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The Ethics and Governance of Human Genetic Databases

European Perspectives

Matti Häyry, Ruth Chadwick,
Vilhjálmur Árnason and Gardar Árnason

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European Perspectives

The Medical Biobank of Umeå in Sweden, deCODE's Health Sector Database in Iceland, the Estonian Genome Project and the UK Biobank were planned to contain health data and genetic data from large populations. Some include genealogical or lifestyle information. They are resources for research in human genetics and medicine, exploring interaction between genes, lifestyle, environmental factors and health and diseases.

The collection, storage and use of this data raise ethical, legal and social issues. In this book, bioethics scholars examine whether existing ethical frameworks and social policies reflect people's concerns, and how they may need to change in light of new scientific and technological developments. The ethical issues of social justice, genetic discrimination, informational privacy, trust in science and consent to participation in database research are analysed, whilst an empirical survey, conducted in the four countries, demonstrates public views of privacy and related moral values in the context of human genetic databases.

The research presented in this book was conducted within the project 'Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison', funded by the European Commission's 5th Framework Programme (QLG6-CT-2001-00062).

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Cambridge Law, Medicine and Ethics

This series of books was founded by Cambridge University Press with Alexander McCall Smith as its first editor in 2003. It focuses on the law's complex and troubled relationship with medicine across both the developed and the developing world. In the past twenty years, we have seen in many countries increasing resort to the courts by dissatisfied patients and a growing use of the courts to attempt to resolve intractable ethical dilemmas. At the same time, legislatures across the world have struggled to address the questions posed by both the successes and the failures of modern medicine, while international organizations such as the WHO and UNESCO now regularly address issues of medical law.

It follows that we would expect ethical and policy questions to be integral to the analysis of the legal issues discussed in this series. The series responds to the high profile of medical law in universities, in legal and medical practice, as well as in public and political affairs. We seek to reflect the evidence that many major health-related policy debates in the UK, Europe and the international community over the past two decades have involved a strong medical law dimension. Organ retention, embryonic stem cell research, physician assisted suicide and the allocation of resources to fund healthcare are but a few examples among many. The emphasis of this series is thus on matters of public concern and/or practical significance. We look for books that could make a difference to the development of medical law and enhance the role of medico-legal debate in policy circles. That is not to say that we lack interest in the important theoretical dimensions of the subject, but we aim to ensure that theoretical debate is grounded in the realities of how the law does and should interact with medicine and healthcare.

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European Perspectives

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1 Introduction: some lessons of ELSAGEN

Vilhjálmur Árnason

The investigation of ELSAGEN (Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison), which was funded by the European Com-mission from 2002 to 2004, was occasioned by plans to construct population-wide databases in the four participating countries: deCODE's database in Iceland, the Estonian Genome Project, UK Biobank and Medical Biobank of Umeå in Sweden. Interdisciplinary research teams – with scholars and students from philosophy, law and sociology – were formed at ethics centres of six universities in these four countries: the University of Iceland, which coordinated the project, Tartu University in Estonia, Lund University in Sweden and the Universities of Central Lancashire, Lancaster and Oxford in the United Kingdom. This research also benefited from the network 'The Ethics of Genetic and Medical Information', financed by the Nordic Academy of Advanced Study (NorFA, now NordForsk) from 2002 to 2006.

This research, therefore, concerns databases which are new or under construction and which will collect information specifically for the intended multi-disease and population health research. A human population genetic database is a collection of genetic, medical and, in some cases, genealogical data from a large number of people, arranged in a systematic way so as to be searchable.[1] As a rule, such databases are intended to provide data for research in human genetics and medicine, exploring interaction between genes, lifestyle, environmental factors and health and diseases. They are mainly non-clinical databanks in the sense that the aim is not to gain information about individuals for clinical intervention but to obtain general knowledge about diseases and to improve health and health services. More specifically, the aim of the research is to identify genes linked to common diseases and to the regulation of drug response as a basis for drug development. Some of the databanks are also intended for clinical use where the aim is to gain data

[1] See HUGO Ethics Committee, 'Statement on Human Genomic Databases', 2002.

about individual participants and inform them about their health risks and possible ways to deal with them (for example, the 'gene card' in Estonia). There are different sets of ethical questions at issue in the cases of clinical vs. non-clinical databanks: ELSAGEN concentrated on the latter, i.e. on issues concerning the collection, storage and use of data mainly intended for genetic epidemiology and pharmaceutical research.[2]

The ELSAGEN research project had two major objectives: (I) to anticipate and address questions raised by recent developments in genetics research by providing knowledge of ethical, legal and social aspects of population-based human genetic databases; and (II) to consult citizens in order to gain knowledge of public views of privacy and related moral values in the context of human genetic databases.

The main theoretical tasks of the project can be divided into five categories: (1) empirical mapping, i.e. finding out what are the actual policies and people's concerns regarding human genetic databases in the four countries; (2) interpretive, comparative analysis of existing laws, policies and views; (3) conceptual analysis of the basic categories in the moral discourse about databases, such as privacy, consent, discrimination and social benefits; (4) critical analysis of arguments, laws, policies and views that have been put forth or voiced concerning these issues; and (5) finally, establishing how existing ethical frameworks and social policies reflect people's concerns and how they need to change in the light of new scientific and technological developments.

In order to deal with these theoretical tasks and to reach the objectives of ELSAGEN, five workpackages were formed. The following is a brief description of these workpackages and a summary of the main lessons to be learned from them. The main results of the research work are described in the individual sections of this book.

1. A Workpackage on National and European Values was divided into (i) an empirical survey which was to provide knowledge about public views on privacy concerning human genetic databases, people's trust in public and commercial organizations with regard to the collection and storage of personal data, and to what extent these views and attitudes vary between the four countries; and (ii) bioethical analysis of the results.

   Some of the most significant results from the empirical survey concern people's perception of the trustworthiness of professionals and institutions. Not surprisingly, previous experience of gene technology

[2] For a general discussion of ethical and legal aspects of databanks, see e.g. B. M. Knoppers (ed.), *Populations and Genetics. Legal and Socio-Ethical Perspectives* (Leiden: Martinus Nijhoff, 2003).

seems to shape citizens' views and concerns in this respect. Thus there is generally more trust in genetic science and scientists among Estonians and Icelanders than there is in England. If people feel that they can trust scientists and institutions, they seem to be willing to further genetic science and believe that it will improve their health and welfare even though in many cases they do not claim to understand the issues. The bioethical implications of the survey are discussed specifically in the concluding chapter of this book.

2. A Workpackage on Social Issues was divided into (i) governance – analysis of the exercise of political, economic and administrative authority in the management of databases; (ii) discourse on databases – analysis of the public discourse on the databases, studying the types of arguments used in the debates; and (iii) social justice – analysis of conceptions and applications of social justice in relation to the databases.

   It is striking that none of the four databanks that were the focus of the research are in operation, at least not according to the plans that were the focus of the ELSAGEN research. Although genetic databank research in Iceland is thriving, the Icelandic HSD project has stalled. The Swedish company UmanGenomics has ceased operating, and the plans in the UK and Estonia are still in (slow) progress.[3] There are different reasons for the slowness or lack of progress in each case, which cannot be discussed here, but the general lesson is that public consultation is an important factor that should be undertaken early in the process. It is time-consuming but crucial for building trust among prospective participants. This requires an extensive informed public debate in time to feed into the policy- or law-making processes. Another important lesson for governance is that political authority and regulation should be kept independent of the commercial interests that most often need to be harnessed in order to finance the projects. This separation is an important precondition for trust, and it requires careful thought about the relationship between community ownership and commercial interests. Finally, on the issue of social justice, there is a tension between global and local relevance. As Chadwick and Wilson have pointed out, while global arguments are used for their implementation, the benefits of databases may reside in their local relevance.[4] Other research has shown that people are motivated by the

[3] The Medical Biobank of Umeå is still functioning, however.

[4] R. Chadwick and S. Wilson, 'Genomic Databases as Global Public Goods?', *Res Publica* 10 (2004), pp. 123–134.

vision that all population groups get equal access to research results.[5] Benefit-sharing discussions need to take account of these complexities as both the justifications and the responsibilities for benefit-sharing change when a local research context is switched to one where concerns of global justice become relevant.[6]

3. A Workpackage on Law was divided into (i) collection of data on laws, regulations and other relevant documents; (ii) analysis of common issues and problems; and (iii) issues such as privacy, consent, responsibility, ownership and access to information which were scrutinized in view of developing a normative framework.

   An important lesson from the legal research is that there is a striking lack of standardized guidelines, and this inhibits co-operation among researchers in this field, even at the European level. The research also revealed a need to map the landscape of population databases and to distinguish in legislation between different kinds of databases and database research. National legislation about human population databases is partly based on misleading paradigms, and such databases are not always covered by the legislation. One problem is that legal definitions do not adequately reflect current practice. This fact points towards the importance of consulting scientists or facilitating dialogues between them and ethical, legal and social scholars about these issues. It is also important to consult the public, of course. The concluding chapter of this book deals with the question of how the law reflects the concerns of the citizens as they appear in the empirical survey.
4. A Workpackage on Ethical Issues was divided into (i) privacy – a conceptual analysis of privacy and an ethical analysis of issues of protection of personal genetic and medical information; (ii) consent – a conceptual analysis of consent and an ethical analysis of issues of consent of participants in population-based human genetic databases; and (iii) genetic discrimination – an ethical and conceptual analysis of the issue of possible genetic discrimination in the context of population-based human genetic databases.

   In the minds of the public, privacy seems to be closely related to trust. It is essential for trust that people have good reasons to believe that their privacy is protected. Even though the main emphasis in the discussion has often been on coding techniques and legal technicalities, there will

[5] K. Hoeyer, T. Mjörndal, B.-O. Olofsson and N. Lynöe, 'Informed Consent and Biobanks: A Population-Based Study of Attitudes Towards Tissue Donation for Genetic Research', *Scandinavian Journal of Public Health* 32 (2004), pp. 224–229.

[6] See K. Simm, 'Benefit-Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Human Genetic Research', *Genomics, Society and Policy* 1, 2 (2005), pp. 29–40.

also be instances in the process where participants have to rely on traditional confidentiality as a professional moral requirement. This is one of the reasons why trust is a crucial matter and also why the professional integrity of the scientists must not be forgotten in the discussion. In her chapter on trust, Margit Sutrop argues that it is important to avoid both blind trust and irrational mistrust in building up support for databases. Trust needs to be based on critical reflection on the competence and goodwill of those trusted and it needs to take into account possible risks related to database research.

People seem also to connect privacy with control of information. However, human population databases are poorly equipped to allow participants much individual control over information once it has been stored. If participants have good reason to believe that they can trust the institutions which regulate the research, the people who work with the information and also the technical system which protects it, the issue of privacy should not be a major obstacle in the effort to balance participants' interests and scientific research interests. A key precondition for this trust is that information will under no circumstances be handed to parties who might be motivated to use it against the participants, such as employers or insurance companies.

This issue relates to the issue of discrimination, which is a major concern of the public. Lena Halldenius argues that the standard account of discrimination needs to be reconsidered in order to account for and effectively prevent genetic discrimination, which requires a strong public health system and strict regulation of private health insurance. Building trustworthy overseeing institutions with transparent and reliable guidelines also serves a major role in ensuring public trust. Participants must be correctly informed about the use of their data and assured that they will only be used for the medical research purposes initially consented to. Non-deception is a precondition for both trust and voluntariness.

Privacy also relates directly to the question of consent for participation in database research because, generally, there is an inverse relation between the stringency of privacy requirements and the emphasis on consent. Anonymization of data (so that it is made irretrievably unlinkable) obviously increases protection and may thus lessen the need for consent, but it also reduces possible research and medical benefits. Since databases are basically resources for research, the data stored in them are mainly intended for (at least) secondary use. Therefore, it is impossible to foresee the exact use of data for research at the time of collection. This creates a particular challenge for the ethics of database research.

The discussion in ELSAGEN was, naturally, oriented towards the particular databases that were under construction in the participating countries and took account of the experiences of them. The emphasis was on the need to find a middle ground between open, unrestricted consent and standard, specified informed consent. It is proposed that participants would be asked to authorize the use of their data for described healthcare research that is foreseeable at the time of collection and for comparable research permitted by research ethics committees. This authorization, which can be regarded as an explicit consent to clear conditions for use, protection and regulation, is in the spirit of informed consent, but it is more general and open.[7] It is argued, however, that such authorization, for participation in research on data that have been collected in human genetic population databases of the type discussed in the ELSAGEN research, meets the moral demands of respecting the person of research participants and provides sufficient grounds for voluntary choice and for regulation that respects that choice.

5. Finally, a Workpackage on Knowledge, Values and Human Rights was divided into (i) fundamental concepts – analysis of the fundamental concepts of bioethics and their relation to human genetic databases; (ii) effects on ethical frameworks – an ethical analysis of how ethical frameworks mutate and change in the light of new technologies; and (iii) database sciences in context – a critical analysis of the social, historical and philosophical context of the science and technology on which the human genetic databases are based.

   The upshot of the analysis of fundamental concepts in bioethics is that the widely accepted 'American' principles of respect for autonomy, protection from harm and observance of justice, paired with their 'more European' counterparts of respect for dignity, precaution and solidarity, are of major importance in the ethical discussion of databases. As Matti Häyry has argued, bioethical principles 'should be employed to promote discussion, not to suppress it' and 'it does not really matter where they came from, if they can be used to promote sensible bioethical discussion'.[8] Respect for dignity and autonomy is fleshed out in responsible procedures of privacy and consent. Protection from harm is a major responsibility of ethical review boards. Observance of justice comes primarily to rest in the procedures for

[7] For an argument along these lines relating directly to the Icelandic case, see V. Árnason, 'Coding and Consent. Moral Challenges of the Database Project in Iceland', *Bioethics* 18 (2004), pp. 39–61.

[8] M. Häyry, 'European Values in Bioethics: Why, What, and How to be Used?', *Theoretical Medicine and Bioethics* 24 (2003), pp. 199–214, at p. 199.

protecting vulnerable research subjects and in the fair distribution of benefits of the research.

In this context it is crucial to note that the existing ethical frameworks for research were primarily formed either for the type of research where there is a direct physical participation, such as in clinical trials, or for more traditional epidemiological and statistical use of data. Participation in genetic database research is of another kind and raises separate questions for ethics and governance. The legislation, governance and ethical regulation of these new kinds of databases must reflect their specific and various research uses and purposes and take into account the experience of the scientists who have been involved in database research practice. Information technology, for example, has not only enabled the construction of these databases but also provided us with new and effective means of keeping participants informed. This offers participants ways of checking the use of data and facilitates dynamic opt-out procedures. Two of the chapters in the section on political considerations are thus on the impact of biobanks on ethical frameworks and on the issues of governance.

Finally, even though much emphasis is laid in this book on actual public concerns and existing legal regulations, it also takes on the theoretical task of critically analysing the cultural context of genetic science and technology. We are entering a new era of multifaceted commercialized databases that have been enabled by an enormous growth in genetics in combination with advanced computer technology. As a consequence, the traditional research ethos is in a state of upheaval and we are facing new challenges. It is important to address people's concerns, but they are often not based on good information about these complex issues and they are largely influenced by genetic ideology. Therefore, empirical mapping, legal interpretation and conceptual analysis must be complemented with a critical examination of the science and technology on which human genetic databases are founded and of the prevailing social discourse. The chapters by Piia Tammpuu and Gardar Árnason are analyses of such discourse which often furthers interests other than those of the public and the research participants.[9] However, a strong protection of these latter interests, as well as informed public discussion and scientific literacy, is a precondition for the possibility of human population databases becoming a genetic wealth of nations.

[9] On this point, see also V. Árnason, 'Sensible Discussion in Bioethics: Reflections on Interdisciplinary Research', *Cambridge Quarterly of Healthcare Ethics* 14 (2005), pp. 322–328.

Part I

Background

2 On human genetic databases

Gardar Árnason

Human genetic databases have the primary purpose of providing data for research in human genetics and medicine. They combine health data and genetic data from a large population, and include in some cases genealogical information or lifestyle information.

The authors of this volume focus on four human genetic databases in as many countries: the Medical Biobank of Umeå in Sweden, deCODE's Health Sector Database in Iceland, the Estonian Genome Project and UK Biobank. To date only the first of the four has been established, but it has had serious operational problems. The Estonian Genome Project and UK Biobank are slowly progressing, but deCODE's plans to establish a health sector database appear to be on hold.

The Medical Biobank of Umeå is owned and operated by the University of Umeå and Västerbotten county council. The University and the county council founded together the company UmanGenomics,[1] which is responsible for the commercial uses of the biobank. The biobank is based on a cohort study of cardiovascular disease and diabetes, which have a relatively high frequency in the county of Västerbotten. Since 1990 residents of Västerbotten county have been invited for a health check-up when they turn forty, fifty or sixty. They have been invited to donate blood samples to the biobank, which has resulted in a database with about 100,000 samples (about 70% donated by participants in the study, the rest donated by participants in other studies) which is growing by about 5,000 samples each year. Information about health and lifestyle is also collected from participants.

The Swedish Medical Research Council drew up detailed ethical guidelines for biobanks in 1999. Informed consent is sought from all participants, both for inclusion of data in the database, and, in principle, for individual studies. A research ethics committee can allow the use of data for studies without requiring informed consent under certain conditions,

[1] See UmanGenomics' website at www.umangenomics.com.

for example if the new study is sufficiently similar to previous studies where informed consent has been given, or if no personally identifiable information is used.[2]

deCODE's Health Sector Database is to be owned by the Icelandic state, but established and operated, through an exclusive licence, by deCODE genetics Inc., a biotechnology company incorporated in Delaware, USA, but based in Iceland.[3] The database is to include data from medical records from the Icelandic population, and the data can be temporarily cross-referenced with genetic data and genealogical data. The database is expected to include data and samples from about 250,000 participants. Informed consent is to be sought for genetic data, but health data is to be collected from medical records unless the individual 'opts out' by signing an opt-out form. Genealogical data is considered public information and no consent is required for its inclusion in the genealogical database.[4]

A Supreme Court decision in 2003 allowed close relatives of a diseased person to prevent data about that person being entered in the Health Sector Database. This Supreme Court judgment requires changes to the current laws on the Health Sector Database, but a new bill does not seem to be on the horizon. The Icelandic database project appears therefore to be on hold.[5] Nevertheless deCODE genetics Inc. has established both a genetic database with around 100,000 samples and a comprehensive genealogical database about the Icelandic nation. Information about health and lifestyle is also collected from participants and the company is doing research on various diseases.

The Estonian Genome Project aims to collect health and genetic data from up to 1 million Estonians. The database will be owned by the state, but operated by the Estonian Genome Project Foundation, a non-profit organization established by the Estonian Government.[6] The Estonian

[2] See A. Abbott, 'Sweden Sets Ethical Standards for Use of Genetic "Biobanks" ', *Nature* 400 (1999), p. 3; A. Nilsson and J. Rose, 'Sweden Takes Steps to Protect Tissue Banks', *Science* 286 (1999), p. 894; Swedish Medical Research Council (MFR), 'Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research', adopted by the Swedish Medical Research Council in June 1999 (Dnr 1999–570).

[3] See deCODE's website at http://www.decode.com.

[4] V. Árnason and G. Árnason, 'Informed Democratic Consent? The Case of the Icelandic Database', *Trames* 8 (2004), pp. 164–177; V. Árnason, 'Coding and Consent. Moral Challenges of the Database Project in Iceland', *Bioethics* 18 (2004), pp. 39–61.

[5] R. Gertz, 'An Analysis of the Icelandic Supreme Court Judgement on the Health Sector Database Act', *SCRIPT-ed* 1:2 (2004), http://www.law.ed.ac.uk/ahrb/script-ed/issue2/iceland.asp.

[6] The information about the Estonian Genome Project is from its website, http://www.geenivaramu.ee, and the website of the Estonian Genome Foundation, http://www.genomics.ee.

database seeks written consent from participants, but it cannot be called informed since no detail is provided about the research or studies which will use the samples and data. The participant is informed only that the tissue sample and medical and genealogical information will be used 'for genetic research, public health research and statistical purposes in conformity with the law'.[7]

Three pilot projects were completed in 2005. By the end of that year the database included samples from about 10,000 participants, and it is expected to grow to 100,000 samples by 2009. The Estonian database differs from the others primarily in that it will be used for clinical purposes, that is, doctors will be able to get information about their patients from the database.

UK Biobank is a project funded by the UK Medical Research Council, the Wellcome Trust, the UK Department of Health and the Scottish Executive,andhostedbythe.Theaimisto
collect tissue samples and health data (including information about lifestyle) from 500,000 volunteers, in order to establish a resource for medical research, in particular studies that are concerned with the interaction between genes and the environment. The first phase of the project started with initial pilot studies early in 2005. The second phase, which is to test the entire process of collecting, storing and using the data, started in late 2005. The full project got under way in 2006.[8]

A public Ethics and Governance Framework was developed in 2003 and revised in 2005.[9] An independent body, the Ethics and Governance Council, was established to oversee the Framework and to safeguard public interests as well as the interests of the participants. According to the Framework, written consent is sought from all participants, but, as is the case in the Estonian Genome Project, participants are not informed in any detail about the studies which will make use of their data.

All four databases raise serious issues concerning the informed consent of participants, since the databases are not made for specific studies but as resources for research in general. Such large-scale databases also raise complex issues regarding privacy protection, access, ownership, benefit-sharing, potential discrimination and public health policy, to name but a few of the issues. Some of these issues are new, others acquire new significance in this context, but none of them are easily solved.

[7] According to the Gene Donor Consent Form on the website of the Estonian Genome Project: http://www.geenivaramu.ee.
[8] See the website of UK Biobank at http://www.ukbiobank.ac.uk.
[9] UK Biobank, 'The Ethics and Governance Framework' at http://www.ukbiobank.ac.uk/ethics/efg.php.

3 American principles, European values and the mezzanine rules of ethical genetic databanking

Matti Häyry and Tuija Takala

Human genetic databanks are, on a local and limited scale, a reality in all countries where healthcare systems are reasonably advanced. Tissue samples, which can be genetically analysed, have for some time been stored in hospitals and laboratories for various medical and scientific reasons. It was not, however, until plans for wider genetic databanks were introduced that governments and the international bioethics community started to discuss seriously the ethical, legal and sociocultural issues involved in storing genetic information.[1]

Our task in the ELSAGEN (Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison) project during 2002–2004 was to prepare a philosophical analysis of the main ethical concepts and principles used in debates concerning nationwide genetic databanks. Particular attention was to be paid to the possible differences between the most prominent American and European approaches to the matter. The following preliminary account was produced at the early stages of the ELSAGEN project – before we had received any knowledge about the results of the other research teams. It therefore formed a hypothesis for our subsequent work rather than establishing any normative conclusions.

From a false start to a new beginning

Our original hypothesis was that there must be a clear distinction between the American and European approaches to the ethics of human genetic

[1] The expressions 'human genetic databanking' and 'genetic databanking' are used interchangeably in this chapter. They both refer to both local and national, limited and wider collection, storage and dissemination of tissue samples and genetic data, although it is worth noticing that some of the criticisms we introduce may make more sense in the case of national or international genetic databanks.

databanking. This is a view held by many philosophers and ethicists in continental Europe, and it reflects the plausible idea that there can be insurmountable cultural differences between Americans and Europeans.[2]

In the course of our inquiry, however, this hypothesis was well-nigh falsified. It seems that, at least on the level of practical rules for genetic databanking, different responses are based on divergent, and not geographically confined, *interpretations* of the various principles, rather than on the *choice* of principles or values.[3] To cite an example, an American bioethicist using the concept of 'autonomy' can advocate the same rules for databanking as a European moralist who insists on describing the situation in terms of 'dignity'. On the other hand, two people who share a belief in, say, the notion of 'justice' can arrive at wildly different practical conclusions.

To demonstrate our findings we have employed, in the chapter, the idea that action-guiding norms for genetic databanking should serve two goals. They should address the concerns different groups of people have, and they should protect and promote the values held and safeguarded by lawgivers. We call these action-guiding norms 'mezzanine rules', because conceptually they occupy the middle ground between the actual beliefs and attitudes of the general public studied by social scientists, and the more idealized views about 'what ought to be done' expressed by philosophers and theologians in their work. We have initially presented the *concerns* that people may have in terms of *issues* like 'privacy' and 'security', identified by legal and ethical experts. While this is enough for the purposes of this chapter, further conceptual and empirical studies in this area are clearly needed.

The questions

We seek in the chapter tentative answers to eight questions, or sets of questions. These are:

- Why is human genetic databanking important, how is it conducted, and what is it in practice?
- Which issues are generally seen as important in human genetic databanking among lawyers and ethicists?

[2] Cf. Matti Häyry, 'European Values in Bioethics: Why, What, and How to be Used?', *Theoretical Medicine and Bioethics* 24 (2003), pp. 199–214.

[3] The terms 'principle' and 'value' are used interchangeably in this chapter, unless otherwise specified. This reflects the American general tendency to speak about 'principles' (in bioethics), and the European general tendency to speak about 'values', even when everybody seems to be talking about roughly similar ethical or moral entities.

- What practical norms of conduct, or mezzanine rules, can be formulated to address these issues?
- How do the formulated mezzanine rules protect and promote the American values expressed by the four well-known Georgetown principles?
- What, if any, are the European values and principles that provide an alternative to the Georgetown model?
- How do the formulated mezzanine rules protect and promote these alternative values and principles?
- How different, or how similar, are the American and European interpretations of ethical genetic databanking?
- What are the lessons to be learned from this preliminary analysis?

The first question is answered only summarily, while the others are examined in more detail.

The contested nature of human genetic databanking

There seems to be no agreement on the ultimate nature of genetic databanks, although several ideas have been expressed. Some see such databanks as public welfare agencies which aim at the greater health of present and future generations. Others see them as eugenic institutions which aim at the improvement of the race. Yet others think of them as commercial ventures to cash in on the value of genetic information, which can then be handed over to individual citizens, communities, nations, scientists or private corporations. The experiences and expectations in Iceland, Estonia, Sweden and the United Kingdom are all slightly different in this respect. It is clear, however, that the most significant *reasons* for establishing and running human genetic databanks include the promotion of commercial interests, the prospect of scientific advances and the promotion of public health.[4]

As to how genetic databanks work in practice, there are many different systems in operation, or being planned. Generally speaking, the following three functions are essential to them:

- the *collection* of tissue samples or genetic data;
- the *storage* of samples or data;
- the *dissemination* of samples or data.

[4] See, e.g., Jeffrey H. Barker, 'Common-pool Resources and Population Genomics in Iceland, Estonia, and Tonga', *Medicine, Health Care and Philosophy* 6 (2003), pp. 133–144; Margit Sutrop and Kadri Simm, 'The Estonian Health Care System and the Genetic Database Project: From Limited Resources to Big Hopes', *Cambridge Quarterly of Healthcare Ethics* 13 (2004), pp. 254–262.

For the purposes of our examination, these three functions sum up the most important practical aspects of genetic databanks.

Which ethical issues have been seen as important in genetic databanking?[5]

The ethical issues typically discussed in the context of human genetic databanking are related, in one way or another, to *privacy*, *consent*, *confidentiality*, *security* and *public interest*. These ethico-legal concepts are not a perfect substitute for people's actual concerns, but they can provide us with a rough outline of the worries individuals and groups have had in similar matters. And they can be employed to test the differences and similarities between the American and European approaches.

Privacy

Genetic databanks need tissue samples or genetic data to function. The only way to procure these is to invade the 'private sphere' of individuals, either by interfering with their physical integrity or by accessing databases which contain personal and potentially sensitive information concerning individuals. The collection, storage and use of such data gives rise to at least three kinds of issues related to the privacy of individuals (and perhaps groups).

Respect for *physical privacy* implies that other people are not normally allowed to seize, search or touch us unless we have given them permission to do so, or they can otherwise justify their actions. There are two exceptions. Consent (to be discussed below) can make seeming invasions on physical privacy legitimate. And even in cases where consent is not forthcoming, other considerations can sometimes justify invasions into our private physical sphere.

There are types of information about us that are considered personal, sensitive and inviolable. Respect for *informational privacy* can mean two things. It can mean that others do not seek or disseminate such information about us. (Consent and confidentiality are important here.) It can also mean that others, who possess such information about us, do not share it with us unless we want them to, or unless they have other valid grounds for doing so.

[5] The following section is heavily influenced by Richard E. Ashcroft's thorough and useful *Ethical, Legal and Social Issues Facing the West London Database Project: A Review of the Literature* (London: NHS Executive London Regular Office Research and Development Office, 2001). There are, however, certain differences in our definitions and approaches. When there are, the source is Matti Häyry and Tuija Takala, 'Genetic Information, Rights, and Autonomy', *Theoretical Medicine and Bioethics* 22 (2001), pp. 403–414.

There are certain decisions which are, so to speak, only ours to make. Some of them concern our bodies, others the attainment and disclosure of information about ourselves. These define the domain of our *decisional privacy*. Respect for this can imply, for instance, that we have a 'right to choose what happens in and to our bodies', as some people have claimed in the abortion debate. Decisions concerning personal data are intrinsically related to the informational aspect of our privacy.

Consent

Permission to seek, store and disseminate genetic information about individuals can be obtained in many ways. The standard approaches in the biomedical context are based on the notions of 'actual', 'implied', 'hypothetical' and 'proxy' consent.

Actual consent is the real, genuine permission of the individuals themselves to collect, store and disseminate their tissue samples or genetic data. In medical contexts, consent is, as a rule, considered valid only if three conditions are met. The individual consenting must be competent, not permanently or temporarily unable to make reasonably clear-headed decisions for herself. The consent must be given freely, not as a result of coercion, intimidation or pressure. And the individual must be informed as to what exactly she consents to, and what the implications of the decision for her will, or can, be.

Implied consent (also known as 'presumed consent') is the notion evoked in cases where individuals have not actually consented or dissented to the procedure in question, but others claim that their permission can, nevertheless, be assumed. The claim can be backed up by various strategies. One is to point out that a genuine opportunity to register dissent has been given to individuals, but they have chosen not to use it. Another is to appeal to related evidence which gives indirect support to the assumption, perhaps by showing that the same people have not in the past dissented to similar practices in other fields.[6]

Hypothetical consent (or 'rational consent') can be used even in cases where we know nothing about the actual or probable attitudes of the individuals involved. We can then hypothesize that they are rational or moral in a sense defined by us, and assert that these qualities necessarily elicit, or should elicit, certain responses from them. We may think that no

[6] On how dangerous it is to read more into what people say than they actually do say, see, e.g., Søren Holm, ' "Parity of Reasoning Arguments in Bioethics" – Some Methodological Considerations', in Matti Häyry and Tuija Takala (eds.), *Scratching the Surface of Bioethics* (Amsterdam: Rodopi, 2003), pp. 47–56.

rational person would object to having her genetic data stored. Or we may argue that since individuals have benefited, or will benefit, from other people's willingness to participate, they cannot therefore claim a moral right to opt out.

Proxy consent is introduced in situations where the individuals themselves are temporarily incapacitated, persistently incompetent or dead. The permission in these cases is not sought from them, but from some other people, usually their relatives or friends. This form of consent is resorted to in medical emergencies, in cases where the individuals themselves cannot make reasonably sound decisions, and in dealings with small children.

Confidentiality

In medical and certain other settings, we can consent to share some private information with other people or institutions, *on the condition that* they do not pass it on to anybody else, or at least not to any unauthorized third parties. In theory, confidentiality can be regarded as an absolute or a qualified requirement.

Respect for *absolute confidentiality* would require that the information acquired will under no circumstances be made public, disseminated or passed on to any other, or any unauthorized, parties. Ethicists have sometimes tried to impose this kind of duty on those who receive, in their professional capacity, sensitive and personal knowledge about their patients or clients. In practice, however, strict obligations like this are often difficult to honour.[7]

Respect for *qualified confidentiality* requires a presumption of secrecy, but recognizes the need, in exceptional cases, to breach the confidentiality of individuals, either to uphold other moral principles, or for their own good, or for the good of others. This is linked with, among other things, public interest. It has been argued, for instance, that family doctors should, or should be allowed to, disclose information about potentially lethal socially transmissible conditions to the family members of their patients. In the context of genetics, the claim has been made that blood relatives should be entitled to have access to each other's genetic records.[8]

[7] See, e.g., Raanan Gillon, *Philosophical Medical Ethics* (Chichester: John Wiley & Sons, 1985), pp. 108–109.

[8] See, e.g., Rosamond Rhodes, 'Genetic Links, Family Ties and Social Bonds: Rights and Responsibilities in the Face of Genetic Knowledge', *Journal of Medicine and Philosophy* 23 (1998), pp. 10–30. Cf., however, Tuija Takala and Matti Häyry, 'Genetic Ignorance, Moral Obligations and Social Duties', *Journal of Medicine and Philosophy* 25 (2000), pp. 107–113.

Security

Genetic databanks need systems and procedures to secure the privacy and confidentiality of the people whose samples and records they collect, store and disseminate; and to ensure the ethical use of the information with which they are trusted. Security issues can be approached from at least two angles, which may be complementary.

The promotion of *objective security* is a matter of safety mechanisms, data protection, scientific risk assessment and good professional practice in handling sensitive information. It can be argued that as long as experts in this field are satisfied with the security of the system, this is, in and by itself, sufficient.

Another aspect of the matter is, however, the *sense of security* felt subjectively by individuals, intersubjectively by groups and communities, or politically by nations and international alliances. Several methods can be employed to create and enhance this feeling of *trust*, which may or may not be a function of the objective measures taken.

In liberal democracies, it is usually held that trust can be rightfully achieved by the openness and transparency of the system, and by the honesty and clear accountability of the individuals working within it.[9] In social democracies, it can also be maintained that the political system, and other systems authorized by it, should be regarded as trustworthy, unless a significant portion of the citizenship questions this through democratic processes.

In political environments which do not emphasize democracy, the best way to lull people into a false sense of security is to inform them only selectively – perhaps even by concealing facts which could alarm the public. Since the study of non-democratic responses to genetic databanks falls outside the scope of the ELSAGEN project, and of this chapter, we shall not explore it any further. It is worth mentioning, however, that the widely acclaimed practice of 'promoting public awareness' can assume radically different forms in different political systems. In liberal democracies, the public can be thought to have a *duty to know* about the facts and conjectures behind political decisions. In social democracies, the *right to know* can be stressed. And in non-democratic societies, people presumably have an *obligation to comply* with the inevitable. The 'awareness' to be promoted will not be the same in all these cases.

[9] On the significance of these, see, e.g., Onora O'Neill, 'Informed Consent and Genetic Information', *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001), pp. 689–704.

Public interest

Public interest is a diffuse matter, and respect for it can mean many things, some of which cannot always co-exist peacefully. For instance, 'there is a public interest in the effective ... administration of ... criminal justice; but there is also a public interest in restraining undue ... surveillance of our personal lives'.[10] The first interest would presumably be served by unquestioned police access to compulsory genetic databanks, the second would probably not.

The tension can be directly seen in the formulation of rules for ethical genetic databanking. Respect for privacy, confidentiality, consent and security are all in the public interest. On the other hand, it can also be argued that economic growth, scientific development and the efficient provision of healthcare are in the public interest. But there are cases in which both sets of interests cannot be fully promoted at the same time. Ethical caution can hinder scientific progress, and short-term economic considerations can be inimical to moral sensitivity.

For the purposes of this chapter, we shall consider, under the label of 'public interest', only those issues that are not necessarily covered by the promotion of privacy, confidentiality, consent and security. The main aspects to be considered could then be:[11]

- *personal harm prevention* – the avoidance of harm to an innocent, specified third party;
- *group harm prevention* – the protection from harm of unspecified individuals or a collective social body (perhaps the nation's or community's 'public morality');
- *personal welfare* – the promotion of a specified individual's good against the individual's own wishes;
- *social welfare* – the promotion of a national or communal good such as public health, or the fair and equitable distribution of benefits and burdens;
- *intrinsic public interest vested in public bodies* – the protection or promotion of the claims of public bodies as the representatives of the 'people's voice';
- *judicial considerations of public policy* – the interest in resolving dilemmas and conflicts of interest in courtrooms by reference to principles like 'sanctity of life', 'dignity' or 'public interest', where no clearly defined legal principles are available.

[10] Ashcroft, *Ethical, Legal and Social Issues Facing the West London Database Project*, p. 5.
[11] Richard E. Ashcroft, 'From Public Interest to Political Justice', *Cambridge Quarterly of Healthcare Ethics* 13 (2004), pp. 20–27.

This list is not necessarily conclusive, but, together with the more specific issues we have identified above, it probably records most general concerns people may have concerning human genetic databanking.

What practical rules of conduct can be formulated to address these issues?

Privacy, consent, confidentiality, security and public interest are all important issues, or principles, which can be seen to express people's focal fears, worries and anxieties. But they can be interpreted in different ways, and they can therefore give rise to different practical policies and action-guiding norms, depending on the reading given to them.

We have presented, in table 3.1, the *mezzanine rules* which can, in principle, be ascribed to genetic databankers in order to address people's concerns in practice. The adjective 'mezzanine' refers to the position of these imperatives between popular concerns (approximated here by the five ethico-legal issues) and the values held by legislators and political decision makers. Since the list includes rules derived from different, and sometimes contradictory, readings, not all of them can be included in completed codes of ethical databanking. The rules for which choices have to be made are marked with the symbols '♠', '♣', '♥', '♦', '♪' and '♫'.[12]

The role of 'public-interest' considerations in many cases is to qualify the use of the other rules. This takes two main forms. In legislation and public policy, various public-interest deliberations can provide reasons for playing down the absolute nature of some rules. In practical work, this can be accounted for by observing the laws regulating genetic databanking. When it comes to decision making in particular situations, however, the effects of avoiding harm and promoting welfare can work in the opposite direction. Even if legislation does not explicitly forbid some types of data collection, storage or dissemination, databank employees can be obligated not to proceed, if they feel that somebody's well-being might be put in jeopardy by their actions.

How do the formulated mezzanine rules protect and promote 'American' values?

Many people believe that *the* American approach to ethical issues is captured by the four-principles model formulated at Georgetown University,

[12] Between 1 and 2, 3 and 4, and 11 and 12 an exclusive choice must be made. If you pick one, you cannot pick the other. Among 5–10, 13–15 and 16–18 more than one can be picked, since rules in these groups do not contradict or exclude each other.

Table 3.1. *The possible mezzanine rules of ethical genetic databanking*

	The mezzanine rules of human genetic databanking	The underlying issues
1.	Do not interfere with people's bodies by extracting tissue samples from them without consent! ♠	Strict physical and decisional privacy
2.	Do not interfere with people's bodies by extracting tissue samples from them without consent, unless there are exceptionally good grounds for doing so! ♠	Qualified physical and decisional privacy
3.	Do not collect, access or use tissue samples or genetic data without consent! ♣	Strict informational and decisional privacy
4.	Do not collect, access or use tissue samples or genetic data without consent, unless there are exceptionally good grounds for doing so! ♣	Qualified informational and decisional privacy
5.	Ensure that the individuals consenting are competent! ♥	Actual consent
6.	Ensure that the consent given by individuals is free! ♥	Actual consent
7.	Ensure that the consent given by individuals is informed! ♥	Actual consent
8.	Ensure that individuals have not dissented from the actions you propose to perform! ♥	Implied consent
9.	Ensure that rational individuals would have consented to the actions you propose to perform! ♥	Hypothetical consent
10.	Ensure that proxies have consented to, or have not dissented from, the actions you propose to perform! ♥	Proxy consent
11.	Do not pass on any information given to you in confidence! ♦	Absolute confidentiality
12.	Do not pass on any information given to you in confidence, unless there are exceptionally good grounds for doing so! ♦	Qualified confidentiality
13.	Ensure that the safety mechanisms do not allow tissue samples or genetic information to fall into the hands of unauthorized people! ♪	Objective security
14.	Ensure people's trust in your operation by openness, transparency, honesty and accountability! ♪	Felt security in a liberal democracy
15.	Ensure people's trust in your operation by giving them an opportunity to voice their opinions politically! ♪	Felt security in a social democracy
16.	Do not harm those with whom you come into contact! ♫	Public interest
17.	Attend to the welfare of those with whom you come into contact! ♫	Public interest
18.	Know and abide by the laws pertaining to your work! ♫	Public interest

Washington, DC by Tom Beauchamp and James Childress, and immortalized in their modern classic *Principles of Biomedical Ethics*.[13] Beauchamp and Childress argue that, if interpreted and weighed sensibly, respect for the principles of 'autonomy', 'non-maleficence', 'beneficence' and 'justice' provides adequate response to all major bioethical concerns anywhere in the world.[14] Since, however, the four moral concepts they employ can be read in different ways, it is not always clear what exactly the American approach based on them would be.

More than four principles?

Autonomy means radically different things in the two moral theories on which Beauchamp and Childress originally founded their model.[15] In the duty-based ethics of Immanuel Kant and his followers, all rational beings have a moral obligation to make their own laws in the light of the universal reason they share with all other similar beings.[16] Autonomous action within this doctrine means action that can be equally accepted by every rational agent. In the outcome-based social ethics of John Stuart Mill and his disciples, on the other hand, individuals should be left free to make their own choices, as long as they do not inflict harm on innocent third parties.[17] An individual's autonomous choices in the Millian sense are not necessarily accepted by anyone else. Depending on the notion used, respect for autonomy can take drastically different forms.

Non-maleficence and *beneficence*, too, can be understood in many ways. Basically they require us not to harm, and to benefit, others in what we do. But while some think that this is a professional obligation that should be limited to our patients and clients, others hold that the duty is more general, and should be extended to anyone who can be affected by our

[13] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th edn (New York: Oxford University Press, 2001).

[14] Cf., however, e.g., Søren Holm, 'Not Just Autonomy – The Principles of American Biomedical Ethics', *Journal of Medical Ethics* 21 (1995), pp. 332–338; Tuija Takala, 'What is Wrong with Global Bioethics? On the Limitations of the Four Principles Approach', *Cambridge Quarterly of Healthcare Ethics* 10 (2001), pp. 72–77; Peter Herissone-Kelly, 'The Principlist Approach to Bioethics, and its Stormy Journey Overseas', in Häyry and Takala, *Scratching the Surface of Bioethics*, pp. 65–77.

[15] E.g., in Beauchamp and Childress, *Principles of Biomedical Ethics*, 1st edn (New York: Oxford University Press, 1979).

[16] E.g., Immanuel Kant, *The Grounding of the Metaphysics of Morals* (*Grundlegung zur Metaphysik der Sitten*, 1785), 440, 439 – Immanuel Kant, *Ethical Philosophy*, 2nd edn, translated by James W. Ellington and with an introduction by Warner A. Wick (Indianapolis: Hackett Publishing Company, 1994), p. 44.

[17] John Stuart Mill, *On Liberty* (1859) – John Stuart Mill, *On Liberty and The Subjection of Women* (Ware, Hertfordshire: Wordsworth, 1996), p. 13.

actions. And to complicate matters further, people do not always agree on the definitions of 'harm' and 'benefit', or on the measures that should be taken to prevent harm or to disseminate benefits.

Justice, finally, is one of the most contested concepts in social and healthcare ethics.[18] Some say it demands qualified fairness in the distribution of burdens and benefits,[19] others claim that respect for people's private economic entitlements is sufficient,[20] and yet others insist that only the equal consideration of interests or fulfilment of needs deserves the name.[21] Every interpretation yields different conclusions in practice.

It can be argued that the nature of the Georgetown model is revealed more by what it *excludes* than by the many lines of thought it embraces.[22] The virtue-based ethics of Aristotle and his modern advocates are usually not given a prominent role in the application of the four principles.[23] This may be one reason why some European moralists see the model as distinctly 'American'.

Strict or qualified privacy?

Respect for physical, informational and decisional privacy, as defined by our mezzanine rules 1–4, would presumably promote all the values expressed in the Georgetown principles. Unsolicited intrusions into our private sphere tend to undermine our self-determination, and to inflict physical and mental harm on us. We would probably be benefited by rules prohibiting such intrusions, and an impartial policy against them could also serve the cause of justice. The question, however, is *how strictly* the rules of privacy should be interpreted to achieve these goals.

If we combine a Millian notion of autonomy, a restricted concept of harms and benefits, and the view that wider considerations of distributive

[18] See, e.g., Rosamond Rhodes, Margaret Pabst Battin and Anita Silvers (eds.), *Medicine and Social Justice: Essays on the Distribution of Health Care* (New York: Oxford University Press, 2002).

[19] John Rawls, *A Theory of Justice* (Oxford: Oxford University Press, 1972); Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).

[20] Robert Nozick, *Anarchy, State, and Utopia* (New York: Basic Books, 1974); Robert M. Sade, 'Medicine and Managed Care, Morals and Markets', in William B. Bondeson and James W. Jones (eds.), *The Ethics of Managed Care: Professional Integrity and Patient Rights* (Boston: Kluwer Academic Publishers, 2002), pp. 55–74.

[21] Peter Singer, *Practical Ethics* (Cambridge: Cambridge University Press, 1979); Matti Häyry, *Liberal Utilitarianism and Applied Ethics* (London: Routledge, 1994).

[22] See, e.g., Häyry, 'European Values in Bioethics'.

[23] One version of modern virtue ethics is the ethics of care – see, e.g., Carol Gilligan, *In a Different Voice* (Cambridge, MA: Harvard University Press, 1982). Another version is presented in Edmund D. Pellegrino and David C. Thomasma, *The Virtues in Medical Practice* (New York: Oxford University Press, 1993).

justice should never enter professional–client relationships, our conclusion is that privacy ought to be observed without any exceptions. Put the other way round, a policy of strict privacy (as defined by rules 1 and 3) is in line with a system of values where

- my freedom to control my own body and knowledge about it is sacrosanct;
- professionals should, in their dealings with me, consider only my well-being as I see it; and
- professionals and legislators should *not* consider the implications of such encounters to other individuals or society as a whole.

This individualistic outlook would also be compatible with actual, as opposed to implied, hypothetical, or proxy, consent (rules 5–7), absolute confidentiality (rule 11), tight security (rules 13–15 combined), and the rejection of any public-interest considerations which go beyond the professional–client encounter (in other words, rules 16–18 would be observed only in so far as the client wants them to be observed). Conceptually speaking, this is a perfectly respectable view, but in practice it is usually qualified by other reflections.

People's concerns about privacy are often moderated by their equally serious concerns about morality, equality and the common good. These can be taken into account by employing the more conditional rules of privacy and confidentiality (2, 4, 12) and the more relaxed approaches to consent (8–10). If the four principles are weighted in the direction of Kantian autonomy, universal well-being and social justice, there is no clash between this approach to practices like genetic databanking and the Georgetown values.

What kind of consent?

Consent in one form or another is, no doubt, important in any system that aims to accommodate the principles identified by Beauchamp and Childress. Tendencies to move from actual to implied or proxy consent can be stronger or weaker in different societies, depending on the relative significance given to personal freedom and public-interest claims. But divergent and even opposite concerns can be addressed by adjusting the readings of the four principles.

One interesting disagreement is based on the two main interpretations of autonomy. In the Millian view, the actual uncoerced consent of the people storing their tissue or information in a databank is paramount. Circumstances in which their permission would not have to be asked can be imagined, but the main rule is that the individuals themselves, as empirical beings, should be asked about the collection, storage and use

of information concerning them. In the Kantian view, in turn, actual consent is not necessarily as important. People are autonomous only in so far as they are rational, and their choices can be seen as autonomous only to the degree to which they fulfil the universal requirements of rationality. This means that if people's actual decisions can be defined as irrational, it can be argued that they are not, in fact, sufficiently competent, free and informed. The next logical step is to replace their actual consent by a hypothetical, or rational, assumption of consent.

