreement without diluting differences between individuals' interests. As Hamlett describes, the purpose of deliberative engagement

> is not simply to ensure that 'excluded groups' are given access to decision making about technology, however desirable this may be in itself … but to express a reasoned, informed, consensual judgment forged out of the initially disparate knowledge, values, and preferences of the participants, as these have evolved through the deliberative experience itself. (Hamlett 2003, 121–2)

The deliberative event incorporated several procedures to increase the opportunity to meet the ideal of deliberative engagement.

Although the target for the deliberative event was limited to 25 participants for reasons of budget and drawing on Goodin and Dryzek's (2006) notion of a mini-public, even that size is intimidating for some people. It is important to structure deliberative events to support the ability of all participants to contribute, and to do so in a manner that encourages participants to express and reflect in a broad range of manners. Professionally mediated large group discussion could help draw out the quieter members, remind participants that they are charged to listen respectfully, and draw out points that might be lost to more assertive or strongly argued points. Using discussion facilitators in small groups of about eight further encourages timid members and exploratory reflection. Emphasizing that the first task was to get interests and issues on the table using the frame of 'hopes and concerns' before critiquing whether they were realistic helped to promote the sense that everyone could contribute. The first 2 days of deliberation were constituted by the movement between receipt of information (discussed below), and facilitated small and large group discussions, with audio recording of the dialogue for further analysis. The emphasis on respectful listening and inclusive participation helped create internal process legitimacy through participation and accountability for explaining oneself and trying to understand each other. This helped to develop a public-spirited perspective on policies issues through cooperation on understanding the range of perspectives in the group and from broader stakeholders and experts.

To avoid premature drawing of consensus due to exhaustion or group-think, the design of the deliberative event was to meet over two weekends with 12 days between the meetings. This period of time was intended to give participants an opportunity to reflect, collect further information, talk to others in their lives, and return to the second weekend of deliberation with a stronger sense of the issues that were important to them or others.

The task for the second weekend shifted from understanding to moving toward group decisions about policy advice. The task in the first biobank engagement was to identify the values that should inform a provincial biobank. Facilitated large and

small groups were again used to encourage inclusive participation and detailed reflection on reasons, narratives, perspectives that were presented. Critical reflection and retelling of others' narratives, combined with arguments and identification of persistent disagreements as well as issues that could not be resolved without further information. Facilitators were encouraged to identify persistent disagreements as much as convergence or consensus positions to avoid forcing agreement. This supported a public-spirited perspective on policies issues through cooperation on identifying both disagreements and agreement. Again, mutual respect between parties through inclusion was reflected in the process, and the quality of decisions and opinions were enhanced through substantive and informed debates that did not exclude less 'reasoned' perspectives.

Informing Participants for Deliberation

The content and presentation of information provided to participants is of central importance to the legitimacy of both the process of deliberation and the outcomes. The range of content to present to participants is a particular challenge. Biobanks are often raised in connection with genetic testing, and opposition to some uses of genetic testing has stimulated criticism from groups concerned about disability discrimination, racism and indigenous rights. Biobanks, understood in their broadest sense as data and tissue repositories, can also be associated with longitudinal cohort studies that attempt to understand how environment interacts with human health. Using the broad definition threatens to undermine the concerns that some groups have about genetic uses of biobanks, but failing to include cohort studies may lead to conclusions that may have unintended consequences for these studies. The information provided as background materials for this deliberation took a wide contextual approach. Through different formats, genetic and cohort uses of biobanks, concerns from perspectives of indigenous communities, disability and racism were included. Expense and lost opportunity costs were considered.

Speakers or participants may base their arguments on assumptions that require assessment but are difficult to notice because they are so commonly a part of the dominant culture (e.g., the assumption that investment in health research will improve health is not always accurate). Providing wider context and critical voices helps raise these assumptions so that they can be part of the deliberation.

The mode of presentation of information is also important. If deliberation is to be open to multiple ways of presenting a position or perspective, then it is probably important to represent that range in the presentation of information. Of course, different people have different learning styles, so it is ideal to have multiple modalities of presenting information. It is important to ensure that the deliberation is not polarized by the influence of strong personalities.