A general commitment to the Georgetown principles does not, then, determine the precise stand legislators can be expected to take on the issue of asking permission for proposed procedures.

The varieties of confidentiality, security and public interest

Concerns for confidentiality, security and the promotion of public interest can be addressed in many ways, and the efforts to address them can usually be made to cohere with respect for autonomy, non-maleficence, beneficence and justice. An absolute commitment to confidentiality can be justified by convenient readings of autonomy and harm, while more qualified guarantees can be supported by giving more weight to the other principles. Objective security can be defended as a safeguard against harm, and trustworthiness can be required in the name of any Georgetown value. For most public-interest demands there is a corresponding norm in the model devised by Beauchamp and Childress.

This is not, of course, surprising, if we recall the aim of the four-principles approach. In the words of Raanan Gillon, the foremost advocate of the principles in England, they are supposed to provide 'elements of common moral language and a basic moral commitment for health care ethics that is neutral . . . and can be shared by all regardless of their background'.[24]

The flexibility of this approach ensures that any consistent selection of mezzanine principles for genetic databanking, as we have defined them, can be seen to promote the 'American' values of bioethics. If a chosen set of practical rules is in conflict with one reading of the four principles, another interpretation can be employed to show that respect for privacy, consent, confidentiality, security and public interest are always compatible with respect for autonomy, non-maleficence, beneficence and justice.

[24] Raanan Gillon, 'The Four Principles Revisited – A Reappraisal', in Raanan Gillon (ed.), *Principles of Health Care Ethics* (Chichester: John Wiley & Sons, 1994), p. 332.

Which 'European' values can provide an alternative to the Georgetown model?

Many people in Continental Europe seem to feel, however, that the American values summarized in the Georgetown principles are useless in ethical and legal discussions on the eastern side of the Atlantic. They have suggested, instead, that Europeans would be more at home with such values, or principles, as *dignity*, *precaution*, *subsidiarity* and *solidarity*.[25] Let us see what can be meant by these values.

Dignity

Most Western religions and philosophies hold that there is something extraordinarily valuable in human beings – something that we share only with other humans, and possibly with God. This something is, or gives us, our intrinsic worth. It cannot, or at least should not, be taken away from us, and it should never be violated. As for the definition of this inner worth, or 'dignity', however, European ethicists seem to be drawn between three slightly different, and not altogether mutually compatible, interpretations.[26]

In the *Christian* tradition, dignity is, so to speak, a part of God in us, which must not be violated in ourselves or in others. According to this interpretation, dignity belongs to every human being, regardless of gender, race, affluence or social status. It also, and especially, belongs to unborn human beings, that is, foetuses and perhaps embryos. And it belongs to all other human beings who, for one reason or another, cannot reason or communicate with others. The protection of dignity in this sense is often closely linked with respect for the 'sanctity of life'.[27] When it

[25] There are other candidates as well, including 'integrity' and 'vulnerability'. See, e.g., Jacob D. Rendtorff and Peter Kemp (eds.), *Basic Ethical Principles in European Bioethics and Biolaw*, 2 vols. (Copenhagen and Barcelona: Centre for Ethics and Law and Institut Borja de Bioètica, 2000); Henk ten Have and Bert Gordijn (eds.), *Bioethics in a European Perspective* (Dordrecht: Kluwer Academic Publishers, 2001). 'Naturalness' and 'not playing God' are also possibilities – see, e.g., Matti Häyry, 'Categorical Objections to Genetic Engineering – A Critique', in Anthony Dyson and John Harris (eds.), *Ethics and Biotechnology* (London: Routledge, 1994), pp. 202–215; Tuija Takala, 'The (Im)morality of (Un)naturalness', *Cambridge Quarterly of Healthcare Ethics* 13 (2004), pp. 15–19. For a partial justification for the selection we have used here, see Häyry, 'European Values in Bioethics'.

[26] See, e.g., Matti Häyry, 'Another Look at Dignity', *Cambridge Quarterly of Healthcare Ethics* 13 (2004), pp. 7–14.

[27] Nicholas Tonti-Filippini, 'The Concept of Human Dignity in the International Human Rights Instruments', in Juan de Dios Vial Correa and Elio Sgreccia (eds.), *Identity and Statute of Human Embryo* (Vatican City: Libreria Editrice Vaticana, 1998), pp. 381–404.

is, the main emphasis is placed on defending human lives against unlawful killings, and in genetics, primarily against eugenic selection.[28]

Many European ethicists combine elements of the Christian view with the philosophy of Immanuel Kant.[29] The *Kantian* interpretation is, however, potentially at odds with its theological rival. According to it, dignity belongs to every *rational* human being, regardless of personal variation. Rationality is, in other words, the basis of our worth. This worth should not, strictly speaking, belong to unborn human beings, but people in this tradition usually think that it does. Neither should it belong to any other human beings who cannot reason or communicate, but, again, according to many European Kantians, it does. The moral principle derived from this idea of dignity is that human beings should always be treated as ends in themselves, never merely as means to other ends.[30]

The most recent appeal to human dignity is *genetic*, and it can be found in UNESCO's Universal Declaration on the Human Genome and Human Rights.[31] This document states that human dignity is based on the human genome, and that to protect dignity we must protect the integrity and 'natural development' of our genome against wrongful, 'unnatural', manipulation.[32]

There are tensions in views that try to combine the Christian, Kantian and genetic readings of human dignity,[33] but the common ground is

[28] For a critique of this view, see, e.g., John Harris, 'Pro-life is Anti-life: The Problematic Claims of Pro-life Positions in Ethics', in Häyry and Takala, *Scratching the Surface of Bioethics*, pp. 99–109.

[29] Immanuel Kant, *The Metaphysical Principles of Virtue* (*Metaphysische Anfangsgründe der Tugendlehre*, 1797), 434–435 – Immanuel Kant, *Ethical Philosophy*, p. 97.

[30] Kant 1785 (cited in note 16).

[31] Adopted by the General Conference of UNESCO at its 29th session on 11 November 1997.

[32] See, e.g., John Harris, 'Is Cloning an Attack on Human Dignity?', *Nature* 387 (1997), p. 754; Karim Labib, 'Don't Leave Dignity Out of the Cloning Debate', *Nature* 388 (1997), p. 15; Axel Kahn, 'Cloning, Dignity and Ethical Revisionism', *Nature* 388 (1997), p. 320; David Shapiro, 'Cloning, Dignity and Ethical Reasoning', *Nature* 388 (1997), p. 511; John Harris, 'Cloning and Bioethical Thinking', *Nature* 389 (1997), p. 433.

[33] For instance, some people do not believe that God has given us our inner worth. For them, the normative basis of the view is Kantian – moral agents have dignity due to their rationality. But then these same people may believe that all human beings should be included in the sphere of dignity. Since some human beings are not rational, the Kantian justification does not work any more. At this point people may resort to the genetic reading and say, 'But we all share the same genome.' But this is question begging. Yes, we do, but why would our genome give us our inner worth? Why does the genome of worms not give them inner worth? Because we are created in God's image? Yes, well, but that is the assumption we set out by rejecting. And so on.

that our inner worth, and thereby our physical, moral and genetic integrity, must be defended both against violations stemming from other people's interests, and from violations arising from our own whims and desires.

Precaution

Many European thinkers have argued that scientific risk assessment and economic cost–benefit analyses do not pay sufficient attention to the potential, and often unforeseen, dangers of new technologies and their use. The idea of 'precaution' is that we should not continue practices, develop technologies or implement policies which may have disastrous consequences.[34] The operative words here are 'may have'. In many cases, we do not have proper scientific evidence of the dangers of practices, technologies and policies. But the principle of precaution permits, or requires, us to ban these activities anyway, if we think that they may have extremely bad outcomes.

Let us clarify one thing about precaution. It is not, as understood by Continental ethicists, a utilitarian concept. It does not allow the balancing of costs and benefits according to their probabilities, like some versions of utilitarianism do. Nor does it allow comparisons between those harms which may follow from the development of a new technology, and those which may follow from its non-development.

The ban on comparisons could be based on the notion that some goals of our actions are, morally speaking, more important than others, and the idea that some of them are also attainable by alternative courses of action. If, for instance, one of our more important aims is to protect the sanctity of life, we cannot normally justify life-threatening policies by appeals to their otherwise beneficial, or harm-reducing, consequences. Even if lives could have been saved by the new policies, this is not necessarily relevant. Perhaps they could have been saved by other policies which do not go against the sanctity of human life. And even if not, the cases cannot be compared, because lives should not be actively saved at the expense of the sanctity of other lives.

[34] See, e.g., Hans Jonas, *Das Prinzip Verantwortung: Versus einer Ethik für die technologische Zivilisation*, 7th edn (Frankfurt am Main: Insel, 1987); Matthias Kaiser, '"The Precautionary Principle and its Implications for Science" – Introduction', *Foundations of Science* 2 (1997), pp. 201–205; Sven Ove Hansson, 'The Limits of Precaution', *Foundations of Science* 2 (1997), pp. 293–306; Matti Häyry, 'Precaution and Solidarity', *Cambridge Quarterly of Healthcare Ethics* 14 (2005), pp. 199–206.

Subsidiarity

The idea of attaining essential goals by alternative means is partly formalized in the principle of 'subsidiarity'.[35] This principle has its origin in Roman Catholic social ethics, where it defines the mutual relationships of the church, the state and the free market.

The highest institution, the church, is responsible for people's spiritual well-being, but it should not normally interfere with the affairs of the state, which aims at people's material well-being. The state, in its turn, is primarily responsible for the security of its citizens, but it should not normally interfere with their pursuit of happiness in the free market. In both cases, of course, there are exceptions. If what the state regulates goes against our spiritual well-being, the church must step in; and if economic exchanges between individuals pose a threat to their security, the state must intervene.

The question concerning genetic databanks is, would it be safe to let the market determine their shape and functions? According to the principle of subsidiarity, state intervention is justified, if the freedom of the market in genetic databanking would pose a threat to people's security. It also follows from the principle in its original form that church involvement is needed if, and only if, people's spiritual well-being is in danger.

Solidarity

In discussions concerning databanks, the principles of dignity, precaution and subsidiarity provide grounds for all sorts of critical comments against storing genetic information. Solidarity, in its turn, lends support to both negative and positive arguments.[36]

If solidarity is grouped with the other three 'European' maxims, and sanctity of life is held in high value, then the ensuing norms are critical. It can be stated that the togetherness and communality we should feel with unborn and incompetent human beings forces us to seek protection for

[35] See, e.g., Russell Hittinger, *The First Grace: Rediscovery of the Natural Law in a Post-Christian World* (Wilmington, DE: ISI Books, 2003). The principle of subsidiarity, which was originally formulated in the encyclical letter *Quadragesimo Anno – On Reconstruction of the Social Order* by Pope Pius XI in 1931, has since then become one of the basic political principles of the European Union – see, e.g., Andreas Føllesdal, 'Subsidiarity', *Journal of Political Philosophy* 6 (1998), pp. 231–259.

[36] Häyry, 'Precaution and Solidarity'.

them. This means that if genetic databanks pose a eugenic threat, or can be seen to do so, they should be viewed with suspicion.

On the other hand, if solidarity is seen as a simple communal form of altruism, appeals to it can be employed in arguments for people's duty to participate in the data collection. The logic is that if a community, or a nation, can be benefited by the existence of an extensive genetic databank, people should not be squeamish about depositing their data in it. Whatever small inconveniences can be in store for them when the data are disseminated and used will be amply compensated for by the solidity of the community, tied together with links formed by the mutual gift of tissue samples and genetic information.[37]

How do our mezzanine rules protect and promote the 'European' values?

In the 'American' part of this chapter it became clear that all the mezzanine rules we have identified support, in one sense or another, the 'American' set of values summarized by the four Georgetown principles. The same can be said, in fact, about the 'European' values of dignity, precaution, subsidiarity and solidarity.

This is only natural, because the principles we have chosen here can be seen to perform, from the systematic point of view, the same functions as the principles named by Beauchamp and Childress. Both sets contain some duty-based elements and some outcome-based elements, and both contain negative rules (prohibitions) and positive rules (prescriptions). Table 3.2 shows how the American set can be presented by using these variables. Table 3.3 shows how the European principles can be fitted into a similar frame (with some minor theoretical adjustments).

The structural similarity suggests that with a convenient choice of definitions we could prove that certain kinds of respect for consent, privacy, confidentiality and public interest would inevitably also promote dignity, precaution, subsidiarity and solidarity. This does not mean that there are no differences between the 'American' and 'European' sets of values. It is just that on a high level of generality, commitment to principles like these does not really dictate the outcome of ethical analyses.

[37] Cf. Bartha Maria Knoppers, 'Human Genetic Material: Commodity of a Gift?', in Robert F. Weir (ed.), *Stored Tissue Samples: Ethical, Legal, and Public Policy Implications* (Iowa City, IA: University of Iowa Press, 1998), pp. 226–235; Hilary Rose, *The Commodification of Bioinformation: The Icelandic Health Sector Database* (London: Wellcome Trust, 2001).

Table 3.2. *Duties, outcomes and American principles*

	Negative	Positive
Duty-based ('deontological' with 'teleological' overtones)	Do not violate autonomy!	Promote justice!
Outcome-based ('consequentialist' with 'teleological' overtones)	Do not inflict harm!	Promote the good!

Table 3.3. *Duties, outcomes and European principles*

	Negative	Positive
Duty-based ('teleological' with 'deontological' overtones)	Do not violate dignity!	Promote solidarity!
Outcome-based ('teleological' with 'consequentialist' overtones)	Do not allow unforeseen evil!	Let people benefit themselves!

How different are the 'American' and 'European' readings?

This is not, however, a result with which all European ethicists would be happy, as they feel that even at the level of general principles there must be a visible difference between the two models. So let us try to take stock of the situation from their point of view. The distinction can, no doubt, be drawn, but, as we see it, this involves two rather disingenuous steps.

First, the American values must be redefined to exclude all references to 'teleological' (virtue-based) thinking, and most references to 'deontological' (duty-based) thinking. The key to this is to define

- *autonomy* in terms of 'whatever the individual wants',
- *maleficence* to refer only to immediate physical harm,
- *beneficence* as general welfare, and
- *justice* as universal impartiality.

The doctrine characterized by these principles is, roughly, a form of 'liberal utilitarianism'.[38] The next stage is to argue that, according to the

[38] See Häyry, *Liberal Utilitarianism and Applied Ethics*; cf. Matti Häyry, 'Ethics Committees, Principles and Consequences', *Journal of Medical Ethics* 24 (1998), pp. 81–85.

doctrine's champions, the best way to promote these values in genetic databanking is by

- *avoiding violations of privacy* (but only in so far as people are actually concerned about it),
- *emphasizing individual consent* (but not so much its being free or informed, if people are not all that interested),
- *respecting confidentiality* (but not if harm to others can be prevented by breaching it),
- *maintaining an adequate level of security* (but only to prevent immediate physical harm or public complaints), and
- *stressing the national and global importance of economic and scientific progress* (but mainly to hide the vested financial and personal interests involved).

We submit that, for what it is worth, *this* is the view of 'American values' many European critics like to evoke.

Secondly, after the redefinition of the Georgetown values, we must rearrange the 'European principles' to exclude all references to utilitarian thinking and some potentially embarrassing admissions to deontological doctrines. If we then decide to be extremely critical against extensive genetic databanking, we can say that, according to truly European ethics,

- *human dignity should never be violated* (especially not by establishing eugenic institutions that present a threat to the sanctity of innocent lives), and
- *precaution requires a ban on any activities that may violate dignity* (even if there is no scientific evidence to suggest that this would be the case).

The conclusion is that genetic databanks should not be established in the first place, because there is an *overriding public interest* in preserving human dignity.

If, on the other hand, we decide to take a more lenient view, we can argue, instead, that

- *genetic databanking serves an essential goal* (which cannot be served in other ways),
- *violations of dignity can be prevented by strict controls* (which can be kept in place in any future circumstances), and
- *solidarity requires us to participate in this common effort* (if not for the medical benefits, then at least in the name of communal togetherness).

The conclusions will then be that

- *privacy* is an individualistic ploy which can be ignored,
- *presumed consent* is quite sufficient for the purposes of data collection and use,
- *confidentiality* can be trumped by social and communal considerations,
- *security* is important to check eugenic uses of the data, and

- *public interest* in solidarity provides a justification for overriding individual interests, where necessary.

Far from banning genetic databanks, this reading makes it the citizens' duty to deposit their tissue samples and information in them.

This excursion into a possible way of distinguishing between American and European values shows two things. The first is that, in order to make the distinction, the position expressed by the Georgetown principles must be considerably distorted. It must be given a utilitarian slant which is alien to most American bioethicists. And the resulting view must be boosted by a narrow definition of harm as immediate physical damage which has seldom been upheld even by utilitarian moralists.[39] The second is that even after these manoeuvres, no unified European response to the ethics of genetic databanking arises. Depending on the definitions, the principles of dignity, precaution, subsidiarity and solidarity are compatible with radically different practical rules and guidelines, most or all of which can also be seen to promote some variations of the Georgetown values.

What are the lessons to be learned from this analysis?

The most direct lesson to be learned from our considerations is that there are no neat, simple, universally definable sets of 'American' or 'European' values which would be directly useful in the ethical regulation of human genetic databanking. The main reason for this is that general principles like 'autonomy' and 'dignity' derive their wide acceptability from openness to interpretation, while their practical applicability depends on their ability to produce exact and unambiguous rules for action. These requirements are, in and by themselves, contradictory.

The model devised by Beauchamp and Childress in Washington has been called the 'Georgetown Mantra', mockingly suggesting that the repeated chanting of the four words could guide medical professionals to make sound ethical choices in their work. Similarly, the four competing principles could be called the 'Brussels Catechism', proposing that by insisting on their validity philosophers and theologians can steer European legislators to arrive at the right regulative decisions. The problem with both 'plans' is that when two legislators have adverse ideas on what 'autonomy' or 'dignity' mean, they can end up defending radically different sets of practical rules however hard they try to repeat the mantra or recite the catechism.

[39] See, e.g., Matti Häyry, 'Philosophical Arguments For and Against Human Reproductive Cloning', *Bioethics* 17 (2003), pp. 447–459.

These observations suggest that if people want to know the concrete values to which politicians and legislators are committed, they should not be content to hear words like 'autonomy', 'dignity', 'solidarity' and 'justice'. They should demand that their leaders disclose the exact practical rules they intend to set on genetic databanking. The same also applies the other way round. If the public authorities truly want to know what their citizens' concerns are, and what troubles potential genetic databankers, the way to proceed is to ask them how they would feel about specific sets of practical guidelines. In terms of acquiring knowledge, then, the norms we have called 'mezzanine rules' here can be used for the purposes (or cross-purposes) of administration and emancipation alike.

4 The languages of privacy

Salvör Nordal

There has been a growing concern for privacy among the general public in the past decades. In Western societies this, paradoxically, is because the public senses both more *and* less privacy than before. On the one hand, people can enjoy more privacy and are more aware of privacy issues than before. With growing wealth, bigger houses and apartments people have more private space. Furthermore there is an increasing awareness of individual rights such as freedom and autonomy, which means people can have more control over their lives and their fate. On the other hand, there is less privacy in modern societies or more possibilities of threats to individual privacy. Various technological inventions, most recently information technology, magnify the possibilities of surveillance and intrusion into individual lives.

In light of this, it may not come as a surprise that scholarly discussion of privacy is fairly recent. In fact we can date the beginning of the discussion to the year 1890 with the publication of Warren and Brandeis' paper 'The Right to Privacy'.[1] The article is believed to have been a reaction to instant photographs and mass-produced newspapers, a new technology of that time.[2] There it was argued that even if privacy was not explicitly expressed in the US Constitution or Bill of Rights, it was to be found there implicitly.

Following the publication of Warren and Brandeis' influential paper, various legal cases appealed to the right to privacy in US legal courts and gradually it has been established as a constitutional right. The awareness of the right to privacy has spread to other Western countries and now, more than a century after the discussion started, the right to privacy has found its way into the European Declaration of Human Rights as one of

[1] Samuel D. Warren and Louis D. Brandeis, 'The Right to Privacy', *Harvard Law Review* 4 (1890), pp. 193–220.

[2] Anita Allen, 'Privacy in American Law', in Beate Rössler (ed.), *Privacies. Philosophical Evaluations* (Stanford: Stanford University Press, 2004), pp. 19–39.

the basic human rights, and from there into the constitutions of many European countries.

Recognizing the right to privacy would be well and good if we did not face some urgent conceptual difficulties. From the beginning the right to privacy has been criticized extensively for lack of clarity. Some have argued that privacy is a hopelessly broad concept and can mean almost anything.[3] More recently privacy has been described as a cluster concept with diverse meanings. Examples of privacy cases have concerned the interest of protection of personal information, the interest of deciding on personal issues such as having an abortion, the interest concerning access to person and personal spaces and the interest of appropriation and ownership of human personality.[4]

In this chapter I am not going to discuss legal cases in the US or the diverse interests privacy is supposed to protect. Instead I want to draw attention to the difficulties of translating the concept of privacy into other languages and cultures, and ask how the conceptual difficulties in English translate into other languages. In my discussion I will especially focus on Icelandic culture and language. Anyone writing about privacy in Icelandic has to tackle the conceptual problems since the Icelandic term has a different origin from 'privacy'. Implementing European directives necessitates some conceptual work and adoption of language and culture. My approach is descriptive; I simply want to present the problems and difficulties.

Different languages

If we look at the meaning of 'privacy' we see some distinct characteristics. The term 'privacy' is importantly linked with private affairs and the private sphere. Private is what is opposed to public and the public sphere; what is private we keep away from the public eye. 'Privacy' refers to protecting that which belongs to private affairs or the private sphere. Another important feature of 'privacy' is that it means a control of private things or affairs. As the term has been interpreted in many legal cases, privacy is the control which an individual has over his or her affairs. He or she has at least the control to decide when or whether to make private matters public. This is so in spite of the fact that the distinction between

[3] Judith Jarvis Thomson, 'The Right to Privacy', *Philosophy and Public Affairs* 4 (1975), pp. 295–314.

[4] Anita Allen, 'Genetic Privacy: Emerging Concepts and Values', in Mark A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997); Judith Wagner DeCew, *In Pursuit of Privacy: Law, Ethics and the Rise of Technology* (Ithaca: Cornell University Press, 1997).

the public and the private is always to some extent grounded in social conventions.

In Icelandic 'friðhelgi' has been used to represent 'privacy' in English. This term can be found in old Icelandic and its meaning comes from two separate words, 'friður' meaning 'peace' and 'helgi' meaning 'sacred' or 'holy'. The concept 'friðhelgi' means therefore something we have in peace or is sacred to us. The term 'helgi' is often used with other terms such as in 'landhelgi' or 'lofthelgi', meaning the territorial waters and airspace. If something has 'friðhelgi' our access to it is restricted in meaningful ways. Icelandic members of parliament have 'friðhelgi' for instance, and that means that an MP cannot be prosecuted for anything he or she says in the parliament; in medieval times churches had 'friðhelgi', which meant that individuals could not be apprehended or killed within the church walls – they had sanctuary. And as in many countries, the friðhelgi of the home is well recognized and has been so for a long time.

From these examples we can see that friðhelgi has a fairly clear meaning. It is a place of something that has restricted access or is our sanctuary. The first difference we see between the English and the Icelandic term is that 'friðhelgi' has no reference to the private or the private sphere, and from the examples above we see that it is used with public as well as private phenomena. Unlike privacy in public, which sounds like a contradiction in English, friðhelgi in public poses no conceptual difficulties in Icelandic.[5] Another difference is the strong social reference and weak reference to individual control within the Icelandic tradition. For friðhelgi to be respected there must be a general consensus within the society. Thirdly, 'friðhelgi' is traditionally not used without specifying what it refers to. This is clear in 'friðhelgi heimilisins' or the privacy of the home. This keeps the clarity of the concept and the connotation intact.

An exception to this tradition was made recently when the Icelandic Constitution was revised to meet some standards of the European Declaration of Human Rights. To capture the meaning of the English term more precisely, the concept 'friðhelgi einkalífsins' was implemented.[6] In Icelandic 'einkalíf' means the private or private affairs and 'friðhelgi einkalífsins' is therefore coming close to the meaning of 'privacy' and reference to the private sphere. And of course with this adoption comes a broader concept than before. This change is only recent

[5] Recently many have argued that it is important to recognize privacy in public. See Helen Nissenbaum, 'Protecting Privacy in an Information Age: The Problem of Privacy in Public', *Law and Philosophy* 17 (1998), pp. 559–596.

[6] This happened in 1995.

and very few cases have been tried referring to this broad notion. It remains to be seen how this new concept will develop and whether it will take on as many disguises as the equivalent term in US courts.

More recently still another term, 'persónuvernd', which literally means protection of persons, has been used in Icelandic for privacy interests and has, for instance, been used for data protection or informational privacy. 'Persónuvernd' does not appeal to individual control but places the emphasis of this interest in other hands, the importance of protecting persons from intrusion or misuse of information. This fact directs our attention to important differences between American and European values in relation to privacy interests.

Anita Allen argues that in spite of a number of formal US privacy laws – there are possibly more of them in the US than anywhere else in the world – such laws are still lacking in many areas, for instance in relation to the internet, genetic information and data protection.[7] In contrast, many EU countries, which have only slowly followed the US tradition, have implemented the Directive of the European Parliament and the Council of Europe on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[8] This directive sets limits to using personal information, for instance in genetic research, and for any use of genetic information. In Iceland, for instance, the Data Protection Authority enforces the law.

It is interesting to reflect on the difference between European and American interests in privacy. The American interest in privacy seems to be more focused on individual control and entitlement – the right to take decisions about individual affairs and control personal information. There is a reluctance to place the protection of privacy in the hands of social institutions rather than individuals, or to regulate business and public institutions in this regard. The European attitude on the other hand seems focused on reaction to informational technology and the importance of building institutions that can serve to protect individuals in this new environment. As I argue elsewhere in this book, building trustworthy institutions might be the only possible way of protecting the interest of privacy in the technology age of cyberspace and genetic databases.[9]

[7] Allen, 'Privacy in American Law'.

[8] Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281, 23 November 1995.

[9] See my chapter entitled 'Privacy' (chapter 21).

One way of exploring the differences between American and European values in relation to privacy is through language and culture. When we translate concepts we are translating cultural references. When standardizing regulations between countries or even on a universal level this problem becomes more pressing. The scholarly discussion of privacy has been dominated by American culture and juristic language. On the surface it may look like Americans are more conscious about privacy than Europeans.[10] A closer look may however show that the opposite is true. Nicola Lacey points out that privacy has to be read between the lines in English law, and from the few examples in this chapter we see that 'friðhelgi' has been a legal term in Iceland since medieval times.[11] These cultural differences merit closer scrutiny. In this chapter I have only touched upon them and the ways in which they might be explored further.

[10] Allen, 'Privacy in American Law', p. 28.
[11] Nicola Lacey, 'Interpreting Doctrines of Privacy: A Comment on Anita Allen', in Rössler, *Privacies*, pp. 40–51, at p. 45.

Part II

Social concerns

5 A sociological perspective: public perceptions of privacy and their trust in institutions managing and regulating genetic databases

Kjell E. Eriksson, Margrét Lilja Gudmundsdóttir, Külliki Korts and Sue Weldon

The principal aim of this part of the book is to provide empirical evidence about public attitudes to genetic information. In particular, we investigated public perceptions of privacy in relation to personal medical and genetic data and people's attitudes to the trustworthiness of public and private organizations in the four countries (Iceland, UK, Sweden and Estonia). It is widely accepted that issues such as the donation of genetic information to population-based genetic databases straddle the boundary between individual legal and ethical concerns and the wider concerns of society, and it is with a view to providing a better understanding of these wider social concerns that the ELSAGEN sociology team are reporting these research findings.

To begin with, we felt that it was crucial to take account of the existing, and very different, social contexts in each of the countries where the databases are being introduced: first of all (in 1998) the widely reported Health Sector Database in Iceland, followed by the UmanGenomics venture in Sweden, the Estonian Genome Project and the UK Biobank. Each of these projects, to collect a variety of genetic, environmental and lifestyle information, has different operating features and is being launched into a different social and legal context. One of our initial concerns was to understand the existing national attitude to new developments in science and technology (particularly biotechnology). In the UK, for instance, after a widespread public debate about the introduction of GM crops, a government report published in 2000 concluded that society's relationship with science had become severely eroded.[1]

[1] House of Lords Select Committee on Science and Technology, *Science and Society*, *Third Report* (London: HMSO, 2000).

Icelanders, on the other hand, appear to be proud to be seen as a rapidly developing and technologically motivated society – in spite of the international debate and (sometimes very critical) media attention given to their pioneering database project. Similarly in Estonia, a recent entrant to the EU and a rapidly developing country, the overall attitude of the public towards science is optimistic. Finally, in Sweden there appears also to be a pragmatic attitude to these new biotechnology developments, and very little public concern or debate.

We were aware, therefore, of the need to tailor our research to these existing circumstances. In the following accounts we describe, first of all, the rationale for our choice of method; then we go on to outline our findings.

6 Estonia

Külliki Korts

Introduction

The Estonian human Genome Project (EGP) was launched in 1999, with a far-reaching ambition to create a national genetic database comprising samples of virtually the whole population. Though the gene researchers have enjoyed a long-standing high reputation in Estonian society, the idea of a nationwide gene bank constituted what could be called the first 'gene issue' catching the attention of the wider public, characterized by low-level personal experience of the existing applications. Before and during the launch of the EGP, which was regulated by a separate legal act, there was a limited debate over the issue but it did not reach beyond a limited scientific community. In addition to generally low public awareness, there exists very little research into public attitudes towards genetics or genetics-based medicine. It is confined to studies of the awareness and support for the EGP project financed by the EGP itself.

Under such circumstances it seemed necessary, in the design of the survey, to collect some information on general attitudes towards science and technology, as well as to formulate questions concerning people's hopes and fears in respect to gene research and technology with reference to the EGP. In order to achieve as much representativeness as possible, the survey was conducted through face-to-face interviews with a nationally representative sample of 917 respondents.

General attitudes towards genetic research

The results of the survey show that, compared to Western societies, the Estonian population at large shares a rather optimistic view of recent developments in science and technology. For the majority (66%), the benefits provided by the new knowledge are valued more highly than accompanying risks. Most respondents (79%) would also allow scientists full freedom to pursue their research as they wish, so long as they observe ethical rules. Furthermore, the Estonian population is characterized by

their remarkably high expectations of genetic research. More than 90% of the respondents agree (or rather agree) to the statement that the development of gene technology means that many illnesses can be cured. But the survey also indicates strong public support for applying these discoveries, in terms of both diagnosing possible illnesses through genetic testing and making respective 'corrections'. Almost 90% of the respondents are in agreement with the statement that people should be encouraged to be tested in young adulthood for disorders that develop in middle age or later in life. Almost as many (80%) also agree that parents have a right to ask for their child to be tested for genetic disorders that develop in adulthood and (86%) that genetic information may be used by parents to decide if children with certain disabling conditions are born. Fewer, but still a considerable majority (68%), consider that couples who are at risk of having a child with a serious genetic disorder should be discouraged from having children of their own. Though these responses might not reflect people's own potential behaviour, they indicate a potential for rather strong social pressure for making use of such preventive measures once these become more widely available, especially taking into account that Estonia has only lately abandoned the Soviet pattern of dealing with disability mainly via exclusion in special institutions rather than giving support and counselling to parents to cope with the situation.

Similarly one can perceive placing social welfare (public safety) above personal privacy in the willingness of three quarters of the respondents to allow the police access to the gene bank during criminal investigations, which is in contradiction with the current legislation forbidding third parties any access to the database. This is where the attitudes of the Estonian public, which are similar to those of other post-Communist countries, diverge most noticeably from the results of the corresponding surveys carried out in Western Europe, which indicate high expectations for genetic research but simultaneously call strongly for caution in each new step.[1]

Compared to the support for the potential uses of new applications of gene technology, the number of people perceiving risks accompanying the wide use of gene tests and similar technologies is much smaller. Approximately half the respondents consider justified the prediction that insurance companies will start to demand gene test results while determining the level of insurance premiums, as well as that employers

[1] Gallup Organization Hungary, *Candidate Countries Eurobarometer on Science and Technology*, Cc-Eb 2002.3 (Brussels: European Commission, 2003); European Commission, Special Eurobarometer 154, 'Europeans, Science and Technology' (Brussels: European Commission, 2001).

will start to demand gene test results from candidates for certain jobs. Fewer people (44%) consider that knowing gene information will start to influence interpersonal relationships; and even fewer (36%) that the spread of use of gene information will lead to a new type of society where the population is divided into 'better' or 'worse' depending on genetic make-up.

However, the high level of optimism and low level of caution can also indicate lack of profounder acquaintance with or reflection on the issue among the general public. As already mentioned, genetic research did not get too much public attention before the idea of the gene bank. But even after two years of intensive propagation of the project, in late 2002 just 62% of the Estonian population claimed to have heard about the EGP and only 7% considered themselves well informed on the issue.

Attitudes towards the EGP

For the majority of respondents who are knowledgeable about the gene project, its perceived benefits, both personal and those for the whole society, seem to outweigh the possible risky consequences. The major advantages of the EGP are considered to be medical (allowing the creation of more effective drugs – 95%; helping the development of Estonian healthcare provisions – 87%); however, its contributions to economic development (bringing new investments – 78%; lessening the 'brain drain' and creating new jobs – 66%) and international recognition (making Estonia better known in the world – 78%; increasing the competitiveness of Estonia – 76%) are also considered important. These features of the gene project correspond remarkably closely to the image created in the media discourse.[2]

Similarly to attitudes to genetic research in general, the negative consequences of the EGP are perceived by a lower proportion of the respondents than the benefits outlined above. Around half of the population considers it possible or rather possible (52%) that the benefits to the Estonian state and nation will be minimal, that the direct beneficiaries will be only investors and pharmaceutical companies and that the samples of the EGP databank will be used in research that includes gene manipulation (56%). A larger number of people (63%) are worried that the data collected by the EGP may leak and may be used against gene donors, e.g. by insurance companies or employers.

[2] See Piia Tammpuu, 'Constructing Public Images of New Genetics and Gene Technology: The Media Discourse on the Estonian Human Genome Project', *Trames* 8 (2004), pp. 192–216.

An interesting contradiction in the public opinion has to do with the specific character of the Estonian gene bank, which is the only one which has granted donors the right to access their own data in the bank or receive a card 'containing the genome of each gene donor'.[3] According to the survey, the vast majority of respondents (86%) believe that people will personally benefit from participating in the project by getting to know their health risks. Indeed, this seems to constitute one of the major appeals of the gene-bank project based on voluntary participation. According to the survey, 83% of potential donors definitely plan to apply for a personal gene card containing their 'genetic information', whilst only 2% decisively reject it. At the same time, however, this is perceived also as the main risk: more than three quarters of respondents consider it very or rather probable (25% and 54% respectively) that many people will suffer from psychological distress when they are informed of their health risks by the EGP.

The generally positive attitude of the public towards the EGP correlates with the level of trust towards different persons and institutions as the most reliable sources of information on the project. Genetic scientists and the employees of the Estonian Genome Project are trusted by more than 80% of the population. Trust towards the persons connected to the project outweighs that towards, for example, the Ethics Committee supervising the activities of the project (73%) and family doctors (71%) – the actual contact persons of the potential gene donors – and other scientists (61%). Especially low trust characterizes the public attitude towards journalists (20%), although, for the majority, printed media and television constitute the principal sources of information on the project, leaving other sources far behind (e.g. family doctor, friends, relatives).

However, all these results have to be considered in the light of a few other significant findings. Despite generally overwhelmingly positive evaluation of the project, only 24% of the population who are knowledgeable about it have decided to take part; more have decided negatively (40%), while many have not made up their minds (36%). Hardly reflecting the final outcome of the project in terms of actual participation rates,[4] these figures reveal rather low actual interest in such issues on the part of the majority of the population. Moreover, the people who intend to participate and who are 'opting out' do not show significant differences

[3] Krista Kruuv, 'Kas hakata geenidoonoriks?' ['Should One Become a Gene Donor?'] *Postimees*, 23 October 2002. Krista Kruuv was the Director of the Estonian Genome Project Foundation.

[4] At the end of 2003, when the pilot study (in three counties) had been going on for more than a year and the nationwide project for a few months, the participation rate was below 10,000, considerably below initial expectations.

in their attitudes towards the project or to genetic research in general. The lack of coherence of views in this respect gives reason to assume that the final decision by the potential donor is susceptible to haphazard influences and will be quite easily refutable under 'unfavourable' circumstances. This means that in the recruitment phase of the project other factors, e.g. trustworthiness and a good relationship with one's family doctor, or specific concerns arising from the procedure of participation, may become crucial.

Consent and privacy

In the Estonian Genome Project, voluntary donors are recruited by family doctors, who take the blood sample and interview the donor. All participants sign a consent form, by which they accept that they can be approached again for supplementary health information, and that this can be gathered also from other sources, e.g. hospitals. There exists also an opportunity to sign a special form, by which their data will be inserted in the databank anonymously. Later, the donor has the right to demand the removal of data that can be decoded (i.e. to make it anonymous). As for the requirement of informed consent, there is a near absolute consensus among the respondents (97%) that it is necessary to ask for written consent from the donors. However, only 40% consider it necessary to allow the donors to demand the anonymization of their data after first consenting. In addition, other survey data reveal a high level of trust towards the working principle of the project: more than half of the potential donors are willing to give the Genome Foundation a free hand with access to other health databases, while only a quarter have decided to forbid it.

However, the majority (95%) consider it most important to be informed about what kind of research will be done using their gene data. In contradiction to the current regulation which leaves consent rather open, there is majority support (81%) for the idea that fresh consent should be required before new research is conducted on existing samples.

Discussion

At the time of the survey, the project enjoyed a notably positive image in the eyes of the general population, at least among the two thirds acquainted with it. The popularity of the project can be traced to its skilful promotion as an inspiring national scientific venture. However, taking into account several characteristics of this acceptance – that general knowledge of the project is rather low, that most of the information is

received from public sources, rather than personal contacts, and that people have considerably higher trust in the persons directly involved in the project than in possible critics – then support is gained on a rather abstract level and might not reflect the actual eagerness of the people personally to become a donor. Though the presentation of the project as a national scientific undertaking is well tuned with the generally high level of technological optimism as well as national pride, it has not had enough appeal for people to mobilize on grounds of solidarity of contribution to the common cause. Rather, for the vast majority of potential donors, the possibility of being granted a personal gene card seems to have more appeal.

Besides, the people who intend to participate and those who are 'opting out' do not show significant differences in their attitudes towards the project or to genetic research in general. This gives reason to assume that the final decision by the potential donor is susceptible to random influences, giving a crucial role to the persons involved in the actual process of recruitment and sample-gathering.

The survey also revealed the importance of the question of control over the contributed DNA sample and health information. It seems, however, that if the people and institutions engaged in the process of gathering, restoring and processing DNA samples are able to retain people's trust, people are satisfied with being kept informed of the fate of their DNA and health information, rather than keeping strict control over their sample.

In conclusion, it can be asserted that general acceptance and support for the EGP has been gained against the background of the generally high level of technological optimism, including high expectations for the new developments in gene technology, as well as the high reputation of the main initiators and designers of the project, giving confidence in the 'rightful' aims of the project. However, success in image creation has not yet been channelled into expected participation. The latter will most probably depend on the way recruitment is done on the ground, both in respect to attracting the first interest, and, even more importantly, in the ability of the EGP to create and maintain rather precarious trust in each phase of gathering, keeping and processing the personal donation.

7 Iceland

Margrét Lilja Gudmundsdóttir and Salvör Nordal

Introduction

In December 1998 the Icelandic Parliament passed a bill authorizing the construction of the Health Sector Database (HSD). The objective of the Act was to 'authorise the creation and operation of a centralised database of non-personally identifiable health data with the aim of increasing knowledge in order to improve health and health services'.[1]

The passing of the Act led to much debate concerning the unique position in Iceland with regard to genetic research. This position was, among other things, due to carefully registered health information over a long period, a homogeneous society and the willingness of the Icelandic public to participate in research. During this period there was a high level of media attention by the national and international press. Opinion polls showed that the majority of the public supported the HSD. In 1998 a Gallup poll concluded that 58% of Icelanders supported the database, 19% were opposed and 22% were neither for nor against.[2] In 2000 another Gallup poll concluded that the overwhelming majority of the public (81%) supported the database, whilst only 9% were opposed and 10% were neither for nor against.[3] The planned database has been a subject for debate and discussion from the outset. Some of the discussions focused on the exclusive licensing agreement with a multinational company authorized by the Icelandic Parliament. In Iceland therefore, discussion about genetic research has mostly been in connection with the HSD and the form of the Act. A large number of articles, by Icelandic specialists as well as by people from other countries, have been written about the HSD and the passing of the HSD Act by the Icelandic Parliament. The main focus is often the issues of individual consent and privacy. However, this

[1] Act on a Health Sector Database no. 139/1998, s. I, art. 1.
[2] 'Meirihluti landsmanna fylgjandi gagnagrunnsfrumvarpinu' ['Majority of population supports Database Bill'], *Morgunbladid* 18 November 1998.
[3] 'Rúmt 81% fylgjandi gagnagrunn á heilbrigdissvidi' ['Over 81% support the Health Sector Database'] *Morgunbladid* 27 April 2000.

debate is affected by previous larger issues of privacy, e.g. Iceland's participation and entrance in the Schengen agreement, the possible establishment of a biobank for the police, and surveillance in public areas as well as in the workplace.

The ELSAGEN study – on method

In Iceland the ELSAGEN survey was carried out in November and December 2002. The sample consisted of 1,500 randomly chosen Icelandic citizens from the entire country, aged eighteen to seventy-five. The method chosen for the data collection in Iceland was a telephone survey. Postal surveys do not give a sufficient response rate in Iceland since the rate is often less than 50% of the sample. Face-to-face surveys are far too expensive and not necessary, while telephone surveys still give an acceptable response and a good picture of the nation. The response rate was 68%. Males accounted for 49.9% of respondents and females 50.1%: the distribution of the sample is very representative of the Icelandic nation.

The empirical research for the ELSAGEN project is the first in Iceland that aims at discovering more about Icelanders' perceptions of privacy of personal information in general and privacy of medical and genetic data in particular, and their trust of private and public organizations that handle such data.

Empirical findings

General attitudes towards genetic research

Scientists have frequently argued that the Icelandic public is extremely willing to collaborate and participate in research. Results from the survey confirm this belief, with 73% of the respondents considering it necessary that individuals give information concerning their health (such as medical records and biological specimens) in order to contribute to progress in biotechnology. Similar findings appear when the respondents were asked about the attitude of the Icelandic public in general towards genetic research. Sixty-eight per cent of the respondents think that the Icelandic public is very or rather positive towards such researches. High expectations of genetic research are also characteristic of the Icelandic respondent, almost every respondent (over 95%) agreeing to the statement that the development of gene technology means that many illnesses can be cured. And 73% are very or rather hopeful regarding influences that biotechnology may have in the future. It is therefore safe to state that the Icelandic public has high expectations of the scientists and their

research. The results also reveal that a considerable number of the respondents (42%) have already participated in genetic research and 65% consider it very or rather likely that they would participate in genetic research in the future.

Protection of medical information, biological sampling and trust towards health service providers

Even though the majority of the survey population (60%) knew little about how their medical information is protected, they seemed to trust health service providers to protect their privacy concerning medical information (in excess of 72%). As part of the survey people were asked about their trust of specific professions and institutions[4] to protect human genetic information kept in medical databases. Results show that four out of every five people are likely to trust family doctors and health service providers. Around 60% of those surveyed said that they trust scientists. But only 38% trust the police – few more than those who trust pharmaceutical companies (32%) and patients' groups (33%). People seem to have least trust towards insurance companies (14%), trade unions (11%) and employers (10%).

Similar findings arise when respondents were asked who should have access to human genetic information held on medical databases.[5] Nearly 76% of the participants thought it standard that those working in the public sector, such as in hospitals and the university, should have access to such information. Just over 37% considered it natural that privately owned companies in biotechnology should have access, and roughly 30% mentioned pharmaceutical companies and the police force. Sixteen per cent of the participants were of the opinion that insurance companies should have access, but as usual the group that tailed were the employers: just over 10% thought that employers should have access to databanks with information on biological samples and individual medical records.

The participants were then asked to what extent they trusted certain agencies or groups to disclose the truth regarding potential risks when dealing with information stored in databanks and genetic research. A list of eight agencies was presented. The results show that university

[4] Family doctors, health service providers, police, scientists, pharmaceutical companies, genealogists, patients' groups, insurance companies, employers, trade unions.

[5] Note that this list was slightly different: specialists – working for the Government, biotechnological companies – privately owned, pharmaceutical companies, insurance companies, police, employers.

scientists are the most trusted. Seventy-five per cent of the respondents gave them their vote of confidence. In second place were specialists working within the public sector. Nearly 60% said that they trusted them to disclose information about potential risks in this area. Finally, the groups who were least trusted were religious groups and politicians. Fewer than 10% of the participants trusted them.

Participants' consent

It has been mentioned that the idea of operating a centralized medical and health database (Health Sector Database) was, according to opinion polls, received favourably by the majority of the Icelandic population. In the study that is discussed here, 77% of those who responded were very or rather supportive of such a database. Twelve per cent were neither for nor against it, and nearly 11% claimed to be very or rather against the database.

One of the main areas of controversy surrounding the Health Sector Database was the matter of not acquiring informed consent of individuals to be included in the database. The assumption was made that each and every individual would be part of the database unless they formally opted out of it. The survey did not go into that issue, but people were asked whether they agreed or disagreed to submitting biological samples which might be obtained from them when undergoing medical research (for example in hospitals or by general practitioners) without seeking prior approval. Eighty per cent disagreed with this line of conduct.

In addition, people were asked if they thought that consent should be sought each time biological samples were collected for purposes of genetic research. The results were not conclusive. Fifty-seven per cent agreed that consent ought to be obtained.

Privacy rights and the protection of personal information

The debate on the infringement of the individual's rights to privacy and protection of personal information has increased considerably these past years. What are the views of the Icelandic people on this issue? According to the results of the survey, nearly 26% of the respondents said that they were very or rather concerned about their rights to privacy being violated. These respondents were then asked what exactly their concerns were. Here an open question was used so that those who answered could mention anything that came to mind. The most frequent concern evolved around the concept of the surveillance society. In this context the well-known Orwellian term 'big brother' was frequently mentioned. Furthermore, people often noted that the manner in which personal

information was being stored was in many ways faulty. There were also concerns regarding the operation of the Health Sector Database. Just over 10% of the respondents had taken certain measures to ensure their personal privacy. The two most frequent measures were to opt out of the Health Sector Database, and to have one's telephone number removed from the general telephone directory.

The right to personal information is an intrinsic part of the right to privacy. In other words, it is important for individuals to control what information regarding their personal lives is allowed into the public domain and what is not. But what sort of information do people consider vital in this context? The respondents were asked to state what type of information they considered most vital in relation to their right to privacy. A list of six categories was presented and people were asked to rank them according to their significance. Those six categories were:

- *financial information* (bank transactions, levels of debt, tax records);[6]
- *information on social status* (status, class, unemployment, education, family situation, social service aid);
- *genotype information* (blood group, biological samples);
- *information regarding the workplace* (level of absence, sick leave, wages);
- *medical information* (medical records from hospitals and general practitioners);
- *criminal records* (felonies, traffic violations).

Results indicate that 36% of the respondents ranked financial information as the most important issue. Trailing behind is medical information, 28% of the participants regarding that as the most significant issue. When looking at background variables, one can see a significant difference in the case of financial information: the older the participants, the greater the likelihood that they would rank financial information as the most important issue.

Conclusion

The level of discussion on privacy issues and personal information has risen considerably in recent years in Iceland. This is mainly due to a number of factors, among which are the plans for the Health Sector Database, numerous other databanks and the increased level of surveillance in various segments of society. In this light, it is interesting to note that only one out of every four individuals claimed to be concerned or worried about diminishing rights to privacy. It is also interesting to see

[6] The information within the brackets was not offered to the respondents. It was only to provide clarification for the interviewers.

that when Icelanders relate to privacy issues, financial matters are of the most importance. People regard financial information to be more important than information stored in medical and hospital records or genotype information stored in biobanks. These results are of great interest and undoubtedly throw some light on the reasons why legislation on the Health Sector Database was passed without any substantial public protest. This may come as a surprise to some, particularly since genotype information is one of the most sensitive types of information that can concern an individual and as such should deserve more protection than other types of information such as medical records or social circumstances, because genotype information can predict an individual's future health.[7] Icelanders do not seem to share this concern. According to the results, they seem to prefer that genotype information should be kept and utilized for research purposes.

It is interesting to see how the respondents answered questions concerning informed consent. The results show that Icelanders seem to focus more on informed consent than the legislation does. There were no questions specifically directed at the Health Sector Database, but recent legislation on biobanks allows the collection of biosamples for research biobanks on the principle of assumed consent.[8] According to the results, a large majority of Icelanders seem to be against such a provision. The results show that a majority of the Icelandic people are in favour of the Health Sector Database. Also, Icelanders seem optimistic about future developments in the discoveries in human genetics, and they think that it is important for people to allow science to benefit from personal information to enhance any future progress in this particular field of study. It is evident that scientists and healthcare workers enjoy the confidence of the Icelandic people to use this information for medical purposes and research. Any controversy that may have surrounded the Health Sector Database has not had any effect on these views. However, it is necessary to point out that those scientists and healthcare workers who enjoy the most trust are those working within the public sector. This stems perhaps from the fact that Iceland has a relatively high quality welfare system and public health service. This is worthy of consideration, especially in the light of increasing demands to introduce privatization into the fields of healthcare and science.

[7] Onora O'Neill, 'Informed Consent and Genetic Information', *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001), pp. 689–704.

[8] 'If biological samples have been collected for the purpose of clinical tests or treatment, the consent of the patient may be assumed for the storage of the biological sample in a biobank' (Act on Biobanks no. 110/2000, s. III, art. 7).

8 Sweden

Kjell E. Eriksson

Introduction

The dramatic developments within biogenetic research during the last decade, and in particular the scientific breakthrough that resulted in the successful mapping of the human genome, as well as the assumed profitability potential in commercial applications of genetic science, have vastly increased the interest in and importance of human genetic databases or biobanks, as they are officially designated in Sweden.

Sweden has a long history of collecting and banking tissue samples for medical purposes, the oldest preserved human biological matter being collected in the later part of the nineteenth century. There are an estimated 80 million samples in Swedish biobanks, collected from the 1940s onward, kept in different ways and consisting of a whole range of various biological matter. The most systematically built biobank is the PKU register, consisting of samples taken from every newborn baby since 1975. The samples are collected in order to detect any of five hereditary metabolic diseases, one being phenylketonuria (PKU). Personal data about mother and child, manually arranged, supplement the samples. The testing is voluntary, but very few abstain. There has also been an attempt to establish a commercial human genetic databank, UmanGenomics. The company was created in 1998 to build and commercially utilize a regional bank of samples in the northern county of Västerbotten. Current reports indicate that the company functions poorly.

Generally speaking, Swedish biobanks have not been a controversial issue for the general public, mainly because their existence has not been generally known. Little was known also of the public perception of privacy and trust and related moral values in the context of biobanks. The purpose of the consultation part of the ELSAGEN project has been to fill this void.

On method

For the purpose of gaining insight into the opinions, attitudes and expectations of the Swedish public in relation to biobanks and genetic research,

a mail survey was carried out. A questionnaire with 113 questions was distributed to a random sample of 1,000 Swedes between eighteen and seventy-five years of age. The questions were aimed at mapping attitudes and opinions and did not measure actual knowledge of the field of genetics. Twenty-one questions dealt with personal data, such as age, sex, education, income and political sympathies.

The questionnaire was sent out in November 2002 and during the next four months non-respondents received up to three reminders. The final response rate was exactly 50%, including respondents explicitly declining to take part. A total of 448 questionnaires make up the population that has been subject to analysis.

An analysis of the returned questionnaires in terms of individual data related to the total Swedish population shows overrepresentation of women, of people with university education, and of people living in big cities. Age distribution is representative for the Swedish population, and immigrants are underrepresented. The inferences to be drawn from the relatively low response rate and the ensuing uneven distribution are that the question of biobanks and related issues are complicated, to a considerable extent not known to, and not part of the everyday concerns of, the general public. As usual, well-educated people, who often live in big cities, are relatively well informed in matters like these; and, equally as usual, women are more responsive to issues posing questions of integrity and other moral values.

There are, throughout the statistical material, surprisingly few and insignificant differences between subgroups made up by variables such as sex, age, education, income, political affiliation and so on, which indicates that abstainers probably had little effect on the general tendencies in the responses.

Empirical findings

The overall dominating impression coming from this survey is the limited knowledge of, and possibly interest in, medical genetic issues in general, and of biobanks specifically. This is, of course, most clearly shown by the 50% non-responders to the questionnaire. But also among the people that actually returned a filled-in questionnaire, this becomes obvious by the high percentage of 'don't know' and other cop-out responses to each of the questions. Quite a few state that 'these are very difficult questions', which must be read as 'these are very difficult questions to answer when one hasn't thought about all the implications of the issue'. On average, there is a 25% dropping off on individual questions.

About two thirds of the respondents had heard of biobanks prior to receiving the questionnaire. It seems reasonable to assume that non-respondents were even more ignorant of their existence. One third had come across biobanks in the last three months. Only one sixth had heard of the law regulating biobanks that came into force during the survey period. Hence, it seems reasonable to conclude that the Swedish public has scant knowledge of the very subject of the study.

Having noted this, the general attitude of the Swedish survey population toward biogenetics can be characterized as cautious optimism. A majority (54%) of the respondents agreed with the statement *The development of gene technology means that many illnesses can be cured*. Only 3% explicitly disagreed. The statement *New genetic scientific discoveries mean that children will be healthier and spared hereditary diseases* did not elicit the same positive response. Nine per cent disagreed, while 36% were in agreement. Taking the choice of 'I partly agree' into consideration means adding about a third of the respondents to the optimists. Looking at the distribution in a gender perspective reveals that the male respondents are more optimistic while women are more cautious. This tendency is prevalent throughout the material.

Consistent with these attitudes are the answers given to the question *Thinking about human genetic research and biobanks, do you see mostly advantages or mostly risks?* Seventy-six per cent find that the advantages outweigh the risks. Again, men are more favourably disposed, as are respondents living in big cities, having university education, and having political sympathies right of middle. When asked if they felt hopeful or worried about the future, considering *the discoveries in genetic research and the creation of biobanks and what this might lead to*, the optimism was less pronounced: only just under 60% said they felt hopeful. Men as well as respondents politically right of middle stand out as more in favour of genetic technology.

The ambivalence expressed in the data comes across in this quote from a respondent, a woman of twenty years who was a university undergraduate:

> I think it's very hard to take a position on biobanks. The dilemma, as well as my own fear, is that the data that comes out can be used to help us avoid illnesses, but it can also be used as a weapon for special treatment and discrimination. I also worry that all research today is profit driven. It makes me suspicious of the researchers' motives, since people in the West generally dream of money and fame, and researchers are people too. On the other hand, if you take away the possibility of economic advantages from research a lot of it would probably stop.

One of the statements put in the questionnaire actually dealt with the kind of society that the existence of biobanks might lead to: *Biobanks might*

pave the way for a 'big brother' society, where the population will be classified as first and second class people, based on their genetic characteristics. Forty-two per cent of the respondents accepted this dystopian scenario as a possible future development, and for some of them the question brought back memories of the eugenic research of the pre-war years: 'We must ask ourselves how, in a hundred years or so, will they look back on the decisions that we make today?'

An overwhelming majority of respondents, 91%, accepted the necessity of research on human genes, but only in order to detect, prevent and cure diseases. Eight per cent accepted free and unrestrained genetic research, and only 1% wanted a total ban on research on human genes. However, it was considered of vital importance that the biobanks used for genetic research are state controlled. Ninety-one per cent of the survey population agreed with the statement *Genetic research must be state controlled in order to avoid harmful effects*. The alternative response, *Genetic research must stand free of government control in order to make new important discoveries*, was agreed to by only 9%. Only if biobanks are publicly owned, is it, according to a majority of respondents, possible to legally control access to genetic matter for research. Present laws are considered insufficient (by 84%; one must keep in mind that only 33% had heard of the new law on biobanks) and confidence that laws and regulations are keeping step with the development of biogenetics is low.

The general approval of genetic research notwithstanding, there is a widespread sceptical, even suspicious, attitude toward genetic researchers. A majority of respondents expressed this in a set of questions devoted to the role and position of the researcher, who is considered unfit to make moral decisions, who should be kept away from political decision-making, who has no respect for the common man, and who only represents the interest of the sponsors of his research. A woman of seventy-one years, a former interpreter, said: 'Mankind is constantly moving forward, and research is required for the development of all things needed. Only responsible, incorruptible people, who are aware of their great task of pushing the development of humanity further, should be conducting research.'

Given the inevitability of biobanks, it remains an important question how genetic data are made available to researchers and for what purposes. Informed explicit consent was seen as the *sine qua non* of genetic testing by 94% of the survey population, and support was just as strong for the right to be taken off the biobank at any time. The position expressed in the answers to these two questions is related to the fear of being secretly included in any register in this day and age of advanced information and communication technology. However, the population is split down the middle on the issue of whether researchers should have free access to all

genetic material once consent is freely given, or whether every new research project requires new consent.

Support for the statement *If others have access to genetic data concerning you, they know much too much about you* is overwhelming: only 11% disagree. This is interpreted as an expression of a general wariness in relation to genetic databanking. So, who can be trusted with access to human genetic data in biobanks? 'Medical specialists' are on top of the list, which is consistent with the general support of medical applications of biogenetics. A 'government committee for research ethics' comes second and 'university scientists' come third, all safely above the 50% mark. Slightly below, with 49%, we find the 'pharmaceutical industry scientist'. The 'police' had a return of 42%, which is consistent with the fact that 75% accept that genetic data may be used to identify suspects of crimes. At the bottom of the list we find 'employers' and 'trade unions', each trusted by one half per cent of the population. As one of the respondents succinctly put it: 'The only one with access to a person's genetic code should be that person.' Similarly, when asked who can be trusted to tell the truth about the risks involved in genetic research, independent scientists and state experts came out on top with 53% and 40% respectively, while other alternatives were below 16%. Significantly, 27% trusted nobody at all.

The concerns of the people in the survey population are most decisively and vividly expressed in the answers to questions that deal with the various applications of genetic research related to biobanks. Between 75% and 90% of the survey population accept research on biobank data in order to facilitate diagnosing illnesses, to make it possible to create individually designed medicine, to help us understand why some people develop diseases and others do not, to identify criminals, and to establish paternity. It is not acceptable, according to the respondents, to use genetic data to develop weapons of mass destruction, or to employ genetic knowledge to create designer babies – not even to the limited extent of making sure the baby is of a certain sex.

There are two areas where access to genetic data is considered particularly controversial, in this survey as well as in the public discourse on biobanks, namely access by private insurance companies and by employers.

Eighty-seven per cent of the survey population found it not acceptable that insurance companies can gain access to genetic data from biobanks. People are obviously conscious of the risks of genetic discrimination, in terms of both whether a person is considered an acceptable risk and how the premiums are fixed. This result is a universal trait in all surveys in all countries, and must be taken very seriously.

Even stronger and more explicit are the returns regarding employers' access to genetic data about employees and job applicants that give

information about health status and possible future illnesses. Ninety-seven per cent will not accept that the employer can demand genetic information of this kind from a job applicant. It is, however, considered more acceptable for the employer to inquire into the possibility of a new employee being a potential danger to colleagues or customers: 20% of the respondents accepted that. Even stronger support, 40%, is expressed when the genetic data are thought to determine if the applicant might be harmed by certain substances prevalent in the workplace. The corresponding figures for current employees are similar to those concerning job applicants.

Concluding comments

The Swedish welfare system, one of the most comprehensive in the world, is made up of individuated social rights, conditioned labour market participation and wage contributions. In order to function justly, the system requires that correct data about the individual's work situation, wage level, taxes paid and various social benefits collected are up to date and readily available. To this end, every Swedish citizen is assigned a unique citizen number, given at birth and composed of birth date (yymmdd) plus a three-digit birth number and a control digit. This number is registered in every public, and most private, registers where the citizen is inscribed, including the public healthcare system, the inland revenue, all welfare benefit authorities, banks, telephone companies, electric companies, etc.

Thus, the Swede waives at birth what many would consider inalienable rights to privacy, and this fact arguably implies a relationship to the state, government and public administration on the part of the adult Swede, characterized by a relatively high degree of trust.

It would not be unreasonable to suggest, hypothetically, that the average Swede can be assumed to take lightly the fact that now also his/her DNA is linked to the citizen number. The current study does not attempt to test such a hypothesis; however, the results can be construed as in part supporting it.

The Swedish public also trusts science in general, and medical science in particular, to work for the common good of society. A recently published study reveals that 84% of Swedes have a high or rather high degree of trust in medical science and research, and, furthermore, that 35% of Swedes want to give priority to genetic research.[1]

[1] Sören Holmberg and Lennart Weibull, 'Vetenskapen står stark i folkopinionen', in Sören Holmberg and Lennart Weibull (eds.), *Ju mer vi är tillsammans* (Göteborg: SOM-Instutet, 2004), pp. 93–102.

In conclusion, the concerns of the Swedish public in regard to human genetic databases are not easily discerned. Available data, from the current study as well as others, suggest that Swedes are primarily concerned by the non-medical applications of human genetic data, by insurance companies and employers, that might lead to genetic discrimination. The concerns expressed in the quotes above deal with this fear, as well as general concerns about manipulating the laws and workings of nature. A leading Swedish historian of science recently suggested that, in fifty years or so, scientists would look back at our time and chuckle at the determinism that characterized our understanding of genetics. A similar concern is expressed in this quote from one of the respondents in the present study:

> I imagine that most diseases are the result of an interplay between inherited and environmental factors, where the latter are most influential. [. . .] But working with environmental factors puts so many more demands on the whole of society; it's easier to focus on one thing. It is an example of the kind of tunnel vision that appears when you divide knowledge into separate disciplines.

9 United Kingdom

Sue Weldon

In June 1999 a proposal for a UK-wide biobank (comprising a collection of DNA data, medical records and lifestyle information) was announced by a funding consortium comprising the UK Department of Health (DoH), the Medical Research Council (MRC) and the Wellcome Trust (WT). The idea they then presented was to use information collected from 500,000 volunteers, aged between forty-five and sixty-nine, as a resource for research into common multi-factorial diseases that affect people in later life. It is known that these are medical conditions that may be caused by a complex range of genetic and other factors.

The UK Biobank (as it was later named) received funding in 2002, but prior to the launching of the project a considerable amount of research and consultation was carried out by the funders and by the Government's advisory body the Human Genetics Commission (HGC) to determine public perceptions in relation to current advances in medical genomics and, more particularly, in relation to the setting up of UK Biobank.[1] For instance, a major public consultation was undertaken (during 2000–2001) by the HGC on the future uses of personal genetic information. As part of this consultation they commissioned a quantitative survey of public attitudes to human genetic information.[2] At the same time the UK Biobank partners – the MRC and the WT – commissioned their own consultation. They carried out a programme of qualitative focus groups and interviews to inform their guidelines and principles (the protocol) governing use and collection of data.[3]

[1] Cragg Ross Dawson, *Public Perceptions of the Collection of Human Biological Samples* (London: Wellcome Trust and Medical Research Council, 2000); Human Genetics Commission, *Public Attitudes to Human Genetic Information – People's Panel Quantitative Study Conducted for the Human Genetics Commission* (March 2001); People Science and Policy Ltd, *Biobank UK. A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust* (London: Wellcome Trust and Medical Research Council, 2002); Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (May 2002).

[2] UK Human Genetics Commission, *Public Attitudes to Human Genetic Information*.

[3] Cragg Ross Dawson, *Public Perceptions of the Collection of Human Biological Samples*.

Data from this existing research has provided valuable information for comparison with other ELSAGEN surveys.[4] The findings have also provided a baseline for the UK investigation of people's perceptions of privacy and trust in relation to genetic databases. The approach for this further investigation was a qualitative focus group method. As the literature suggests, focus groups are useful in allowing people to generate their own questions, frames and concepts.[5] This method is designed to enable researchers to explore people's perceptions as they operate in a social context, allowing people to respond using their own categories and associations, in contrast with surveys which impose the researcher's meanings of abstract concepts such as 'privacy' and 'trust'.

General attitudes towards genetic research

The initial consultations to determine people's general attitudes to new developments in medical genetics were carried out by UK Biobank's funders and the HGC. These consultations were conducted at a time when the protracted public debate and concerns about the introduction of genetically modified food were still being discussed in the media. The following overall themes that emerged from these investigations to some extent reflect the heightened concern and explain the ambivalence about new developments in the biosciences.

In the first place this is evident in the quantitative survey, commissioned by the HGC, which suggested that although 90% of those surveyed agreed that new genetic developments will bring cures for diseases, a third expressed concern that human genetics is tampering with nature and therefore unethical. A similar ambivalence was recorded by the qualitative research (commissioned by the MRC and the WT) which suggested that although better understanding of genetics research could lead to a more positive view, many people believed that new research was driven by scientific curiosity rather than social purpose.[6]

The MRC/WT qualitative research reported substantial evidence of recent erosion of trust within the UK, in general practitioners (GPs) and other medical practitioners, after a series of health-related scandals. It was also reported that medical research carried out by public bodies is trusted more than research carried out by pharmaceutical companies.

[4] K. Korts, S. Weldon and M.L. Gudmundsdóttir, 'Genetic Databases and Public Attitudes: A Comparison of Iceland, Estonia and the UK', *Trames* 8 (2004), pp. 131–149.
[5] R. Barbour and J. Kitzinger (eds.), *Developing Focus Group Research* (London: Sage, 1999).
[6] Interestingly, this insight links with people's perceptions of GM food, cloning and designer babies.

In the quantitative survey (carried out for the HGC) 70% expressed little or no confidence that rules and regulations are keeping pace with new research developments. Similarly, when asked who they would trust to use genetic information held on genetic databases responsibly, the quantitative HGC survey revealed that the greatest number (87%) would trust their GP/family doctor, closely followed by health professionals (74%), with only 59% trusting the forces of law and order (the police).

There was general agreement by 70% of those surveyed by the HGC report that genetic information should be publicly owned – and available to all for use at no charge. This agreement was irrespective of whether the information had been collected and developed by publicly funded research or commercial organizations. However, it should be noted that no questions were asked about the extent to which free and public information should be used to make private profits.

More than half of those surveyed felt that information from genetic testing by a doctor should not be shared with other organizations and 70% rejected the suggestion that insurance companies or employers should be able to see the results. Notably, however, there was universal support for the police to take DNA samples for serious crimes.

More than half (61%) of those surveyed agreed that commercial organizations should have access to information only if individuals could not be identified. The qualitative research highlighted concerns about genetic information, more particularly the term 'DNA' having associations with police investigation of criminals and 'big brother' surveillance. Other privacy issues included concern about misuse of information by insurance companies and employers to discriminate against people on the basis of their genetic predispositions to disease.

The ELSAGEN study

The aim of the ELSAGEN social research was to achieve a deeper understanding of people's perceptions of privacy and their trust in the guardians of biobanks and the institutions setting them up and regulating them. The UK team felt that the findings of this existing research, although useful, had left unresolved questions about how people were framing their responses to questions relating to these issues and that the empirical research needed to take one step further to address those questions specifically.

The rationale for this approach has been described above. Six focus groups were carried out from November 2003 to April 2004 in locations throughout Britain. They were chosen for variety of location, urban and rural. The intention was to obtain a generalized selection of 'the public'

and the groups comprised six to eight people, equal numbers of men and women, aged from eighteen to seventy, and with a variety of socio-economic backgrounds (the final group was adjusted to address an ethnic bias that had inadvertently been introduced). Each of the discussions lasted for an hour and a half and was tape recorded and transcribed.

The aim was to get a more grounded feeling for any particular perceptions arising in the UK context. For instance, what are people's attitudes about safeguarding their privacy and on what basis would they place trust?[7] The first part of the research explored the context in which these attitudes to privacy have arisen in the UK. The second part was devoted to concerns about trust. Trust, or rather lack of trust in the institutions regulating scientific innovation, has increasingly been identified as a key problem in the UK.[8] The results presented here indicate that although the ethical concerns about privacy need to be fully explained, it is the issue of trust that is a key dimension in people's responses to the idea of biobanks.

Concerns about privacy

In order to get a good sense of people's perceptions relating to private space and personal autonomy, the focus groups began with a general discussion about people's attitudes to privacy. Discussions revealed spontaneous and strong feelings about personal space, i.e. not having people watching what you are doing, that could be attributed to many British people. Personal autonomy was another factor that arose in relation to what kinds of information should be kept private. This was felt to be a matter of personal choice. However, in discussing the need to balance the right to personal privacy against the need for public safety and national security, the research revealed that most people accepted that a 'right to privacy' could not be enjoyed by everyone in every situation: they reflected on the need to 'draw the line' between individual rights and social constraints. Surveillance aspects of a 'big brother' state were also raised and – in the context of terrorist threats – there was genuine ambivalence about a perceived need for greater public security that needed to be balanced against an erosion of privacy.

[7] It is often suggested, for instance, that in the UK we are deeply hung up about privacy because people are generally reluctant to carry an ID card. But then why are we so willing to accept CCTV cameras and to volunteer personal information to banks and to supermarket loyalty card schemes?

[8] See, for instance, House of Lords Select Committee on Science and Technology, *Science and Society*, *Third Report* (London: HMSO, 2000).

Perceptions of privacy in relation to information are believed to be at the core of ethical concerns about genetic databases, and perceived invasions of privacy relating to information were raised spontaneously by the UK research participants. Many people raised the subject when talking about personal finance as well as medical information: they were particularly concerned about the perceived increase in the use of personal information as a 'commodity' to be bought and sold in the marketplace and the blurring of the boundaries between public and private institutions in the UK.

Medical information is felt to be particularly private, although many people reflected on the convenience of computerized records and of multiple access points. But it was felt that there needed to be confidentiality safeguards to protect people from discrimination – for instance by employers and insurance companies.

Concerns were raised about the security of large databases containing private information – specifically in relation to the perception that all computer systems are inherently vulnerable ('they hacked into the Pentagon didn't they!').

Furthermore, specifically in relation to the donation of samples to genetic databases, there was concern about losing the right to determine the future use of the DNA sample and the associated information. People did not feel that this concern could adequately be addressed by a process of individual informed consent and anonymization of their personal data.

Trust in institutions regulating biobanks

It is generally felt that success in creating large biobanks will depend a great deal on people having a lack of concern about, or trust in, the way their data will be collected, stored and used. In the UK there is a high level of scepticism, and policy documents now recognize that confidence in the regulation of genetic research cannot be assumed. The focus groups confirmed a general scepticism in relation to who can be trusted at the policy level. It was obvious that people would not place their trust in unprincipled institutions or in people whom they felt might misrepresent the real issues: 'There's all this corruption and God knows what else! . . . They [the Government and government policy bodies] never tell the truth . . . they can't give you a straight answer and now they want us to trust them with our genetic codes!'

The complexity of institutions acting as public–private partnerships – with both a public function, i.e. to provide healthcare, and also a commercial interest – has made it very difficult for people to place their trust

in those organizations' ability to maintain a social welfare function. Furthermore it was felt that information is difficult to secure if 'someone can make a buck out of it'. Information is now a valuable commodity and can be bought. The attitude that predominates is that: 'now everything is up for sale and everyone has a price!'. Under these circumstances there is more potential for discrimination and it was felt that private medical information might be used by insurance companies and employers to discriminate against people on health grounds if this could help them to secure an economic benefit.

The obvious answer to this would be to regulate the use of private medical information by private companies. But would people trust in rules and regulations, and what evidence do people have for judging the effectiveness of regulation? It was felt that a high level of trust would be essential to encourage active engagement and participation because non-participation would be the only form of control, or 'agency'.

Discussion

The UK focus groups identified the issues mentioned above as the key concerns about privacy and trust. Overall, the research indicated a need to understand better how people perceive privacy issues in the context of their personal circumstances. For instance, the research uncovered little evidence of people wanting to claim property rights over their samples, but neither did they want to see commercial interests doing so. The message is that, in the UK, people are willing to make their donation for medical research and to promote public health, but they are much more cautious about this when they lack confidence in the strict maintenance of the boundary between public good and private profit.

In 2002 the HGC published the results of their consultation on the issues relating to handling and storage of personal genetic information.[9] In this report they identified personal genetic information as being one of the most sensitive and important issues surrounding genetics. In bringing together these issues they proposed two basic principles to govern the use of genetic information: a principle of solidarity to promote the common good and a principle of respect for individual persons. However, the UK focus group findings suggest that a stark separation between rights to personal privacy and public interest might be an oversimplification. Furthermore, if the surrender of rights to personal privacy is to be

[9] Human Genetics Commission, *Inside Information*.

negotiated against a principle of solidarity for 'public interest', it is clear that confidence will be dependent upon how well the public sphere is regulated. The safe and sustainable operation of databases, the linking of datasets and the arrangements for access by third parties depend on controlling the misuse of personal data. People need to feel that they can *trust* in the governance of the research agenda and the public sphere.

10 Public discourses on human genetic databases

Piia Tammpuu

Introduction

The establishment of human genetic databases in different societies has brought along scholarly and public debates about the principles and implications underlying such biotechnological ventures. While raising a number of similar issues and concerns, such as the usage and security of the data stored in a database, protection of individual privacy and confidentiality, forms of consent required for genetic donation, questions of ownership, etc., the extent and nature of these debates as well as the responses given by the general public and professional groupings have varied from one context to another. Insights into these debates appear to be crucial for understanding and interpreting the formation of public opinion that has relevance both for the decision-making process related to the planning of such databases as well as to the legitimacy of the decisions.

The current chapter aims to examine particular discourses and framings applied by different actors in the domestic debates on national genome projects and their significance with respect to the public acceptance of these projects, particularly in the initial phase of their implementation. According to the definition proposed by Robert Entman, framing can be understood 'as a discursive strategy of communication in which some aspects of a perceived reality are selected and given more salience in communication in order to promote particular problem definition, causal interpretation, moral evaluation and/or suggested treatment'.[1]

The analysis focuses on the case of the Estonian Genome Project (EGP) while drawing comparison with the Icelandic Health Sector Database (HSD) which has received considerably more attention in scholarly discussions on human genome banks so far. Following mainly the example of the Icelandic database, the EGP was designed as a

[1] Robert M. Entman, 'Framing: Toward Clarification of a Fractured Paradigm', *Journal of Communication* 43 (1993), pp. 51–58.

population-based database linking medical records of health data with genetic information on Estonian people to identify and analyse genetic causes of illnesses. According to the initial plans, the database was supposed to include genetic samples of around 1 million Estonians, that is in principle the entire adult population of the country. The implementation of the whole project proceeded relatively quickly after the introduction of the preliminary idea and vision in 1999 until the pilot project and beginning of the data collection in 2002. However, by the beginning of 2005 the future of the EGP – having managed to gather approximately 10,000 genetic samples, i.e. only a tenth of what was initially planned for the pilot phase – was anything but certain, regarding both its financial as well as its scientific prospects.

As the comparative analysis with the Icelandic database suggests, it was the particular rhetoric and its successful adjustment to the local context by the initiators and major representatives of the database projects, who had a high reputation and trustworthy image in these societies, which worked mostly to persuade the public. This in turn was backed by the weakness of the media and its inability to create a reasoned argumentation and inclusive debate in the public sphere that would have resulted in more deliberate and calculated decision-making.

Human Genome Project as a public issue

With the changing relationship between science, society and the market, the formerly recognized autonomy of science has largely become contested. Scientists in general appear to be more and more dependent on public acceptance and evaluation in order to secure funding of their work and to continue research.[2] This has a certain influence also on the communication of science. As Hilary Rose points out, the combined support of the market and the state, characterizing, for example, techno-scientific projects such as the international Human Genome Project, has required 'selling' the new genetics to diverse audiences, including investors, lay people and government representatives.[3] Consequently, communication of science to the broader public is seen to be leaning increasingly on the tools of public relations in order to maintain the legitimacy and authority

[2] See, e.g., Gerard Delanty, 'Constructivism, Sociology and the New Genetics', *New Genetics and Society* 21 (2002), pp. 279–289; and Walter P. von Wartburg and Julien Liew, *Gene Technology and Social Acceptance* (Lanham, MD: University Press of America, 1999).

[3] Hilary Rose, 'Risk, Trust and Scepticism in the Age of the New Genetics', in B. Adam, U. Beck and J. van Loon (eds.), *The Risk Society and Beyond: Critical Issues for Social Theory* (London: Sage, 2000), p. 67.

of science in public, as well as to attract the interest of business entrepreneurs and investors.[4]

On the other hand, the advance of the biological sciences and development of biotechnologies make the general public, according to Jürgen Habermas, confront questions 'whose moral weight greatly exceeds the substance of ordinary matters of political dispute'.[5]

The media is attributed a major role in public understanding and perception of new genetic science. It is argued that the public conceives 'biotechnological reality' largely based on what the media conveys about the subject, given the fact that the possibilities to gain information through a direct personal experience seem to be limited. Here the constructions of 'biotechnological reality' mediated to the public via the media are routinely produced through selective presentation of themes, facts and claims, as well as through a particular choice of news sources that give preference to certain kinds of representations and argumentations.[6] Nevertheless, the democratic media is expected to provide a fair, balanced and multisided reporting and news coverage, as well as to allow free and open debate on issues of public significance.

With respect to the Icelandic Health Sector Database, different opinions about public acceptance have been put forward in scholarly debate. Some authors refer to the extensive public debate that took place in Icelandic society at the time when relevant legal regulations were drafted as well as to the fact that public opinion was mostly supportive towards the database.[7] Other authors, on the other hand, have strongly argued that the debate about the Health Sector Database in Iceland did not represent community consent and the decision-making procedure through which the HSD was made possible was seriously flawed, as 'the quantitative facts about extensive debate and overwhelming majority opinion must not be confused with the qualitative notion of

[4] In this respect it is noteworthy that the Estonian Genome Project, for example, was awarded first prize in the annual competition of public relations projects in 2000 organized by the Estonian Public Relations Association.

[5] Jürgen Habermas, *The Future of Human Nature* (Cambridge: Polity Press, 2003), p. 17.

[6] See Jan M. Gutteling et al., 'Media Coverage 1973–1996: Trends and Dynamics', in Martin W. Bauer and George Gaskell (eds.), *Biotechnology – The Making of Global Controversy* (Cambridge: Cambridge University Press, 2002); Alison Anderson, 'In Search of the Holy Grail: Media Discourse and the New Human Genetics', *New Genetics and Society* 21 (2002), pp. 327–337; Alan Petersen, 'Biofantasies: Genetics and Medicine in the Print News Media', *Social Science and Medicine* 52 (2001), pp. 1255–1268; and von Wartburg and Liew, *Gene Technology and Social Acceptance*.

[7] See, e.g., Gísli Pálsson and Kristín E. Hardardóttir, 'For Whom the Cell Tolls: Debates About Biomedicine', *Current Anthropology* 43 (2002), pp. 271–301.

consent to participation in the database which implies an understanding of the issue consented to'.[8]

Background of the Estonian Genome Project

The idea of establishing an Estonian genome project dates back to 1999, that is a year after the plans of the Icelandic Health Sector Database had been introduced and intensively discussed in Icelandic society. The Estonian Genome Foundation (*Geenikeskus*), established by a private initiative of thirty-four individuals among whom were several prominent Estonian geneticists and medical professionals, politicians and science journalists, proposed the initial vision of a national gene bank.

The idea was put into practice in principle by the adoption of a special law – the Human Genes Research Act (HGRA) – passed by the Estonian Parliament in December 2000 and enforced in January 2001. It is also notable that the Act itself, providing rather detailed regulations for the establishment of the Estonian Genome Project, was approved by the Parliament within a very short period of time.[9] In March 2001, the Estonian Government established the Estonian Genome Project Foundation (*Geenivaramu*), a non-profit foundation responsible for the preparation and implementation of the Estonian Genome Project. The public limited companies E-Geen and E-Geen International, whose task was to attract investors and secure the financing of the project, were founded soon afterwards. According to the agreements signed between the Estonian Genome Project and these two companies in December 2001, the latter obtained exclusive rights to access the database and to sell the data for commercial purposes.

The collection of genetic samples was started in three Estonian counties in October 2002. Within the so-called pilot phase, the project hoped to draw in some 100,000 gene donors. However, by the beginning of 2005, only some 10,000 DNA samples were stored in the database – which was ten times less than intended and a hundred times less than initially promised.

As the key dates listed above indicate, the implementation of the whole project took place relatively quickly. However, growing disagreements between the Estonian Genome Project Foundation and E-Geen led to the

[8] Vilhjálmur Árnason and Gardar Árnason, 'Informed Democratic Consent? The Case of the Icelandic Database', *Trames* 8 (2004), p. 169.

[9] The bill drafted under the guidance of the Ministry of Social Affairs was passed at the second reading only with minor modifications and without a particular debate or contestation in public in December 2000, i.e. three months after the first introduction and reading in Parliament in September 2000.

termination of former agreements at the end of 2004, as a result of which the future of the project was left completely undetermined.

Of the main principles of the EGP, two aspects are perhaps of particular relevance with respect to public acceptance and perception of the project. First, participation in the national gene bank was left strictly voluntary, including the requirement of signing a written form of informed consent by a gene donor. Thus, unlike the presumed consent in the case of the Icelandic Health Sector Database where people were assumed to be willing to give their data to the database, unless they explicitly decided to opt out, participation in the Estonian Genome Project relied primarily on individual initiative and motivation (the opt-in principle). In this respect, representations and images of the databank proposed in public may be seen to be highly relevant, persuading people whether to participate in the project or not. The second aspect, which was truly novel at the time when the EGP was designed, is the right to get personal feedback about one's genetic data and to learn about one's genetic risks which was granted to gene donors by the HGRA. Such personalized genetic information was promised to be delivered to gene donors in the form of a personal 'gene card'. According to survey data from 2002, the possibility of receiving a personal 'gene card' appeared to be a major incentive for people intending to donate their sample to the databank.[10]

Analysis of public discourse on the Estonian Genome Project

Given the overall complexities characterizing the interaction between the formation of public opinion and public discourse, a comprehensive and systematic analysis of the media coverage of the EGP was carried out within the ELSAGEN project in addition to a sociological public opinion survey.

The study covered a four-year period from January 1999 to December 2002, i.e. the temporal frame from the introduction of the initial idea of the national genome project until its first phase of implementation. All major dailies (*Postimees, Eesti Päevaleht, SL Õhtuleht, Äripäev*) and weeklies (*Eesti Ekspress, Sirp*) with national circulation were included in the study. As a result of online searching based on a comprehensive list of key words, in total about 235 articles from the aforementioned four-year period were included in the final analysis. For comparison, according to

[10] See Külliki Korts, 'Introducing Gene Technology to the Society: Social Implications of the Estonian Genome Project', *Trames* 8 (2004), pp. 241–253.

a media study in Iceland, more than 500 news and other items were published in a single newspaper, a major Icelandic daily, alone within twenty-eight months of the first reading of the bill on HSD in April 2000 until the granting of deCODE's licence for constructing the database in January 2000. This has allowed characterization of the Icelandic public debate as truly 'extensive',[11] while the Estonian domestic debate appears to be rather modest in comparison.[12]

Both (quantitative) content analysis, focusing on authors and news sources, and on the distribution of risks and benefits constructed in the press, as well as qualitative discourse analysis were applied as methods of research. While the content analysis enabled researchers to follow certain trends and shifts in the media coverage over the four-year period, the more detailed analysis of texts allowed deconstruction of metaphors, various tools of rhetoric, and strategies of framing and contextualization applied by different groups in the public debate.

Framing and contextualization of domestic debates

The beginning of the domestic gene debate dates back to 1999 when the Estonian Genome Foundation was established. As explained in the press, the aim of the Genome Foundation was to unify Estonian gene technologists working in different laboratories, 'in order that Estonia would stay in the first rank of this rapidly developing field', as well as to 'help the society understand where geneticists have arrived and where they will arrive' (*Eesti Päevaleht* on 27 January 1999).

From the very beginning of the domestic gene debate, the initiators and proponents framed the idea of establishing a national gene bank in terms of both a 'necessity' as well as a 'chance'. On the one hand, the idea of the genome project was presented in the global context of biotechnology and biomedicine as two rapidly developing and highly promising fields. On the other hand, the idea was connected to/linked with the post-socialist context of Estonia and its symbolic environment.

Geneticists and medical scientists, as well as journalists who mostly took over the arguments of the former, justified the foundation of the national gene bank mainly with the emergence of the new 'individualized medicine' that necessitates genetic knowledge and research in society, and will provide people with more effective genetics-based methods of

[11] See Pálsson and Hardardóttir, 'For Whom the Cell Tolls'.

[12] It should be mentioned however that, beside the printed press, special TV and radio programmes on genetics, gene technology and the genome project were launched in Estonia during that time.

diagnostics and treatment, as well as personally tailored drugs corresponding to one's genetic make-up. As such, the genome project was initially introduced to the public as a scientific-medical project, contributing to personal and public healthcare. Invoking notions like 'entrance into the gene century', a 'new era in medicine', 'gene revolution', 'breakthrough in biotechnology', geneticists and medical scientists, as well as journalists and politicians endorsing the implementation of the EGP, argued that Estonia is driven by broader developments in medicine and biotechnology that cannot be either avoided or ignored. As such, the project was conceived to signify merely another instance of technological advancement.

Enclosed in this way within the common developments in biotechnology, Estonia was also depicted as participating in an international 'gene race', competing with countries planning or completing similar human genome databanks. Here the risk of missing the chance and losing the honourable and desirable first prize in the competition was frequently served as an argument to further the completion of the EGP by its initiators and proponents.

Geneticists and biomedical experts engaged by the Genome Foundation and the EGP claimed that Estonia had a number of advantages towards becoming a leading country in the field of gene technology. Strong traditions in molecular biology, on the one hand, and technological innovativeness, reflected mainly in the rapid growth of the IT sector during the decade after Estonia's re-independence, on the other hand, were used as support for this assumption. It was emphasized that gene technology may be one of the few fields where such a small country as Estonia can compete with big Western countries on an equal footing, or even achieve an advance. Of course, here the Icelandic Genome Project was often given as an example and comparison.

These expectations were likewise implied in several headlines, particularly in 1999: 'Gene sale will make Estonia well-known' (*Postimees* on 24 May 1999), 'Estonia's chance is in gene technology' (*Eesti Päevaleht* on 31 May 1999), 'EGP – The gas deposit of Estonian state' (*Eesti Ekspress* on 4 November 1999), 'Gene technology and transit are Estonian trumps for the coming years' (*Postimees* on 1 December 1999).

In the context of Estonian post-socialist transition and symbolic Return to the West, in which the public debate and the particular discursive framing were embedded at large, the establishment of a national gene bank thus served as further evidence of Estonia's post-communist 'success story' and as a 'big chance' for the country. Emphasizing Estonia's potential in genetics and biotechnology, the genome project was assumed to put Estonia on the world map (or back on the world map)

and to shape Estonia's international image and reputation as that of an innovative and competitive small country:

> The Estonian gene project is our next big national venture after re-independence. It concerns all living Estonians, besides several generations of those who are already dead, and many generations who are not born yet ... The success or failure of the gene project will determine Estonia's reputation as a state adjusting to the global world of science. (Anu Jõesaar, journalist, *Eesti Päevaleht* on 18 January 2002)

Such a framing and contextualization, applied by different social groups and public figures supporting the idea of establishing a national gene bank, continued to characterize the media coverage of the EGP throughout the four-year period and have been easily copied by foreign journalists, as the following excerpt exemplifies:

> Sometimes revolutions begin in the most unlikely of places. Iceland is a piece of volcanic rock in the middle of the Atlantic Ocean, inhabited by less than 300,000 people. Estonia is now the easternmost outpost of the European Union, after an overwhelming majority of its people voted on 14 September to join the EU. The country only gained its independence from the former Soviet Union in 1991, and the consequences of Soviet rule are still reverberating. But both countries are leading the way in the next revolution in medicine by establishing DNA and health databases of their populations, something that most larger countries have not yet begun to consider.[13]

Thus, in addition to scientific and medical benefits, the project was seen to produce economic profits and raise the general living standard by contributing to the development of high technology, attracting foreign investments and creating new jobs, especially for domestic biomedical specialists. Similar economic arguments, for example, were also used to support the establishment of the Icelandic database.[14]

Symbolic power of metaphors

Even before the detailed plans of the EGP were introduced in public, one of the main initiators and public proponents of the project, Andres Metspalu, Professor of Biotechnology at the University of Tartu, declared that it would become the Estonian Nokia, drawing here a parallel with the Finnish Nokia, a leading telecommunication company in the world, and also a national symbol of Finland that is known and recognized worldwide:

[13] Holgar Breithaupt, 'Pioneers in Medicine', *EMBO Reports* 4 (2003), pp. 1019–1021.
[14] See Pálsson and Hardardóttir, 'For Whom the Cell Tolls'.

Estonia's chance is in information and gene technology ... If these two will co-operate, there may emerge the desired Estonian Nokia. (Andres Metspalu, *Äripäev* on 27 May 1999)

Mini-societies like Iceland and Estonia that are genetically homogeneous and have a good health-care system and scientific base can accomplish the leap to the new medicine much faster than big countries that are still standing at the starting line ... Estonian Nokia may be hidden in our genes and in the Icelandic example. (Alo Lõhmus, journalist, *Postimees* on 18 September 1999)

The proposal for an 'Estonian Nokia' was initially put forward by Lennart Meri, the former President of Estonia, in his speech in 1999 concerning resources for the further development of the country. The metaphor of the Estonian Nokia became immediately popular and was continuously repeated in discourses on future scenarios of the country and debates about Estonia's social and economic development. Thus the search for an Estonian Nokia came to characterize the overall post-socialist identity narrative of the country and became central also to the rebuilding and construction of national identity.

It can be said that labelling the EGP as the Estonian Nokia turned out to be a powerful metaphor which symbolized innovation and technological advancement as the key factors determining development and success in the modern world based on high technology. Given the fact that the selection and use of metaphors appears to be strategic rather than accidental, and that repeated metaphors come to affect people's perceptions and understandings of scientific issues and events,[15] the portrayal of the EGP as the Estonian Nokia definitely helped to bring about a broader resonance in society regarding the EGP. As such it attributed to the genome project a meaning of a national (nationwide) enterprise extending beyond the (narrow) realm of scientific-medical research, and calling for joint efforts of Estonian people and providing a common point of reference for identification with the objectives of the project.[16]

Similar observations have also been made in the Icelandic context, where domestic discourse on the gene bank has called upon nationally meaningful phenomena and a sense of commonness, e.g. by establishing parallels between the databank and national fisheries, or evoking the

[15] See, e.g., Gutteling et al., 'Media Coverage 1973–1996'; Dorothy Nelkin, 'Molecular Metaphors: The Gene in Popular Discourse', *Nature Reviews Genetics* 2 (2001), pp. 555–559; Celeste M. Condit, *The Meanings of the Gene: Public Debates about Human Heredity* (Madison, WI: University of Wisconsin Press, 1999); and José van Dijck, *Imagenation: Popular Images of Genetics* (New York: New York University Press, 1998).

[16] See also Amy L. Fletcher, 'Field of Genes: The Politics of Science and Identity in the Estonian Genome Project', *New Genetics and Society* 23 (2004), pp. 3–14.

significance of genetically bounded citizenship of the country based on continuity with the Viking past. As Pálsson and Hardardóttir argue, both supporters and opponents of the Icelandic database have appeared to be informed by 'deeper' cultural and political considerations; and public support of the project cannot be separated from a specific local history and the nationalistic discourse of Icelanders, emphasizing the uniqueness of the Icelandic biological and cultural heritage.[17]

Weighing risks and benefits

In the context of public acceptance of the genome project, the overall framing of the issue in terms of risks and benefits in the media coverage is also significant. From 1999 to 2002, approximately half of the articles discussing possible advantages and/or disadvantages of the genome project and gene technology focused only on benefits, while about one third discussed both concerns and benefits, and one fifth considered only risks or disadvantages.[18]

As the analysis of risks and benefits represented in the Estonian media coverage reveals, at the beginning of the debate in 1999 the domestic media appeared to be mostly supportive of the idea of establishing a national gene bank, focusing primarily on the scientific and medical benefits promised to arise from the project (see figure 10.1).

The initial enthusiasm of the initiators of the EGP that was generally shared by journalists was followed perhaps by a more balanced debate in 2000 when various risks and benefits were contrasted more explicitly in public discourse. However, the Human Genes Research Act, regulating the establishment of the database and the rights of gene donors in detail, was passed by Parliament in December 2000 with almost no prior debate in public or any involvement of the scientific community at large. The adoption of the Act, on the contrary, enabled the initiators of the project to 'switch off' from the public agenda or repel criticism concerning a range of potentially controversial and sensitive issues, such as the terms of individual participation in the project, protection of genetic data, rights of gene donors, etc. In principle, the adoption of the HGRA, claimed to provide Estonia with a clear advance in comparison with other countries planning to establish their genome projects, gave a 'green light' to the foundation of the

[17] Pálsson and Hardardóttir, 'For Whom the Cell Tolls', pp. 281–282; see also Sigrídur Thorgeirsdóttir, 'Genes of a Nation: The Promotion of Iceland's Genetic Information', *Trames* 8 (2004), pp. 178–191.

[18] For the risks and benefits suggested in the press, see Piia Tammpuu, 'Constructing Public Images of New Genetics and Gene Technology: The Media Discourse on the Estonian Human Genome Project', *Trames* 8 (2004), pp. 192–216.

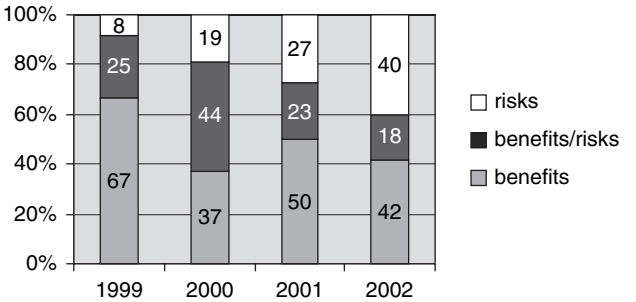

Figure 10.1 Distribution of risks and benefits in the articles on human genetic research and the EGP in Estonian press in 1999–2002.