In response to these concerns, information was presented in a wide range of media. Literature reviews produced an 18-page booklet written for a tenth grade level of reading that was circulated in advance of the deliberation, and available

online. The booklet was supplemented by two binders of media and peer reviewed literature that was available in print or online. The first day commenced with stakeholder and expert presentations. Presenters were encouraged to consider the booklet and take issue with it to encourage an openly critical approach to information. The issue of undue influence of the presenters on the deliberation was addressed by having them present early on the first day but not participate in subsequent small and large group discussions. They were available through the organizers to answer questions throughout the period of deliberation. Assessment of the discussions suggests that participants critically engaged the speakers' presentations in their small groups (MacLean and Burgess 2010).

There were several other approaches to providing information and perspectives on biobanks in addition to the recruitment for diversity, the pre-circulated booklet, binders and speaker presentations and availability for questions are described above. A model of biobanking and how it relates to the community (e.g., schools, homes, environment) and the research environment (e.g., health clinics, university, public and private laboratories) was constructed from Lego© to provide an opportunity to visualize and manipulate the concepts and relations (cf., Burgess et al. 2008). Participants were oriented to a private website that permitted them to ask questions and hold discussions during the 12 day break between deliberative events. During this intervening period, a few participants reported on additional readings and websites. Several participants reported discussions with their families, friends and coworkers when they returned on the second weekend. All materials presented on the website were also printed out and put up on the walls of the deliberation venue for review by the participants. The 12 day break seemed to enable many participants to gather more information, whether from friends and family or online.

Outcomes and Decisions Arising

Participants were told that their deliberations would be assessed and reported to funders and policymakers who were responsible for funding and regulating biobanks.[4] A speaker with responsibility for several biobanks and leading a project to organize access to collections in BC assured the participants that their deliberations would influence the governance of the biobanks for which he had responsibility. He also explained how the deliberations could influence the standard of practice for biobanks in Canada and beyond. The most concrete demonstration of these effects was the recruitment of a participant from the deliberation onto the BC BioLibrary governing body as a public 'representative' and the subsequent deliberation in 2009

[4] Including the Canadian Institutes of Health Research (CIHR) Ethics Office, CIHR Institute for Genetics, Health Canada Policy Branch, Canadian Biotechnology Secretariat, Canadian Tumour Repository Network (CTRNet), BC BioLibrary: Banking for Health, BC Cancer Agency Tumor Tissue Repository, Better Biomarkers of Acute and Chronic Allograft Rejection (Genome Canada), The James Hogg iCAPTURE Centre, St. Paul's Hospital.

focused on key policy and practice decisions for the BC BioLibrary. The former participant-representative described her experience at the second BC deliberation (2009) and observed the entire deliberation as a means of informing her ability to work as a public representative.

The BC Biobank deliberation had several types of decisions arising. Most salient are the conclusions of the final large group discussion of the event:

1. Strong support for biobanks
2. Governing body independent of funders and researchers
3. Standardising procedures for effectiveness

While these are the most obvious conclusions of the deliberation, defining the precise parameters of what constitutes the 'results' of a public deliberation is itself not a trivial exercise. For instance, in this deliberation several types of data were collected:

- Audio recordings of all proceedings were transcribed and coded using qualitative data analysis software
- Ethnographic and other notes taken by observers of the deliberation
- Flip chart notes made by facilitators and participants themselves
- Presentations made by small groups to the larger group based on the conclusions of their deliberations; these were subsequently turned into three 'small group reports' by the respective small group facilitators and ratified by the participants
- One large group report based on a final 1.5 h discussion in the large group, compiled by M Burgess and ratified by participants

No single data source exclusively constitutes the results of the deliberation. Although the ratified large group report is an obvious contender, it does not contain a lot of the range, detail and nuance of argument that was evident in the deliberation. The three small groups have the benefit of containing more details and covering a larger range of issues than the final large group discussion (though not as much as is available in the transcripts); moreover, they also have the advantage of being ratified by participants. However, each small group only represents of a third of the participants. Finally, the coded transcripts of the deliberation do not have the advantage of participant ratification, but they do contain a lot of detail that never made it to any of the group reports. Further, participants did not reach consensus on every issue they discussed, recording persistent disagreements that present challenges for reporting and interpretation for policy implications.