EGP, leaving aside the principal questions as to whether a national gene bank should be established at all and what could be its scientific justification.

In 2001, already more practical issues concerning the financing and investments of the project had risen on to the public agenda and were considered at length in the press. In the light of the revealed commercial interests underlying the project, the formerly promised medical and scientific merits became publicly contested.

The issues of public awareness and voluntary participation in the project, as well as of the mediating role of family doctors between gene donor and the EGP, entered the discussion to a large extent only in 2002 with the implementation of the first phase of the EGP. At the same time, a large share of media coverage was devoted to the introduction of technical details concerning the logistics and storage of gene samples.

On the whole, it appears from the domestic media coverage that the principal decision-making concerning the foundation of the national gene bank was preceded by only a limited debate in public, while criticism expressed in the press emerged largely in response to the decisions already made.

Major agents represented in public debates

However, given these particular ways of framing the EGP in public, it is not only their rhetorical and symbolical weight that is significant or relevant, but also their origin in terms of the agents behind them.

With respect to the social groups and opinion sources involved in the domestic gene debate, the public discourse on the EGP can be regarded mainly as an expert discourse, in the sense that, besides journalists, it is

have commented on the topic. Among news sources, geneticists and medical scientists as well as various financial and legal experts involved in the establishment of the EGP, including administrative staff and board members of the EGP, have been asked to comment on the topic most often, accounting for more than half of all commentaries and references. The most frequently quoted source over the four-year period was Andres Metspalu, Professor of Biotechnology at the University of Tartu, also one of the main founders of the genome project and a board member of the EGP. As such, Metspalu appeared as one of the main spokespersons and promoters of the EGP since the issue was first introduced to the public. At the same time, scientists and scholars from other fields or geneticists not directly engaged with the project were asked to comment on the issue less frequently, thus limiting the potential range of arguments and positions.

As various studies regarding the communication of science have revealed, journalists frequently rely upon scientists as their main sources of information. 'Establishment scientists' or those 'institutionally powerful' are regarded as more trustworthy and credible sources than 'independent' scientists.[19] Besides the scientists and experts involved in the Genome Foundation and the EGP, there has been almost no other institutionalized voice equally represented in the public debate, neither by the scientific community nor by other professional groupings.

A global comparative survey of media coverage of biotechnology over two decades has revealed that groups that focus primarily on beneficial aspects of modern biotechnology, such as scientists and industry representatives, appear to be referred to in the media discourse more than other groups, leading to a 'positively biased' media coverage.[20] Overall there have been only a few figures, mainly from the medical community and the social sciences, who have consistently and publicly criticized the implementation and regulations of the project from a scientific as well as an ethical/individual's point of view.

On the journalists' side, on the other hand, there appear to be only a few who have specialized in issues of science and/or genetics, and their reporting tends to a large extent to reflect the so-called 'scientific conformism'. As revealed from the media coverage, journalists writing on the subject are not used to questioning or critically examining the information provided by geneticists and biomedical experts, but take over their assumptions and devices of rhetoric without critical consideration. Thus, there appears little recognition of the changing relationship between science, society and the market. Journalists are not used to questioning or contesting the credibility

[19] Anderson, 'In Search of the Holy Grail'; Petersen, 'Biofantasies'.
[20] Gutteling et al., 'Media Coverage 1973–1996'.

and/or neutrality of geneticists and medical professionals enforcing the implementation of the genome project. The press rarely scrutinizes the statements, actions or potential conflicts of interest of scientists to the same extent that they do those of leaders in politics or business, for example. Given these findings, it is noteworthy that, according to the findings of the public opinion survey in 2002, geneticists and staff of the EGP enjoy the highest credibility rating in the eyes of the Estonian public compared to other possible information sources about the EGP.[21]

Implications of public discourse

When asked about the possible benefits and risks associated with the Estonian Genome Project, more than two thirds of the Estonian people agreed with various medical, social and economic 'benefits' that the EGP would allegedly bring about on a societal level, as widely suggested in public by the representatives of the Estonian Genome Project Foundation. At the same time, the perception of possible risks – mostly those that could occur on an individual level – appeared to be somewhat lower.[22]

The discursive strategies of framing described above are powerful means to influence public opinion. In the words of Leon Mayhew,

> [as] persuasion must rest on convincing others that proposals are in their own interests, and because trust in the persuader requires that the audience believe in the sincerity of the persuader, the entire process rests on a perception that the persuader shares the aims of the persuaded. Setting forth a suggestion predicated on an appeal to common interests amounts to asking another to join in a common identity or a joint effort.[23]

Hilary Rose has argued with respect to the Icelandic database:

> The successful branding of deCode as Icelandic and as Stefansson's personal project is key to its popular acceptability . . . For reasons of geography and history, a progressive civic nationalism is still vibrant within Icelandic culture, and Stefansson has managed brilliantly to locate deCode and the Health Sector Database inside a narrative of both scientific and national progress. The general public sees his charismatic nationalism and his enthusiasm for scientific innovation as exactly what Iceland needs.[24]

[21] See Korts, 'Introducing Gene Technology to the Society'.
[22] For more detail see ibid.
[23] Leon H. Mayhew, *The New Public: Professional Communication and the Means of Social Influence* (Cambridge: Cambridge University Press, 1997), p. 78.
[24] Hilary Rose, 'The Commodification of Virtual Reality: The Icelandic Health Sector Database', in A. Goodman, D. Heath and S. Lindee (eds.), *Genetic Nature/Culture: Anthropology and Science Beyond the Two-Culture Divide* (Berkeley: University of California Press, 2003), p. 80.

If the names of the countries and persons in this quotation are substituted, this statement could be almost equally applied to the Estonian Genome Project. It has been the successful contextualization of the project both globally and locally, making its aims identifiable for many by appealing to a shared common identity, and a high level of public trust that have allowed the initiators and proponents of the project to achieve public acceptance and support.

However, according to the same sociological survey, carried out within the ELSAGEN research project in the autumn of 2002, that is at the time when the pilot project of the Estonian Genome Project was carried out and more than three years after the idea of the project was first publicly discussed, 62% of Estonian people claimed to have heard about the Estonian Genome Project, while only 7% considered themselves to be well informed about the project. Asked where they had got information about the project from, 45% mentioned newspapers and journals as their primary sources about the database issue, 37% named television and 10% radio.[25]

Conclusions

According to Habermas, in a situation where biotechnological research has become tightly interwoven with investors' interests and with the striving for progress and success by national governments, 'the developments of genetic engineering have acquired a dynamic which threatens to steamroll the inherently slow-paced processes of an ethicopolitical opinion and will formation in the public sphere'.[26] The case of the Estonian Genome Project exemplifies these tendencies utterly. The Estonian media failed to provide an arena for critical and inclusive public debate on the genome project, resulting in non-deliberative decision-making about the project.

As the analysis of the media coverage of the EGP reveals, public discourse pertained to rhetoric rather than substantive argumentation,[27] and focused mostly on benefits rather than risks created by the implementation of such a database. The public reception of the Estonian Genome Project has obviously been influenced by the rhetorical persuasion permeating the public debate. Appeals to common benefits arising from the projects and the supposed altruism of people driven by the idea of a 'common good' and national solidarity have allowed the 'hiding' of

[25] See Korts, 'Introducing Gene Technology to the Society'.
[26] Habermas, *The Future of Human Nature*, p. 18.
[27] See also Tiiu Hallap, 'Science Communication and Science Policy: Estonian Media Discourse on the Genetic Database Project', *Trames* 8 (2004), pp. 217–240.

ethical and moral implications accompanying the expansion of human genetic research and genetic knowledge in society, as well as the commercial interests underlying the genome project. Similar conclusions have also been drawn about the public debate in Iceland, much of which has been characterized as 'uninformed, misleading and prejudicial'.[28]

In this sense, what is of concern is not merely the prevailing and dominant framing that the media tends to apply while reporting about issues of biotechnology and genetics, and its implications on public perceptions, considerations and decisions. Also of concern is the broader question about the overall capability of the media to support the functioning of a deliberative public sphere, ideally contributing to a reasoned debate and being in principle open to all.

[28] Árnason and Árnason, 'Informed Democratic Consent?'.

Part III

Legal issues

11 Regulating human genetic databases in Europe

Jane Kaye

The advances in computer technology and high-throughput DNA sequencing have led to a substantial increase in the amount of genetic research being conducted throughout Europe.[1] This, in turn, has led to the establishment of many different kinds of genetic databases. Population genetic databases, which have been the focus of the ELSAGEN project, represent one kind of human genetic database that is currently being developed in Europe. There are many more genetic databases that are not as well known and have not been subjected to the same intense international scrutiny and debate. Examples include web-based digital collections such as Ensembl,[2] collections made as 'add-ons' for clinical trials or genetic databases established for one-off, specific research projects. Scientists have expressed concern that the current regulatory framework for human genetic databases within Europe is inadequate.[3] In May 2004 the EC Expert Group on Genetic Testing recommended that 'action be taken at the EU level ... to follow and address regulatory issues related to collections of human biological material and associated data and their uses'.[4] The concern is that the lack of standardized guidelines inhibits co-operation amongst researchers and the sharing of samples from genetic databases across national borders. The research of the ELSAGEN legal team has shown that there are significant obstacles to achieving a uniform European regulatory system for human genetic databases. The purpose of this chapter is to discuss some of the preliminary issues that would need to be addressed before such a regulatory system could be developed within Europe.

[1] My thanks go to Dr Sue Gibbons and Dr Andrew Smart for their assistance in developing some of the ideas in this chapter and the ELSAGEN law team for increasing my knowledge of the law in each of the jurisdictions of the ELSAGEN project partners.

[2] Ensembl website, http://www.ensembl.org/ (accessed on 17 February 2006).

[3] A. Husebekk, O.-J. Iversen, F. Langmark, O.D. Laerum, O.P. Ottersen and C. Stoltenberg, *Biobanks for Health – Report and Recommendations from an EU Workshop* (Oslo: Technical Report to EU Commission, 2003).

[4] European Commission, *25 Recommendations on the Ethical, Legal and Social Implications of Genetic Testing* (Brussels: EC Directorate-General for Research, 2004), recommendation 21.

Defining human genetic databases

One of the major obstacles to developing a uniform system of regulation is the lack of an agreed definition of 'genetic database' based on an understanding of the many different types of genetic databases that currently exist. Considerable confusion surrounds what human genetic databases should be called and a variety of terms appear in the literature, such as 'gene bank', 'biobank', 'DNA bank' and 'population genetic database'. With the exception of 'population genetic database', these terms are not based on any agreed definitions or recognized types of genetic databases. This suggests that we may still be in the period of innovation where the (legally) material distinctions between different types of genetic databases have not been clearly defined and articulated. Another possible reason for this lack of conceptual clarity is that there is no clear idea of the numbers and types of human genetic databases that currently exist within Europe, in contrast to the highly publicized and much-debated population genetic databases which are well documented. Therefore, the EC Expert Group on Genetic Testing also recommended that an inventory of existing biobanks be created, as well as a system to evaluate and monitor their current usage.[5]

Definitions of genetic databases can be found in the laws of Iceland, Sweden and Estonia,[6] but these are limited in their scope and may not capture genetic databases *per se* nor all of the different types of genetic databases that exist in each jurisdiction. For example, in Sweden, a 'biobank' is defined as 'biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates'.[7] This definition is very similar to the definition in the Icelandic Act on Biobanks no. 110/2000. These definitions have a broad scope to cover 'biological material' but this may mean that they may exclude DNA. This appears to be the case in the UK, where the definitions of 'relevant material' and 'bodily material' in the new Human Tissue Act currently focus on cellular material, and do not include extracted DNA.[8] Such definitions also exclude information that could be derived from, or is connected with,

[5] Ibid., recommendation 20c and d.
[6] In the UK there has been little attempt to develop a legal definition of genetic databases, although there is general legislation in the form of the Human Tissue Act 2004 to cover the use of biological samples.
[7] Biobanks in Medical Care Act 2002:297 (Lag om biobanker i hälso- och sjukvården m.m.), chapter 1, s. 2, Swedish Parliament.
[8] Human Tissue Act 2004, s. 53(1), UK Parliament.

the samples. These legal definitions are problematic when applied to genetic databases as they cannot incorporate digital genetic databases such as Ensembl which only include data. They also do not reflect current practice in genetic research where little distinction is made between the physical sample, the information that derives from it, and the personal information and the family history that accompanies it.

In contrast, the specialist statutes developed in Iceland and Estonia for their population genetic databases include data in the definitions of the databases. In the Icelandic Act on a Health Sector Database, the database is 'a collection of data containing information on health and other related information, recorded in a standardised systematic fashion on a single centralised database, intended for processing and as a source of information'.[9] However, this definition does not mention the DNA sample collection. In Estonia the legislation has not maintained a distinction between a DNA physical sample and information. According to the definition there, the Estonian Gene Bank is 'a database established and maintained by the chief processor consisting of tissue samples, descriptions of DNA, descriptions of state of health, genealogies, genetic data and data enabling the identification of gene donors'.[10] This definition reflects the contents of the genetic database, which take various forms, but all of its elements are given the same protections and treatment under the Act.

Thus, the current law can be problematic in relation to genetic databases. Before any uniform regulatory system is developed in Europe there needs to be a careful analysis of current practice regarding genetic databases in order to develop a typology of the different types of genetic databases that currently exist; the content of the collections; their purposes and uses; procedures regarding management and access; and how these may vary in the public, not-for-profit and commercial sectors. Without this information it is not possible to design and implement a regulatory system that will apply to all types of genetic databases and will facilitate co-operation between researchers leading to the greater use of existing genetic databases. Such analysis would also bring greater conceptual clarity to the debate and may lead to a reduction in the number of terms that are used to denote human genetic databases. It could provide a basis for the development of an appropriate regulatory system, based on a principled approach to the issues raised by the use of genetic information.

[9] Act on a Health Sector Database no. 139/1998, art. 3(1).
[10] Human Genes Research Act 2000 (Inimgeeniuuringute seadus, RT I 2000, 104, 685), chapter 2, cl. 10, Estonian Parliament.

Learning from the population genetic database debate

Any uniform regulation of genetic databases within Europe should be based upon a coherent set of principles to ensure that the law is consistent, effective and relevant for researchers and society. The controversial population genetic database proposals, such as the Icelandic Health Sector Database, have led to an extensive international debate over the principles that should be applied to human genetic databases.This debate has highlighted in particular the need to consider the familial nature of genetic information and the perceived risk to privacy that genetic databases may present. The principal issues raised by the debate are: consent, especially for secondary research purposes;[11] feedback to participants;[12] benefit-sharing;[13] the public interest;[14] participation in decision-making;[15] protecting privacy;[16] access;[17] ownership;[18] and intellectual property rights.[19] Further research needs to be carried out on how the complex notion of public interest should be construed and protected if the human genome is to be regarded as the common heritage of humankind.

However, not all of these principles have relevance for all other types of genetic databases, as it could be argued that the characteristics of population genetic databases raise specific and unique issues (particularly in

[11] E. Wright Clayton, K. K. Steinberg, M. J. Khoury, E. Thomson, L. Andrews, M. J. Ellis Kahn, L. M. Kopelman and J. O. Weiss, 'Informed Consent for Genetic Research on Stored Tissue Samples', *Journal of the American Medical Association* 274 (1995), pp. 1786–1788.

[12] S. Eriksson, 'Should Results from Genetic Research be Returned to Research Subjects and their Biological Relatives?', *Trames* 8 (2004), pp. 46–63.

[13] S. Wilson, 'Population Biobanks and Social Justice: Commercial or Communitarian Models? A Comparative Analysis of Benefit Sharing, Ownership and Access Arrangements', *Trames* 8 (2004), pp. 80–90.

[14] Ruth Chadwick and Kare Berg, 'Solidarity and Equity: New Ethical Framework for Genetic Databases', *Nature Review Genetics* 2 (2001), pp. 318–321.

[15] R. R. Sharp and M. W. Foster, 'Involving Study Populations in the Review of Genetic Research', *Journal of Law, Medicine and Ethics* 28 (2000), pp. 41–51.

[16] Graeme Laurie, *Genetic Privacy: A Challenge to Medico-legal Norms* (Cambridge: Cambridge University Press, 2002).

[17] J. E. McEwen, 'DNA Data Banks', in M. A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997).

[18] Antonio Casado da Rocha, 'Ethical Aspects of Human Genetic Databases: Distinctions on the Nature, Provision, and Ownership of Genetic Information', *Trames* 8 (2004), pp. 34–45.

[19] Henry Greely, 'Informed Consent and Other Ethical Issues in Human Population Genetics', *Annual Review of Genetics* 35 (2001), pp. 785–800; T. Caulfield, 'Regulating the Commercialization of Human Genetics: Can We Address the Big Concerns?', in A. K. Thompson and R. F. Chadwick (eds.), *Genetic Information: Acquisition, Access, and Control* (New York: Kluwer Academic/Plenum Publishers, 1999); B. M. Knoppers and C. Fecteau, 'Human Genomic Databases: A Global Public Good?', *European Journal of Health Law* 10 (2003), pp. 27–41.

relation to privacy). It would be inappropriate to apply the principles that have been developed in relation to genetic epidemiology to other types of genetic databases without carefully considering the implications of doing so. For instance, a blanket requirement that all genetic databases should establish their own independent oversight bodies, such as UK Biobank has done, may be unduly burdensome if applied to a collection of several hundred samples, maintained by one research group, for a single research project. It is essential for legislators to be aware of the principles that have developed out of the debate on population genetic databases when developing a uniform regulatory structure for Europe. However, it would be inappropriate to apply these principles to all genetic databases without some assessment as to how this might affect current research practice and the management of genetic databases that are currently operational across Europe.

Should genetic databases be regulated differently?

There has been an ongoing debate as to whether genetic information should be treated as 'special' and be the subject of separate regulation and governance structures.[20] This is because genetic information has characteristics that test traditional legal principles. For example, the way in which current European law (with the exception of the Estonian Human Genes Research Act 2000) makes a distinction between a sample and information, and focuses predominantly on individual rights (which obscures the fact that genetic information is personal, as well as having implications for the family, the group and the population), has implications for the regulation of genetic databases. The research of the ELSAGEN legal team suggests that the law at a national and international level has been unable to deal with the issues raised by genetic databases. As noted above, the response of legislators in Estonia and Iceland has been to develop specialist legislation for population genetic databases. This approach has served a number of purposes. It has filled a legal vacuum where there has been no regulatory mechanism to deal with the issues raised by genetic databases. It has also served political ends as politicians have been able to be seen to be responding to public concern by instituting a system of oversight and accountability. This suggests that the issues raised by genetic databases are to some extent 'special' and do need to be addressed discretely when developing a regulatory system.

The dilemma is whether genetic databases should be regulated through separate regulatory structures tailored especially for them, or be incorporated

[20] L. O. Gostin and J. G. Hodge, 'Genetic Privacy and the Law: An End to Genetics Exceptionalism', *Jurimetrics* 40 (1999), pp. 21–58.

into existing governance and legal instruments. The ELSAGEN research has demonstrated that there are considerable differences in the laws in different member states despite the fact that legislation and regulations often have been based on the same European Directives. This 'hard-law' regulatory approach may not achieve the uniform regulatory framework for genetic databases that scientists and researchers seek. An alternative approach has been described by Halliday and Steinberg for the regulation of the non-therapeutic use of human embryonic stem cells in research.[21] They argue that, instead of relying on regulation at member state level, the European Union could have a significant impact by introducing guidelines for all research funded by the European Commission. There are limitations to this approach when it is applied to genetic databases as many are established without European Commission funding. As the EC Committee on Genetic Testing has stated, further action needs to be taken at the EU level 'to follow and address regulatory issues' around genetic databases.[22]

In conclusion

The purpose of this chapter has been to identify and discuss some of the issues raised, and further research that would need to be carried out, before developing a uniform, regulatory system for genetic databases across Europe. The ELSAGEN legal research has shown that current European law (other than specialist legislation) does not deal adequately with the issues surrounding genetic databases. Much of this is due to a lack of knowledge about the different kinds of genetic databases that currently exist within Europe and how they are currently governed. In order to develop a uniform regulatory framework within Europe further research needs to be carried out to develop a typology of genetic databases based on currently existing databases that would include digital and biological collections. There also needs to be an analysis of the principles upon which a regulatory structure should rest, which could, to some extent, be informed by the population genetic database debate. This chapter has not provided answers to the dilemma of regulating genetic databases, but has simply identified key issues that will need further consideration. The real challenge will be to find a regulatory mechanism (or mechanisms) that will further scientific collaboration and the exchange of samples and information, whilst at the same time protecting the interests of all participants.

[21] S. Halliday and D. L. Steinberg, 'The Regulated Gene: New Legal Dilemmas', *Medical Law Review* 12 (2004), pp. 2–13.

[22] European Commission, *25 Recommendations on the Ethical, Legal and Social Implications of Genetic Testing*, recommendation 21.

12 Consent and population genetic databases: a comparative analysis of the law in Iceland, Sweden, Estonia and the UK

Hördur Helgi Helgason

Introduction

Ever since the birth of the idea of human rights, it has been generally accepted that human beings should generally be free to make their own decisions, at least in their personal matters. Mill famously proclaimed that 'the individual is not accountable to society for his actions, insofar as these concern the interests of no person but himself'.[1] Similarly, it has become generally recognized that there exists a private sphere in the life of every person, and that the privacy of this sphere should be observed by others.[2] The details of these concepts, of self-determination and privacy, are in many respects vague, for a variety of reasons. Their substance varies from state to state, for example as to what extent an individual can make decisions that are harmful to him or her. The boundaries of these concepts are also in constant, albeit limited, flux, for example as to what personal matters are to be considered 'private'. In addition, a consensus on these issues has hardly been reached anywhere, even within a single state, and they therefore remain a source of continuing debate.

Although the particulars of these rights have not achieved universal recognition, and will perhaps never do so, the fact that the fundamental concepts of self-determination and privacy are generally acknowledged has wide-reaching consequences. An example of an activity affected by this is the processing of personal data. Since people are generally thought to be entitled to a private sphere in which to practise their right to self-determination, and personal data is an example of what could fall under such a sphere, then personal data should only in exceptional cases be processed without regard to the will of those to whom the data relate. In other words, processing of an individual's personal data should generally only take place on the basis of that person's consent.

[1] John Stuart Mill, *On Liberty* (London: Penguin Books, 1985 [1859]), pp. 68–69.
[2] Peter Blume, *Protection of Informational Privacy* (Copenhagen: DJØF Publishing, 2002), pp. 1–3.

Since the scope and substance of the underlying human rights principles remain a source of continuing debate, consent, as a requirement for the processing of personal data, is consequently implemented in different and often conflicting ways, even in processes which are fundamentally similar. A comparison of such processes can thus be enlightening, not only with respect to the different routes that have been chosen to incorporate consent, but also in regard to the extent to which consent is considered to be a requirement for the processing to begin with.

This chapter aims to compare the different approaches to consent taken in the same type of processing conducted in four different states: Estonia, Iceland, Sweden and the United Kingdom. What constitutes consent in different legal systems, how specific the consent needs to be, what form it must take, whether the motives for consenting matter and who is considered to have the required adequacy to give it, will be the main points of comparison here. The processing in question takes place in so-called 'population genetic databases', which have been discussed earlier in this book. This type of processing adds an interesting angle to the general question of the purpose of consent in the processing of personal data, since what is being processed is not only the data themselves, but also source material – biosamples – which has been extracted from the relevant subjects. Furthermore, the data in question can in many instances not be said to be purely personal data, i.e. relating to a single individual, but are also familial in nature. This fact casts doubt on the assertion that the consent of just one of the persons to whom such data relate is adequate authorization for a particular use of said data.

Each of the legal Acts which form the basis for the comparative analysis in this chapter falls into one of the following two categories. On the one hand, there are general legal Acts that govern the processing of biosamples and genetic data in human genetic databases, e.g. the Swedish Biobank Act[3] and Ethical Review Act (ERA),[4] the UK's Human Tissue Act,[5] Iceland's Act on Biobanks,[6] and the relevant data processing Acts in each of the four states, which are all based on the EU Data Protection Directive.[7] On the other hand, there are legal Acts that are meant to deal

[3] Biobanks in Medical Care Act 2002:297 (Lag om biobanker i hälso- och sjukvården m.m.), Swedish Parliament.
[4] Ethical Review Act Concerning Research Involving Humans 2003:460 (Lag om etikprövning av forskning som avser människor), Swedish Parliament.
[5] Human Tissue Act 2004, UK Parliament.
[6] Act on Biobanks no. 110/2000 (Lög um lífsynasöfn), Icelandic Parliament.
[7] Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281, 23 November 1995.

only with specific database projects but have limited or no application outside these specific projects. These are the Estonian Human Genes Research Act (HGRA),[8] which regulates the Estonian Human Genome Research Project (EGRP), and the Icelandic Act on a Health Sector Database (HSD Act),[9] which is to be used to manage the Icelandic Health Sector Database (HSD).

The following is a comparison of the way in which these legal instruments deal with seven issues concerning consent in population genetic databases.

1. Is consent required?

Consent is not only the most common basis for processing of personal data in general; it is an even stronger requirement in specific areas of personal data processing, for example in the field of medical research. The reasons for this emphasis on consent in that type of processing are mainly historical. In the aftermath of the Second World War, the medical community established so-called 'informed consent' as a basic requirement for any research conducted on human beings. This and other requirements for conducting such research are put forth in the World Medical Association's Declaration of Helsinki.[10]

Despite the importance of consent in medical research, there are a few instances where it is generally not thought to be required. First, consent can be very difficult or even impossible to seek, e.g. where the proposed subject group is extremely large or where the subjects are deceased. In such cases, a comparison of the potential importance of the research and the impact on the privacy of the prospective subjects can lead to the research being authorized, even if no consent is obtained. This processing can in turn be subject to other conditions, for example that the use of personal identifiers be kept to a minimum or that only personally non-identifiable data be processed.

Second, the processing in question will need to be considered 'medical research', dealing with real 'participants', its subject being their 'personal data'. For example, consent need not be a requirement in cases of

[8] Human Genes Research Act 2000 (Inimgeeniuuringute seadus RT I 2000, 104, 685), Estonian Parliament.

[9] Act on a Health Sector Database no. 139/1998 (Lög um gagnagrunn á heilbrigdissvidi), Icelandic Parliament.

[10] World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 52nd WMA General Assembly, Edinburgh, October 2000.

hospitals' routine, internal quality studies or in cases where the research never extends to personally identifiable data on the subjects.

Third, consent is in some instances not required, regardless of whether subjects can be reached or not. For example, the Icelandic HSD Act does not provide for any seeking of consent from those of the intended subjects from whom consent could be sought. Despite the overwhelming support of the HSD project by the Icelandic people, the Act does not state that it is based on a presumption of consent by the participants (see section 2 below), nor that it is based on the nation having, as a group, consented to the processing (see section 3 below). Instead, the Act focuses on providing practical opt-out methods for those who do not wish to participate. It can therefore be argued that the Act is not based on any sort of consent by the participants. The general legislation in Iceland, and the relevant legal Acts in the other three states, are all based on some form of consent from the subject, or at least the presumption of such consent. One of the reasons for requiring consent, or at least the presumption of it, is the protection of those who do not have the ability to give their consent, even if contacted, e.g. young children and mentally challenged individuals. It bears mentioning that the Supreme Court of Iceland has recently established that an individual can, at least in certain circumstances, block the processing of data on members of his or her immediate family, due to the possibility that the data may reveal information relating to said individual.[11] However, when taking into account this familial nature of the data being processed, it is arguably not only impractical but even bordering on impossible to obtain consent from every individual to whom the data relate, instead of just the principal subject.

2. How explicit does a consent need to be?

In cases where consent is required, legislation in the four states runs the gamut when it comes to requirements for how clearly the consent is expressed, from requiring it to be fully and clearly given, to its being taken for granted in the absence of proof to the contrary.

Estonia provides arguably the clearest legal requirement that consent given for participation in a population genetic database be explicit. The Estonian Human Genome Research Act (HGRA) requires a donor's consent to be explicit, without exception. According to article 12, section 2, partial or conditional consent for becoming a gene donor is considered not to be valid. No presumption of consent is provided for.

[11] Icelandic Supreme Court Decision of 27 November 2003 in case no. 151/2003.

Compare this with the situation in Sweden, where the Biobanks in Medical Care Act (BBA) requires consent for collection of biosamples to be explicit, but the same does not apply to genetic data. Important exceptions to the requirement of explicit consent are made in the Personal Data Act, including permission for sensitive personal data to be processed for health and hospital care purposes without the consent of the data subject. This exception makes almost all non-consensual processing of personal data in relation to biobanks and genetic databases lawful.

The Icelandic Act on Protection and Processing of Personal Data holds similar provisions, stemming from article 8, paragraph 3 of the EU Data Protection Directive, and articles 33 and 34 of the preamble to the Directive. These provisions of the Act have so far not been interpreted as being as open as comparable provisions in the Swedish legislation. However, explicit consent is not the rule in Iceland, since the Act on a Health Sector Database (Act on a HSD) is not based on explicit consent, and the Act on Biobanks requires explicit consent only in cases where biosamples are harvested for the purposes of storage in a biobank.

As in Sweden and Iceland, the UK adopts the Directive's general requirement for consent for the processing of health data to be explicit, but there are exceptions to this rule for research purposes and in the public interest. Where the UK differs slightly is that data that has already been collected for research can be used for related secondary research purposes as long as this is not used to support decision-making about the individual, nor should it cause the individual substantial distress or damage. In the UK, conditions are attached to the research exemption. Exemptions will also be allowed in the public interest by the Secretary of State, according to section 60 of the Health and Social Care Act.[12] The new Human Tissue Act is to govern the storage and use of biosamples, for which consent is required under the Act, but it is not to apply to the removal of such samples, which the pre-existing law will therefore continue to govern.

3. Can there be informed consent?

As mentioned in section 1, the Declaration of Helsinki not only makes consent a general requirement for medical research, but calls for a special kind of consent called 'informed consent'. For a consent to be considered

[12] Health and Social Care Act 2001.

'informed', article 22 of the Declaration dictates that, before it is obtained, the subject needs to be informed of the following: the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should also be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

Because of the unique nature of population genetic databases, at the time of data and biosample collection many of the aforementioned issues are unclear, e.g. what research will be conducted and by whom. It has therefore been argued that it is inherently impossible to base the gathering and storing of biosamples and associated data, in population genetic databases and in biobanks, on this kind of consent.

Although it may not be possible to base this type of processing on 'informed consent', as defined by the Declaration of Helsinki, legal Acts and other sources of law in each of the four states require, to a varying degree, that information be provided to the research subject, or biosample donor, before his or her consent is obtained.

In Estonia, extensive information must be provided to an individual, before his or her consent can be obtained for participation in the Human Genome Research Project, including information regarding the rights of the participants in the project, information on the Estonian Genome Project Foundation, the aims and financing of the project, possible further use of the data, ownership of data and biosamples, and encoding and decoding procedures. Additional information is to be provided in a so-called 'gene donor information kit', which contains information such as leaflets, contact information, and the text of the Estonian Human Genome Research Act.

In Iceland, medical research, biosample donation and the processing of sensitive personal data must, in cases where consent is stipulated, all be based on consent that is preceded by the presentation of certain information to the data subject. The information to be given does vary somewhat between the different types of processing. For example, while the Icelandic Act on Biobanks requires prospective donors to be provided with information about the purpose of the donation, its usefulness and the associated risks, and that the biosample will be stored indefinitely in the biobank, the Act on the Protection and Processing of Personal Data requires the consent to reflect that the data subject be aware of the

purpose of the processing, how it will be conducted, how data protection will be ensured, and 'that the individual can withdraw his or her consent, etc.'. Finally, the Act on the Rights of Patients requires a patient, before consenting to participation in medical research, to be presented with detailed information on the scientific research in question, the possible risks and benefits involved, what the participation entails, and the patient's right to refuse to participate, and to withdraw, at any time, from participating in the research.

In Sweden, according to article 16 of the Ethical Review Act, a biosample donor must be informed about the general plan for the research project, the purpose of the research, methods to be used, consequences and risks that the research may bring about, who the leader of the research project is, that participation is voluntary, and that there is the right to withdraw from the project at any time.

The United Kingdom takes a different approach to requirements for information that needs to be presented to prospective subjects, before their consent is obtained. Although the UK, like Sweden, has not enacted legislation that applies to specific population genetic databases, general legal Acts that apply to such processing do contain such requirements. According to the Human Organ Transplant Act,[13] subjects must actually understand the nature of the medical procedure to be performed and the risks involved, but established common law principles require only competence to understand by the subjects,[14] not that they actually do understand what they are consenting to. The level of this test has been gradually increased, to where not only an understanding of the information given is required, but also an understanding of the effects and ramifications of decisions that are made (the 'Gillick test'[15]). Some scholars[16] maintain that the current test[17] of capacity to consent is even more stringent, involving a three-stage analysis by the subject: comprehending and retaining treatment information; believing it; and weighing it in balance to arrive at a choice. Thus the focus, under UK law, is not simply on the information provided, but on the comprehension by the subject of that information.

[13] Human Organ Transplants Act 1989 (c. 31).
[14] *Chatterton* v. *Gerson* [1981] QB 432; [1981] 1 All ER 257.
[15] From *Gillick* v. *West Norfolk and Wisbech Area Health Authority* [1986] 1 AC 112; [1985] 3 All ER 402.
[16] Alasdair R. Maclean, 'Now You See It, Now You Don't: Consent and the Legal Protection of Autonomy', *Journal of Applied Philosophy* 17 (2000), pp. 277–288.
[17] *Re C (Adult: Refusal of treatment)* [1994] 1 WLR 290; [1994] 1 All ER 819.

4. Should consent be specific?

Closely related to the question of informed consent is the contentious issue of whether consent for participation in a population genetic database must be limited to a particular processing, e.g. a particular type of medical research, or whether it can be more vaguely defined, for example by giving only a broad description of the purpose for the processing such as to 'research health for the public benefit'.

In legislation that has been specially drafted for genetic databases, for example in Estonia, it has been seen as sufficient that a broad description of the purpose is allowed. The Estonian Genome Research Project is based on a purely open consent with regard to what types of research will be conducted. The only requirement is that the purpose of the research must comply with the Human Genome Research Act.

Similarly, the legislation governing the Icelandic Health Sector Database provides only for a vague description of the types of research to be carried out. However, since no consent is required for participation, the project cannot be said to be based on open consent. However, in cases where consent for the processing of health-related data, including genetic data, is required by law in Iceland, the Act on Protection and Processing of Personal Data requires such consent to be specific. The same requirement is put forth in the Act on the Rights of Patients,[18] when a patient's participation is solicited in a particular medical research. The Act on Biobanks does not however stipulate that a specific consent needs to be given, only that the purpose of the collection needs to be stated.

The same applies in Sweden, according to chapter 3 of the Biobank Act, with the added exception that if biosamples are to be used for a different purpose, then the donors' consent will need to be renewed.

In the UK, the legal requirements are flexible and somewhat vague regarding the specificity and form of consent for biosamples. Broadly speaking, the Human Tissue Act 2004 requires 'appropriate consent' to store or use relevant material for various listed purposes such as research.[19] The Act does not define consent. However, the Code of Practice on Consent under the Act[20] states that 'appropriate consent' need not always be in writing. Rather, the process of seeking, gaining and recording consent should be 'appropriate and proportionate' to the type of procedure intended, the sample required and its proposed use.

[18] Act on Patients' Rights no. 74/1997 (Lög um réttindi sjúklinga), Icelandic Parliament.
[19] Human Tissue Act 2004, s. 1 and Sched. 1.
[20] Human Tissue Authority, Code of Practice – Consent (Code 1, July 2006).

Consent 'should be generic' where appropriate, and is a 'process' not a one-off event. By contrast, in cases where the Data Protection Act 1998[21] requires consent for the initial collection of health data, such consent would need to be explicit, according to schedule 3, paragraph 1 of the Act.

5. How freely must consent be given?

While the requirement that consent be given freely and without constraint or under duress is an underlying principle in UK law and medical guidelines, it is not expressly put forth in the national legislation that deals with the processing of biosamples. In Iceland and Sweden it is considered to be a general principle that consent shall be given freely, but that is also stipulated in a number of provisions of national legislation, including article 3 of the Icelandic Act on Biobanks and article 17 of the Swedish Ethical Review Act. Estonia provides a clear enactment of this requirement, making it criminal to induce a person to donate organs or tissue, or to become a gene donor. The same applies to conducting medical research that is not based on valid consent.

Regarding health data, all four states have implemented the EU Data Protection Directive, and the implementing legal Acts consequently contain provisions that implement the Directive's definition of 'consent', in article 2, as a 'freely given specific and informed indication of [the subject's] wishes'.

6. Can a group consent?

As the research in a population genetic database concerns the whole population, there has been a debate as to whether the community should give consent to the genetic database's establishment. In Iceland this was the subject of much debate. It could be argued that the Icelandic Health Sector Database project may be considered to be based on group consent. The rationale for such a conclusion is built on the premise that the project is based on presumed consent. That premise is questionable in the case of the HSD, as is discussed above in section 1. It is of questionable value to consider this project to be based on presumed consent, solely because it provides for an effective way for individuals to exit from the project. However, if the HSD is thought of as being built on presumed consent, then considering such consent to have been individually 'given' would imply that it was thought that each individual would have consented, if he

[21] Data Protection Act 1998, UK Parliament.

had been approached in person. In fact, the grounds for considering the project to be based on presumed consent are quite different. The justification there is that the overwhelming support by the Icelandic people justifies the presumption of consent. It has never been suggested that it was anticipated that each and every person would assent. Therefore, the presumption would relate to the group, or a large majority of it, instead of its individuals. Consequently, if the HSD is to be thought of as being based on presumed consent, then that consent can be thought of as being a group consent in nature.

Another recent development suggests that group consent might need to be planned for in relation to population genetic databases. The Supreme Court of Iceland has established, as mentioned briefly in section 1 above, that a person can block the transfer of data on a close family relative into the HSD, at least if the relative is deceased. The principal rationale of the Court for recognizing this right is this: due to the close relations, the data might reveal health information on family members beside the one to whom the data primarily relate. This is an interesting conclusion, especially in light of the lucid requirement, in Appendix B to the Operating Licence for the HSD,[22] that a person's consent needs to be secured if genetic information on him or her is to be transferred to the HSD. The main point of interest in this ruling of the Court, however, is the inference that data in the database is, at least in part, familial in nature. Here, the group is not society as a whole, but the person to whom the data in question primarily relate and also his close relatives. Will the right of such groups to have their collective consent recognized be acknowledged in the future? Perhaps this verdict is a step in that direction.

This issue has not been addressed in any of the other three states and there is no international or national legal requirement for group consent. By comparison, article 26 of the Convention on Human Rights and Biomedicine, which has been signed by all of the states except the UK, requires that there must be public discussion and consultation, in contrast to consent, on developments in biology and medicine.[23]

[22] Agreement Between the Minister for Health and Social Security and Islensk Erfdagreining Ehf. Relating to the Issue of an Operating Licence for the Creation and Operation of a Health Sector Database, 21 January 2000, Annex B. Transfer of Data to the Health Sector Database (Rekstrarleyfi til ad gera og starfrækja gagnagrunn á heilbrigdissvidi, vidauki B. Flutningur upplysinga í gagnagrunn á heilbrigdissvidi).

[23] UNESCO, Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS 164.

7. Must consent be given in a special form?

No special form of consent is generally prescribed, either in Iceland or in Sweden, although the requirement that consent be 'formal' in the Icelandic Regulation on Scientific Research in the Health Sector must probably be interpreted as a stipulation that consent for such research be given in written form. Also in Sweden the consent has to be documented and public authorities generally 'recommend' consent to be given in written form. In Estonia, a written consent is required by law for participation in the Human Genome Research Project, and a standardized consent form is provided for that purpose. The UK medical guidelines generally require written consent and this is the norm in practice for any kind of research. This position is reinforced in section 3(3) of the Human Tissue Act, where consent for storage or use of a biosample must have been given in writing if the subject has died.

The general principle in all four states is therefore that consent must be written, although this is not always explicit in the law. Little consideration has been given to other possibilities, such as giving consent via electronic means.

13 Third parties' interests in population genetic databases: some comparative notes regarding the law in Estonia, Iceland, Sweden and the UK

Lotta Wendel

Introduction

Population genetic databases typically share a common rationale, namely to be used for medical research regarding genetically related diseases and for the health and medical care of the population concerned. Nevertheless, the material and information gathered in population genetic databases attracts interest from individuals and institutions far beyond the medical and scientific community. In this chapter the law in Estonia, Iceland, the UK and Sweden is discussed in relation to such third-party interests in population genetic databases.[1]

Broadly speaking, interests from third parties can be divided into three types, with different agendas and varying relations to the donor. The regulative response to each interest mirrors the normative choices in casu, but also the more general characteristics of the legal tradition in each jurisdiction.[2]

The first type of interest in the genetic database relates indirectly, though nevertheless immediately, to concerned individuals, namely the genetic relatives. Their interest is based on the fact that genetic relatives share genetically significant characteristics. Information regarding hereditary diseases in the genetic database is accordingly relevant also for persons other than the individual donor. The closer the kinship, the higher the relevance of the information. Regulation regarding feedback to genetic

[1] For editorial reasons it has not been possible to take legal changes after 30 June 2004 into account.

[2] The general characteristics of the legal models in these four jurisdictions are highlighted by Susan M. C. Gibbons, 'Governance of population genetic databases: a comparative analysis of legal regulation in Estonia, Iceland, Sweden and the UK', chapter 15 in this volume.

relatives is discussed elsewhere in this book.[3] But when acknowledging the familial nature of genetic information, it could also be argued that genetic relatives should be legally recognized as independent bearers of individual legal rights in relation to the genetic database. As will be shown below, a legal right of this kind has so far been introduced only in Iceland.

The second type of interest is based on the argument that general societal concerns outweigh concerns regarding the privacy of the individual donor. When genetic databases, gathered for research and medical purposes, are used for forensic purposes, the legal basis is founded on arguments of this kind. DNA analysis is increasingly used as a tool to identify, confirm or eliminate suspects in criminal investigations, and to identify victims or establish links between different crimes. This has led to the establishment of national DNA databases for use in criminal investigations in most European countries.[4] Still, clinical genetic databases remain of interest for forensic purposes as criminal genetic databases only include information about persons who have had previous contact with the police. But if the criminal investigative authorities can gain access to clinical genetic databases, these collections inadvertently become extensions of the national DNA databases that exist for the prevention of crime. This has implications for the privacy of the donor as well as for future research. In the UK and Sweden these questions have attracted considerable attention.

Finally, the third type of interest dealt with here is signified by financial considerations. Employers' and insurers' inclination to make cost–benefit and actuarial calculations provides a rational foundation for asking for genetic information in order to deny or revoke employment and insurance, or to set much higher insurance premiums, for perceived high-risk individuals. The fear of misuse of genetic information in this respect has made the four compared jurisdictions react in different manners, but only Estonia has, so far, issued explicit prohibitions banning employers and insurers from collecting or requiring job applicants, employees and applicants for insurance or insured persons to provide tissue samples or descriptions of DNA.

Whether third parties' interests may lead to access or other rights to the genetic database or not, depends, of course, on the contents of the

[3] See Ants Nõmper, 'Transforming principles of biolaw into national legislation: comparison of four national laws in three aspects', chapter 14 in this volume.

[4] For an overview, see e.g. Margareta Guillèn, Maria Victoria Lareu, Carmela Pestoni, Antonio Salas and Angel Carracedo, 'Ethical-Legal Problems of DNA Databases in Criminal Investigations', *Journal of Medical Ethics* 26 (2000), pp. 266–271.

consent given when the donor originally agreed to participate.[5] This chapter will, however, concentrate on situations where consent is withheld or cannot be obtained. In the context of employment and insurance, at least, the value of individual free consent to third-party access must also be comprehended as merely illusory. The lop-sided power relation between the employee, insured or applicant for a job or insurance on the one hand, and the employer or insurer on the other, makes it hard for the individual to withhold consent without negative repercussions. This view has made the WHO Human Genetics Programme propose that insurance companies, schools, employers, government agencies and any other institutional third parties that may be able to coerce consent should not be allowed access even with the donor's consent. Access without the donor's consent should only be allowed for forensic purposes or where information is directly relevant to public safety.[6] However, more recent international documents have failed to acknowledge the potential for undue influence. For example, article 14(b) of the International Declaration on Human Genetic Data states that human genetic data and biosamples linked to an identifiable person should not be disclosed or made accessible to third parties – in particular, employers, insurance companies, educational institutions and the family – except where the donor consents, or for an important public interest reason in cases restrictively provided for by domestic law.[7]

The familial nature of genetic information

The most dominant principle that underpins the legal frameworks in each of the four countries is that of individual rights. The liberal legal tradition is particularly conspicuous in the UK and under Swedish legislation, as all regulation in these countries targets individuals, and the only rights that may be attributed to family members are directly derived from the original individual donors, as for example when parents consent to the participation of their child in a genetic database. There have been no measures introduced in either country to recognize that genetic information

[5] The legal construction of consent in the four jurisdictions is dealt with in another chapter in this book. See Hördur Helgi Helgason, 'Consent and population genetic databases: a comparative analysis of the law in Iceland, Sweden, Estonia and the UK', chapter 12 in this volume.

[6] WHO Human Genetics Programme 'Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services' (WHO, 1998), table 10 (proposed ethical guidelines for access to banked DNA).

[7] UNESCO, International Declaration on Human Genetic Data, adopted by the General Conference of UNESCO at its 32nd Session on 16 October 2003.

also has implications for other family members. This is despite the fact that information contained within population genetic databases typically will include DNA samples, family histories and genealogies that place the individual within a network of relationships. It is only in Estonia and Iceland where these issues have been specifically addressed. One reason for this contrasting picture may be that statutes exclusively addressing population genetic databases have, so far, been introduced only in these two countries.[8] Constructing laws of this nature must inevitably raise questions regarding the special nature of genetic information.

The Estonian legislation recognizes the familial nature of genetic information, but targets solely the protection of the individual interests of the donor. The Estonian Gene Bank contains the names, dates of birth and blood relationships of the ascendants and descendants of a gene donor. These genealogies may only be used within the genetic database for organizing biological samples, and creating descriptions of DNA and descriptions of state of health on the basis of blood relationships.[9] Family members have no right to access this information or any other information about the gene donor. The gene donor's rights cannot be transferred either. Estonian legislation also prohibits asking a gene donor questions about her or his particular family members. Only general questions about diseases that have appeared in the family, without specifying particular relatives or even classes of relatives, are allowed.[10] This legal solution might provide some protection for the privacy of the donor and her or his family and also safeguard the right not to know. It might still be argued that general questions about diseases in the family might pinpoint family members, especially if reported diseases are very rare.