Our response to these conceptual problems was to differentiate between the *deliberative outputs* and the *analytical outputs* of the deliberation. Deliberative output rely primarily on the ratified collective statements made by participants. Reporting deliberative outputs should not require considerable analytical treatment beyond presenting a comprehensive overview of participants' explicit collective position on a given topic. Most importantly, because deliberative outputs should be ratified by participants, they need to be formulated in such a way that participants recognize their own positions (unlike some academic papers involving complex

analysis of data). In the case of the 2007 BC Biobank Deliberation, we defined the deliberative output as constituted by the three small group reports and the large group report based on the final group discussion, all of which were ratified by participants. Inconsistencies between reports require differentiation between two levels of consensus, which provide an indication of how much strength to read into a given position on an issue. In particular, we differentiate between:

1. Areas of strong consensus: deliberative consensus was achieved in discussions in the large group with all participants,
2. Areas of limited consensus: 1 or 2 groups reached deliberative consensus, but the issue was not discussed in the remaining group(s), and was not raised during the final large group discussion. (Issues that were discussed in all 3 groups were generally also raised in the large group discussion.)

Persistent disagreements were also identified in the deliberative outputs; we view the articulation of disagreement as especially significant for indicating contentious areas that must be attended to by policy that seeks to reflect the range of public interests associated with biobanks.

In addition to these deliberative outputs (for a comprehensive outline, see O'Doherty and Burgess 2009), the deliberation yielded important insights on several dimensions. For instance, an ethnographic and transcript analysis of the deliberation yielded important insight about the discursive logics utilized by participants (Walmsley 2010). Similarly, approaching the transcripts using the analytical lens of positioning theory provides a novel understanding of the way in which participants draw on different aspects of their identity to warrant the positions they take during deliberation (O'Doherty and Davidson 2010). These types of analytical output are not only useful evaluations of the proceedings of the deliberation, they also help us to develop a deeper understanding of the dynamic processes underlying the social activity of deliberation.

A further critical issue to consider in this context is the implementation of results of deliberation. In the design and implementation of the BC Biobank Deliberation particular attention was given to the way in which issues were presented to participants for deliberation. In particular, the problems associated with biobanks were presented from sometimes dramatically different perspectives on biobanking before participants were asked to deliberate themselves. Together with facilitation, these alternative framings were intended to avoid deliberations being 'captured' by one set of vested interests. Moreover, the deliberations were minimally structured with regards to content as participants were given only two deliberative tasks: (1) discuss your hopes and concerns for biobanking and (2) design a BC biobank. The purpose of this deliberation structure was to avoid a framing of the issues being pre-imposed by the researchers, and allow framing to be emergent from the deliberations themselves (see also Walmsley 2009). This design choice has several implications. On the one hand, we have a strong degree of confidence in the validity of the deliberative outputs. Because of the absence of content framing to structure deliberation such conclusions as full consensus on 'in principle' support for biobanks have high

credibility. On the other hand, the lack of tight framing of questions to be deliberated means that it is difficult to infer policy input from the deliberations.