Iceland is, so far, the only one among the compared countries that to some extent has recognized the familial aspect of genetic information in so far as legal rights for family members have been acknowledged. In the case *R. Gudmundsdottir* v. *The State of Iceland*,[11] the Supreme Court acknowledged a right for a daughter to block information regarding her deceased father being transferred to the Health Sector Database, the population genetic database of Iceland. The verdict was based on the fact that information about the daughter could be inferred from data related to the hereditary characteristics of her father which might also

[8] Estonia: Human Genes Research Act 2000 (Inimgeeniuuringute seadus, RT I 2000, 104, 685), Estonian Parliament; and Iceland: Act on a Health Sector Database no. 139/1998 (Lög um gagnagrunn á heilbrigdissvidi), Icelandic Parliament.
[9] Human Genes Research Act, s. 14.
[10] Ibid., s. 14(3).
[11] Icelandic Supreme Court Decision of 27 November 2003 in case no. 151/2003.

apply to herself. Under her constitutional right to privacy,[12] she was therefore granted a right to prevent the medical records of her father being transferred into the Health Sector Database.

This Icelandic case challenges the traditional legal understanding of close relationships as it implies the sharing of blood or DNA as being the focal relational tie. If the case is acknowledged as setting a legal precedent, several difficult analogies must be addressed, as the case appears to draw a distinction between social, biological and legal parenthood on the one side and genetic parenthood on the other. If only genetic offspring have the right to block the use of medical records of a deceased parent, courts must start to examine the origin of every child making similar claims. Adopted children cannot be acknowledged as having the same rights as genetic children. On the other hand, children who have been given up for adoption may still have legitimate claims based on the hereditary characteristics that they share with their genetic parents. The same applies to children conceived by means of egg or sperm donation as their social or biological parents may differ from their genetic parents. Investigations regarding genetic origin are of a very sensitive nature and may very well be perceived as being equally invasive to the privacy of the persons concerned as participation in the Health Sector Database. Using genetic ties as a legal foundation for blocking participation in the Health Sector Database might accordingly make some people less eager to exercise the right that they have been acknowledged as having through the Icelandic verdict.

If, on the other hand, courts choose to accept the traditional legal concept of parenthood, every legally recognized child must be given the right to block the transfer of medical records of a parent to the Health Sector Database. Beyond any doubt, this would be the easiest way to avoid sensitive investigations regarding the genetic origin of the child. However, such a legal solution must, at the same time, be interpreted as a way to circumvent the law. Granting the right to every legally recognized child, regardless of the actual genetic relationship, cannot be considered to be based on the constitutional right to privacy. For the right to privacy, according to the Supreme Court of Iceland, applies only to people who share hereditary characteristics. Instead, if the verdict is interpreted as providing every legally recognized child with the same right, this must be regarded as the emergence of a new rule. According to traditional legal principles, the personal rights of individuals lapse on their death in so far

[12] Constitution of the Republic of Iceland 1944 (Stjórnarskrá lydveldisins Íslands 33/1944) with the rule of privacy in art. 71, establishing the right to 'immunity of privacy, home, and family life'.

as legislation does not provide otherwise. In its verdict, the Supreme Court states this fact and concludes that the Icelandic legislation does not contain any rule that can provide the daughter with a possibility to act as her deceased father's substitute. Yet, unintentionally, implying a rule of this nature might be exactly what the Supreme Court has done. In conclusion, the outcome of the case in this aspect is yet to be determined in future jurisprudence and case law.

Forensic use of human genetic databases

All four countries draw a clear legal distinction between criminal and clinical genetic databases. In Iceland, Sweden and the UK legislation that clearly targets the police authorities' independent work with DNA material has been issued,[13] but the UK legislation undoubtedly provides the most extensive approach in this area. Since 2001, the UK legislation has allowed for the retention of samples taken from persons who are not suspected, not prosecuted, or who are acquitted of crimes, under certain circumstances.[14] The data and samples remain the property of the individual police forces that submit them to the National DNA Database. As of 31 March 2003, the National DNA Database of the UK contained well over 2 million DNA samples.[15]

The use of clinical genetic databases for forensic purposes is subject to much lesser legal interventions in the compared jurisdictions. As was pointed out above, according to the International Declaration on Human Genetic Data, access to human genetic databases for reasons linked to important public interests needs support laid down expressly in domestic law.[16] Furthermore, the same opinion was put forward in 1992 in a recommendation from the Council of Europe Committee of

[13] Iceland: Act on a Police Department's Genetic Database no. 88/2001 (Lög um erfdaefnisskrá lögreglu), Icelandic Parliament; Sweden: Police Data Registers Act 1998 (Polisdatalagen 1998:622), Swedish Parliament; and the UK: Police and Criminal Evidence Act 1984 (PACE), as amended by Criminal Justice and Police Act 2001; Criminal Justice and Public Order Act 1994; Anti-terrorism Crime and Security Act 2001; Criminal Justice Act 2003.

[14] PACE, s. 64 as amended by the Criminal Justice and Police Act 2001, s. 82. The law was found to be in accordance with human rights requirements in the case *R (on the application of Marper)* v. *Chief Constable of South Yorkshire* [2002] EWCA Civ 1275, [2003] HRLR 1 (CA) at para. 16, where Lord Woolf CJ stated that it 'represented an attempt by the Parliament to achieve a fair balance between the interests of the law-abiding public as a whole and the individual citizen'.

[15] National DNA Database Annual Report 2002/2003 (London: Forensic Sciences Services, 2003), p. 11.

[16] UNESCO, International Declaration on Human Genetic Data.

Ministers regarding the use of DNA for forensic purposes.[17] However, only Estonian legislation provides unambiguously in this aspect, as it prohibits access to the population genetic database by the police, prosecutors and courts.[18] In the remaining three jurisdictions access for forensic purposes follows from common legal principles or relies on statutes that aim at regulating criminal investigations in general.

In the UK and Sweden, two cases regarding the legal possibilities to override the confidentiality of genetic information for criminal investigative purposes have led to concerns. In the UK, the case arose when a man was charged with recklessly infecting a partner with the HIV virus.[19] The prosecution needed to prove that the accused knew that he was infected at the material time and therefore sought access to a blood test that the accused had voluntarily provided previously as part of a health testing programme in a prison. The Scottish court stated that the interests of everyone that serious crime should be effectively investigated and prosecuted outweighed any confidentiality concerns. The patient–doctor relationship does not permit doctors (or other medical staff) to decline to give evidence that may incriminate their patients. Accordingly, the prosecution obtained a court order requiring the hospital staff to de-encrypt the data and reveal the results of the confidential blood test of the accused.

This case made several UK bodies express concerns and call for statutory ring-fencing of research databases or explicit statements to be given to donors that the police may gain access to their records.[20] The Human Genetics Commission feared that the latter suggestion would seriously discourage participation in research, so urged instead for the UK Government to consider using legislation to prevent access to genetic databases by law enforcement authorities.[21] The Department of Health responded to the concerns by concluding that current legislation already presupposes a production order or a warrant granted by a circuit judge. According to the Department of Health, the police need clear grounds to apply for such orders

[17] Council of Europe, Recommendation No. R (92) 1 of the Committee of Ministers to member states. The use of analysis of deoxyribonucleic acid (DNA) within the framework of the criminal justice system, adopted by the Committee of Ministers on 10 February 1992 at the 47th meeting of the Ministers' Deputies, para. 3.

[18] The Human Genes Research Act, s. 16(1) provides that the Gene Bank 'may be used only for scientific research, research into and treatment of illnesses of gene donors, public health research and statistical purposes. Use of the Gene Bank for other purposes, especially to collect evidence in civil or criminal proceedings or for surveillance, is prohibited.'

[19] *Her Majesty's Advocate* v. *Stephan Robert Kelly* [2001] ScotHC 7 (20 February 2001).

[20] Human Genetics Commission, *Inside Information: Balancing Interests in the Use of Personal Genetic Data* (May 2002), paras. 9.53 and 9.54.

[21] Ibid., paras. 5.50 and 9.55.

and requests are expected to be made and granted only in the most exceptional circumstances. Unfortunately, the Department of Health provided little guidance as to what was to be considered sufficiently exceptional.[22]

The statement of the UK Department of Health nevertheless highlights one significant difference between the UK and the Swedish cases, namely that the considerations regarding disclosure never reached a court in the Swedish case. Here, the medical doctor in charge of the biobank in question complied directly when the criminal investigative authorities requested a blood sample. The requested blood sample originated from the man who was suspected and later convicted for the murder of the Minister of Foreign Affairs, Anna Lindh. The request of the police rested on the coercive means for confiscation provided for in the Code of Judicial Procedure.[23] The National Board on Health and Welfare investigated the delivery afterwards and stated that the Biobanks in Medical Care Act[24] aimed at assuring to a person who agrees to the keeping of biological material, which may be traced back to him or her, an absolute control over the future possible use of the saved sample. Giving police or prosecutors access to a tissue sample in a biobank was therefore regarded as accepting that the sample could be used for a completely different purpose than that to which the donor had consented and, in addition, in a manner that could be of considerable disadvantage for the donor. In situations like this, when interests are conflicting, the fundamental obligation must be, according to the Board, to put the paramount interests of the authority in question first, in this case to protect the interests of the biobank. The Board therefore criticized the representatives of the biobank for being more compliant with the police and prosecutor than was necessary and for not seeing that the question was tried by court.[25] The Board also urged the Government to issue clear legal guidance for the future and suggested that the privacy concerns in the Biobanks in Medical Care Act should have legal precedence over the regulations on confiscation.[26] So far no clarification has been presented.

[22] Department of Health, Genetics White Paper, *Our Inheritance, Our Future – Realising the Potential of Genetics in the NHS* (June 2003, Cm 5791), paras. 5.38 and 5.40.

[23] Code of Judicial Procedure 1942:740 (Rättegångsbalk), Swedish Parliament.

[24] Biobanks in Medical Care Act 2002:297 (Lag om biobanker i hälso-och sjukvården m.m.), Swedish Parliament.

[25] Beslut Tillsynsärende – tillhandahållande av blodprov ur PKU biobanken i samband med åklagares beslut om beslag. Dnr 44-8765/03, 5 December 2003.

[26] Tillhandahållande av vävnadsprover vid utredning av brott. Dnr 51-10082/2003, 5 December 2003. The urge for clear legal guidance was also emphasized by the parliamentary investigation on genetic integrity: see SOU 2004:20 Genetics, Integrity and Ethics, Final Report from the Committee on Genetic Integrity (SOU 2004:20 Genetik, integritet och etik. Slutbetänkande av Kommittén om genetisk integritet), p. 131.

The cases discussed here show that there is an obvious trend towards the use of clinical genetic databases for forensic purposes and that these collections may very well become *de facto* extensions of the criminal genetic databases.[27] As has been pointed out previously, this has raised concerns from the research community that individuals will be less likely to participate in genetic research. But, in contrast, there are also indications that the general public is in favour of forensic access to non-police genetic databases. As an example, a UK survey on public attitudes showed that three in five respondents (61%) considered this to be an appropriate power – a quarter thought it inappropriate.[28] But in my opinion this result may be questioned. In comparison it can be mentioned that the respondents in the same survey were asked to consider whether or not DNA samples taken from acquitted individuals should, or should not, be retained on the police genetic database. Opinion here was very evenly split, with 46% saying that they felt that samples should be kept, while 48% said they should be removed from the database.[29] This implies that a considerable proportion of the population, at least in the UK, believes that it is wrong to maintain genetic databases of innocent people for forensic purposes. In conformity with this opinion, it is reasonable to assume that the same population would also consider it wrong to use clinical genetic databases for forensic purposes.

In any case, it must be regarded as unsatisfactory that the question of how to strike a balance between the conflicting interests of solving crimes on the one hand, and donors' integrity on the other, is left unsolved to such a large extent. It may also be questioned whether the laws of the UK and Sweden are clear and unambiguous enough to be in accordance with international legal documents in the area.

Employers' and insurers' interests

The concern that genetic information might come into the wrong hands has perhaps been most evident in relation to the employment and the insurance sectors. Even if the regulations on genetic databases in the

[27] In Sweden, the police have, after the Anna Lindh case, also continued to ask for information from the PKU biobank when investigating crimes. See, for example, the case tried by the Swedish Supreme Administrative Court, RÅ 2004 ref 102, where access to the files was denied.

[28] Human Genetics Commission's survey of public attitudes: Human Genetics Commission, *Public Attitudes to Human Genetic Information – People's Panel Quantitative Study Conducted for the Human Genetics Commission* (March 2001), pp. 39–40.

[29] Ibid., p. 38.

four jurisdictions all target health and medical research purposes, concerns remain about the possibility of others gaining access to the genetic information with the consent of the donor. As was pointed out in the introduction to this chapter, the risk of undue influence in this context has provided a foundation for international legal documents. The fear of genetic discrimination in this area has also been touched upon in international legal documents. In the explanatory report[30] to the European Convention on Human Rights and Biomedicine,[31] article 11 (where genetic discrimination is prohibited), it is pointed out that the article shall be understood as referring only to unfair discrimination.[32] Furthermore, article 12 implies that genetic testing in connection with insurance or employment is prohibited even if there is consent, unless the testing is motivated by the person's state of health.

Since the Convention is binding only on the ratifying states and not individual persons or institutions, any prohibition against genetic testing or against demands for genetic information must be implemented in domestic law in order to be of direct value for the individual who runs the risk of discrimination. This is particularly important as the Convention's undefined limitation to 'unfair' discrimination calls for clarification.[33]

In the context of genetic databases, Estonia is the only one among the four compared jurisdictions that has clearly implemented safeguards against genetic discrimination. According to the Act governing the Estonian Gene Bank, employers are prohibited from collecting genetic data on employees or job applicants and from requiring employees or job applicants to provide biological samples or descriptions of DNA.

[30] Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, unclassified CM (96) 175 final (Strasbourg: Council of Europe, Committee of Ministers, 1997).

[31] Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS 164.

[32] The prohibition against genetic discrimination in the Convention on Human Rights and Biomedicine builds upon the 1950 European Convention for the Protection of Human Rights and Fundamental Freedoms and, in relation to this Convention, the European Court of Justice has also repeatedly stated that discrimination is prohibited only when it lacks 'objective and reasonable justification'. For an elaboration on the concept of genetic discrimination, especially with regard to the demand for unfairness, see Lena Halldenius, 'Genetic discrimination', chapter 20 in this volume.

[33] It must also be noted here that the UK has not ratified the European Convention on Human Rights and Biomedicine. Sweden has also not ratified the Convention, but has signed it and is currently making several efforts in order to make ratification possible (e.g. SOU 2004:20 Genetics, Integrity and Ethics, pp. 343–352).

Employers are furthermore prohibited from imposing discriminatory working and wages conditions for people with different genetic risks. Insurers are prohibited from collecting genetic data on insured persons or persons applying for insurance cover and from requiring insured persons or persons applying for insurance cover to provide biological samples or descriptions of DNA. Insurers are also prohibited from establishing different insurance conditions for people with genetic risks and from establishing preferential tariff rates and determining insured events restrictively.[34]

In Iceland specific legislation regarding employers' and insurers' interests in the area has not been enacted so far. As for the UK and Sweden, the topics are currently under investigation. Here, employers' possibilities to ask for or use genetic information exist in a grey zone. The question is whether or not the interest that the employer wants to protect is proportionate to the violation of the integrity of the employee. On the other hand, neither in the UK nor in Sweden has there been any evidence that employers so far are asking for or using genetic data for recruitment or occupational health purposes.[35] Pending a wider review in the UK, a draft code of practice, strongly opposed to workplace genetic testing, has been issued.[36] In Sweden, the review has, so far, led to legislative proposals stating that nobody may stipulate as a condition for entering into an agreement that another party should undergo a genetic examination or submit genetic information about herself or himself. The proposed prohibition applies also if the person concerned has consented. But, where the insurance sector is concerned, it is suggested that the Swedish Government should promulgate exceptions entailing that insurance companies would be entitled to enquire after and use genetic information under certain circumstances.[37]

So far, Sweden and the UK have chosen similar strategies regarding insurance. The Swedish Government has entered into an agreement with the Swedish Insurance Association regarding genetic examinations.[38] According to the agreement, the members of the association will not ask for genetic examinations or the results of such examinations from the

[34] Human Genes Research Act, ss. 27, 28.
[35] For the UK, see Human Genetics Commission, *Inside Information*, para. 7.1. For Sweden, see SOU 2004:20 Genetics, Integrity and Ethics, p. 127.
[36] Information Commissioner, *The Employment Practices Data Protection Code: Part 4: Information about Workers' Health* (draft, 2004).
[37] SOU 2004:20 Genetics, Integrity and Ethics, pp. 363–365.
[38] Agreement Between the State and the Swedish Insurance Association Regarding Genetic Examinations, 31 May 1999 (Avtal mellan staten och Sveriges Försäkringsförbund avseende genetiska undersökningar av den 31 maj 1999).

insured or applicants for insurance. In the UK use of genetic information by insurers is subject to a voluntary moratorium agreed with the Association of British Insurers (ABI) until November 2006. DNA genetic test results will not be used by ABI members except where the tests have been authorized by the Government's Genetics and Insurance Committee.[39] Since both agreements have limited applications they cannot be considered satisfactory in terms of the Convention on Human Rights and Biomedicine.

Conclusions

In this chapter the laws regarding three different kinds of third-party interests in population genetic databases have been discussed. Only in Iceland has the recognition of the familial nature of genetic information led to some kind of legal rights for family members. But the verdict of the Supreme Court of Iceland in the case referred to above gives rise to further questions and it remains to be seen how it will be applied in the future.

All jurisdictions, with the exception of Estonia, seem to be inclined to be in favour of using medical research genetic databases for forensic purposes, relying on the opinion that general societal interest must override the integrity of the individual donor. Applicable laws were, however, issued for other purposes and were not initially intended to govern this situation. In contrast, Estonia holds the opposite position in this aspect, since police access to clinical genetic databases is clearly prohibited. But since criminal genetic databases, on the other hand, are not regulated at all in this jurisdiction, it still cannot be argued that genetic integrity is an overarching principle in Estonian legislation in general.

The third interest touched upon in this chapter, namely employers' and insurers' interests in making use of genetic information, is so far only explicitly regulated in Estonia. Despite the awareness of the risks for the individual in this context, which several international legal documents reflect, the three remaining jurisdictions have so far failed to provide clear legal guidance. Current investigations in Sweden and the UK might, however, lead to some result.

In conclusion, this very brief account indicates that regulation regarding third-party interests in genetic databases is an area of law in the making. Which ways the respective jurisdictions, perhaps with the exception of Estonia, determine to follow, remains to be seen.

[39] Human Genetics Commission, *Inside Information*.

14 Transforming principles of biolaw into national legislation: comparison of four national laws in three aspects

Ants Nõmper

Feedback

Main principles at stake

The main considerations in the discussion about feedback are the right not to know, the duty of confidentiality and the duty of care.[1] The central question is whether the operator of a genetic database has a duty to inform the participants or third parties about findings of research conducted on data deriving from this database. One must not forget that such research may be carried out many years after a research subject has decided to take part in the population-based genetic project. Living conditions, attitudes towards life, health, social and family status and other aspects which may have had an impact on a person's decision to know or not to know his/her genetic data may have changed significantly, so that the decision which seemed to be right for a research subject five years ago may not seem right in the light of altered circumstances. The question is even more complex in cases where a project has not been designed as a pure research undertaking (the UK Biobank) but also involves elements of a clinical relationship (the Estonian Genome Project) due to additional duties arising from this relationship.

Right not to know

Among the above-mentioned three principles, the right not to know is probably the most modern one given the fact that the roots of international

[1] The author owes thanks to Jane Kaye and Sue Gibbons for their valuable comments while drafting this chapter. This chapter was drafted in 2004.

recognition of confidentiality and duty of care can be traced back to the Hippocratic Oath. Nevertheless, the right not to know is widely recognized nowadays and has found its way also into major international documents on biolaw.

A comparison of current laws in Iceland, Sweden and Estonia shows considerable differences in respect of the right not to know. The Estonian Human Gene Research Act (HGRA) explicitly recognizes a participant's right not to know his or her data which has been entered into *Geenivaramu*, the Estonian genebank, whereas the Swedish Act on Biobanks does not set forth such a right and the participants can rely only on general principles of medical law. In Iceland the right not to know can be found in article 6 of the Act on Rights of Patients. The situation in the UK is less clear.

Although clear recognition of a right by law is preferable, more important is the question of exercising such right. It may be surprising, but the participants of population genetic databases do not always have the option to choose between knowing and not knowing; although it is generally the case that participants are asked whether or not they want to know their data. For instance, the informed consent form used within the framework of the Estonian Genome Project informs the participants about the existence of the right not to know, but does not provide for an opportunity for the participants to make a decision on whether or not they want results to be fed back to them. Thus the right not to know does not always deliver a solution and this leads us to the next question – what principles are there for determining the duties of a biobank operator in cases where the operator does not know the will of a participant regarding feeding back of information?

Duty of care

It is widely known that more information about one's health does not necessarily improve one's health – or, to put it in another way, a doctor can do harm by providing information as well as by withholding information. In the patient–doctor context, this issue has been long debated and certain standards are quite widely accepted. But to what extent does the standard in the context of population genetic databases differ from it? One has to bear in mind that the time period between intervention (for instance taking blood for genotyping) and gaining results of research is often not measured in hours or days but in months and years. Secondly, particularly the lack of a clinical setting means that new information cannot be put into adequate clinical context and can therefore easily misinform the research subject. Moreover, concerns can be expressed

whether, given their education, doctors are able to interpret new information properly.

Based on these counter-arguments, the initiators of the UK Biobank have taken the approach not to inform the participants about the results of conducted research save the results of health checks carried out upon recruiting the participant. This approach departs clearly from older recommendations of the UK Medical Research Council, which suggest that in case of new findings about serious treatable conditions, 'the clinician involved has a clear duty of care to inform the research participant'.[2] The latter approach can also be linked with good clinical practice and research policy, which suggests that there may be a moral obligation to feedback[3] even though there is not always a legal obligation. Time will tell which approach the courts in Iceland, Sweden, Estonia and the UK will accept as there is no relevant statutory or case law in these countries currently.

One additional criterion which could be of relevance to deciding whether a population genetic database operator is obliged to inform participants, is how the project has been presented to the public and what kind of legitimate expectations a participant may therefore have. Initiators of the UK Biobank have underlined right from the beginning that the project must be 'presented emphatically as being a research endeavour, not a healthcare endeavour'.[4] On the contrary, the Estonian Genome Project promises to provide each participant 'with an opportunity to assess his or her health risks and diagnose illnesses more precisely, prevent falling ill and receive more effective treatment in the future'.[5]

Another issue, which unfortunately cannot be explored in depth, is the question of informing participants of new information which has been published in scientific literature. Already before setting up the Icelandic project, voices in scientific literature required the development of mechanisms to notify participants of opportunities to receive significant health-related information from their DNA samples in the light of recent scientific discoveries.[6] These voices are not reflected in national laws at all.

[2] Medical Research Council, Human Tissue and Biological Samples for Use in Research, Operational and Ethical Guidelines (April 2001), section 8.3.

[3] Although the Declaration of Helsinki fails to mention it. World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 52nd WMA General Assembly, Edinburgh, October 2000.

[4] UK Biobank, 'The Ethics and Governance Framework', section I.B.3.

[5] See Estonian Genome Project, Gene Donor Information Leaflet.

[6] George J. Annas and Sherman Elias, 'The Major Social Policy Issues Raised by the Human Genome Project', in George J. Annas and Sherman Elias (eds.), *Gene Mapping. Using Law and Ethics as Guides* (Oxford: Oxford University Press, 1992), p. 10.

Duty of confidentiality

Having recognized that there could be a duty of care at least towards research subjects, one must ask also about the extent of such a duty. Does this duty of care extend to affected family members or other groups in society? The answer will depend on the value which each society places on confidentiality. In all four jurisdictions under observation the duty of confidentiality clearly outweighs the duty of care in respect of family members or other persons possibly affected by conducted research (duty to warn). Actually, the superiority of the duty of confidentiality is so massive that it is hard to determine whether a researcher even has a legal duty to warn third persons save in some exceptional circumstances.

In the USA the courts have been prepared to extend the duty of care to other family members. In the case of *Pate* v. *Threkel*,[7] the Supreme Court of Florida ruled that a daughter of a woman, who had a hereditary disease, has the right to sue the mother's physician. However, the Court did not support her claim, stating that the physician's duty to warn of a genetically transferable disease will be properly fulfilled by warning only the patient.[8] Thus, even though modern genetic studies have considerably strengthened the legal position of the 'groups between', such strengthening has not introduced any duty on researchers to warn third persons about research subjects' genetic make-up.

Genetic counselling

Genetic counselling as an internationally recognized right

There is little doubt in modern literature concerning biomedical research that, due to the amount and complexity of information which such research can reveal about a person, proper (pre- and post-participation) genetic counselling should be available to persons who participate in biomedical research. This understanding is supported also by studies which show that people who have received proper genetic counselling are significantly less likely to suffer short- or long-term psychological

[7] *Pate* v. *Threkel* 661 So.2d 278 Fla. (1995).

[8] For more about this case and related cases see Lori B. Andrews, 'Contacting Relatives and Recontacting Patients', in B. M. Knoppers, C. Laberge and M. Hirtle (eds.), *Human DNA: Law and Policy. International and Comparative Perspectives* (The Hague: Kluwer, 1997), pp. 136–138.

problems and, in many cases, decide not to take a genetic test at all.[9] Genetic counselling itself is not a modern 'thing' as it made its first appearance before the Second World War as 'genetic advice'. To relieve it from the burden of eugenics, the term 'genetic counselling' was introduced in 1947.[10]

Nowadays, genetic counselling is defined and understood as a procedure to explain the possible implications of genetic testing or biomedical research, its advantages and risks and, where applicable, to assist the individual in the long-term handling of the consequences.[11] Within the context of population genetic databases, genetic counselling typically will be carried out not upon recruitment of a research participant but before any participant accesses his or her data in the database. Therefore, for instance, the operator of the Estonian database has announced that there will be no genetic counselling of participants at the database set-up phase.[12]

This commonly accepted need for genetic counselling has found its way also into different legal instruments, most influential of which is probably the Convention on Human Rights and Biomedicine (see article 12). Although UNESCO's Universal Declaration on the Human Genome and Human Rights does not address this issue, article 11 of UNESCO's International Declaration on Human Genetic Data clearly emphasizes the role of genetic counselling, calling it 'ethically imperative at all stages'.

Transformation of the right to genetic counselling into national laws

Research conducted within the framework of the ELSAGEN project has shown that the internationally recognized right to genetic counselling is not always supported by national law. To be more precise, there is only one country, Estonia, where the right to genetic counselling is legally enshrined, though, as explained below, with some shortcomings. In the other three countries genetic counselling is not expressly addressed in law.

Estonia is the only country which expressly grants to participants in the national genetic database project a right to genetic counselling.

[9] James Sorenson, 'What We Still Don't Know about Genetic Screening and Counselling' in Annas and Elias, *Gene Mapping*, p. 208.

[10] Deborah Hellman, 'What Makes Genetic Discrimination Exceptional?', *American Journal of Law and Medicine* 29 (2003), p. 107.

[11] UNESCO, International Declaration on Human Genetic Data, adopted by the General Conference of UNESCO at its 32nd Session on 16 October 2003, art. 2(xiii).

[12] See Estonian Genome Project, website, http://www.geenivaramu.ee.

According to article 11(4) of the HGRA, every participant has the right to genetic counselling upon accessing his or her data stored in the genetic database. So, at first glance, it looks like the HGRA meets the above-cited international requirements. However, these international instruments, the HGRA and, to a certain extent, also academic discussions concentrate only on the right to genetic counselling. They overlook issues regarding financing and other practicalities of exercising this right. Thus, although the HGRA apparently meets international standards, when it comes to putting the right into practice, the situation is anything other than satisfactory.

The HGRA does not contain further stipulations as to financing of genetic counselling and who is obliged to provide counselling. In general, there are two alternative sources of finance for genetic counselling in addition to participants' own funds – the health insurance system and the operator of *Geenivaramu*. Currently, genetic counselling is not included in the list of services which either the National Health Insurance Fund, which allocates tax money, or private insurance companies provide for insured persons. Moreover, not everyone is covered by a health insurance scheme in Estonia. Therefore, the possibility cannot be excluded that, even if genetic counselling will be provided to insured persons, not every participant will receive genetic counselling. And we must seriously consider the question: is it really a task for the national health insurance scheme to finance genetic counselling? In other words, the only real alternative is that genetic counselling will be conducted by the operator of *Geenivaramu* for (almost) free. If genetic counselling will not be provided for a very reasonable price a large proportion of participants will be, in fact, deprived of their right. Additionally, other circumstances like lack of qualified counsellors or unawareness of the right may unduly restrict the accessibility of genetic counselling. Therefore, the law should not only furnish participants with the right to genetic counselling but also make it the clear responsibility of an operator of a genetic database to provide genetic counselling under reasonable conditions.

Benefit-sharing

International guidelines on benefit-sharing

The issue of benefit-sharing in genetic research has been constantly in the spotlight of discussions since the Human Genome Project was launched. The concept of benefit-sharing encapsulates the sharing of the benefits of the research at a community level. Reimbursements made to participants to cover their direct expenses and income forgone cannot be viewed as

benefit-sharing but will usually be dealt with within the context of prohibiting financial gain from participation in biomedical research.[13]

During these discussions, the concept of benefit-sharing has significantly developed and changed from simply addressing the issue[14] through just proposing exact numbers for distribution of profits[15] to more sophisticated model recommendations culminating with article 19 of the Draft International Declaration on Human Genetic Data.

Transformation of benefit-sharing into national laws

Generally speaking, benefit-sharing consists of two major parts of comparable importance.[16] First is the more 'tangible' and easily measurable part in the form of direct financial return, which includes different payments and reimbursements to, and sharing of intellectual property rights with, public bodies. The second part, which may have even more value, is what one might call 'intellectual or indirect return'. Intellectual return can also have numerous outputs, starting from general education of the population about genetics to improvement of the healthcare system. Another feature which distinguishes these two types of benefit-sharing is the role of database operators. In relation to financial return, the database operator is usually the intermediate body that allocates financial return received from the private sector to society; whereas, in respect of intellectual return, the database operator itself generates some value to be shared with the society. This division into financial return and intellectual return serves as a ground for the analysis of implementing benefit-sharing rules in national laws below.

Financial return Population genetic databases are expected to create enormous financial value and boost the biotech sector that has not overcome the bursting of the stock market bubble some years ago.

[13] Stipulations on prohibiting financial gain can be found, for instance, in UNESCO, The Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO at its 29th Session on 11 November 1997, art. 4, and in the Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS 164, art. 21.

[14] See article 12(a) of UNESCO's Universal Declaration on the Human Genome and Human Rights.

[15] HUGO Ethics Committee, *Statement on Benefit Sharing* (London: Human Genome Organization, 2000) proposes, among other suggestions, the dedication of 1–3% of annual net profits to healthcare infrastructure and/or to humanitarian efforts.

[16] Return of benefits has certainly more aspects than these two but there is no room in this chapter to explore the issue of benefit-sharing fully.

Based on this vague expectation, the market value of deCODE genetics jumped after receiving the licence to set up the Health Sector Database above US $2 billion[17] and the operator of *Geenivaramu* is expecting to raise money in the amount of US $100 million to cover the costs of the project. This huge financial value will be created using altruistically donated samples and data. In the end, any innovation developed from the research on these samples and data will be protected by patents and other intellectual property rights. Thus, without adequate benefit-sharing mass donation, a gift, will be transferred into exclusive rights – a practice which has been properly labelled as biopiracy.

On the other hand, one has to bear in mind that benefit-sharing should not lead to unjustified restrictions of enterprising spirit. It is well known that money has no nationality – it usually goes where it has the best opportunity to grow. Therefore, imposing extra 'bio-tax' or adopting unfavourable patent regulations may not share the benefits but rather eliminate the possibility that there will be benefits some day. Investors and clientele of population genetic databases will move on to other countries where the situation is less restrictive. The situation is even more complex due to the fact that there are already some population genetic databases where sharing of intellectual property rights has not been provided for at all. It will be extremely difficult for other projects, where intellectual property rights are more or less shared with the public sector, to compete on global markets with projects with a lower standard of benefit-sharing.

There is no mention of benefit-sharing in the national laws of Estonia, Sweden or Iceland. There is also no provision under UK law, although this has been discussed in relation to the UK Biobank. Thus, all these states would have to take steps to introduce benefit-sharing principles into their national laws. However, it would be improper to assume that no benefit-sharing whatsoever has been foreseen in relation to genetic databases to be established in these countries. Agreements entered into between public or at least publicly controlled authorities (Minister for Health and Social Security in Iceland, County Council of Västerbotten in Sweden and Estonian Genome Project Foundation) and commercial entities (*Íslensk erfdagreining ehf.*, UmanGenomics and AS EGeen respectively) provide for a set of payments and sharing of intellectual property as described in table 14.1.

[17] Current market capitalization of deCODE genetics is about US $524 million (stock traded at NASDAQ on 20 February 2006 for US $9.58, shares outstanding 54,700,000).

Table 14.1. *Shareholding in genetic databases and benefit-sharing agreements*

	Health sector database[19]			
	UK Biobank[18]	Iceland	*Geenivaramu*,[20] Estonia	UmanGenomics, Sweden
Shareholding	Only public sector through the Medical Research Council and the Wellcome Trust	Private investors, public sector has no shareholding in deCODE genetics	Estonian Gene Bank Foundation owns 2.5% of EGeen International which has exclusive commercial access to database through its Estonian subsidiary AS EGeen[21]	County of Västerbotten and University of Umeå owned 51% of UmanGenomics[22] but due to local laws were forced to sell their shareholding
Direct payments to public sector	Pay-per-access system, amount of access fee not known	Annual payment of 900,000 EUR Annual profit payment of 6%, max. 900,000 EUR	Annual payment of 300,000 EUR Annual profit payment of 0.5%, unlimited	Annual payment of 200,000 EUR Annual profit payment of 5% until 22 April 2002
Reimbursement of costs to public sector	Not applicable since public sector sets up the biobank	Estimated cost of project is 120,000,000 to 240,000,000 EUR, i.e. about 1,000 EUR per participant[23] Reimbursement for physicians, total sum unknown	Estimated cost of project is up to 100,000,000 EUR, i.e. about 100 EUR per participant[24] Reimbursement for physicians (data collectors), 30 EUR per participant, total sum unknown	Not applicable since biobank already existed

Intellectual property rights	Special IP policy will be developed to avoid improper exploitation of biobank	Public sector will receive no intellectual property rights	All patents applied by EGeen are going to be in equal co-ownership of EGeen and Foundation Foundation will receive 3% of EGeen's turnover based on transfer of IP rights	Public sector will receive no intellectual property rights

[18] UK Biobank, 'The Ethics and Governance Framework', p. 6.
[19] Does not include benefit-sharing in connection with the genealogical database and biobank which deCODE genetics has already established. Unless cited otherwise, information is based on terms and conditions of deCODE's operating licence: see Agreement Between the Minister for Health and Social Security and Islensk Erfdagreining Ehf. Relating to the Issue of an Operating Licence for the Creation and Operation of a Health Sector Database, 21 January 2000.
[20] Unless cited otherwise, information is based on Ants Nõmper and Krista Kruuv, 'The Estonian Gene Project', in Judit Sándor (ed.), *Society and Genetic Information: Codes and Laws in the Genetic Era* (Budapest: CPS and CEU Press, 2003), p. 216.
[21] Alo Lõhmus, 'EGeenist saab USA tütarfirma', *Postimees*, 7 February 2002.
[22] Alison Abbott, 'Sweden Sets Ethical Standards for Use of Genetic "Biobanks"', *Nature* 400 (1999), p. 3.
[23] Bill on a Health Sector Database, submitted to the Icelandic Parliament at 123rd session, 1998–1999, Notes to the Bill, s. I(2).
[24] Bill on Human Genes Research, submitted to the Estonian Parliament, Notes to the Bill.

Intellectual return Unlike financial return, stipulations on intellectual return are present in some national laws, though mainly in the form of declarations of intent. So, for instance, the Estonian HGRA provides that the chief operator of *Geenivaramu* shall promote the development of genetic research and use the results of genetic research to improve public health (art. 3(2)). This implies that whatever new knowledge the project may create, it is a task of the Estonian genetic database operator to apply it for the benefit of society. Similarly, one of the tasks of the operator of the UK Biobank has been seen to be communication of knowledge based on studies using the UK Biobank to the participants of the project.[25] In both cases, no further guidelines on implementation can be found. Therefore, in practice, one cannot argue that, for instance, Icelandic or Swedish legislation, which does not require any such kind of intellectual return, protects the interests of the society less well.

Conclusion

It appears that population genetic databases have not provoked changes in the primacy of the duty of confidentiality. Participants can rely on researchers' duties of confidentiality in all four jurisdictions without fearing that information will be fed back to their family members or other interested persons. However, although questions regarding feedback of information to the participants (right to know/right not to know) are commonly addressed by different legal means, the application of regulation is sometimes misconceived. For instance, the informed consent form used in the Estonian Genome Project does not allow participants to choose whether or not they want to receive feedback.

Due to the fact that only in Estonia are participants entitled to receive information in personally identifiable form, only this country expressly recognizes the right to genetic counselling. Nonetheless, in order to ensure that this right will not remain only a right on paper, clear regulation in respect of financing and providers is needed. Whether or not genetic counselling will be provided for free may be of crucial importance to those deciding upon taking part in the project.

In cases where a genetic database will be financed by private investors, the public sector will receive some payments to ensure benefit-sharing.

[25] UK Biobank, 'The Ethics and Governance Framework', s. III C 1.

Nevertheless, it seems that payments only for accessing the database are not enough[26] to meet the recommended standards of benefit and therefore the approach of sharing intellectual property, which has been adopted in Estonia and appears will be followed also by the UK Biobank, is more desirable.

[26] See Henry T. Greely and Mary Claire King, Public Letter to the Government of Iceland.

15 Governance of population genetic databases: a comparative analysis of legal regulation in Estonia, Iceland, Sweden and the UK

Susan M. C. Gibbons

Introduction

A fundamental issue concerning population genetic databases ('PGDs') is how they should be governed – in particular, to what extent formal and informal mechanisms of legal regulation can and should be used to control their setting up, operation and management.[1] To date, the law's proper role within the genetic context generally remains ill-defined. The question of governing biobanks through legal or quasi-legal means remains conspicuously under-theorized.[2] Meanwhile, the forms, extent and effectiveness of governance structures vary markedly between jurisdictions. It is illuminating to contrast Estonia, Iceland, Sweden and the UK. These countries demonstrate a range of regulatory models – from the ad hoc, piecemeal, pragmatic UK approach, with its morass of legislative provisions, common law, codes of practice and guidelines, through to the specifically tailored, purpose-designed Estonian legislative code. Comparing salient features from these jurisdictions, in four key areas, highlights potential strengths and weaknesses. Such analysis reveals strong grounds for investigating the feasibility of constructing a uniform, coherent, principled international legal framework to help govern PGDs as a matter of priority.

To some extent, uncertainty over the precise content, relevance and impact of existing laws (particularly in the UK), and disagreement over the preferred methods and ambit of regulation, reflect deeper normative uncertainties. Some commentators doubt whether law is capable of

[1] Grateful thanks to my ELSAGEN legal team colleagues for invaluable assistance.

[2] P. Martin, 'Genetic Governance: The Risks, Oversight and Regulation of Genetic Databases in the UK', *New Genetics and Society* 20 (2001), p. 157; Judit Sándor (ed.), *Society and Genetic Information: Codes and Laws in the Genetic Era* (Budapest: CPS and CEU Press, 2003).

addressing PGD governance issues given its essentially reactive nature, inflexibility and the dynamism of technological advances.[3] Others question whether harmonization is possible – even within Europe – given the diverging legal, social, cultural and other values, structures and contexts.[4] Yet, potentially, legal institutions offer much. First, by setting and policing legitimizing boundaries, law may help to protect the integrity of scientific enterprise. Secondly, a clear, theoretically coherent, predictable legal framework may foster scientific progress by facilitating legitimate research. Thirdly, legal regulation may protect individual rights and societal interests from abuse or unwarranted infringement. Policy-makers in all four jurisdictions variously have used legal means to tackle PGD governance – including by mandating participants' consent, ensuring data protection/security, establishing biobank licensing or registration/notification systems, and rendering ethical reviews compulsory. This suggests a general consensus that law has a vital role to play.

Forms of legal regulation

The forms of law used in the four jurisdictions cover a wide spectrum. At one end is the 'hard law' Estonian approach, relying almost exclusively on legislation. The Estonian Genome Project (*Eesti Geenivaramu*) is governed predominantly by the Human Genes Research Act ('HGRA') and associated regulations.[5] The HGRA regulates the gene bank's creation and maintenance, including how the chief processor may collect, store, use, disseminate, publish and destroy biosamples and personal data. Ambitiously, the HGRA sought to codify into one comprehensive, standard law the majority of rules needed to govern human genetic research and stakeholders' interactions.

Unusually – and unlike the other countries – the HGRA does not differentiate between tissues and data. All four jurisdictions have implemented the EC Data Protection Directive ('DP Directive')[6] via primary legislation (with variations). However, in Iceland, Sweden and the UK separate legal regimes apply to biosamples and personal data. Standards

[3] R. Brownsword, 'Regulating Human Genetics: New Dilemmas For a New Millennium', *Medical Law Review* 12 (2004), p. 14 and other articles in that special issue.
[4] S. Halliday and D. L. Steinberg, 'The Regulated Gene: New Legal Dilemmas', *Medical Law Review* 12 (2004), pp. 2 and 3.
[5] Human Genes Research Act 2000 (Inimgeeniuuringute seadus, RT I 2000, 104, 685), Estonian Parliament.
[6] Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281, 23 November 1995.

often differ, for example in relation to consent, leading to potentially inconsistent results. Thus, in the UK, common law principles, non-binding guidelines, codes of practice and the Human Tissue Act 2004 all apply to biosamples; whereas somewhat different (and unfortunately widely misunderstood) rules apply to consent vis-à-vis research uses of health data under the Data Protection Act 1998, related guidelines and other statutory provisions.

Iceland is similar to Estonia as specific legislation governs the Icelandic Health Sector Database (HSD).[7] Indeed, the Estonian drafters used Iceland as a model. However, many crucial governance issues – notably security[8] and the various monitoring bodies' functions – largely are left to be dealt with in the Operating Licence or regulations. Otherwise, neither Iceland, Sweden nor the UK has legislation aimed directly at PGDs. While Iceland and Sweden have general biobank-related statutes,[9] the UK lacks even this. All three jurisdictions rely on combinations of non-specific legislative provisions, regulations, ordinances, judicial decisions and/or administrative guidelines. Consequently, it can be difficult to say (and predict) how these legal instruments interact, and how they should be adapted, interpreted and applied to PGDs.

At the opposite end of the regulatory spectrum from Estonia lies the UK. The UK framework embraces a disorganized, fragmented, confusing array of overlapping, potentially relevant but also potentially inconsistent statutory and common law rules, decisions and non-binding guidelines. One notable feature is the prevalence of quasi-legal or informal regulation. Several governance matters germane to PGDs – including ethical review, data processing, confidentiality, disclosure of medical records, consent and individual access to information – are controlled, entirely or partially, via non-binding codes of practice or guidance documents. Overall, such documents are respected and complied with. Nevertheless, their advantages of flexibility and expertise are offset by disadvantages including uncertainty or conflict over appropriate standards, a lack of 'teeth', reduced visibility and public scrutiny, and the conferring of *de facto* law-making power upon often democratically unaccountable institutions.

[7] Act on a Health Sector Database no. 139/1998 (Lög um gagnagrunn á heilbrigdissvidi), Icelandic Parliament and associated regulations.

[8] Agreement Between the Minister for Health and Social Security and Islensk Erfdagreining Ehf. Relating to the Issue of an Operating Licence for the Creation and Operation of a Health Sector Database, 21 January 2000, Annex G, Technology, Security and Organisation Terms of the Data Protection Commission.

[9] Act on Biobanks no. 110/2000 (Lög um lífsynasöfn), Icelandic Parliament; Biobanks in Medical Care Act 2002:297 (Lag om biobanker i hälso- och sjukvården m.m.), Swedish Parliament.

Supervisory bodies and notification requirements

Legitimacy, accountability, protection of rights and interests, prompt compliance and public trust and confidence all require effective mechanisms for monitoring those who create, operate and use PGDs. Comparing the four jurisdictions reveals a mixed picture.

Supervisory bodies

In accordance with the DP Directive, all four countries have independent data protection authorities. They must ensure that data controllers respect key data protection principles and the requirements for fair and lawful processing of personal (including genetic) data. They can investigate and, if necessary, take formal steps to compel compliance or punish misconduct. European harmonization measures largely have succeeded in establishing broadly equivalent minimum standards. But the authorities' respective roles and powers vary in several noteworthy respects.

The Icelandic Data Protection Authority has greater powers than the police to enter and inspect premises and seize material without court orders. By contrast, the UK Information Commissioner first must obtain judicial warrants. Overall, the Information Commissioner's authority is narrower and more circumscribed than in Iceland, Estonia or Sweden. The Swedish Data Inspection Board oversees both data processing generally and processing under the Biobanks in Medical Care Act ('BBA'). The Icelandic Data Protection Authority and Estonian Data Protection Inspectorate similarly have specific statutory oversight of biobanks – again, unlike the UK. But their mandates are broader still, encompassing aspects of both data and biosample processing. Thus, under the HGRA, the Estonian Inspectorate supervises not only the collection, (de)coding and other processing of personally identifiable *data*, but also all such processing of *biosamples*. Its broad powers include prohibiting, suspending or terminating processing. To those from countries where data and biosamples are regulated separately, this may seem curious, perhaps even incongruous. It is debatable whether synthesizing information and bodily/genetic material is conceptually sound and desirable or unduly reductive and problematic.

While data processing governance is fairly consistent and developed, the quality of oversight for tissue collection, storage and handling is substantially weaker and more haphazard. In Estonia and Iceland specially created bodies perform this function for the national genome projects. But actual experience in Iceland has been less than ideal. Under the Act on a Health Sector Database, three bodies share responsibility for

overseeing the HSD: the Monitoring Committee, Data Protection Authority and Interdisciplinary Ethics Committee. The Monitoring Committee is meant to supervise the building and operation of the HSD (in so far as it falls outside the Data Protection Authority's remit), to ensure legislative compliance, and to follow deCODE's contractual negotiations with health data suppliers. But in practice it has not fulfilled these tasks, particularly the latter. Moreover, it is unclear what it is meant to do once the HSD is up and running. The provisions describing its role and responsibilities are vague.

In Sweden, the National Board on Health and Welfare ('NBHW') oversees only those biobanks that are subject to the BBA (being biobanks originally established within the professional activities of public sector healthcare providers). All others effectively operate without external supervision. The NBHW can issue binding regulations/guidelines and non-binding recommendations, and investigate and sanction unlawful practices. But control over biosamples *per se* lies entirely in the hands of biobank operators.

Weakest of all is the UK position. Aside from the Human Fertilisation and Embryology Authority, whose remit covers only gametic materials and embryos, no UK authority has any specific mandate to monitor the creation, management or operation of biobanks. Professional and/or advisory bodies may exert indirect influence. But there is no formal governance system. Faced with this legal vacuum, UK Biobank formed its own independent Ethics and Governance Council, and drafted an Ethics and Governance Framework document.[10] Neither possesses legal status. UK Biobank may amend its Ethics and Governance Framework document at will. Meanwhile, the Council is not a legal entity. Its role is purely advisory.

Notification/licensing

A similar pattern emerges in respect of registration requirements. As required by the DP Directive, in all four jurisdictions data controllers must notify the data protection authority, which maintains a public register. But comparable procedures for tracking dealings in biosamples again diverge markedly. Estonia and Iceland require PGD operators to be licensed. Operating licences set out specific obligations and standards, and biobanks may not be set up or run without them. Yet, even strict licensing schemes do not guarantee rigorous policing. In principle, the

[10] UK Biobank, 'The Ethics and Governance Framework'.

Icelandic Minister of Health and Social Security, who issues licences under the Act on Biobanks,[11] should monitor licence-holders' activities. In practice, though, there is little effective supervision.

Without at least a notification system, external monitoring of biobanking activity becomes difficult if not impossible. Nobody knows what databases or tissue collections exist, how they are used, or by whom. This uncertainty characterizes the UK. Outside the data protection and Human Fertilisation and Embryology Act 1990 contexts, no formal mechanisms for identification or control (such as licences, inspections, registration or even notification) exist. Widely criticized, this lacuna has been narrowed to some extent. Under the Human Tissue Act 2004, many of those who store human biosamples for research purposes must be licensed. A new body, the Human Tissue Authority, will set up, monitor and enforce the licensing system.

Bucking the apparent trend in favour of licensing, Sweden has adopted a softer approach. As with data protection, the BBA imposes a compulsory notification requirement. Biobank operators need not hold licences, and anyone may set one up. But decisions to establish healthcare sector biobanks must be reported to the NBHW, which administers a public register. Operators also must notify decisions to pass biosamples to third parties. The biobank register was meant to function as a supervisory tool to introduce some measure of public control. But, once again, in practice much biobanking activity goes unchecked.

Ethical review

Another fundamental governance concern is to ensure that PGD resources are disseminated and used only for legitimate purposes, under strict conditions preserving their integrity and security. In all four jurisdictions biomedical research projects customarily undergo prior ethical review. This is considered especially important where the law permits research without donors' explicit consent. However, the ethics committees' roles, status, powers and responsibilities have reached different stages of evolution.

Formally speaking, the UK is the least developed. Over 200 research ethics committees ('RECs') exist within the National Health Service, with additional private sector bodies. Yet, strictly speaking, researchers have no legal obligation to submit protocols or proposals for ethical clearance. The principal documents relevant to RECs are non-binding

[11] Act on Biobanks no. 110/2000.

guidelines and circulars. RECs have no legal personality. Their role is advisory. Lacking enforceable powers, they can neither veto uses of data or biosamples nor halt projects that violate ethical conditions. In practice they enjoy considerable status and influence – partly because professional bodies and research funders typically demand external ethical approval. UK Biobank will integrate itself into the existing framework, and have its own dedicated, independent Ethics and Governance Council. But that advisory Council too lacks 'teeth'.

Like the UK, Sweden historically relied on a voluntary approach until the Ethical Review Act ('ERA')[12] placed mandatory ethical review on a statutory footing. Every research project involving the handling of certain sensitive personal data, or conducted on traceable biosamples, must be reviewed by a Regional Board of Research Ethics. Unlike the BBA, the ERA captures all biobanks. A Central Board for Research Ethics supervises ERA-regulated activities and hears appeals. Undertaking unapproved research or contravening ethical conditions are criminal offences.

Iceland and Estonia similarly enshrined ethical review of projects seeking to use their national database projects within legislation. One surveillance body designated to oversee the Icelandic HSD is the Interdisciplinary Ethics Committee. But its functions and powers are vague. Under the draft Security Target, it is supposed to evaluate studies requesting access to the HSD, and define parameters for determining what subsets of data they may receive. More generally, the National Bioethics Committee has specific duties and powers. By law, all serious scientific research involving human subjects must have prior ethical approval. Significantly, Icelandic ethics committees have a legislative duty to *monitor* the progress of approved research projects, coupled with power to halt projects that breach stipulated ethical conditions.

In Estonia too, gene bank users require prior approval from the Estonian Genome Project Ethics Committee. However, as in Iceland, the Committee's role is not defined in any detail in the HGRA, being left to by-laws (the Committee's articles of association) and agreements between the chief processor and main authorized processor. The Committee's principal task is to ensure adherence to legal regulations, by assessing the gene bank's procedures and drawing its supervisory and management boards' attention to any circumstances conflicting with ethical norms. Significantly, though, its powers are circumscribed. The HGRA requires its consent before the chief processor may decode data to identify any donor(s). This aside, its assessments are not binding.

[12] Ethical Review Act Concerning Research Involving Humans 2003:460 (Lag om etikprövning av forskning som avser människor), Swedish Parliament.

Enforcement powers and sanctions

All four jurisdictions make at least some provision for civil remedies, criminal prosecutions, official complaints procedures, and/or judicial review of laws or administrative decision-making. But considerable variations, gaps and deficiencies can be detected.

In the data protection realm, enforcement mechanisms mostly are consistent and accord with the DP Directive. All four countries' data protection authorities may institute proceedings for violations. In Estonia, however, violations are classed as administrative wrongs (misdemeanours) not criminal offences (in contrast to the other three countries); and the only penalties available are fines (not fines or imprisonment, as in Iceland and Sweden). Significantly, the Icelandic Data Protection Authority may levy daily fines until data controllers comply with its stipulations. In all four countries individuals may seek civil compensation from data controllers for wrongful damage. In Iceland this is limited to financial loss.

While the general biobank laws and specific PGD statutes in Sweden, Estonia and Iceland confer various individual rights, often no explicit enforcement procedures are laid down. Thus, in Estonia donors possess many express 'paper' rights, including having data destroyed if their identifications are disclosed unlawfully, and accessing their genetic data. But the HGRA neither contains enforcement provisions nor creates any actionable wrongs, civil or criminal. The chief processor is expected to police authorized processors' activities. But this role is implicit.

In Iceland, the state may revoke the HSD operating licence for material breach of the law or licence terms and claim the database. Unlike Estonia, it is a criminal offence to violate applicable laws, punishable by fines or imprisonment. In Sweden too, intentional or neglectful violation of the BBA is punishable by fines.

Unlike the other three countries, much UK law pertinent to biobanks stems from principles articulated by the courts. Judicial decisions play a crucial role. Leading common law and equitable doctrines – including consent, negligence, breach of confidence and privacy – offer limited measures against misconduct or abuse. Extra-legal sanctions, such as the threat of disciplinary proceedings or refusal/withdrawal of research funding, also apply. Yet, overall, effective means to prevent or punish violations of appropriate norms and standards are regrettably lacking. Furthermore, English courts lack constitutional judicial review powers. They cannot strike down legislation, even if incompatible with fundamental rights. Yet, such judicial power may contribute significantly to governing PGDs effectively – as evidenced by the Icelandic case of

Ragnhildur Gudmundsdóttir v. *The Icelandic State*.[13] There, the Icelandic Supreme Court held that certain guidelines applicable to the HSD monitoring bodies were too indefinite. More precise, *statutory* law-making was required to safeguard the constitutional guarantee of privacy.

Conclusion

As this brief analysis shows, the nature, status, extent and effectiveness of PGD governance structures diverge – often markedly – between the four jurisdictions surveyed. Their shortcomings demonstrate a pressing need for governance reform, particularly vis-à-vis biosamples. Relative consistency in the data protection field suggests both that legal forms and institutions can perform a vital role in aiding PGD governance, and that harmonization, at least to some extent, may be realistic and desirable. The time is ripe to pursue imaginative, principled supranational and national legal reform as a matter of priority.

[13] Icelandic Supreme Court Decision of 27 November 2003 in case no. 151/2003.

16 The legal jigsaw governing population genetic databases: concluding remarks on the ELSAGEN legal findings

Jane Kaye

The legal research in the ELSAGEN project demonstrates that the governance structures for population genetic databases are not uniform or harmonious across Europe. The issues that have been raised by population genetic databases are not always addressed in the legal documents of each of the jurisdictions, and are often treated differently in the law of each jurisdiction. This is because countries have a 'margin of appreciation' in implementing European directives and conventions but also because there is currently no European instrument that specially relates to population genetic databases.[1] As a result, new legislation has been written; the courts have been forced to develop the law; and existing governance structures have been used for population genetic databases. This section will highlight some of the common issues that have been raised in part III regarding the nature of the current governance structure for population genetic databases within Europe.

The lack of uniform implementation

An example of the lack of uniform implementation is the European Union Directive 95/46/EC on data protection which has been implemented into Icelandic, Swedish, Estonian and UK national law. The Directive requires that any use of health data must only be carried out with explicit consent, although there are a number of exceptions to this rule. The Directive allows data to be processed without consent 'to

[1] The Steering Committee on Bioethics of the Council of Europe is in the process of formulating an instrument on research on stored biological materials which will provide a set of guidelines for all European countries.

protect the vital interests of the data subject or of another person';[2] or in cases where the 'processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services';[3] in cases of 'substantial public interest' laid down in law;[4] and in cases were research does not involve personally identifiable data. Each country has been allowed a 'margin of appreciation' in implementing these requirements that they can exercise according to the historical, social and cultural norms of their country. According to Helgason (chapter 12), this has resulted in a broad interpretation of the exemptions in Sweden so that almost all processing of health data can be done without consent for healthcare purposes. In contrast, these exemptions have been given a narrow interpretation in Iceland. This has huge implications for research and whether consent is required in different jurisdictions for the same type of activities.

Examples of the differences in the consent requirements are the requirements for medical research, the use of personal data and biological samples across the four jurisdictions. It is only in Estonia, where there has been specialist legislation, that the requirements for consent are uniform for all the elements of the population genetic database. In Sweden, Iceland and the UK there are different requirements for consent because each country has implemented specific European law that relates to each of these elements rather than genetic databases in particular. For example, in Sweden secondary use of personal data without consent would be permissible but this would not be the case for secondary use of a biological sample. In the UK explicit consent is required for the use of identifiable data, but the Human Tissue Act 2004 defines the procedural requirements for obtaining the consent but not the content of the consent that is required for research use of biological material. This has been further defined in the Code of Practice of the Human Tissue Authority.[5] Therefore there can be differences in the requirements for consent in each country depending on whether a researcher is dealing with personal information or biological samples, but there are also differences between jurisdictions. This has implications for companies or researchers who wish to carry out research across Europe, collaborate in joint projects or share samples.

[2] Council Directive 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ 1995 No. L281, 23 November 1995, art. 8(2)(c).
[3] Ibid., art. 8(3). [4] Ibid., art. 8(4).
[5] Human Tissue Authority, Code of Practice – Consent (Code 1, July 2006).

The extension of existing principles

The use of genetic information in population genetic databases tests existing legal approaches. The tradition in each of the jurisdictions is to protect individual rights rather than the interests of other family members or the wider population. This is problematic when applied to genetic information that does not just relate to the individual but also has implications for other family members. Helgason has demonstrated that in each of the jurisdictions consent for the use of personal information or biological samples has been traditionally conceptualized in law as the concern of the individual and an expression of autonomy and self-determination. However, this has been challenged in Iceland with the Supreme Court decision of *R. Gudmundsdóttir* v. *The State of Iceland*,[6] where a young woman argued that she had a right to veto the input of her deceased father's data on to the Health Sector Database. By supporting this claim, Helgason suggests this case opens the way for the consideration of the interests of other family members in the data on their relative, which raises the question whether consent will be required from the family or other groups in the future. Wendel (chapter 13) argues that this case raises a number of questions about the legal understanding of family relationships. The Court, by giving rights to the genetically related child to block information going on to the Health Sector Database, gives rights to children who have a blood tie. This could have implications for parents who give up children for adoption or donate eggs or sperm. It is only in Estonia, with its specially crafted legislation, that the familial nature of genetic information is recognized. However, access to the information in each individual's file is controlled by that individual and the other family members are excluded from access unless consent is given.

Governance in other ways

Many of the issues raised by population genetic databases are not necessarily dealt with in legislation and regulations. Genetic discrimination is an example of where the requirement of article 11 of the Convention on Human Rights and Biomedicine to prohibit unfair genetic discrimination is not implemented directly into national law but may be implemented through other means. It is only in Estonia where these requirements are given effect in legislation. In contrast, in Sweden and the UK the

[6] Icelandic Supreme Court Decision of 27 November 2003 in case no. 151/2003.

preference has been to use voluntary agreements with the insurance industry to protect against genetic discrimination. In the UK there is a moratorium on use of genetic tests for insurance and employment purposes, whereas in Sweden there is a limitation on the use of tests. Mechanisms other than legislation have also been used for benefit-sharing as there is no legislation in any of the jurisdictions on benefit-sharing. Instead, as Nõmper illustrates (chapter 14), agreements have been made between the parties detailing a set of payments for access and the sharing of intellectual property rights, rather than this being defined in black letter law.

The use of existing governance systems

In each of the four jurisdictions existing governance systems such as data protection authorities, research ethics committees and bodies that oversee the collection of biological samples play a key role in the governance of population genetic databases. As Gibbons points out, both the Icelandic and the Estonian Data Protection Authorities have statutory authority to oversee the use of data in the population genetic databases. In contrast, in the UK, the Information Commissioner has fewer enforcement powers than in the other jurisdictions and tends to have a more passive role in supervision than the equivalent authorities in Estonia and Iceland. The National Board on Health and Welfare (NBHW) in Sweden currently oversees biobanks, and in the UK the Human Tissue Authority has a similar role. However, these bodies do not deal specifically with the issues raised by population genetic databases. In Iceland and the UK new bodies specific to the population genetic databases have also been established in place of reliance on existing governance bodies. This has largely been due to political pressure for accountability, but, as Gibbons (chapter 15) points out in the UK, the Ethics and Governance Council of the UK Biobank was established because of the lack of a suitable existing oversight body to take on this role.

In conclusion

The law that applies to population genetic databases is not uniform or harmonious across Europe and there are considerable differences between the jurisdictions that have been studied in Iceland, Estonia, Sweden and the UK. The research of the ELSAGEN law team suggests that it is only with a specific legal instrument, such as in Estonia, that the issues raised by population genetic databases will be dealt with in a comprehensive, coherent and consistent way. However, it is evident from

the ELSAGEN legal analysis that to try and have uniform governance systems across Europe may not be feasible, even though this may be desirable in order to protect the interests of researchers and participants and further facilitate research. The next step is to consider the avenues that may be available to develop a European governance structure for genetic databases.

Part IV

Ethical questions

17 Introduction: ethical questions

Vilhjálmur Árnason

The ethical research in the ELSAGEN project reflects the questions that have been most pressing in the public discussion about human genetic databases: How can we ensure that information about participants in database research will be securely stored? Would it be justifiable to grant insurance companies and employers access to this information? How can we trust the scientists who handle the information to act responsibly? What are the appropriate requirements for consenting to participate in database research? Are we to regard human genetic databases as local or global goods and how can the benefits reaped from database research be fairly distributed?

These and related questions have been intensively debated in the countries where plans have been made to set up population genetic databases. The public debate was most extensive in Iceland, while the discussion has been more limited to academic circles in the UK, Sweden and Estonia. It is understandable that such questions have been at the heart of controversies about database research because the public concerns centre around issues of an ethical nature. While people are willing to advance science, they want to make sure that it will neither harm the participants nor benefit only the researchers.

In the following chapters, the authors analyse the key notions implied in the public concerns in relation to population genetic databases: those of social justice, genetic discrimination, informational privacy, trust in science and consent to participation in database research. One of the main challenges of these analyses is to show how the new type of research resources and technology may affect the traditional ethics of research. The notions of privacy, consent and trust in the medical context have, for example, been formulated in light of a traditional doctor–patient or participant–researcher relationship which differs in substantial respects from the type of research environment created by multiple database complexes mainly intended for epidemiological and pharmacogenetic research.

18 Pursuing equality: questions of social justice and population genomics

Sarah Wilson and Ruth Chadwick

The claim that human genomic databases should be seen as a global public good has been used to support the development of such projects. In a previous article we have suggested that the description of databases as global public goods fulfils a strategic purpose, grounded in claims to justice and equity and supporting calls for a more equitable distribution of the benefits of genomic technologies.[1] We identified some of the complexities associated with using the 'public good' concept in this context, and noted that tensions may arise as the benefits of databases may lie precisely in their local, geographical relevance. These tensions and complexities increase both when taking into account the development of international collaborations such as P3G, and in paying greater attention to the complex interplay of social, political and scientific perspectives as they relate to genes, ethnicity and race.[2] Furthermore, because the language of benefits and burdens is used in defence or in criticism of such projects, an analysis of the conceptual framework within which such arguments are set will shed light on the validity of the arguments. In the analysis that follows we suggest that whilst the concept of global public goods might be a useful strategy for human genomic databases, there are factors which count against it as a useful strategy. In particular, issues of race and ethnicity may be relevant factors, and these may present problems with the concept in several ways. First, specific developments will have a differential impact on different groups – this is essentially the point of, for example, pharmacogenetics. Such differentiation may either widen or reduce health inequalities. Secondly, apart from the actual impact of any benefits or burdens, there is a perception issue, in that interpretation of the benefits may be different for different reasons. This may relate to scepticism towards any race-targeted developments, and also to different cultural understandings of the relationship

[1] R. Chadwick and S. Wilson, 'Genomic Databases as Global Public Goods?', *Res Publica* 10 (2004), pp. 123–134.
[2] Public Population Project in Genomics website, http://www.p3consortium.org/.

between genetics and identity. As a consequence, enlisting participants in these projects may prove problematic, due to an unwillingness to participate, perhaps for historical reasons.[3] Finally, at a deeper level there are different understandings of ethics and the appropriate role and resourcing of research, and indeed of the concept of global public goods itself.

Our argument proceeds by outlining the global public goods argument, followed by an introduction to the key issues relating to race, ethnicity and genetics. The factors identified above are then explored in terms of their impact on the global public goods argument, beginning with a consideration of racially targeted drugs, followed by a section on the different interpretation of benefits, both at a practical and at a theoretical level. We conclude that whether the global public goods argument is a useful strategy is not a simple matter and depends on a number of variables. Furthermore, we suggest that considerations of the application of genetic technologies should be considered within the context of global public health.

Global public goods

The concept of public goods was initially used primarily within a national rather than an international context, but increasingly the concept is being expanded to encompass the global arena. The language of public goods is being used in discussions of social justice and human genomic databases at an international level. For example, the Human Genome Organization (HUGO) refers to the concepts of social justice and public goods in the statement on human genomic databases.[4] The statement adopts the principle that 'Human genomic databases are global public goods' and refers to issues of social justice in stating as a recommendation that 'the free flow of data and the fair and equitable distribution of benefits from research using databases should be encouraged'.[5]

In our previous article we noted that the argument for construing genomics as a global public good depends on seeing it as a natural good

[3] As evidenced by the opposition to the Human Genome Diversity Project referred to later in this chapter. See also the Tuskegee Syphilis Study, which 'has become a powerful symbol for the fear of exploitation in research and ... is offered as the reason why few blacks participate in research trials': further information at http://www.healthsystem.virginia.edu/internet/library/historical/medical_history/bad_blood/.

[4] HUGO Ethics Committee, 'Statement on Human Genomic Databases', 2002.

[5] This seems to be part of a more general move towards exploring the potential of the concept of global public goods to address questions of international and global social justice. For a more detailed discussion of global public goods and human genetic databases see Chadwick and Wilson, 'Genomic Databases as Global Public Goods?'.

by focusing on features intrinsic to genomics knowledge. We identified the key steps in the argument as follows:

1. Public goods are goods which are non-rivalrous and non-excludable. A good is non-excludable if persons cannot be excluded from accessing it, and non-rivalrous if one person's use of the good does not diminish the supply of that good.[6]
2. Global public goods are public goods the enjoyment of which is not limited to any specific geographical area.
3. Knowledge is the archetypal global public good.
4. Genomics is a form of knowledge.
5. Genomics knowledge is a global public good.
6. *A fortiori*, genomic databases, in so far as they contain genomics knowledge, are a global public good.

The public good concept continues to be interpreted in various ways, and alternative accounts presented. In our previous work we have suggested that, amongst others, there are both normative and economic accounts. In the normative account, an item or thing *should be* considered as a good – so, for example, orphan drug provision should be a public good because it is necessary to have a public response to such an important issue. Naming something as a public good requires that the provision of the good be viewed as a public rather than a private matter. An economic interpretation of the concept relates to the so-called market failure of certain goods – there is no market for a good which people can access for free, so it will not be provided by private companies, for the market would be so small as to be of no interest to commercial companies.

By demonstrating the importance of taking into account the distinction between natural and social goods we highlighted the influence of social and political realities on the definition of public goods. Social and political considerations provide other supporting factors for assessing genomic databases as global public goods, not least of which is the perceived potential for public health benefits. However, despite some strong public good characteristics, genomic databases as they are currently being developed are generally following a private good model. Whilst the information may be non-rivalrous, it is obviously not non-excludable, as is evidenced by its commercialization. Furthermore, because of the restrictions on access imposed through either financial or technological constraints it might be said that the information itself is not non-excludable. Such commercialization, amongst other factors, means it is problematic to

[6] An example frequently cited is that of a lighthouse: a lighthouse lights the sea for everyone, no one can be prevented from receiving the benefits of the light, and the light is not diminished no matter how many persons are benefited by it.

think of genomic databases in terms of public goods. Other factors relating to the claims made for the databases undermine the argument for the global relevance of the databases.

A particular example relates to the now-stalled Icelandic Health Sector Database (HSD) project. The value of the HSD is said in part to stem from the homogeneous nature of the Icelandic population, combined with the record-keeping qualities specific to the nation of Iceland. The 'common heritage' argument is therefore problematic, as the database does not spring from the common heritage of mankind, but from the specific heritage of the Icelandic people. Furthermore, attention to the specificity of this database leads one to wonder how far the information contained on the HSD will be globally representative, or whether it will prove of specific use only in the Icelandic context. Both of these factors question the definition of databases as global public goods – at the most the Icelandic HSD may be a public good within Iceland, as its usefulness may be restricted to this context.

Related questions arise in considering the African-American biobank initiated by Howard University, Washington. The intention is that the Genomic Research in the African Diaspora (GRAD) biobank will help in understanding and responding to diseases that differentially affect African Americans, by collecting data from persons of African descent. Whilst claiming the need for a specific African-American database, it is also suggested that the project has a broader relevance to genomics research, as 'Africa is the trunk of the human evolutionary tree.'[7] These seemingly contradictory claims of specific national or racial ownership or usefulness sitting alongside those to commercial worth based on the international relevance (or saleability?) of the information illustrate the problematic nature of conceptualizing genomics information in either/or terms. In turn this shows the problems of trying to make a clear distinction between private and public goods. The claims to international relevance of both of the databases mentioned here suggest that in geographical terms genomic databases are likely to be global goods.

These questions relating to the local and the global become increasingly complex when race and ethnicity are considered more closely. For example, questions of representation for the UK Biobank may present more problems than in the Icelandic or Estonian projects. As the Ethics and Governance Framework background document notes, 'given the diversity of the UK population, perfect representation cannot be

[7] C. Rotimi quoted in J. Kaiser, 'African-American Population Biobank Proposed', *Science* 300 (2003), p. 1485.

expected, but wide representation can. This will mean actively seeking some minority or hard-to-reach candidates.'[8] Further attention to the perspectives of race and ethnicity bring to the forefront other ways in which the concept of genetic databases as public goods is problematic.

Race/ethnic identity and genetics

Constructions and categorizations of 'race' and ethnicity remain contested areas within both the natural and the social sciences, indeed it has been suggested that this area of study has displaced 'preoccupation with class and other forms of social inequality'.[9] The concepts are similarly contested within the context of health research. As Mark Robinson has suggested, 'the use of ethnicity in health research has been characterized by different approaches according to research aims and the paradigms used'.[10] Importantly, Robinson identifies the need to problematize discussions of ethnicity and to explore the context within which the concepts are used: 'If ethnicity is treated as an explanatory variable it becomes important to ask not only what it is used to measure, but how its interaction with other potential influences is treated.'[11] Genetic information adds a further layer to these discussions. The standardized retort to fears of genetic determinism is that 'most human genetic variation is due to differences among individuals within populations rather than to differences among populations',[12] and, furthermore, that 'any two humans are approximately 99.9% identical in their DNA sequences'.[13] Such statements function to minimize the ways in which the 0.1% difference and the existing, albeit small, variation between populations are the crucial factors in genetic research.[14]

The characteristics of genetic inheritance, combined with the complex human history of population origins and movements, migration and cultural and environmental factors, have led to a situation in which distinctions

[8] UK Biobank, Ethics and Governance Framework background document, 2003, p. 5.
[9] D. T. Goldberg and J. Solomos, *A Companion to Racial and Ethnic Studies. Blackwell Companions in Cultural Studies* (Malden, MA: Blackwell Publishers, 2002), p. 1.
[10] M. Robinson, *Communication and Health in a Multi-Ethnic Society* (Bristol: Policy Press, 2002), p. xiii.
[11] Ibid., p. xiv.
[12] M.-C. King and A. G. Motulsky, 'Mapping Human History', *Science* 298 (2002), p. 2342.
[13] International HapMap Consortium, 'Integrating Ethics and Science in the International HapMap Project', *Nature Reviews Genetics* 5 (2004), p. 467.
[14] As the scientific rationale for the HapMap project states: 'Any two humans are approximately 99.9% identical in their DNA sequences, but the 0.1% by which they vary contributes to differences in their risk of getting certain diseases and their responses to drugs, infectious agents, toxins and other environmental factors' (ibid., p. 467).

between population groups can be identified genetically. More specifically, communities that have been defined and restricted through practices of endogamy and consanguinity tend to share specific, identifiable genetic characteristics. Such 'founder effects' have enabled interesting validation of historical kinship claims that had previously been dismissed,[15] and recent research has demonstrated that it is possible to identify the major population origin of groups through genetic information alone.[16] However, a commentary upon this research stresses the complexity of factors involved, and the need to avoid reducing concerns to genes alone: 'Disease susceptibility may be genetic but not geographically clustered, or geographically clustered but not genetic, or neither, or both.'[17] It is therefore important to be aware of problems associated with using 'race' as a definition, particularly the danger of allowing race to act as shorthand for common environmental factors or cultural practices and thereby wrongly to identify the causal factors in health issues – an issue of particular relevance to the geographically or ethnically defined databases previously mentioned.

Implications of different 'racial' or ethnic genetic responses

Individual differences in responses to prescribed drugs, manifesting as lack of effectiveness or, more seriously, adverse drug reactions, are one driver of research into pharmacogenetics. This has proved to be one of the key motivating forces towards amassing genetic and related information within biobanks. Pharmacogenetics research is precisely about designing drugs around genetic markers, and the resulting stratification of persons, inevitably in some cases along apparent ethnic or racial lines. Such information may provide the basis for discrimination or stigmatization, a concern expressed by the HapMap consortium:

> If a higher frequency of obesity-associated variants were found in the samples from one population and this information was then erroneously applied to all or most of its members and to members of closely related populations, entire populations could be stigmatized or suffer discrimination, especially in places where individuals with ancestry from those populations are a minority.[18]

[15] In particular, the case of the 'black Jews': see for example http://www.freemaninstitute.com/Gallery/lemba.htm.
[16] N. A. Rosenberg, J. K. Pritchard, J. L. Weber, H. M. Cann, K. K. Kidd, L. A. Zhivotovsky and M. W. Feldman, 'Genetic Structure of Human Populations', *Science* 298 (2002), p. 2384.
[17] King and Motulsky 'Mapping Human History', p. 2343.
[18] International HapMap Consortium 'Integrating Ethics and Science in the International HapMap Project', p. 471.

Whether discrimination is a direct or an indirect result of stratification, specific developments will have a differential impact on different groups. Such developments are already making their way into the prescribing arena, as the example of a drug approved in 2005 by the US FDA shows. BiDil is a drug to treat heart failure that appears to be dramatically more effective than existing drugs for black Americans, but has little effect on white Americans. Such racially marketed treatments have the potential to either widen or reduce existing health inequalities: in the case of BiDil it might be argued that here is an example of a treatment option which increases benefits to a group that normally suffers from unequal access to treatment. However, it has been suggested that other racial groups would be denied the drug because insurance companies would not pay for it. It is also possible to foresee that the identification of a tendency towards a particular disease amongst a certain population may lead to an increase in insurance premiums such that equality and access are further diminished.[19]

This illustration suggests that pharmacogenomic prescribing may not automatically lead to increased access to healthcare, and this is obviously not the motivation for the pharmaceutical companies: as has been said about the BiDil example, 'Many critics view the study as a clever strategy to extend the patent on drugs that are now widely available in generic form – and to obtain a premium price for them.'[20] Furthermore, it may be that such developments increase the number of 'orphan drugs' or orphan disease populations – where the market is so small there is no economic incentive to produce the drug, and government measures are necessary to encourage developments in such areas. Historically, such orphan diseases have been catered for by legislative incentives, but as a respondent to the Nuffield Council public consultation identifies, such legislation involves 'subsidy, directly or indirectly, of the pharmaceutical industry by the public purse'. The report recommends that 'policies to provide further incentives through public subsidy require careful examination [and] should include reconsideration of the definition of an orphan medicine, with particular reference to the implications of genetic stratification of both patients and diseases'.[21] Here the relevance of the normative and economic definitions of a public good is clear, for one of the key factors in economic definitions of public goods is a failure of the market to supply due to insufficient incentive. Thus the realities of healthcare provision,

[19] T. Maugh, 'Drug for Only Blacks Stirs Hope, Concern', *Los Angeles Times*, 9 November 2004, A1.
[20] Ibid.
[21] Nuffield Council on Bioethics, 'Pharmacogenetics, Ethical Issues', 2003, pp. 52–53.

and of drug development, impact upon the strategic use of the global public goods argument in several ways. The potential for databases to form the basis for such stratifying research, and the likely impact of such stratification, coincides with the global public goods argument in a further way. That is, it may be problematic in terms of the framing of the argument as it may be contrary to the requirement that a broad spectrum of socio-economic groups be benefited.

Apart from the actual impact of any developments arising from genomic databases, there is also a perception issue. That is, interpretations of benefit may be different for different reasons, such as different cultural understandings of disease and genetics, of identity, and different perceptions of the benefits of genetic technologies.

Benefits and costs: alternative interpretations

While benefit-sharing is usually considered in terms of clinical and economic benefit, and the risks of research associated with the participating individual, there are broader social issues, including questions of social identity, which do not get taken into the equation.

One facet of this is that genes fundamentally identify biological kinship, rather than race or ethnicity, and this may be seen as disruptive in a context where family and kinship bonds are not necessarily based on biological relation.[22]

Similarly, there is disagreement about the benefits claimed for genetic research, and concern expressed about the potential risks to communities from such research, as set out in this 1995 criticism of the failed Human Genome Diversity Project:

> The HGD Project's assumptions that the origins and/or migrations of Indigenous populations will be 'discovered' and scientifically 'answered' is insulting to groups who already have strong cultural beliefs regarding their origins. What will be the impact of a scientific theory of evolution and migration that is antithetical to an Indigenous group's common beliefs? Will these new theories be used to challenge aboriginal territorial claims, or rights to land?[23]

These community and cultural implications bring to the fore additional costs and benefits associated with genetic research, which are not usually perceived from a mainstream perspective. Viewed in this different light, the claim for genomic databases as global public goods looks questionable,

[22] See, for example, Dena Davis, Hastings Center report on Genetic Research and Communal Narratives, July/August 2004.

[23] D. Harry, 'The Human Genome Diversity Project: Implications for Indigenous Peoples', *Abya Yala News* 8, 4 (1994).

with a significant part of the global public more concerned with the disutility of the technology than with any potential good.

At a deeper level, there are different understandings of ethics, and of moral frameworks, reflected in responses to research, and to the concept of global public goods itself. This is reflected in a concern with equity and social justice, and with context-appropriate research priorities, as expressed by Debra Harry: 'why the tremendous interest in saving the genes of Indigenous people and not the people themselves?'.[24] A similar argument was made in a statement by the Philippine Solidarity Group, referring specifically to resourcing and research priorities: 'The $23–35 million to be spent over five years can be better put to providing basic social services needed for Indigenous Peoples' survival and rights protection.'[25]

The themes of resourcing, commonality, difference and (dis)benefit are further expressed in the continuing statement:

> After the rest of the world have squandered their own resources, the resources that Indigenous Peoples have sacrificed lives and limb to maintain are suddenly being made common heritage for the appropriation of transnationals that rarely benefit Indigenous Peoples. Developed drugs are often sold to Indigenous Peoples at exorbitant rates.[26]

It is telling that the very argument being used as a strategy in defence of the sharing of genomics technology, with the aim of enhancing social justice, is here reflected back as a strategy for further colonization, disempowerment and exploitation. Such a perspective should lead us to consider whether the concept of global public goods is one which could only have developed from the dominant and powerful nations. Does the strategy work to combat injustice, or in fact serve to obscure it? Given the current social and political realities, it seems increasingly problematic to claim genomic databases as global public goods, when it is primarily the developed countries that will benefit from the technology and treatments developed. Furthermore, the perspective of indigenous persons questions the wisdom of increasing geneticization, and funding for advanced technologies, when the majority of the world's primary healthcare needs remain unmet. If the global public goods argument was strategically applied to public or primary healthcare needs rather than to specific technologies, it might be a more powerful tool.

[24] Ibid.
[25] Philippine Solidarity Group Toronto, 'PSG Supports Indigenous Peoples', NativeNet (1993).
[26] Ibid.

19 Benefit-sharing and biobanks

Kadri Simm

Introduction

The Human Genome Project and the related research and development activities have raised important dilemmas within a number of domains.[1] One of the concerns that cuts across political, economic, social and ethical dimensions is the issue of justice in genetic research and in its possible applications. Benefit-sharing pertains to the distribution of benefits but also of burdens arising from the research and development activities in human genetics. It concerns the issue of what is owed to those people participating in research but also to those who might not have taken part personally but live in the same community or even population where research is undertaken. Furthermore, human genetics is part of a large technological development with universal impact and this raises concerns regarding the accessibility and availability of the results of research also on a much wider, global scale, thus linking the issue of medical ethics to that of global justice. In what follows, the concept of benefit-sharing will be examined by drawing out some conceptual issues, mostly having to do with the justificatory basis for benefit-sharing.

Dissecting the concept

Although the debate on benefit-sharing is recently much linked to the human genome research, the subject was a significant issue for some time before the prominence of human genetics. Various international documents have stressed the importance of the concept in principle: for

[1] I am grateful to Margit Sutrop, Vilhjálmur Árnason and Sigurdur Kristinsson for their help and insights with this chapter. This chapter has benefited from financial support from the Estonian Science Foundation grant 'Ethical Aspects of Genetic Databases and New Technologies' (No. 6099).

example, the International Covenant on Economic, Social and Cultural Rights, article 15(1)(b), states: 'The States Parties to the present Covenant recognize the right of everyone to enjoy the benefits of scientific progress and its applications.'[2] Both the UNESCO Declaration on the Human Genome and the HUGO Statement on Benefit-Sharing identify it as an established requirement towards various parties in research settings.[3]

Agricultural context and the property argument

The earliest applications of benefit-sharing originate from plant genomics and concern agricultural resources.[4] They were propelled by occasions where results of research and development activities accomplished throughout the centuries by local communities were seized by big industry, and the latter proceeded to capitalize alone on a certain product through patenting. Once the patent has been granted, the local community[5] from a developing country has no means and few resources to challenge the situation.[6] The management of biological resources, especially in traditional cultures, does not acknowledge the logic of patenting and denies that what is essentially a result of close co-operation (of mostly unidentifiable and unlimited groups and individuals) can be 'owned' by someone to the exclusion of others.[7] In the criticisms of patenting, the arguments are not necessarily against the practice in principle, as it is acknowledged that investment and innovation should be rewarded. Rather concerns have been raised regarding the way patenting is conducted – through privileging certain powerful agents and by installing

[2] International Covenant on Economic, Social and Cultural Rights, 16 December 1966, in force 3 January 1976, 993 UNTS 3, (1976) 6 ILM 360.

[3] UNESCO, The Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO at its 29th Session on 11 November 1997; HUGO Ethics Committee, *Statement on Benefit-Sharing* (London: Human Genome Organization, 2000).

[4] See, for example, the Convention on Biological Diversity (excluding human genetic resources), Rio de Janeiro, 5 June 1992, in force 29 December 1993, 1760 UNTS 79; (1992) 31 ILM 818.

[5] It is important at least to acknowledge here the fact that 'community' is a very complex, ambiguous and often contested notion. See, for example, HUGO Ethics Committee, 'Genetic Benefit-Sharing', *Science* 290 (2000), p. 5489.

[6] In the biomedical research context, I agree with Ruth Macklin's suggestion that the major difference between developed and developing countries lies in the likelihood of the majority of the population having access to the results of successful research (Ruth Macklin, *Double Standards in Medical Research in Developing Countries* (Cambridge: Cambridge University Press, 2004), p. 11).

[7] Stephen B. Brush, 'Bioprospecting the Public Domain', *Cultural Anthropology* 14 (1999), pp. 535–555.

confrontation among those whose work has been relevant for the final outcome. Benefit-sharing is not solely fuelled by claims towards royalties but is maintained by anxieties linked to the ways patents will regulate and limit access to necessary resources, thus having the potential to shape the livelihood of many people. Within patenting discourse the extensive financial sums and the research capabilities of large enterprises dwarf the long-spanning and piecemeal contributions of local people. Benefit-sharing has been an attempt to acknowledge the latter and provide a more inclusive and nuanced perspective for the assessment of these contributions.

The agricultural framework has furnished benefit-sharing with an argument that is based on the notion of property, recognizing that genetic resources provided for research might be owned in some sense. Benefit-sharing based on the property argument is thus mostly associated with the struggle to end biopiracy and the patenting of various plant and animal resources without proper regard to the contributions of local populations or without recognizing biological resources as belonging to communities or nations. This type of benefit-sharing is characterized by the distributive principle of desert, where local populations have a legitimate claim to a share based on their contribution in developing and nourishing a certain valuable biological entity or through the recognition of this entity as their property (and thus their having a right to it). Another important aspect of benefit-sharing in this context pertains to a recognition that the sharing should be done amongst a community or population as a beneficiary, and should not target specific individuals.

The ownership argument and the benefit-sharing arrangement built around it is more controversial in human genetics. Ownership here might include either the aspect of control over a certain resource or a capability to subject this resource to commercial transaction.[8] Ownership could be conceptualized as either private or common property. The UNESCO Declaration on the Human Genome and Human Rights suggests the concept of common or shared property in the human genome by establishing the genome as a heritage of humanity in a 'symbolic sense'.[9] The

[8] Jane Kaye, Hördur Helgi Helgason, Ants Nõmper, Tarmo Sild and Lotta Wendel, 'Population Genetic Databases: A Comparative Analysis of the Law in Iceland, Sweden, Estonia and the UK', *Trames* 8 (2004), pp. 16–17.

[9] In reality, international documents that stress the need for benefit-sharing exist side by side with others, like the WTO's Agreement on Trade Related Aspects of International Property Rights (15 April 1994, 1869 UNTS 299, (1994) 33 ILM 1197), that directly contradict the ideas and principles embedded in the former. Thus, while the notion of shared property has been established symbolically, parallel conventions detail the opposite private ownership rights and duties in utmost practicality.

second possibility is that of private ownership in bodily material, but this has not been legally established so far.[10] It has been argued that the holder(s) of the genetic data have not done anything to make their so-called property valuable and therefore, at least in terms of patenting, should not have similar rights to researchers who have added value to it – a sort of Lockean understanding of mixing one's labour with natural resources.[11] No conclusive compromise has so far been reached on this issue, either philosophically or in legal terms, while patents continue to be granted to DNA sequences at an alarming rate.

Population biobanks provide an interesting focus for various speculations regarding the property argument – the Icelandic case of national genetic heritage being the best known one. The ownership question has not been directly dealt with in Iceland; it is only legally established that the operator of the database is not the owner of the resources.[12] In the Estonian database the samples are an unalienable property of the state-controlled foundation and donors waive all rights to profits. But with many other population biobanks it is still an open question whether the property argument in principle could provide a basis for a benefit-sharing arrangement, be it based on the notion of common or of private property.

Medical context and compensating for risks taken

When benefit-sharing became a relevant concern in biomedical research, it necessarily included aspects that have traditionally characterized the relationship between the researcher and the research participants. Traditionally, benefit-sharing arrangements in medicine have been based on the logic of compensating for risks and inconveniences that have been accepted by participants in order for research to proceed. The risk discourse delineates a recipient community and those responsible for creating these risks have a duty to compensate within the reciprocal setting. In parallel with the benefit-sharing rationale of non-human biological resources, it is possible to refer to a sense of desert

[10] The first infamous case attempting to do so concluded that even if one would own the specific cells in one's body, this did not mean that the cell lines derived from it would be owned (see *Moore* v. *Regents of University of California*, in Charles Erin, 'Who Owns Mo?', in A. Dyson and J. Harris (eds.), *Ethics and Biotechnology* (London: Routledge, 1994)).

[11] R. Chadwick and K. Berg, 'Solidarity and Equity: New Ethical Framework for Genetic Databases', *Nature Review Genetics* 2 (2001), p. 320. Locke of course had an important clause to the property-creation process, namely that this was only allowed when 'there was still enough and as good left' (John Locke, *Two Treatises of Government*, Cambridge: Cambridge University Press, 1996 [1690], II, 5, §§ 26 and 33). It is questionable whether patenting gene functions and sequences does leave enough for others.

[12] Kaye et al., 'Population Genetic Databases', p. 18.

characterizing the principle upon which distribution of benefits is based. Additionally, well-established ethical principles like the duty to avoid harm (non-maleficence) as well as the duty of beneficence provide substantial rationale for benefit-sharing within this largely altruistic setting. But the rise of genetics in general and the very scope of the Human Genome Project have introduced significant novel aspects to this traditional medical background.

For example, genetic research as undertaken in the form of population biobanks swells the number of participants considerably and also blurs the very concept of participant as genetic information is by nature shared. Those possibly affected by research can be a much larger group of people than those participating in the traditional sense of the word. Medical and legal frameworks that have been focused on the person as a separate identity 'whose interests – and records – can neatly be separated from those of their families'[13] are challenged by genetics, and the dichotomies of self/other might not be directly applicable.[14]

Thus it is increasingly problematic to rely on the strictly reciprocal basis for benefit-sharing. Traditionally, the fact that risk-takers were clearly identifiable also limited the number of recipients. But such logic of correspondence does not respond adequately to the novel complexities created by the large biobanks and it is inattentive as regards other social concerns that point to the important contingencies related to the commercialization and globalization of the medical industry.

Social context and compensation as fair

Discussions regarding benefit-sharing in human genetic research have increasingly stressed that everyone should benefit and that all humankind should be involved in the sharing.[15] The introduction of *universal benefit-sharing* entails several important changes to the justification and employment of the concept in comparison with previous applications. The aim is

[13] Cathleen M. Kaveny, 'Jurisprudence and Genetics', *Theological Studies* 60 (1999), p. 135.

[14] Margrit Shildrick, *Leaky Bodies and Boundaries. Feminism, Postmodernism and (Bio)ethics* (London: Routledge, 1997), p. 181.

[15] Levi Mansur, 'Gene Discovery, Ownership and Access for Developing Countries in the Era of Molecular Genetics', *Electronic Journal of Biotechnology* 5, 1 (15 April 2002), http://www.ejbiotechnology.info/content/vol5/issue1/issues/05/; María Graciela de Ortúzar, 'Towards a Universal Definition of "Benefit-Sharing"', in B.M. Knoppers (ed.), *Populations and Genetics. Legal and Socio-Ethical Perspectives* (Leiden: Martinus Nijhoff, 2003), pp. 473–486; Ted Schrecker, 'Benefit-Sharing in the New Genomic Marketplace', in Knoppers, *Populations and Genetics*, pp. 405–422.

to engage with the challenges of global justice, thus not responding only to fairly limited concerns of distinct research projects but being occupied with the way access to research results is provided or denied to everyone else. These worries are sustained by the way in which research results have been largely unavailable to the majority of the world population. This is due to various reasons – e.g. the high cost of novel drugs and therapies, the patenting of research results that limits access, as well as the way research priorities are skewed towards the interests of the affluent nations and disproportionately little research is done on illnesses that are prevalent among the populations of the developing countries.[16]

Therefore one of the most influential arguments behind universal benefit-sharing refers to large-scale exploitation, to the past and present inequalities of power and resources in the world. These inequalities are capitalized upon by big international corporations as well as the powerful nation-states, creating and enforcing further injustice between developing and developed countries. In terms of both genetic and non-genetic resources there is a shared universal feeling of unfairness when richer countries exploit the poorer ones.[17] Insisting that the human genome is a common property or that biobanks should be global public goods – all these different arguments have in common a worry that the present biotech revolution will turn out to increase the inequalities of the world and enlarge the so-called North–South divide.[18] It is this line of thought linking benefit-sharing to issues of justice and the disconnection of the matter from the particularities of the medical sphere (in terms of justifications and general principles) that adds a new angle to the benefit-sharing discussion. Here the reason for benefit-sharing is a moral one – those who have the power and are able to act in alleviating suffering have the moral burden of doing so.[19]

For these diverse and substantial reasons, the concept of universal benefit-sharing would have to depart from the more contextualized rationales of sharing characterizing this undertaking within non-human genetics and traditional medical research, moving towards the inclusion of humanistic ideals like responding to human needs and respecting the

[16] This is the infamous 90/10 gap where 90% of the investments into medical research are spent on the health issues of 10% of the world population (Global Forum for Health Research, 'The 10/90 Report on Health Research 2000').

[17] Kåre Berg, 'The Ethics of Benefit-sharing', *Clinical Genetics* 59 (2001), pp. 240–243.

[18] HUGO Ethics Committee, 'Statement on Human Genomic Databases', 2002; WHO, *Genomics and World Health*, Report of the Advisory Committee on Health Research (Geneva: WHO, 2001).

[19] Chadwick and Berg, 'Solidarity and Equity'; Nuffield Council on Bioethics, 'The Ethics of Research Related to Health Care in Developing Countries', 24 April 2002.

principle of equality. This is why concepts like solidarity have been put forward to provide an alternative rationale for distributing the benefits in a more inclusive manner.[20] The UNESCO Universal Declaration on the Human Genome and Human Rights has recognized the fundamental unity of humankind manifested in our sharing of the genome and suggested the linkage of this unity to the concept of human dignity and diversity. Many of the concerns of global justice are echoed in some form or another also on the level of social justice and thus have special relevance for large biobanks.

One of the reasons why benefit-sharing has increasingly been applied outside the confines of the medical sphere is that arguably medicine itself has changed considerably. Certainly not all medicine can be straightforwardly equated with business, but the developments in genetics have brought this characteristic to the forefront, and gradually our hopes and dreams in medicine are linked up with the rather expensive, as well as extravagant, promises of genetics. Medical industry has become big business: for example, the pharmaceutical trade sector has for a while been the most profitable in the world.[21] The phenomenon of globalization has raised a number of new challenges, especially with respect to the coupling of commercialization and corporate biotechnology. Commercialization has meant that the main investments in healthcare and genomics nowadays originate from the private sector and the slice of not-for-profit research is getting smaller. It is also increasingly difficult to draw a clear line between the biomedical companies and their research and other disciplines: technologies and knowledge merge across domains, blurring the boundaries between medicine, food, agriculture, cosmetics and other sectors.[22] Perhaps benefit-sharing has become such an issue because people have realized that their volunteering is not matched by altruism from the other side, and consequently compensation to enforce a degree of justice is required.[23] If big profits are accrued by industry, then a feeling of fairness would demand the sharing of these profits with participants in some form or other. The commercialization of research has meant that contributions that were traditionally interpreted within the

[20] E.g., HUGO Ethics Committee, *Statement on Benefit-Sharing*.