The outcomes of the first BC Biobank Deliberation thus provided useful guidance to biobankers and regulators. However, to provide more specific guidance on biobanking protocols, a second deliberation was conducted that was geared towards the particular case of the BC Biolibrary (Watson et al. 2009). In this second deliberation the conclusions of the first deliberative engagement was combined with consideration of the particular dilemmas faced by biobankers in an institutional context to frame more specific questions (O'Doherty and Hawkins 2010). The results of this second deliberation are currently being used by the BC Biolibrary to structure institutional protocols and governance on a more fine-grained level.[5]

At the most basic level of analysis, both deliberations demonstrated that it is possible to have informed deliberative engagement on biobanks in which the participants respectfully engage and produce clear articulations of convergences and divergences of group opinion (Burgess et al. 2008). The manner and substance of discussions suggest that the strong support for biobanks that was ratified by the large group did not simply reflect the dominant discourse of presumed health benefits from investment and facilitation of science. In the large group discussions there was consideration of how even scientific research without health benefits was viewed as a worthwhile output of biobanks. Small groups articulated varying levels of trust in the scientific community, leading to large group discussion of the role of industry in biobanks, with both supportive and critical perspectives being expressed. As reported by Walmsley (2009), one small group elected to present their early discussions as a play rather than through a single representative. Their presentation was about mad scientists and whether the actions of unscrupulous or naïve scientists could lead to unethical uses of biobanks and related research. Other groups raised the issue of unanticipated consequences, sometimes by referring to other instances of science leading to unintended consequences (cf., Wilcox 2009). While it is not possible to rule out that the support for biobanks was a reflection of the unexamined faith in health research, it is also clear that there was explicit opportunity to consider and challenge that assumption. Further, the one strong condition for biobanks was governance that is independent of funders and researchers (Burgess et al. 2008; Secko et al. 2009).

In addition to the reports described above the organizing team for the deliberation presented invited and submitted peer reviewed conference and policy events as well as publications. These included invitations to speak at workshops and conferences for groups with responsibility to write policy briefs and revise ethics guidelines relating to genetic testing and biobanks. A colleague from the Mayo Clinic in Rochester, Minnesota observed the event and collaborated to use the deliberative design at Mayo. The Western Australia Office of Population Health Genomics adopted the design for use with stakeholders, and then again with public participants. The outcomes from their process were used to revise the draft OECD guide-

[5] For a comprehensive overview of the deliberative outputs of the 2009 event see O'Doherty et al. (2012).

lines (OECD 2009) to write their own draft policy on biobanks. Although difficult to track, these extended communications enhanced the possibility of outcomes arising from the deliberative engagement.[6]

Conclusion

Informed deliberative input of diverse publics into policy is achievable. This is not to say that it is always possible or desirable. Some issues, deadlines, and political or economic contexts will make it less desirable or feasible to attempt to seek informed public input on a policy question. For example, the existence of a human right or of a legal obligation is unlikely to be aided by informed deliberative public input. Alternatively, how to implement human rights concerns in complex social environments that present disincentives might be amenable to a process designed to build a civic awareness and commitment. The recruitment, process and informing of participants is relatively expensive, and must be done carefully. Further, opportunities for this kind of engagement have the chance to be transformational in sense that participants are stimulated to extend the informed deliberation beyond the confines of the mini-public to wider social groups and even beyond the topic of the deliberation. But when there is little effect as a result of deliberative events, it is also possible to further disillusion participants and observers about their ability to influence important decisions. It is vital that deliberations be carefully assessed in terms of the appropriateness of the issue, whether there is adequate time and resources, and a genuine opportunity to influence the decisions, whether policy or implementation of policy at a practical level.

In situations involving policy or implementation decisions that must reflect the collective interests of a diverse population, informed deliberation can support legitimate decision making bodies by providing the architecture of convergences and divergences of informed deliberative group opinion. Although this is not sufficient to determine policy, it can provide input that anticipates how a population will respond given additional information and an orientation toward what is in the collective interests while considering their own individual or sub-group interests. This may be particularly helpful in complex situations with strong interest groups who may have disproportionate influence on the decision making bodies. Further, deliberation in a mini-public as described above is an opportunity to determine a more robust perspective on public interests than is reflected by top-of-head responses to survey questions without running the very high expense of attempts to be representative of the population. The costs of deliberative mini-publics are not insignificant, but the investments of public funds and shaping of the future of society presented by some policy choices easily justify supplementing decision making with the deliberations of informed publics.

[6] For a review of additional deliberations and the importance of involving decision makers in the events to enhance outputs, see Burgess (2014).

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