[21] HUGO Ethics Committee, 'Genetic Benefit-Sharing'.

[22] Robert L. Ostergard Jr, Matthew Tubin and Jordan Altman, 'Stealing from the Past: Globalization, Strategic Formation and the Use of Indigenous Intellectual Property in the Biotechnology Industry', *Third World Quarterly* 22 (2001), pp. 643–656.

[23] It is important to acknowledge that much research is still sponsored by governmental or non-profit organizations that respond more directly to public health needs on various scales and are less (or even not at all) motivated by profit figures that are an important consideration in for-profit enterprises.

altruistic framework characterizing scientific research are increasingly viewed as investments or calculated stakes in an arrangement geared to produce profit.

Besides various international and social justice concerns that have relevance in benefit-sharing, the HUGO Statement on Benefit-sharing has also suggested that medical enterprises might have special moral obligations. This is based on an understanding that human health is of fundamental value and access to healthcare is a basis upon which much else in life depends. Illnesses often diminish the choices we have in life, thus linking this issue to a principle of equal opportunities.[24] While the fulfilment of this principle has traditionally been the responsibility of governments, the HUGO statement introduces an alternative possibility that acknowledges the increasing influence and power that non-state actors have in our globalizing world.

To conclude, I do not argue for the counterpositioning of the medical sphere versus the new genetics-as-business sphere in terms of benefit-sharing. I would rather insist that the continuing prevalence of market forces in biomedical research is having a considerable effect on the rationale for benefit-sharing. The traditional medical research settings are inadequate to respond to the concerns that have been raised by commercial research. Discourses are shifting and new arguments and justifications are advanced through the introduction of alternative perspectives. However, to discuss these transformations further, the notion of benefit should be clarified.

Sharing what?

The HUGO ethics committee has expressed in its statement on benefit-sharing that:

> A benefit is a good that contributes to the well-being of an individual and/or a given community (e.g. by region, tribe, disease-group ...). Benefits transcend avoidance of harm (non-maleficence) in so far as they promote the welfare of an individual and/or of a community. Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations.[25]

Benefits put forward by the scientists, as well as the pharmaceutical industry, patients, investors and public health officials, span a wide array of potentially valued 'goods', from improved health and better

[24] Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).
[25] HUGO Ethics Committee, *Statement on Benefit-Sharing*, G. Benefit-Sharing (1).

science to financial gains and wider social benefits. What is behind the notions of benefits and burdens of genetic research that are employed in various discussions? The HUGO definition is rather vague and, I think, intended to be so, but below I sketch an outline of issues that have been named by various actors internationally and especially in the context of biobanks. This overview of the health, financial and scientific benefits is by no means exhaustive but rather illustrative, and no judgement is presently made concerning the actual deliverability of these promises.

1. Health-related benefits may be identified at different levels, starting at the individual level with the promise of personalized medicine. With the advent of pharmacogenetics, knowledge of personal genetic information is envisioned to become an important factor in choosing suitable drugs and lessening the many adverse side-effects accompanying current treatments. Possibly, therapies and other medical interventions will also be 'tailored' to one's genetic make-up. At the collective level, disease-related populations and conceivably ethnic minorities might benefit from genetic research into their specific conditions or genetic constitution. At the state level, more efficient ways to organize healthcare and plan policies, perhaps even to better the 'average' health, have been hoped for. Even more universally, benefits to humanity at large, like the eradication of diseases, have been linked to genetic research. Population biobanks are seen as one of the most important tools in identifying gene-related diseases and are thus a likely element in providing benefits at any level.
2. Financial benefits can be discerned at various levels. The issue of profits to the investors and especially to large pharmaceutical companies has created concerns within the benefit-sharing discussion. Direct financial benefits to research participants are generally not allowed for fear of inducement. But, for example, in the Estonian case the public will indirectly also benefit financially because of shareholding and an arrangement that provides for an annual payment by the principal private investor and co-ownership in patents. On a larger scale, economic benefits could include the development of biotech and related sectors, establishment of new jobs and companies, and a reversed brain drain (a popular example again in Estonia and Iceland).
3. The scientific benefits refer to the development of science and knowledge as a value in itself, regardless of whether it is useful or applicable. There might be new and cheaper research opportunities opened up to local scientists (Estonian academic institutions will, for example, be able to access the collected data without paying fees).

This list demonstrates the all-encompassing scope of the hopes and dreams with respect to developments in genetic research and complicates

the issue of benefit-sharing further. A differentiation is useful between the *universal* list above (describing the entire positive potential of the genetic enterprise) and a *specific* benefit-sharing framework directed towards those who directly participate in research.[26] These two issues should not be joined if we still want to make use of the sharing framework, and by differentiation much confusion is avoided because a number of benefit-sharing arguments function only in a specific context, whereas others have relevance universally. For example, compensation for risks taken is an important aspect where smaller research projects are concerned and desert might be considered a relevant distributive principle. Alternatively, compensation for fairness and the principles of need and equality gain significance in cases of successful drug development for diseases rampant in the poorer areas of the world.

Benefit-sharing and population biobanks

The practice of benefit-sharing, especially as first applied in agriculture, introduced a perspective that recognizes the contributions of communities and populations. Human genetics complicated the issue further as genetic information is by nature shared, thus involving individuals and communities who might not have participated in research in the traditional sense. As research is increasingly associated with for-profit companies and practices, this has given credence to additional concerns of political, social and economic origin. Of course, in principle 'genetic research on a global scale' is still made up of specific research projects, but many calls for benefit-sharing ask us to look beyond these specific projects and assess the impact of the entire phenomenon, inclusive of factors outside the regulated medical sphere. It is like taking stock of the ocean instead of focusing on the drops of water making it up.

Population biobanks provide an intersection for benefit-sharing concerns – whilst mostly focused on medical research, they ill-fit the traditional medical frameworks (for example, besides benefit-sharing the appropriate redefinition(s) of informed consent have been a significant challenge). The very scale and scope of population biobanks have introduced new concerns for fairness and justice that call for a different justification for benefit-sharing. But, of course, fairness and various justice-related concepts are notoriously difficult to agree upon. For instance, whose concerns are to be taken as relevant? In small-scale research

[26] Kadri Simm, 'Benefit-Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Human Genetic Research', *Genomics, Society and Policy* 1, 2 (2005), pp. 29–40.

projects this is easier to assess than in biobanks, where significant social concerns might arise.

It is also important to draw attention to the way justifying arguments for benefit-sharing determine the recipients of those benefits. In other words, certain justifications necessarily exclude or include specific groups or communities. For example, when we consider the genome to be a common property of humanity, the sharing should be done among all human beings. On the other hand, when benefit-sharing is conceptualized as a compensation for voluntarily taken risks, it would seem unfair to share benefits with those who have not taken any risks. Furthermore, different justifications can be contradictory and the employment of those competing concerns can complicate the issue further.

In biobanks the question will inevitably be raised as regards who in particular will benefit. Can and should a relevant community be delineated when not everyone will be involved? The case of individual benefits (as in the Estonian promise of giving individual feedback based on DNA samples) could be a strictly desert-based undertaking. The Icelandic project has promised cheaper drugs based on research results, but it is unclear whether that would include non-participants. By contrast, the UK Biobank explicitly does not promise personal gains and insists on the altruistic motivation of the participants: they expect the participation of the elderly but the expressly stated objective is to benefit all (also outside the UK), thus making solidarity central in sharing scientific benefits.

It is an open question whether population biobanks would rather follow the traditional reciprocal form of benefit-sharing or whether more inclusive arrangements based on solidarity are taken up. The concept of benefit-sharing has been transformed as ethical, social, political, economic and scientific developments have had their impact on research. The rationale for benefit-sharing within biobanks can rely on competing discourses, and it is largely up to the organizers as well as the participants to decide upon the content of this notion.

20 Genetic discrimination

Lena Halldenius

The argument in this chapter proceeds from an empirical fact and a conceptual dissatisfaction. 'Genetic discrimination' is now an ethical and legal issue. In countries like France, Denmark and Norway insurance companies and employers are banned from asking individuals to undergo or disclose results from genetic tests. There is backing in the Council of Europe's Convention on Human Rights and Biomedicine[1] and the Universal Declaration on the Human Genome and Human Rights.[2] The term 'discrimination' is explicitly used in these documents. In Sweden, legislation was recently proposed by a parliamentary committee. The proposals affect both the insurance sector (previously regulated in a trade agreement) and the employment sector (previously unregulated).[3]

The genetic discrimination scare is exacerbated by plans to build population genetic biobanks and databases in several countries, like Estonia and the UK. In Sweden there is no such comprehensive genetic project underway, but the PKU register holds blood samples from every individual born in Sweden since 1975. These large-scale biobanks raise ethical issues not only about consent procedures, data protection, and whether people should have a right to know (or not to know) what their genetic make-up looks like. They also raise issues about the ethical viability of third-party use. Genetic information is ever becoming more and more accessible. With the advent of large-scale biobanks and genetic

[1] 'Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited', Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997, ETS 164, art. 11.

[2] 'No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity', UNESCO, The Universal Declaration on the Human Genome and Human Rights, adopted by the General Conference of UNESCO at its 29th Session on 11 November 1997, art. 6.

[3] SOU 2004:20 Genetics, Integrity and Ethics, Final Report from the Committee on Genetic Integrity (SOU 2004:20 Genetik, integritet och etik. Slutbetänkande av Kommittén om genetisk integritet).

databases, an increasing proportion of the population will have undergone genetic testing. Even though insurance companies and employers may balk at asking people to take a genetic test for the purpose of assessing the level of risk they represent, they might well be interested in accessing genetic information that is already there. Who – if anyone, apart from scientists and healthcare professionals – should be allowed to use and benefit from this information? This is the context of the genetic discrimination debate.

My concern is whether genetic discrimination and the regulation of it can be given a reasonable foundation in philosophy. Of particular interest is on what grounds we identify instances of discrimination. We make distinctions between people all the time. Whenever an employer hires someone, someone else is filtered out. On what grounds do we distinguish between fair and unfair filtering?

First, can there be a well-supported conception of discrimination that admits genetic information in principle among its grounds? I argue that 'the standard account of discrimination' cannot explain genetic discrimination in those sectors with which we are concerned. One cannot refute an account of a normative concept merely to support a political proposal, so we need to see if there are other reasons for questioning the standard account. I find at least two. Proceeding from these, I argue for an alternative account that fares better. This alternative is capable of explaining genetic discrimination.

I briefly address the regulation of the insurance sector. Even on my account of discrimination, distinguishing between genetic and non-genetic medical information seems unwarranted. I consequently question the assumption that genetic information is exceptional.

The standard account of discrimination

This is the standard account of discrimination: discrimination is decision-making representing or resulting in harm[4] for an individual on grounds that are irrelevant in the context. The ground is a personal characteristic (of a certain kind).[5] For example: a female (or male) employee is paid less than her male (or his female) colleague where no factors explain the wage difference other than sex and the employee's sex is irrelevant for the job. The parentheses stress that this account is symmetric. Even

[4] Whether harm is *represented* by the unfairness or whether harmful *consequences* are required in addition to the unfairness does not matter for my argument.

[5] What that means and the problem it represents is discussed in the section 'Ground selection'.

if women are systematically disadvantaged on the labour market, it is as wrong to pay a woman more (because she is a woman) as it is to pay a man more (because he is a man).

By calling this the standard view, I do not imply that it consistently informs legislation; no account does. But it tends to be implied when discrimination is discussed as a form of unfairness. In addition, context-relevance has intuitive appeal. It seems reasonable to say that distinguishing on the grounds of sexual orientation is wrong on the labour market generally, but right when hiring staff for a gay rights organization.

Let X be a personal characteristic of the right kind and C the decision-making context. The structure of the standard account is: To disadvantage a person P because of X in C is discrimination if and only if X is irrelevant in C.[6]

Can the standard view explain genetic discrimination?

If we accept genetic discrimination as a genuine case of discrimination – it instantiates the appropriate form of unfairness – the standard view faces a problem that concerns the relevance criterion itself. The moral intuition feeding the standard view is that fairness demands that decisions affecting individuals be made on context-relevant grounds. But the relevance criterion may conflict with what fairness requires; it is not a stable criterion for fairness. Genetic information is an example.

Take the insurance case. Pre-symptomatic genetic information may be used in determining whether insurance will be offered and at what price. Negative decisions based on such information display all the trimmings of discrimination: a decision disadvantaging an individual because of a personal characteristic the individual does not control. The problem is that the characteristic is context-relevant.

Private insurance runs on the principle of risk calculation. In calculating the risk a person statistically represents, substantial information is needed. Banning the use of genetic information puts a restriction on that principle. Some characteristics that are irrelevant in other contexts are relevant in insurance decisions. A disability is relevant for premiums on health insurance. We might think this is unfair but it is context-relevant.

[6] Definitions of discrimination tend to contain two features: 'differential treatment' (or 'treating less favourably') for 'arbitrary', 'irrational' or 'irrelevant' reasons. The variations of the second feature amount to the same thing, since reasons are supposed to be arbitrary or irrational because they are irrelevant. I regard all these varieties as falling within the standard view. See e.g. Will Kymlicka, *Contemporary Political Philosophy* (Oxford: Oxford University Press, 1990), p. 240, and Jan Narveson, *Moral Matters* (Peterborough, Ont.: Broadview Press, 1993), p. 243.

Similarly, a predisposition for a genetic disorder is relevant for the risk of illness and premature death.[7]

A possible response is that using genetic information in insurance decisions is thereby fair. This assumes that relevance is sufficient not only for making decisions non-discriminatory but also for making them fair, which is not right. Discrimination is a *form* of unfairness.

Another response is that such decisions do not count as discrimination but are unfair for other reasons. Maybe it is unfair to be disadvantaged because of a personal characteristic one cannot help having, whether relevant or not. But that would make discrimination conceptually redundant. If it is always unfair to be disadvantaged because of a personal characteristic one cannot help having, why bother to argue that it is unfair when the characteristic is context-irrelevant?

A third way is to look for an alternative view of discrimination. Doing that is not justified simply on the strength of an intuition concerning genetic information – perhaps the intuition is wrong – so we need to consider whether there are other reasons for questioning the standard view. Let me formulate three general requirements that an account of discrimination should meet. (I do not claim that this list is exhaustive.) The standard view fails on two out of three, giving us at least two reasons to look for an alternative.

General requirements

An account of discrimination needs to satisfy certain requirements. What they are will always be contentious. The requirements I suggest here are not exhaustive.[8] I find them reasonable and hope that the ensuing discussion will make the case for each. What I claim is that an account that satisfies these requirements is stronger than one that does not. Consequently, an account of discrimination should

1. have a defence against unfair background factors or biased institutions;
2. have a principle for ground-selection, i.e. be able to pick out those X that can be ground for discrimination, in a non-arbitrary, non-question-begging way;
3. not be conditioned on bad intentions.

[7] Within the European Union a general ban on sex-differentiated prices and terms for goods and services has been proposed. It includes private insurance and would outlaw sex-differentiated insurance premiums. The standard account can no more explain this proposal than it can explain genetic discrimination.

[8] In fact, a fuller list can be found and is discussed in my 'Dissecting Discrimination', *Cambridge Quarterly of Healthcare Ethics* 14 (2005), pp. 455–463.

The standard view meets the third requirement. Discrimination occurs when the ground for a decision is a context-irrelevant personal characteristic (of the right kind). The decision-maker's intention can be anything: prejudice, ignorance, even benevolence. ('Better not put John the gay guy in with the Alpha-males in the boardroom; they'd make life hell for him.') The decision-maker's intention is not part of the classification. Arguing that no harm was intended does not excuse the unfairness. This is a strength we want to retain.

Now let us look at the first requirement.

Unfair relevance

The relevance criterion in the standard view is context sensitive: 'relevance' is the relevance of a property in a given situation. This needs to be distinguished from *moral* relevance. To exemplify: sex is *morally* irrelevant – i.e. not allowed to influence our moral principles – but still *context-relevant* when hiring therapists for a shelter for battered women.[9] If P is disadvantaged because of X in C, the correct follow-up question is not 'Is X morally relevant?' but 'Is X relevant in C?' If X is relevant in C, then there is no discrimination against P in C.

A legitimate question is *what is it that makes X relevant in C?* The rub is that X may be relevant in C for reasons that are unfair. Institutions are shaped by those who have the power to do so. The labour market was shaped for male workers with wives at home. When a group is excluded from or subordinated within an area of society, that area is unlikely to fit them very well. Relevant characteristics for doing well in C may be a function of such inequalities.

This is illustrated by a Swedish court case.[10] A female midwife sued her employer for wage discrimination, arguing that her job was as qualified as that of a male hospital technician who was paid considerably more. The court found in favour of the defendant, arguing that the technician's qualifications had wider market appeal. It is a relevant factor in an employment situation (C) that an employee may be better paid elsewhere and hence has an incentive for leaving (X). Consequently, on a

[9] See John Rawls' 'things that are irrelevant from the standpoint of justice' (*A Theory of Justice* (Oxford: Oxford University Press, 1972), pp. 18f), referring to morally irrelevant factors. This distinction is often overlooked in the discrimination literature. One example is Narveson: 'Discrimination *is treating some people less favourably than others for morally irrelevant reasons*' (*Moral Matters*, p. 243).

[10] *Midwife* v. *Örebro County Council* (Labour Court 2001 no. 13).

sex-segregated labour market, where women's qualifications have lower market value, paying women less is not discrimination.[11]

Legislators try to meet this difficulty with regulation of so-called 'indirect discrimination',[12] targeting rules and procedures that appear neutral but in practice disadvantage a particular group. Relevance is, however, still the test.

A rule requiring 20/20 eyesight for employment is a disadvantage to the visually impaired, but if the job is to fly a Boeing 747 we do not question it. This kind of case is unproblematic. It gets trickier when a rule is context-relevant for unfair reasons; in this respect indirect discrimination is no different from direct discrimination. Say that it is company policy only to employ people who are likely to bring in a certain number of clients. In consistent application of this policy the company does not employ people of colour since they believe correctly, in this example, that an all-white staff will gain them customers and money. Making money is what companies are supposed to be doing, so the rule is context-relevant. Indirect discrimination does not solve the problem of unfair background factors. It changes the field of application but not the principle of evaluation.

The standard view lacks resistance against characteristics being context-relevant for unfair reasons. Consequently it cannot deal with disadvantages that are so entrenched in the institutional culture that they have come to be regarded as morally innocuous or even natural.

Ground selection

Let us turn to the second requirement: an account of discrimination should be able to pick out those X that can be ground for discrimination, in a non-arbitrary, non-question-begging way.

The ground for discrimination is a personal characteristic, but of what kind? There appears to be something special about characteristics that

[11] Harriet Bradley (*Gender and Power in the Workplace. Analysing the Impact of Economic Change* (Basingstoke: Macmillan, 1999), chapter 5) shows how inequalities are attributed to 'natural' features, like female domesticity. On inequalities making differences relevant, see Joanne Conaghan, 'Feminism and Labour Law: Contesting the Terrain', in Anne Morris and Thérèse O'Donnell (eds.), *Feminist Perspectives on Employment Law* (London: Cavendish Publishing, 1999), pp. 31–32: 'the assumption [is] that where such differences [in productivity enhancing characteristics] *do* exist and, howsoever derived (for example, as a consequence of unequal access to educational or training opportunities, or the gendered allocation of labour in the home), they *are* relevant to decision making, regardless of the gendered consequences which may flow from them'.

[12] Council Directive 97/80/EC of 15 December 1997 on the burden of proof in cases of discrimination based on sex, OJ 1998 No. L014, 20 January 1998, art. 2.

can be ground for discrimination (henceforth D-characteristics); what is it? The relevance approach seems incapable of answering that question.

There is a familiar list: sex, ethnicity, religion, sexual orientation and disability. Predisposition for genetic disorders is a new entry. Items have been added as they have become political concerns. But what about obesity, poverty or an irritating habit of picking one's nose? What is the principle for identifying an X of the right kind?

One possibility is that D-characteristics can be the source of group identification. If so, D-characteristics are special in affecting not only the directly disadvantaged individual, but also others who are offended by association. The characteristic is such that it *matters* to the collective identity of people who have it. The items on the list often do. But this begs the question. We are after a principle to explain why sex is a D-characteristic whereas left-handedness might not be, but people can identify with others on the basis of anything they want. Perhaps being left-handed is the most important thing in my life. People are not less protection worthy because their group identity is non-ethnic or non-religious.

Another alternative is that D-characteristics are immutable, the idea being that it is particularly bad to be disadvantaged because of a characteristic one cannot help having. Apart from being unhelpful for religious converts and transsexuals who are disadvantaged because of what they have turned themselves into, it is not obvious why adopted characteristics are less protection worthy. They might matter even more to people than inborn ones.

Maybe a characteristic cannot be a D-characteristic if the person is responsible, even involuntarily, for it. A disability is not a D-characteristic if, say, self-inflicted through reckless driving. But identifying D-characteristics should not require contestable judgements of a person's moral track record.

A final suggestion is that D-characteristics are particularly potent sources of harm, perhaps *because* they matter to people who have them. But the standard view does not require a separate notion of harm. Even if it did, using it to identify D-characteristics before the fact would again beg the question.

The relevance approach fails the second requirement.

An alternative account

The more entrenched a practice is in an institutional culture, the more likely it is to be unreflectively reproduced within a culture believed to justify the practice. That is why an account of discrimination needs to

meet the third requirement. Discrimination is an individual act individually experienced but is no anomaly in a well-working world. It is an individuated experience of a collective phenomenon. The individual act and experience should, therefore, be characterized and assessed in relation to the institutional culture in which it takes place.

In any institutional culture, there are patterns of inequality and relations of dominance between persons and groups. I use *dominance* to signify a power relation with the stable feature of being asymmetric. Social relations may feature fleetingly asymmetric power-imbalances, such that the upper hand moves easily from one to the other. An agent A is *dominant* in relation to S only if A has the stable capacity to interfere at will in the life chances, options and interests of S, in a way that has sanction in the institutional culture and is largely out of S's control. S is dependent on the will of A. The preferential right of interpreting the social status of the dominated group (and to define it as a group) lies largely outside of the group itself. This asymmetry is institutionally stable.[13] Whatever X makes it true of S that S is dominated is S's vulnerability marker (V). On the generic level C is the institutional culture (CG) in which such markers are identified. On the specific level C is the decision-making context (CS) where a V explains the disadvantage to an individual.

Discrimination is the manifestation of dominance relations in decision-making affecting individuals. The vulnerability markers are D-characteristics. An act counts as discrimination if it is correctly explained in these terms.

Inequalities may be so deeply embedded in the institutional culture that they are conceptualized as fair also by the judicial system.[14] An account of discrimination should be able to deal with that. This account does – it meets the first requirement – since discrimination is traced explicitly to such factors.

It also meets the second requirement; it has a principle for ground-selection. Characteristics are D-characteristics to the extent that they

[13] On dominance relations, see Lena Halldenius, 'Non-domination and Egalitarian Welfare Politics', *Ethical Theory and Moral Practice. An International Forum* 1 (1998), pp. 335–353; Lena Halldenius, 'Solidaritet eller icke-dominans? Frågor om välfärdsstatens politiska legitimitet', *Tidskrift för politisk filosofi* 4 (2000), pp. 31–42; Lena Halldenius, *Liberty Revisited. A Historical and Systematic Account of an Egalitarian Conception of Liberty and Legitimacy* (Lund: Bokbox, 2001). Also Philip Pettit, *Republicanism. A Theory of Freedom and Government* (Oxford: Clarendon Press, 1997), and Quentin Skinner, 'A Third Concept of Liberty', *Proceedings of the British Academy* 117 (2003), pp. 237–268.

[14] In an earlier case between the parties referred to in note 10 above (*Midwife* v. *Örebro County Council* (Labour Court 1996 no. 41)), the Court referred to the wage hierarchy in the public sector and the upheaval of the wage structure that a ruling in favour of the plaintiff would cause. The Court explicitly used an established hierarchy to argue that a wage difference did *not* constitute discrimination.

function as vulnerability markers within dominance relations in an institutional culture. The principle has the same structure as the one we failed to find for the standard view: X may count as D in CS if V in CG. There is in theory no limit as to what characteristics can be vulnerability markers; they will vary over time and between institutional cultures. The point is that we have a principle, not that there are no hard cases. The items on 'the list' – sex, sexual orientation, religion, ethnicity, disability and probably others as well – are strong candidates.

We need to note one thing. A D-characteristic functions systematically as a vulnerability marker, which does not mean that it has that function in every instance. A disadvantage can happen to someone who is gay without being correctly explained by the dominance relation that exists in a society where heterosexuality is the norm. Perhaps this individual is a bad worker. The dominance relation has to be the explanation in the specific case.

As a bonus, this account explains some intuitions about ground selection. D-characteristics are potent sources of harm and they may well be a source of identification, not least *because* they are vulnerability markers. Religion, for instance, will matter even more to people whose affiliation is under threat.

The dominance approach meets the third requirement and retains the strength of the standard view in not conditioning discrimination on anyone's state of mind. Relations of dominance can but need not be accompanied by derogatory attitudes. They are not contradicted by instances of benevolence. To identify dominance we do not need to know with what intention people act; we need to know in what relationship they stand to others. Intentions are taken into account to the extent they are indicative of such relations; whether they are benevolent or malevolent is not decisive. It might be true that the Alpha-males would give the gay guy hell in the boardroom and that may constitute a benevolent reason for not promoting him. But the benevolence is not the operative factor, the underlying relations of asymmetric power are.

The standard view is symmetric. If disability is on the list, it is as bad to favour the disabled over the able-bodied as to do the reverse. The dominance approach rejects this symmetry. If disability is on the list, it is because disability is a vulnerability marker in the institutional culture. On that explanation favouring the disabled and favouring the able-bodied are not morally equivalent.

Regulation

There is room for reasonable disagreement over vulnerability markers. Identifying them requires a contestable analysis of the institutional culture.

Since context-relevance is not the distinguishing criterion, people's vulnerability to harm because of personal characteristics can be ground for discrimination even when the characteristics are context-relevant, like genetic information in the insurance sector. This opens the way for a ban of the use of genetic information in insurance decisions. But there is more to say.

A characteristic can be a vulnerability marker *because* it is unregulated. Vulnerability markers require an institutionally stable power asymmetry. Such asymmetry may exist merely for regulatory reasons. That seems to be the case with genetic information in the insurance example. My account requires that S is dependent for her welfare on the will of insurance companies. To the extent there is healthcare available to all, adequate non-risk-assessed public health insurance, and support for dependents, S is not. Where such protection does not exist and private insurance is the only option, S is vulnerable to the will of insurance companies. Consequently, where there is no general protection, using genetic information in insurance decisions is discrimination and should be banned.[15] I concur with that argument. But one problem remains.

It is the principle on which private insurance runs – actuarial calculations of risk – that makes me vulnerable as a carrier of a genetic disorder in an institutional culture with inadequate healthcare protection. But in the absence of such protection, non-genetic factors make me equally vulnerable. Still, legal bans on the use of genetic information distinguish between genetic and non-genetic medical information. What ground is there for making that distinction?

One suggestion is that genetic information is particularly intimate; disclosing it is a worse blow to our integrity than disclosing non-genetic medical information. This idea is common, yet unconvincing. Is it more threatening to a person's integrity to have it disclosed that she carries a gene for breast cancer than having people know that she is infected with HIV? Our integrity is threatened by the disclosure of sensitive personal information, whether genetic or not.

Another suggestion is the risk of misuse when companies are allowed to make decisions based on uncertain predictions. As a carrier of a breast cancer-gene the risk that I develop cancer may be very moderately increased compared to other people. But misuse of non-genetic

[15] The risk that 'adverse selection' counteracts such regulation is discussed in Niklas Juth, Marcus Radetzki and Marian Radetzki, *Att nyttja genetisk information. Hur mycket ska försäkringsbolagen få veta?* (Stockholm: SNS Förlag, 2002); and Niklas Juth, 'Insurance Companies' Access to Genetic Information: Why Regulation Alone is Not Enough', *Monash Bioethics Review* 22 (2003), pp. 25–39.

information is equally likely. In a Swedish case, a child was refused private health insurance on the basis of a casual note in his medical records saying he had dry skin. The insurance company argued that dry skin indicated a risk of developing skin disease.

The principle of risk calculation puts individuals who (are believed to) represent a high risk at a disadvantage, whether or not the risk is due to genetic factors. Many argue that genetic discrimination provides a strong argument for public health insurance.[16] It does, but only as an example of what we already know: commercial decisions should not influence people's access to welfare protection.

Regulating genetic discrimination can be done in two ways: through the provision of public health insurance or through restrictions on private health insurance. The consequences of risk calculation for high-risk individuals are reason for substantial public insurance, and provide a case for regulating the private insurance sector. Distinguishing between genetic and non-genetic medical information when doing so requires a good reason for regarding genetic information as exceptional. That reason has still to be provided.

[16] See Ronald Dworkin, *Sovereign Virtue* (Cambridge, MA.: Harvard University Press, 2000), p. 435; Juth, Radetzki and Radetzki, *Att nyttja genetisk information*, pp. 154–156; Juth, 'Insurance Companies' Access to Genetic Information'.

21 Privacy

Salvör Nordal

Genetic databases are often seen as a threat to individual privacy.[1] This is apparent in surveys that show concerns of the general public when it comes to the use of personal information in genetic research.[2] The most obvious reason why people worry about their privacy in this context is fear of misuse of information, stigmatization of groups and unjustified intrusion into people's personal affairs.

In this chapter I will examine the justifications for privacy claims with regard to population-based genetic databases like the Icelandic Health Sector Database (HSD). My aim is to show that the popular definition of individual privacy as control over personal information is not likely to be a useful tool for protecting the interests associated with informational privacy. This is so because of the nature of personal information, because of difficulties with distinguishing adequately between sensitive and non-sensitive information, *and* because of the nature of computerized databases. I will argue that if we want to take privacy interests seriously in this context we need to look in new directions for securing them.

Informational privacy

In the literature on privacy we find little consensus on the meaning or scope of the concept. Ever since it was first argued that we have a right to privacy, many diverse definitions have been defended and criticized. More recently, scholars have argued that privacy should be understood as a cluster concept that covers several privacy interests.[3] Anita Allen, for instance, identifies four different clusters of privacy – informational

[1] I would like to thank Vilhjálmur Árnason, Sigurdur Kristinsson and Gardar Árnason for their comments on earlier drafts of this chapter.

[2] See the contributions in part II of this volume.

[3] See Judith Wagner DeCew, *In Pursuit of Privacy* (Ithaca: Cornell University Press, 1997); and Anita Allen, 'Genetic Privacy: Emerging Concepts and Values', in Mark A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997).

privacy, decisional privacy, physical privacy and proprietary privacy – and argues that they may all apply to the issue of genetic research in one way or another. In the case of genetic *databases*, however, informational privacy is most important and it will be my focus here.[4]

It is important to separate the question why informational privacy is important for us, i.e. what interests privacy is meant to protect, from particular definitions of informational privacy, i.e. what privacy is taken to consist in. By keeping these issues apart we are able to examine whether 'privacy' as commonly defined does really do the job of protecting our privacy interests. This approach does not assume that the connection between interests and definition in this respect is contingent; on the contrary, I believe that privacy is a normative concept. My point is rather that the popular definition of privacy as an individual control over personal information, does not result in the protection of the interests commonly expressed regarding genetic databases and therefore needs to be redrawn.

So what interests is privacy meant to protect? From the beginning, privacy has been associated with our interest in keeping personal information from others. This interest seems to be embedded in social conventions and courtesy rules; we are, for instance, expected not to nose around in other people's things and private affairs without their consent. We can identify at least two ways of explaining this interest in privacy. On one hand, we have an individualist account of privacy where privacy is seen as 'an intrinsic part of [people's] self-understanding as autonomous individuals'.[5] On the other hand, the reason why protection of privacy is seen as important may be that disclosure of sensitive information might be hurtful or make us vulnerable in many ways; it might cause us shame and embarrassment and loss of respect in our community, and at worst it may be a ground for discrimination or stigmatization.[6]

In the literature, informational privacy is often described as individual control over personal information. Judith Wagner DeCew says, for instance: '[informational privacy] shields individuals from intrusions as well as the fear of threats of intrusions, and it also affords individuals control in deciding who has access to the information and for what purpose'.[7]

Two things are of interest here. The first is the emphasis on *individual control*. Generally the advocates of privacy have highlighted the

[4] See, for instance, Allen, 'Genetic Privacy'. Judith Wagner DeCew takes a similiar view in her book *In Pursuit of Privacy*.
[5] Beat Rössler, *The Value of Privacy* (Cambridge: Polity Press, 2005), p. 116.
[6] R. G. Frey, 'Privacy, Control, and Talk of Rights', in Ellen Frankel Paul, Fred D. Miller, and Jeffrey Paul (eds.), *The Right to Privacy* (Cambridge: Cambridge University Press, 2000), p. 46.
[7] DeCew, *In Pursuit of Privacy*, p. 75.

importance of individual control over information about their personal matters. Individuals should be able to decide for themselves whether information about them is communicated to others, and informational privacy should prevent others from obtaining information about an individual without his or her consent. In this sense privacy protection is seen as an expression of autonomy, i.e. as the right to make decisions concerning one's own personal interests. If privacy is grounded in the value of individual autonomy, control of personal information might be essential; if, however, we see its importance primarily as protection against discrimination or vulnerability, the requirement of control may be relaxed in some cases. It is, for instance, problematic for individuals to have control over personal information in the context of genetic databases, both because genetic information is not strictly individual, and also because, as will be argued here, the nature of databases is such that it frustrates the possibility of individual control.

The second issue concerns what counts as *intrusion into private matters*. Generally speaking, personal information constitutes information on each individual. Here personal information is understood in a broad sense as any information concerning persons. Thus personal information does not necessarily have to be private or sensitive. Our name is listed in the phone book, information on our appearance is available to everyone who sees us and so on. So what personal information should count as private or sensitive? Is personal information private or sensitive if it cannot be obtained without access to the person or to his or her private sphere? Is information sensitive in virtue of being able to hurt persons if made public or misused in any way? Does this rule out privacy protection of information within the public sphere? These are hard questions and, as I hope will become more apparent when discussing genetic databases, I believe that the focus on the distinction between sensitive and non-sensitive personal information is directing us away from the real issues. Not only is it very difficult to come up with a criterion that distinguishes sensibly between such kinds of information but it also turns out that with computerized databases, information that is generally thought to be non-sensitive can become sensitive in a different context or a different situation.

Personal data in genetic databases

As many surveys show, genetic and medical information is generally ranked among the most highly sensitive information.[8] Therefore it does

[8] See the contributions in part II of this volume, in particular the chapter on Sweden (Kjell E. Eriksson) and the chapter on the UK (Sue Weldon).

not come as a surprise that many see genetic databases as a threat to individual privacy.

The Health Sector Database (HSD) in Iceland is of special interest because it creates the possibility of linking three different kinds of personal data.[9] The HSD will contain information taken from medical records, but it can be linked with two other databases, one containing genetic data and the other genealogical data. These data are different with regard to privacy protection. It has been argued that genetic data are more sensitive than any other information on individuals: 'Genetic information is uniquely powerful and uniquely personal, and thus merits unique privacy protection.'[10] Medical data contain sensitive information on individuals such as diagnosis of health status, treatment and lifestyle information. Apart from concerning highly private matters, medical information has been disclosed in a confidential and trusted relationship between doctors and patients. Genealogical information, however, at least in Iceland, is considered public information and is readily available in books and newspapers and no privacy restrictions apply to it. The HSD can therefore be linked to information from both ends of the spectrum: from what some argue is the most sensitive personal information to purely public information.

It has been argued not only that genetic information is highly sensitive and, as such, merits unique privacy protection but also that it is exceptional in a profound way compared with other personal information. By examining and comparing genetic and genealogical information, I hope to show however that this view is not very convincing.

Surely genetic information contains sensitive information on individuals such as genetic make-up and likelihood of getting genetic diseases in the future, information that is closely linked with medical history.[11] But this is only partly true of genetic data, since they also contain genetic information anyone can observe from seeing us, such as hair and skin colour. Genetic information is therefore, as Onora O'Neill puts it, neither intrinsically medical nor intrinsically intimate.[12] How should we then categorize genetic data? It seems to me difficult to categorize them

[9] As mentioned in other parts of this book, it is unlikely that HSD will ever be constructed.

[10] George Annas, Leonard Glantz and Patricia Roche cited in Thomas Murray, 'Genetic Exceptionalism and "Future Diaries": Is Genetic Information Different from Other Medical Information?', in Rothstein, *Genetic Secrets*, p. 61.

[11] Interesting discussion on genetic information may be found in Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), and Murray, 'Genetic Exceptionalism and "Future Diaries" '.

[12] Onora O'Neill, 'Informed Consent and Genetic Information', *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001), p. 697.

either as sensitive or non-sensitive, but rather some genetic information is sensitive and some is not.

Another feature of genetic information which renders it highly sensitive, some argue, is that it constitutes 'a future diary'. This means that our genetic make-up can reveal personal information and predict future health of individuals. Furthermore, this information that is still coded in our DNA is gradually being decoded and having this information available may affect the individual's view of himself and his prospects. Again it is true that DNA information can reveal information relevant for future health conditions, but genetic data is not unique in this sense. We can predict future health from present lifestyle factors such as smoking or obesity.[13] We can therefore say that information that is not regarded as private or sensitive – information that we take no precaution in protecting – can, just like genetic data, reveal much about our future health.

Thirdly, it has been pointed out that genetic information not only concerns the individual but reveals information on other family members as well. We are genetically related to our siblings and parents and information on one family member may imply information on another. Identical twins have for instance the same genetic make-up. If one of them reveals genetic information then she is in fact giving information on the other as well. How should we react to this? Do we need consent of both? What if there are disagreements? It is of course true of some other personal information that it is familial just like genetic information. This is often overlooked by privacy advocates. By reporting in public that a member of a large family has inherited a certain amount of money or property from his parents, one may reveal personal information on the family wealth that other members would have chosen to keep secret.

Finally, it has been argued that genetic information gives us unique power to discriminate against individuals or groups. Most often the case is made against discrimination of employers and insurance companies. But is genetic data unique in this sense? Unfortunately we have frightful historical examples of stigmatization of groups taking place long before the discoveries of DNA. This is still true; we can use information gathered from the public sphere as a ground for misuse and stigmatization against individuals. We could take examples from Iceland, a nation where public records of families go far back and where many people take pride in their knowledge of relations between individuals.[14] These relations are for instance published in obituaries in the daily newspapers, and books are

[13] Ibid.

[14] The public interest in *The Book of Icelanders*, the genealogical database constructed by deCODE, is a good example.

published on families and family relations. All this public information is readily available and can reveal information on the health of individuals and families and is of course available to employers and insurance companies just as to anybody else.

In a society where much knowledge about its members is publicly available, it is debatable whether and in what sense genetic information is uniquely different from genealogical information. For a family with a high probability of a disease like breast cancer or Huntington's disease, it might even be better for members of families that are subjected to higher insurance rates to take genetic tests. Genetic information is after all more reliable than information on family health and, in the case of the Huntington's, it is quite decisive. Family members who do not have the gene for Huntington's may therefore protect themselves from being unjustifiably discriminated against by taking a test.

This discussion manifests the difficulty with drawing the line between sensitive and non-sensitive information. Whether information is sensitive or not may depend on the context rather than the content. Gathering information from the public sphere can give us quite a good profile of individuals or families and this can result in stigmatization if misused. Furthermore, bio-samples contain complex information on the individual that can be classified both as sensitive and as non-sensitive. Moreover this discussion shows that we do not always have the control over information on ourselves that the privacy literature often assumes. We are part of a web of relatives, both genetically and historically. Thus genealogical, genetic and medical information all contain information not only on a particular individual but also on his or her relatives. The control over this information is therefore shared with many.

Computerized databases and privacy protection

We have seen that genetic information may be hard to protect if we focus on privacy as control over sensitive information. This problem becomes even more apparent in the context of information technology.

The public sphere is seen as open and accessible to everyone. Moreover, when we are acting in public we give away personal information freely. When we walk on public streets and buy in public shops, those around us can see what we do, how we behave, what we are wearing, what we are buying and so on. We have thereby given away various kinds of personal information, and a person who complains of privacy loss has misunderstood something essential about the public sphere.

With recent technology development this simple description of the public sphere is changing dramatically. Our movements and actions in

the open public space are not only open for others to see and observe; they may possibly be monitored, stored and kept in databases. We used to be able to assume that we were anonymous in public. It is well known that in crowded streets we are seen by many but observed by none.[15] This has changed. It is said that the average Londoner who goes to work may well be photographed in 300 different places in the central area, and on Oxford Street alone there are seventeen monitors on the street, not counting any of the shops.[16] All this information about our wanderings in public is kept in databases for future scrutiny. Is this a privacy loss? After all, we give this information freely and carelessly in public.

Not only is it possible to store enormous amounts of data in computerized databanks, this data can also be linked with various other data. This makes it possible to construct extensive profiles of persons. It is difficult to imagine the development of technology in the near future, or the possible uses of all this data that accumulates in modern society. This brings me to the point of individual control. If we are willing to donate our biosamples or health records to a database, what are we accepting? It is unlikely that we will have any control over how this data will be used once it is in the database. How can we secure that personal data is not used in contexts that differ from the originally intended ones? Should we be asked every time someone wants to use this data? From this we see the difficulties we have and will have of controlling data stored in databases.

We can give our consent for some personal information, but we can hardly control whether we enter some database at all. All living Icelanders are for instance listed in the *Book of Icelanders*, which is a database containing the genealogical information of 95% of the Icelandic population since the settlement of Iceland over 1,000 years ago, simply by being on public records. And we cannot disappear from these records. Who knows how much information on us is stored in computerized databases or where these databases are? But we know that once we are in them we can hardly expect much control over our personal information. Thus the information technology magnifies the problem of individual control. This does not mean that we cannot have any control but rather that we need to face the limitations in this respect and regulate databases accordingly.

By making too much of the distinction between databases containing sensitive information and those which have no such information, I believe that we have been too careless in regulating the second form of databases. Instead we should be more concerned about various databases, such as

[15] Helen Nissenbaum, 'Protecting Privacy in an Information Age: The Problem of Privacy in Public', *Law and Philosophy* 17 (1998), pp. 559–596.
[16] *Newsweek*, 8 March 2004.

genealogical databases, whereas this data can be used as a ground for misuse and stigmatization, as I have explained above. We therefore need stronger privacy protection for *all* kinds of databases containing personal information, not only those we believe at present to have sensitive information.

How can privacy be protected?

The discussion so far has shown how difficult it is to have any control over personal information in databases and how difficult it is to make the distinction between sensitive and non-sensitive information in this context. Privacy, understood as control of personal information, does not capture the difficulties we face.

How should we react to this conclusion? One reaction might be to dismiss the fear of loss of privacy as misplaced. Given, however, the concerns of the general public we should not be too hasty in dismissing them. The empirical evidence of actual fear of privacy loss should be taken seriously. Privacy is not all about control over personal information. One important reason for worrying about privacy is the fear of misuse and stigmatization, and privacy protection should be directed at these issues.

One reason why the general public may be concerned about insufficient privacy protection is the fact that individuals have little control over their personal information. If, as I have argued, individuals cannot be given the control over their personal information that they would need in order to protect it themselves, they will have to rely on someone else to protect it. Who should that be? My answer at this point is similar to the one Onora O'Neill offers in relation to informed consent, namely *trustworthy institutions*. We have to acknowledge that individual control is limited in this respect and build up institutional safeguards once individual control is no longer applicable.

This solution is not without problems. Even if we have little control over our personal information we have some control and we should not give it up entirely to institutions controlled by others. What we need to do is to find the balance between maintaining individual control where that is possible and building up trustworthy institutions. We need, for instance, to establish security standards and protection of personal information that refers to the usage of information in databases and who has access to it, and regulations on how different personal data are linked together.

Building up trustworthy institutions is a vast task and relies on a democratic public sphere.[17] In recent years, however, the public sphere

[17] O'Neill, 'Informed Consent and Genetic Information', p. 702.

has been transforming in ways that might make this task more difficult than before, and that brings me to what may be another reason why the general public is concerned about their privacy. With big companies and corporations, we are seeing an expansion of the private sector at the cost of the public one. In many Western societies, private companies are taking over more and more of the healthcare sector and scientific research. The public and the private sectors differ in an important sense, where the primary goal of the former is public service with democratic discussion and transparency, and the latter aims at profit and efficiency. In surveys we see different levels of trust towards these two sectors. This is evident in the surveys from Iceland, for instance, where scientists in public universities and physicians within the public healthcare system are the most trusted, but researchers within private companies are considerably less trusted. With the diminishing of the public sector we are moving away from the public sphere, towards expanding the social sphere, which is in Hannah Arendt's terms, a sphere of jobholders and the activity of sustaining life.[18] This development seems to be contrary to proper privacy protection that requires active and democratic public spheres to preserve the trust needed to protect privacy interests.

My aim in this chapter has been to indicate some of the problems we face concerning privacy and information technology. I have focused particularly on privacy as a control of personal information and argued that this definition does not capture the problem we face with computerized databases. My intention has been not to refute this definition altogether but only in the context of this particular technology. Traditionally, privacy interests have been voiced as a reaction to new technology and an intrusion into the private sphere, with possibilities such as tapping telephones and taking photographs from a distance. This is the main reason for the emphasis on individual control. More recently, information technology has created new kinds of threats and blurred the line between the public and the private, making it important to protect not only sensitive or private information but public information as well. The way to tackle this problem is not to undermine privacy but to think about it in a new fashion. It requires, among other things, trustworthy institutions, which in turn need a strong public sphere.

[18] Hannah Arendt, *The Human Condition* (Chicago: University of Chicago Press, 1958), p. 46.

22 Trust

Margit Sutrop

Trust is a basic element of our social life.[1] We need trust since we are social beings and any form of co-operative activity involves trust. There cannot be any successful business or any happy marriage, if partners do not trust each other. In addition, trust is a central and crucial value in the doctor–patient relationship. Furthermore, trust is especially important for an ethically adequate practice of science.

Public trust in science depends on scientists' behaviour as well as on the public understanding of science and acceptance of the applications of new scientific developments. Trust can be destroyed if some scientists do not follow the rules of good scientific practice and are caught in dishonesty or conflict of interest. More broadly, trust also depends on whether people trust scientists to do socially responsible science and believe that society will be able to control and maintain risks which new technologies and high-tech medicine supposedly introduce.

In many European countries polls document lack or loss of public trust in science and new technologies.[2] There are certainly different reasons for this and it is difficult to say whether the public mistrust is a response to prior untruthfulness and abuse of trust or whether it is rather caused by an uneasiness attending rapid progress in science and technology.[3]

Trust is especially important in the context of large-scale genetic databases as they are proposed in Iceland, Estonia, the UK and elsewhere. As these projects progress, one becomes increasingly aware of the fact that in

[1] This chapter was produced as a part of the ELSAGEN project and of the Estonian Science Foundation grants numbers 4618 and 6099. It has profited a lot from the comments made by Kadri Simm, Tiina Kirss, Vilhjálmur Árnason and Sigurdur Kristinsson. I also wish to thank Mairit Saluveer for introducing me to the discussion on trust.

[2] European Commission, Special Eurobarometer 224, 'Europeans, Science and Technology' (Brussels: European Commission, June 2005); European Commission, Special Eurobarometer 225, 'Social Values, Science and Technology' (Brussels: European Commission, June 2005).

[3] The most challenging discussion of public trust in science has been provided by Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002).

the end their success will depend on public trust towards the individuals and institutions who are carrying out the projects.

The aim of this chapter is to discuss what kind of trust we need and how to build and maintain trust. I will start with the conceptual analysis of trust, mapping different levels of trust relationships in the context of genetic databases. I will then proceed to show why both blind trust and irrational mistrust should be avoided.

The concept of trust

There is no unanimous agreement on what trust is. Trust has been defined as a feeling, an emotion, a disposition, an activity or knowledge that another will behave in a certain way. None of these descriptions seems to be quite adequate. Annette Baier has given the most influential account of trust and she distinguishes trust from reliance, as there are times when we rely on something to happen but do not trust anybody.[4] According to Baier, trust is reliance on another's goodwill and this necessarily means being vulnerable.[5] She describes the difference between trust and reliance through a difference in our reactions. Breaches of trust make us feel betrayed, whereas if we rely on something to happen (e.g. a car to start) and it does not, we simply feel disappointed or angry. Richard Holton argues that this difference in our reactions shows that trusting a person to do something 'involves something like a participant stance towards the person whom one is trusting'.[6] Robert C. Solomon and Fernando Flores believe that 'trust is a matter of reciprocal relationships' and therefore it makes sense to speak about trust only in relation to human agents and institutions.[7] *Reliance* and *confidence* have to do with predictability and law-like regularities and therefore we speak about the *reliability* of a watch or a car. I agree with Solomon and Flores and I will use the word trust to describe our relationships to other people and institutions.

Let us first try to ascertain what trust is about. Baier suggests that trust involves reliance on another's goodwill but to my mind this is not all that trust depends upon. Trust certainly involves reliance on the other's competence or capacity to behave as expected, as it is not enough to

[4] Annette Baier, 'Trust and Anti-Trust', *Ethics* 96 (1986), pp. 231–260; Annette Baier, 'Trusting People', *Philosophical Perspectives* 6 (1992), pp. 137–153.
[5] Baier, 'Trust and Anti-Trust', pp. 234–235.
[6] Richard Holton, 'Deciding to Trust, Coming to Believe', *Australasian Journal of Philosophy* 72 (1994), pp. 63–76, at p. 64.
[7] Robert C. Solomon and Fernando Flores, *Building Trust in Business, Politics, Relationships, and Life* (Oxford: Oxford University Press, 2001), p. 14.

believe that one has goodwill; one also has to believe that another will be able to do it. For example, we should not trust a doctor to treat an illness only on the basis of his goodwill. A patient's trust in a doctor relates also to the latter's competence. One trusts that he is up to date with medical information and is competent in the field. Thus it is evident that trust relates to both goodwill and competence. This concerns not only doctors but all actors.

A Wittgensteinian approach is taken up by Olli Lagerspetz who asks what we do when we speak of trust. In his words, 'to see an action as an expression of trust is to see it as involving a demand – a tacit demand – not to betray the expectations of those who trust us'.[8] I agree with Lagerspetz that trust is a tool of human interaction and that it involves expectations about others' behaviour. But there is always a risk that our tacit demand will not be fulfilled. Even rational decisions to place trust may be wrong since we always operate with limited knowledge about others. Granted, trust is earned by previous behaviour, but a record of previous trustworthiness only shows that it is likely that the person can be trusted.

Suppose there is a man who has always had a temptation to steal something but has been too afraid of being caught. When a situation arises where it is likely that nobody will learn of his stealing, he may follow his hidden desire. Therefore his previous behaviour does not give us any guarantees. But the situation may also be reversed – a person who has acted badly in the past might sincerely want to improve his behaviour but now nobody trusts him. Thus our trust can be based on a false belief that can make trust or mistrust inappropriate.

But does trust always involve belief? Richard Holton has argued that in order to trust one need not believe.[9] He gives an example of a shopkeeper who decides to trust his employee, although the latter has been convicted of petty theft. Holton argues that the shopkeeper can decide to trust the man without believing that he will not steal. He may trust him because he wants to give him moral support, a new chance to earn trust.

This is certainly not an unlikely case. The way we treat former criminals or fellow men who have done something bad, shows that we can trust without the belief that they are trustworthy. But contrary to Holton, I think that when we do decide to trust, a certain kind of belief must still be involved. It is not a belief about the likelihood of the other's behaviour but simply a belief in his ability to change his behaviour. We cannot decide to trust when we do not believe that the other person can

[8] Olli Lagerspetz, *Trust: The Tacit Demand* (Dordrecht: Kluwer Academic Publishers, 1998), p. 5.
[9] Holton, 'Deciding to Trust, Coming to Believe', p. 63.

live up to our expectations (although certainly our expectations may be higher or lower in different cases).

However, to suggest that trust involves belief (even if sometimes a false one), seems to indicate that it meets the requirements of rationality. In reality, however, our trust often goes beyond or against the available evidence. This can only be explained by the fact that trust also involves an emotional element which need not be rational. Just as we can be afraid of a dog even if we know that it does not bite, we cannot sometimes help mistrusting someone despite evidence to the contrary. Although many critics have tried to limit trust within rationality, these attempts are not totally convincing. In my view (mis)trust may be both rational and irrational and we should take feelings and emotions seriously. Imagine a person who knows that a certain airline is one of the most trustworthy companies but is still afraid of flying with it, since he remembers the recent plane crash that may have been the only one during the last hundred years of the company's history. In this case his mistrust is based more on his feelings than on his judgement of the likelihood that one of the airline's planes might crash again.

Sometimes we place trust without any previous judgement and rely mostly on our feelings, whereas at other times our trust is based on a rational belief that the other will do something. Expectations can be based on both belief and emotion or a combination of these and it is difficult to prioritize between them.

There are different forms of trust: simple, basic, blind and authentic trust. Simple or naive trust is simple because it is not given but taken for granted (an infant's trust for their primary caretakers); it cannot be articulated and reflected upon. Basic trust is established on the basis of simple trust in childhood and provides the basis for one's entire personality and attitude towards the world. Blind trust differs from simple trust as it is not innocent any more. It is irrational as one sees but refuses to see. Irrational blind trust is similar to irrational mistrust, as both are a matter of unwillingness to consider contrary arguments and obvious evidence. Authentic trust is authentic because it is 'open to evidence and is the product of experience, resolve, and commitments'.[10] Since one can never know whether the other will do what we expect him to do, trust is typically construed as risk taking – one has to place trust without guarantees. Restoration of breached trust takes a long time and therefore it is important to think continuously about how to create and maintain trust.

[10] Solomon and Flores, *Building Trust in Business, Politics, Relationships, and Life*, p. 65.

Mapping trust relationships in the context of human genetic databases (HGDs)

Let us now ask why trust is essential in the context of HGDs. A short answer might be that the success of each HGD project is largely dependent upon the willingness of the targeted population to participate and upon the belief of the investors and policy-makers that the project might bring future benefits. But is this situation significantly different from other research projects, which cannot be carried out without the trust of all parties?

Since HGDs are simultaneously scientific, healthcare and sometimes business projects, both individual and collective interests are involved. Researchers, physicians, patients, biotechnology firms and pharmaceutical companies are all excited about the scientific and therapeutic potential presented by genetic databases. Nevertheless, their interests and motives for participating in genetic research may be different or even competing. Researchers may be motivated by intellectual curiosity, obligation or self-esteem; biotechnology firms and pharmaceutical companies are interested in financial return; patients and their families might be motivated by an interest in treatment or cure for a disease as well as by altruism or even duty.

Since there are so many different parties involved in the HGD projects, there are various trust relationships that all matter for eventual success. Trust can have different objects:

I. One can trust/mistrust individuals
   a) who are carrying out the project (employees of the database, GPs collecting the data)
   b) who will have access to the data (doctors, academic or industrial scientists, computer specialists).

II. One can trust/mistrust institutions
   a) that are responsible for carrying out the project (deCODE, UK Biobank, Estonian Genome Project Foundation)
   b) that are funding the project (venture capitalists, public institutions, private or public trusts)
   c) that are overseeing it (ethics committees, other oversight bodies)
   d) that will have access to the data (research institutes, pharmaceutical companies, biotech firms, police, governmental institutions).

Trust additionally depends on various aspects and elements of these trust relationships: recruitment, access and confidentiality, feedback, uses to which the data will be put, financing of the project (public or private, whether it is the best use of money), governance of the project, aims of the project, scientific value of the project (reliability of the data) and the perception of the public.

In order to create and maintain trust, we ought to think about all these different levels of trust relationships. One should also be aware that it is one thing to create trustworthy institutions and another to choose trusted persons to run them. In addition, it is important to provide reliable systems in relation to data protection and securing privacy and confidentiality.

What kind of trust do we need?

The sociological study conducted in Iceland, Estonia and the UK in the framework of the ELSAGEN project in 2002 demonstrated the differences in attitudes towards proposed HGDs.[11] Estonians and Icelanders showed greater technological optimism than the UK people. In all three countries the creation of the genetic database had been generally accepted with varying levels of support; however, the UK population was characterized by a higher level of caution. The qualitative research showed that their anxieties focused around two main areas – that employers and insurance companies might get access to the data and that the collected data would be used for commercial purposes which, in turn, might lead to patenting and exploitation. In Iceland, the popularity of the database appeared to be high; in Estonia the strong public support could have been especially related to the proposed medical goals (a promise to provide every participant with personal feedback about his or her genetic make-up, if desired).

Competence proved to be an important feature of trust. This issue surfaced when genetic scientists were considered to be most trustworthy sources of information about the database by both the Estonian (91%) and the Icelandic (71%) public. In the former case it is remarkable to note that the high level of public trust vested in the employees of the EGP (trusted by 80% of the respondents) surpassed that of the ethics committee supervising the activities of the project. In Iceland too, trust towards authorized overseeing bodies was considerably lower.

On the one hand, it is probable that the mistrust of medicine, science and biotechnology in the UK has been caused by poor government handling of the emergence of BSE in cattle, by the one-sided attitude to the introduction of GM crops, etc. On the other hand, there is a longer tradition of critical debate in Britain than in Estonia, where the genetic database is the first biomedical topic discussed publicly.

[11] Külliki Korts, Sue Weldon and Margrét L. Gudmundsdóttir, 'Genetic Databases and Public Attitudes: A Comparison of Iceland, Estonia and the UK', *Trames* 8 (2004), pp. 131–149.

Since the UK public has already had bad experiences with scientists, the British people tended to mistrust science in general. Many people seemed to distrust persons and institutions that were going to use the database even if there was not enough evidence for mistrust. At the other extreme, there are Estonians who have an irrational trust in science and researchers. This trust may be blind to all possibilities of betrayal. The lack of critical analysis of possible risks and benefits may bring a serious backlash in the future. The promoters' limitless hype of the benefits of genetic databases has raised considerable expectations among the public. Should it turn out that HGDs do not solve major health problems and do not improve the treatment of genetic illnesses, this might lead to a decline of public trust in genetic databases and science more generally.

The attitudes seem to range from irrational mistrust to irrational trust. Irrational blind trust means obeying the authorities without taking any responsibility, and usually indicates a lack of self-trust and blind loyalty. A stance of irrational mistrust on the basis of irrational judgements might be harmful as well. Because one's previous expectations have been betrayed, one wants to protect oneself against future breaches and betrayals. What blind trust and irrational mistrust have in common is a certain mindlessness. One can be mindlessly rebellious as well as mindlessly conformistic.[12] Whereas blind trust ignores the risks that something could betray trust, irrational mistrust overestimates the possibilities of betrayal. The opposite of both is critical reflection, which is the basis of authentic trust.

Authentic trust seems to be based on autonomy. In order to make autonomous choices, one needs information. But it is interesting that there is no correlation between information and trust. One cannot say that the more informed one is, the more likely it is that one is ready to place trust. According to the recent study of the Europeans' awareness of the 'new scientific discoveries', 54% of Estonian respondents were poorly informed in this field, only the Lithuanians (60%) being less well informed.[13] Citizens in the United Kingdom seem to have a low lack of information (34%), whereas Icelanders have quite a high rate of people claiming that they are poorly informed (47%). These results are interesting since we have seen that the idea of the creation of the HGD found more support in Estonia and Iceland than in the UK. This seems to indicate that the blind trust is based on lack of information and critical thinking.

[12] This has been indicated to me by one of my reviewers, Sigurdur Kristinsson.
[13] European Commission, Special Eurobarometer 224, 'Europeans, Science and Technology'.

It is important to know whether public trust in the individuals and institutions which carry out HGD projects can be based on adequate information and understanding. Is it at all possible, as a member of the public, to be informed and understand what is going on? I think that the answer is 'no'. Decisions to place trust do not have a basis of sufficient information, since the complexity of the HGD projects makes it highly unlikely that most individuals will grasp adequately what is at stake. Moreover, some of the relevant information is not available to anyone at the time of consent: the time of the storage of samples and data has not been limited; it is not possible to foresee all the uses of the samples and associated data nor to specify who the users will be. The participants have to give their consent based on goodwill and therefore to place trust without guarantees. Since there is a lack of information and – due to the complexity of the project – also a lack of understanding, participants' trust depends on their general trust in science and society/state.

Onora O'Neill has suggested that since informed consent provides only limited protection to individuals, it becomes important to build trustworthy institutions.[14] Here the *governance* of the databases becomes a significant issue for creating trust. Usually it is assumed that the interests of the donors and communities will best be protected by national or regional governments. However, if the government itself is involved in setting up the database, this impartiality is threatened. As pointed out by Austin et al.,'the governmental sponsorship of some genebanks creates a conflict between the government's interest in the success of the genebank and its responsibility to protect citizens and participants'.[15] I think the authors are right in suggesting that public ownership itself is no guarantee for the protection of the privacy of individuals. It all depends on how democratic the state is and how trustworthy the political institutions.

However, creating trustworthy institutions does not in itself secure trust. As Solomon and Flores have discussed: 'One can be perfectly trustworthy but, because of circumstances or the paranoia of everyone involved, not be trusted.'[16] People may, for example, mistrust persons or institutions that set up and manage HGDs because they suspect that commercial interests are in play. A potential source of tension is between donor altruism and public funding on the one hand and the potential commercial benefits of private companies on the other.

[14] Onora O'Neill, 'Informed Consent and Genetic Information', *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001), pp. 689–704, at p. 702.
[15] Melissa A. Austin, Sarah E. Harding and Courtney E. McElroy, 'Monitoring Ethical, Legal, and Social Issues in Developing Population Genetic Databases', *Genetics in Medicine* 5 (2003), pp. 451–457, at p. 452.
[16] Solomon and Flores, *Building Trust in Business, Politics, Relationships, and Life*, p. 77.

Thus, to create trust it is necessary to show goodwill and competence. Since trust is a relationship, an interaction, building trust requires talking and thinking about trust. Furthermore, since trust involves vulnerability and risk, it is preferable to discuss possible risks, since blind trust is a very unstable foundation for a large-scale and long-term enterprise. If we are unaware of potential risks, we cannot protect ourselves. Abused public trust will be very difficult to restore. But reflection on possible risks should not lead to irrational mistrust which is a cynical refusal of trust. What we need is authentic trust which is reflective and involves rational choice. Our thinking about trust (which involves taking risks) will help us to maintain trust and to equip us against possible breaches of trust.

23 Informed consent and human genetic database research

Sigurdur Kristinsson and Vilhjálmur Árnason

Introduction

Since the Second World War, leading documents have espoused voluntary consent as essential to the morality of research involving human subjects. The Nuremberg Code thus begins by declaring that 'the voluntary consent of the human subject is absolutely essential'.[1] The Declaration of Helsinki similarly states, as one of the 'basic principles of all medical research', that 'the subjects must be volunteers and informed participants in the research project'.[2] Over the past fifty years, the principle of informed consent has become a cornerstone of institutionalized research ethics, and many nations have committed themselves to it through their laws and regulations.[3]

In recent years, the practice of informed consent has been challenged as researchers have gained the power to accumulate and process ever larger amounts of data, including genetic data. Is it necessary to obtain informed consent for research on data that has irreversibly been rendered anonymous?[4] Is it conceptually possible to give informed consent to participation in unspecified, future research projects?[5] Is it possible for researchers to provide the necessary information and

[1] *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, 2 (Washington, DC: US Government Printing Office, 1949), 181–182, art. 1.
[2] World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 52nd WMA General Assembly, Edinburgh, October 2000, art. 20.
[3] Henry Greely, 'Human Genomics Research: New Challenges for Research Ethics', *Perspectives in Biology and Medicine* 44 (2001), pp. 221–229, at p. 224.
[4] Ibid.
[5] See Sigurdur Kristinsson, 'Databases and Informed Consent: Can Broad Consent Legitimate Research?', in Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason (eds.), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases* (Reykjavík: University of Iceland Press and Centre for Ethics, 2004), pp. 111–119.

assurances of privacy to participants in research using data-mining technology?[6]

Any answer to such questions depends on assumptions about what informed consent is and why it is morally important. In order to tell what counts as a departure from the rule of obtaining informed consent, one must have a conception of what informed consent is, and in order to tell which departures are justified, one must have a considered view of what makes informed consent morally important.

Our aim in this chapter is twofold. First, we address the philosophical questions of what informed consent is and why it is morally important. Second, we turn to one of the practical issues that have recently seemed to challenge the principle of informed consent, i.e. the issue of research involving health databases and genetic databases. We argue that institutionalized definitions of informed consent should not be applied directly in the context of database research. Such definitions are ultimately attempts to live up to more fundamental moral commitments. Instead of insisting on the enforcement of duties that have been institutionalized for traditional research, we need to focus on what these fundamental commitments are and how they can be preserved in new and evolving contexts. Institutional frameworks for regulating research must thus be simultaneously informed by lasting moral insight and current factual circumstance.[7]

What is informed consent?

The Council for International Organizations of Medical Sciences (CIOMS) offers the following definition, as part of its International Ethical Guidelines for Biomedical Research Involving Human Subjects:

> Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.[8]

[6] See Herman T. Tavani, 'Genomic Research and Data-Mining Technology: Implications for Personal Privacy and Informed Consent', *Ethics and Information Technology* 6 (2004), pp. 15–28.

[7] Notable attempts to reconcile informed consent with the realities of databank research include Henry Greely, 'Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information', *Wake Forest Law Review* 34 (1999), pp. 737–766; and Timothy Caulfield, Ross E. G. Upshur and Abdallah Daar, 'DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model', *BMC Medical Ethics* 4 (2003).

[8] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS and WHO, 2002).

This definition embodies the five elements that most commentators see as essential to a definition of informed consent, i.e. (1) competence, (2) disclosure, (3) understanding, (4) voluntariness and (5) consent.[9] According to this common view, a person who satisfies all five conditions has given his or her *genuine* informed consent to participation in research, because his or her consent has all the morally relevant characteristics of consent.

Genuine informed consent should be distinguished from legally or institutionally effective consent.[10] Informed consent in the latter sense is relative to prevailing rules, laws and regulations, and these are variable across time and place. Effective consent is no guarantee of genuine informed consent, however. A potential subject may give all the required signatures, be deemed competent by the appropriate parties, and be of legal age, without having adequately understood the necessary information. Neither is genuine informed consent guaranteed by the fact that researchers have performed all the duties that codes and guidelines impose on them. Still, the most important purpose of the rules that define effective consent, and of informed consent clauses in ethical codes and guidelines, is presumably that of promoting genuine informed consent, or perhaps maximizing the chances of it occurring.

The concept of genuine informed consent cannot be read directly from codes or guidelines, no matter how well crafted. However, they provide some evidence of the conception of genuine informed consent that has in fact guided efforts to institutionalize it. For example, they tell us how people have interpreted the scope of the disclosure element, i.e. what should be regarded as 'necessary information'. In the CIOMS guidelines referred to above, this takes the form of a list of no fewer than twenty-six items. Codes also tell us something about how the notion of voluntariness has been understood, by requiring researchers to inform potential subjects that they are not required to participate and that they are free to withdraw at any point. Clues about how competence is understood may be gleaned from requirements that the subject be of legal age, and that what minors are asked to sign be called 'assent' rather than 'consent'. Finally, recommendations about the wording of informed consent forms may tell us something about how the requirement of understanding has

[9] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 5th edn (New York: Oxford University Press, 2001), p. 79.

[10] Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), pp. 280–283; and Beauchamp and Childress, *Principles*, pp. 78–79.

been interpreted.[11] Still, even the best of recommendations do not *define* the concept of genuine informed consent.

What is genuine informed consent?

One way to approach this question is to presuppose the elements of competence, disclosure, understanding, voluntariness and consent as definitive of the scope of the concept, and then consider each element in turn. In what follows, we aim to clarify what it means to satisfy these conditions. However, our account will necessarily be somewhat open-ended in so far as the precise characterization of each element as a necessary condition for informed consent depends in part on what the moral purpose of informed consent is supposed to be. This dependence on moral purpose cannot be argued for here, but we believe such an argument could be offered based on what we say below.

Competence

Competence is always relative to a task. The same person may be competent to do one thing but incompetent to do another. It can also be temporally unstable. A person might lose a particular competence, temporarily or permanently. Finally, competence is a matter of degree. One person may be more competent than another to perform a given task, and the same person may be more competent for the task on one day than on another. However, practical reasons exist for treating competence to make a particular decision as an all-or-nothing property in contexts where it must be determined who has the right to make it.[12] The property will then be deemed to exist just in case the person's actual competence to make that decision falls below a certain level. A person's decision to participate in research should thus not count as informed consent unless her competence to make that decision rises above the relevant threshold.

Which capacities are required for giving consent to participation in research, and what standards can be used for judging whether people have those capacities? The capacities concern the ability to understand relevant information, assimilate it to prior background knowledge, values and priorities, and to make a decision that rationally takes account of these. Failures of competence may thus be failures to understand relevant

[11] See, for example, Center for Disease Control, 'Consent for CDC Research: A Reference for Developing Consent Forms and Oral Scripts' (1998).

[12] Beauchamp and Childress, *Principles*, pp. 70–72; and Joel Feinberg, 'Autonomy', in John Christman (ed.), *The Inner Citadel* (New York: Oxford University Press, 1989), p. 29.

propositions, failures to anticipate what experiencing a possible outcome would be like, various failures of rationality, such as wishful thinking and inability to grasp probabilities, and failures of resolve to follow through on one's decision. Even false background beliefs may result in reduced competence, since false background beliefs can impair the understanding of relevant propositions.

It is not clear whether 'incorrect' values and priorities could similarly result in failed competence. This seems to depend in part on the moral purpose of informed consent. If the purpose is taken to be risk-prevention, for example, then an attitude of aversion to risk would indeed seem to be a required competence. In general, the purpose of risk-prevention would seem to require the consenter to enjoy a relatively high degree of competence.

Disclosure

Disclosure means that the potential subject is given all the information that is relevant to the decision of whether or not to participate. Despite its customary place among the elements, disclosure does not, in the end, seem to be a necessary condition for genuine informed consent. Imagine a person who, for whatever reason, already knows and understands all the relevant information, even though it has not been disclosed to her by the researchers. They simply ask her whether she would like to participate in their study. Given that the person is competent and no coercion or manipulation is involved, it seems that her acceptance could count as informed consent, even in the absence of disclosure. What the disclosure element describes is thus not a conceptual requirement for genuine informed consent, but rather a duty – albeit a very important one – that in all or most actual contexts has to be carried out in order for informed consent to occur.

What information should be considered relevant to the decision of whether or not to participate? Research codes, and national laws and regulations, offer an abundance of advice on what to disclose. Basically, 'consent is informed when it is given by a person who understands the purpose and nature of the study, what participation in the study requires the person to do and to risk, and what benefits are intended to result from the study'.[13] More specifically, researchers are normally required to disclose the expected duration of participation, describe the procedures, describe how the confidentiality of records will be maintained, state that

[13] Council for International Organizations of Medical Sciences (CIOMS), *International Guidelines for Ethical Review of Epidemiological Studies* (Geneva: CIOMS, 1991).

participation is voluntary and that the participant can withdraw at any point without penalty or loss of benefit.[14] Further requirements have accumulated as research has developed. For example, researchers may now be required to disclose their 'policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject'.[15]

Is there a principled way to determine which information to disclose, or do we simply have to defer to an evolving tradition? An obvious possibility is that relevance ought to be judged based on whether the potential subject's decision would be affected by the disclosure.[16] There are difficult problems here, both theoretical, such as whether it matters if the subject's response to disclosure would be rational, and practical, such as whether procedures can realistically be tailored to subjective informational needs. But the underlying idea seems plausible. It directs us towards asking what most people would reasonably want to know before accepting an invitation to take part in a study. Most people would reasonably want to know who is asking, what the risks and potential benefits are, how privacy will be protected, what the study aims to achieve, and what it requires the participant to do. Guidelines for how to draft informed consent forms thus seem to reflect requirements that most people would probably find reasonable in the standard type of context.

Understanding

The purpose of disclosure is to help the subject understand the relevant information about the study before she decides whether to participate. Understanding a proposition goes beyond the ability to repeat or remember it. We might say that it involves being aware of what the world would be like in the relevant respects if the proposition were true. Understanding a single proposition thus brings into play not only the recognition of words and syntax, but also background beliefs about the referents of those words. False background beliefs can result in a flawed understanding. For example, if I had enough false beliefs about the nature of bronchitis, I might not adequately understand the information conveyed in the phrase 'you have bronchitis'. By the same token, poor

[14] See *45 Code of Federal Regulations* 46.116. Available online at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.
[15] CIOMS, *International Ethical Guidelines for Biomedical Research*, 5.16.
[16] See Beauchamp and Childress, *Principles*, p. 83.

background knowledge can limit understanding of the conceptual and causal implications of propositions that describe participation in a proposed study.

This simple fact accounts for what is perhaps the greatest practical difficulty in securing informed consent: information that could be conveyed to experts in a few sentences may require pages of explanation to non-experts, before background beliefs have been educated to the minimum required for understanding. Yet, the more pages of explanation the information requires, the less likely it is that it will be read closely. Even if we struck the optimal balance between thoroughness and accessibility, we could fall short of the goal of having most participants base their decision on a significant understanding of all the relevant information.

Understanding is generally affected by competence. Information about risk, for example, is notoriously difficult to process rationally, involving as it does probabilities and the assessment of possible outcomes. Genuine informed consent would be practically impossible if it required 'full' understanding, so the question is just how much understanding is sufficient. As before, that judgement depends in part on the moral purpose of informed consent.

Voluntariness

Voluntariness may be characterized by two necessary conditions: to be voluntary, an action must be (1) intentional and (2) significantly free from controlling influences.[17]

Intentionality To be intentional, an action must be conceived of by the agent under its identifying description. For example, Oedipus did not intentionally perform the action of killing his father, since he did not know that the man he killed was in fact his father. Unfortunately, the same behaviour can be described in countless ways that are all true, but cannot all be relevant. Participation in research can be described as having one's blood drawn, contributing to the advancement of science, helping the economy, and so on. Voluntary participation in research must be based on the subject's awareness of all aspects of the participation that are relevant to describing the act.

Awareness of risks and potential benefits is directly related to intentionality. A subject might intend to contribute to the cure of cancer through participation in research that in fact ends up yielding no new

[17] The following account of voluntariness is indebted to the account of autonomous action developed by Faden and Beauchamp, in *A History and Theory*, pp. 235–269.

knowledge. Although that unfortunate outcome was not intended, participation was undertaken with awareness that this was a possible outcome, however unlikely. The subject intended to participate in research, knowing that this would be one of the possible outcomes. Intentionality is clearly easier to achieve the more foreseeable and commonly known the possible outcomes are. In contexts where relevant outcomes are foreseeable without being commonly known, potential subjects need to be informed in order for their participation to be voluntary. In contexts where possible relevant outcomes are poorly understood by even the researchers themselves, it is hard to see how participation can be voluntary.

Non-control In addition to intentionality, voluntariness requires the absence of significant controlling influences. Such influences could be either internal or external. A compulsive hand-washer intends to wash her hands and yet is not in control of her own actions, because of internal controlling influences. Voluntariness thus requires a minimal degree of rational control over one's actions. External controlling influences can take the form of coercion or manipulation. An action is coerced if it is motivated by a credible threat of some harm that will be imposed if the action is not taken. Manipulation occurs when the agent's assessment of her options is deliberately altered through non-rational means, such as selective information, deception or relentless propaganda.

Even if external influences do not strictly control actions, in that they do not necessitate them, they influence them in a way that clearly seems incompatible with the notion of voluntariness relevant to informed consent. A decision to participate in research is not voluntary in the required sense if the agent's subjective or objective conditions have been deliberately adjusted through non-rational means so as to make it very likely that the decision goes one way rather than another. By contrast, voluntariness seems quite compatible with rational persuasion, whereby the agent is presented with relevant considerations in a way that supports her in coming to a reasoned conclusion. A decisive factor in determining whether an influence is compatible with voluntariness thus seems to be the degree to which it supports rather than undermines the agent's practical rationality.

Consent

Consent may be construed generally as agreeing that what a proposition describes should happen. Consenting to a proposition does not carry its normal moral significance if the consenter does not understand the

proposition or has misunderstood it. Moreover, consenting to a proposition does not include consenting to propositions that are logically entailed by it or describe its causal consequences.[18] However, if these logical entailments and causal predictions are part of common knowledge, it seems that consenting to the original proposition *implies* consent to the derived ones, and thus justifies treating the person as if she had explicitly consented to them all. The 'opacity' of consent is therefore not a persuasive reason for thinking that in order to legitimate research, informed consent documents would have to list all the relevant entailments and trace all the foreseeable relevant consequences of the propositions they put forward.[19]

Consent is morally significant in many situations where rational agents interact or affect each other's interests. It is *prima facie* wrong to use people or put them at risk without regard to whether they themselves agree to be so used or put at risk. So anyone who intends to act in a way that makes use of other people or puts them at risk should ensure that they actually agree to the proposed course of action, would agree to it, or at least could agree to it.

These considerations raise a host of persistent questions that are relevant to debates over informed consent: Which interactions are such that consent is morally required? When consent is not explicit but rather implied by one's actions, what is an acceptable sign that consent has actually occurred? For example, when is accepting a benefit a sign of consent to some unspoken expectation of something in exchange? Or, to take an example relevant to the notion of 'presumed consent', is failure to withdraw from an announced co-operative scheme a reliable sign of actual consent? Addressing these questions falls beyond the scope of this chapter, but as with other topics discussed in this section, much depends on what the moral purpose of informed consent is ultimately supposed to be.

Why is informed consent morally important?

Moral reasons for seeking informed consent seem to fall into two major categories. First, informed consent can be regarded as a means of protecting or promoting the well-being of individuals, especially potential subjects. Second, informed consent is often associated with the value of

[18] Onora O'Neill, 'Informed Consent and Genetic Information', *Studies in History and Philosophy of Biological and Biomedical Sciences* 32 (2001), pp. 689–704, at p. 692.

[19] This is argued more fully in Kristinsson, 'Databases and Informed Consent', pp. 114–116.

autonomy. Informed consent can then be valued either as a means of enabling people to be autonomous, or as a way of treating persons with respect.

Welfarist reasons

Welfarist[20] reasons for seeking informed consent point out the ways in which informed consent tends to promote or protect well-being. Informed consent may be of benefit to each individual subject. Each person may be assumed to want to protect herself from harm, and also to be in a good position to know what sort of thing would be harmful to her. Given these assumptions, informed consent is reasonably regarded as an important component in a wider, institutionalized effort to protect people against unnecessary risks through participation in research.[21] Another possible benefit to the individual subject could be a feeling of assurance that she is not being exploited, that her privacy is being protected, and that she does not have to participate in research unless she wants to. It may also add to the individual's well-being to know that she is contributing to a goal that she deems important, such as seeking a cure for a particular disease, or doing what she considers to be her moral duty.

The practice of informed consent may also have social benefits. It may inspire trust in the institution of science, thereby promoting public willingness to participate and contribute to scientific research. This, in turn, could hasten progress and increase the number of future patients whose lives can be improved because of new discoveries.

On the downside, informed consent procedures require time and expense, and they could detract from the scientific value of some findings by reducing the size and representativeness of samples.[22] From the

[20] Welfarism is the view that we ought, morally, to promote the well-being of individuals. It is often associated with consequentialist moral theories, according to which the rightness or wrongness of actions, plans, intentions, policies, rules, institutional practices, etc. depends on the value of their overall, long-term consequences. However, welfarism is also compatible with other theories about the relation between what is right and what is intrinsically valuable. A deontological theory may hold that it is a duty to benefit others, or even that people have a right to certain benefits. What all theories that incorporate welfarism have in common, however, is the view that individual well-being is a goal that ought to be promoted.

[21] Historically, risk prevention seems to have been the primary motivation for instituting informed consent procedures. According to Faden and Beauchamp (*A History and Theory*, p. 152), 'the earliest and premier moral and legal concern about subjects has historically been to *control the risks* presented to subjects by research, not to *enable autonomous choice* about participation'. However, our analysis of the moral reasons to seek informed consent does not depend on this historical thesis.

[22] See Greely, 'Breaking the Stalemate', p. 761.

welfarist point of view, all such foreseeable disadvantages must be weighed against the expected benefits. The moral assessment of the practice of informed consent thus requires, according to welfarism, a willingness to revise rules and practices when that would seem most beneficial overall. It is doubtful, then, whether welfarism results in a strong moral right to informed consent, as opposed to a *prima facie* (i.e. defeasible) duty to seek informed consent.

Autonomy reasons

Autonomy, or respect for autonomy, is by far the most commonly cited moral reason for seeking informed consent, although it is not always obvious what autonomy means in this context, and how it figures in the moral justification of informed consent. There are at least two possibilities. On the one hand, we might conceive of the autonomy of individuals as a goal, and informed consent as either a means to or a partial instantiation of that goal. On the other, we might follow Kant and take autonomy to be a property that a practical principle would have if it was given by reason alone. Informed consent would then be justified, and indeed necessary, in virtue of being required by an autonomous principle.[23]

Autonomy as a goal Informed consent practices might receive their moral justification from the fact that they promote individual autonomy, or enable individuals to be autonomous, which in turn is a value that ought, morally, to be promoted. There is not much overall consensus in the philosophical literature on what individual autonomy consists in.[24] It may consist in having desires, beliefs and goals 'of one's own', as opposed to responding mindlessly to the environment or past conditioning. It may also consist in acting in a way that expresses one's authentic qualities, as opposed to trying to resist them based on norms or expectations that are less central to one's self. Finally, it may consist in being in control of one's actions and perhaps the broad contours of one's life, as opposed to being forced, through coercion or manipulation, to act and live in certain ways. These conditions of independence, authenticity

[23] See Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002), pp. 83–86.

[24] For samples of the relevant literature, see James Stacey Taylor (ed.), *Personal Autonomy: New Essays on Personal Autonomy and its Role in Contemporary Moral Philosophy* (Cambridge: Cambridge University Press, 2005); Catriona Mackenzie and Natalie Stoljar (eds.), *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (New York: Oxford University Press, 2000); and Christman, *The Inner Citadel.*

and control have all been defended as essential to individual autonomy, and each condition arguably requires the autonomous individual to be able to act based on her own rational deliberation, duly informed and free from coercion and manipulation.

Informed consent may promote individual autonomy in at least two ways. First, it may enable individuals to choose autonomously whether or not (and to what extent) to participate in research. Autonomous choice in this area is no doubt good and desirable for most people, although choosing whether to participate in research is probably rarely of monumental personal significance or an occasion for a particularly robust exercise of the capacity for autonomy.[25] Our overall chances of leading autonomous lives would not seem destroyed or even greatly reduced even if we were never given a choice concerning research participation, as long as we are not actually harmed by involuntary participation.

Second, the practice of informed consent may be regarded as part of a social condition that contributes to the attainment of individual autonomy. The institution of informed consent may assure the public that scientific researchers will not coerce or manipulate them or jeopardize their privacy. These assurances may in turn give individuals a sense of freedom, which enhances their capacity for autonomy in general.[26] This indirect benefit may be an important consideration, but it does not seem to provide informed consent with the strong moral significance it is commonly assumed to have. What actually seems offensive about research without informed consent is not just the fact that it undermines public trust in the institution of science, although it certainly does, but rather simply the fact that it involves coercion, manipulation and interference with personal privacy.

Autonomy as the basis of constraint Informed consent seems to receive its most significant moral justification from being a way of treating persons with respect. It is a bit confusing that in Kant's ethics, the term autonomy does not refer to a condition or capacity that individuals might attain to various degrees, but rather to the property that a practical

[25] See O'Neill, *Autonomy and Trust*, p. 38.

[26] The argument here is parallel in structure to John Stuart Mill's argument in *On Liberty* (1863), that liberty is justified by its contribution to the development of individuality: see Mary Warnock (ed.), *Utilitarianism, On Liberty, Essay on Bentham* (London: Collins, 1962), pp. 184–204. Another parallel is Joseph Kupfer's argument that assurances of privacy are justified in virtue of contributing crucially to the development of individual autonomy: see *Autonomy and Social Interaction* (Albany: State University of New York Press, 1990), pp. 123–148.

principle would have if it was grounded in reason alone.[27] However, Kant argued that reason does in fact demand that persons be treated with respect, and that the following is an autonomous principle: 'Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only.'[28] The word 'humanity' here refers to our rational nature, for as Kant explains: 'The ground of this principle is: *Rational nature exists as an end in itself*.'[29] This principle of respect for persons has wide intuitive appeal, even among those who do not agree with Kant that it is grounded in pure reason. In Kantian spirit, we might say that *persons deserve respect because they have the capacity for individual autonomy* in the sense outlined in the previous section. Perhaps, then, informed consent can be construed as a way of making sure individuals with a capacity for autonomy are never treated as mere means but always at the same time as ends.

The problem is that before Kant's principle can be applied it needs to be interpreted, and this cannot be done quickly or definitively. Deducing specific duties from Kant's abstract formulation of the principle requires complex arguments that make various assumptions that are open for debate. Having said that, we may note that the most plausible candidates for Kantian duties have turned out to be the duties not to coerce or deceive rational agents.[30] If these are indeed Kantian duties, we may say that informed consent procedures are grounded in Kantian ethics to the extent that they serve the purposes of non-coercion and non-deception. Their justification is then not the promotion of individual autonomy, but rather respect for persons with a capacity for individual autonomy. Regardless of whether we accept all of Kant's background theory, we may agree that the principle of humanity captures a basic moral requirement that provides what seems to be the most significant justification for informed consent.

Informed consent and human genetic databases

We are now in the position to address directly the questions posed at the beginning of this chapter regarding consent for participation in research on data that have been collected in human genetic population databases

[27] See O'Neill, *Autonomy and Trust*, pp. 83–86; Thomas Hill, 'The Kantian Conception of Autonomy', in Christman, *The Inner Citadel*, pp. 91–105; and Matti Häyry, 'The Tension Between Self Governance and Absolute Inner Worth in Kant's Moral Philosophy', *Journal of Medical Ethics* 31 (2005), pp. 645–647.

[28] Immanuel Kant, *Foundations of the Metaphysics of Morals*, transl. Lewis White Beck (New York: Macmillan, 1959 [1875]), 47/429.

[29] Ibid. [30] See O'Neill, *Autonomy and Trust*, pp. 86–89, 97.

of the type discussed in the ELSAGEN research. It seems to us that database research of this kind presents major challenges to the task of obtaining consent which satisfies the moral requirements we have discussed. Such databases are resources for research on multiple diseases which involves cross-matching of genealogical, genetic and healthcare information. We believe that this poses problems both for institutionally effective consent and for genuine informed consent.

Institutionally effective consent?

If institutionally effective informed consent were to be obtained before information is placed in a database, this would require that specific research plans were already formed to make it possible to explain the main ingredients of informed consent to the prospective participants. Otherwise, there are no specific objectives to be explained, no determinate risks or benefits to be assessed. The only specific ingredient that could possibly be explained is the right to withdraw information from the database at any time. The standard disclosure requirement is hard to meet in the case of databases which are intended to be resources for various research that is only partly foreseen at the time of collection. Informed consent to specified research would thus require continuous re-contact. But due to the large number of participants and the heavy emphasis on coding this would be complicated, expensive and cumbersome. It would not only jeopardize individual privacy and be burdensome for participants but also, according to many scientists, severely limit the research possibilities which research databases are intended to provide.[31] If these scientists are right, the possible benefits of database research, which requires different methodology and a more flexible interplay of information than traditional research, would be lost.

Genuine informed consent?

Genuine informed consent implies that participants can be informed about the research and that they have understood the information. Clearly, the difficulties with instituting consent have implications for the possibility of genuine consent as well. Continued re-contact where

[31] L. J. Melton III, 'The Threat to Medical Records Research', *New England Journal of Medicine* 337 (1997), pp. 1466–1469; A. Buchanan, 'An Ethical Framework for Biological Samples Policy: A Commissioned Paper', in National Bioethics Advisory Commission (NBAC), *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, 2 vols. (Rockville, MD: NBAC, 2000), vol. II, pp. B1–B31, at pp. B19–B20 and B29.

people are presented with ever new research protocols can irritate them and it would take major effort and manpower to explain to each participant each time the parameters of the research and facilitate the dialogue which is necessary for informed consent in the genuine sense. Moreover, as Onora O'Neill has argued, 'consent achieved by overwhelming an agent's cognitive capacities provides no genuine justification'.[32] Combined, the amount and complexity of information that participants in database research would be expected to understand in order to provide genuine informed consent, might be regarded as 'overbearing' in the sense of the Nuremberg code. For these reasons, it is not realistic to require that informed consent be obtained to specified research in the case of population databases.

Open consent?

Due to the unsuitability of specified informed consent for participation in research on information in population genetic databases, there is an increasing pressure to ask for an unrestricted open or blanket consent for this type of research. By blanket consent is meant that participants are asked to consent to the use of their information 'for any future medical research', provided only that the research is approved by ethical review boards or science ethics committees. The main advantage of this position is that it would greatly increase the flexibility for researchers, in particular if the information was made irretrievably anonymous. Provided that participants understand that their (irretrievably anonymous) data might be used for purposes they regard as immoral or repugnant, we see no reason to object to an open consent policy. However, if the information was coded but linkable, as it will be in the relevant databases under discussion, such a policy would be much more questionable since the participants' interests in being informed are increased. The main problem with an open consent policy is, however, that it fails to provide the necessary conditions for consent that were discussed above (disclosure, understanding, voluntariness). There is no information to be disclosed so there is no basis for understanding to take place, except that participation in research will be decided by science ethics committees in accordance with national regulations about research. This means, in effect, that participants are asked for permission to let science ethics committees act on their behalf and make decisions concerning their interests. Surely, a participant could act voluntarily in this regard but participation

[32] O'Neill, 'Informed Consent and Genetic Information', p. 701.

would not be voluntary in the sense that 'relevant outcomes' of the research are foreseeable. In effect, this means that open consent is more a question of trust than voluntariness. This appeal to trust is rather weak, however, since it is not based on any information concerning the research.

Another method of not seeking genuine informed consent is that of presuming the consent of those who do not opt out of a database. An example of this is the law about the Icelandic Health Sector Database, where consent for transfer of data from medical records into a central database is presumed unless people opt out of the database.[33] We think that presumed consent with an opt-out possibility can be a defensible option where the information is used for traditional epidemiological research for healthcare and health policy purposes within a national healthcare setting. But the situation is quite different when the information is handed over to a third party which is not involved in the patients' care[34] and has commercial research purposes. Moreover, physicians cannot be expected to allow such access to medical records without explicit consent of their patients, because the purpose goes clearly beyond what can be reasonably construed as the patients' implied consent at the time of collection. An additional concern is that a presumed consent policy is especially unsuitable for protecting the interests of the vulnerable in the population, both because some of them are unlikely to follow the national debate which is an important background for presumed consent and because others are often overly eager to participate due to unsubstantiated beliefs in benefits. In general, a presumed consent policy legitimizes carelessness and ignorance among citizens about research participation rather than igniting reflective judgement or deliberation. This is contrary to the spirit of contemporary research ethics.

Authorization as consent to conditions of use of data

In order to avoid the pitfalls of presumed consent, informed consent to specified research and unrestricted open consent to participation in database research, some authors have proposed alternatives that are intended to strike a balance between the researchers' need for flexibility and the ethical demand for protection of participants' interests.[35] Rather than

[33] This transfer has not taken place for reasons that cannot be discussed here. See V. Árnason, 'Coding and Consent. Moral Challenges of the Database Project in Iceland', *Bioethics* 18 (2004), pp. 39–61.

[34] See the World Medical Association Declaration on Ethical Considerations regarding Health Databases, art. 17.

[35] E.g., Greely, 'Breaking the Stalemate'; Caulfield, Upshur and Daar, 'DNA Databanks and Consent'; and Árnason, 'Coding and Consent'.

asking for consent to each particular research proposal, participants would be asked to authorize the use of their data for a limited range of described healthcare research that is foreseeable at the time of collection and for comparable research permitted by science ethics committees. They would also be informed about the conditions for use of the data, such as how research on the data will be regulated, how they will be connected to other data, who will have access to the information and how privacy will be secured, and that they will only be used for described healthcare purposes. Participants would be informed that they and/or their proxies will be regularly informed about the research practice and that they can at any time opt out of the research if they choose.

There are several advantages to this proposal as compared to unrestricted open consent. Such an authorization would both allow participants 'to meaningfully act on their continuing interests in their health information'[36] and provide science ethics committees with a meaningful ground for determining further use of the information. Such a policy would maintain the motivation for participants to reflect on their participation in research and to be informed about how their data are used and for what purposes. An authorization policy would thus contribute to informed and responsible research participation that can underpin public trust in research practices. None of these would flow from an open consent policy for database research.

The remaining and key question in the context of our argument is, however, whether such an authorization serves the purposes of non-coercion and non-deception. The answer to this question rests upon three issues: (1) whether research participants are provided with information that people would reasonably want to know; (2) whether it provides enough information for participants' choice to be voluntary; and (3) whether they need to participate or continue participation in research against their own will. The first issue is about whether participants are given all the information that is relevant to the decision of whether or not to participate. We believe that in epidemiological genetic database research, which is the type of research we have in mind, such general information about the type of research intended on the data and for what purposes, how the research is managed and how the data are protected, is the most relevant information for a person who is considering whether to participate or not. More specified information about particular research proposals can be crucial for participants in clinical research but in database research of the type we are discussing there is no interest in using

[36] Caulfield, Upshur and Daar, 'DNA Databanks and Consent', p. 3.

information about individuals directly in clinical research which would radically change the nature of the research participation and the risks associated with it.

The second issue is whether such authorization describes the options for participants in a full enough way so that they can be voluntarily chosen. Clearly, this is not so in the case of unrestricted open consent but we have reasons to believe that authorization for database research meets this requirement. We argued above that voluntary participation must be based on the subject's awareness of all aspects of the participation that are relevant to describing the act. It is the very purpose of authorization to describe the relevant foreseeable outcomes of the research as well as the conditions for the use of data. Further use of the information is restricted to comparable research where members of science ethics committees can reasonably argue that the additional research would not have affected the initial participants' decisions to participate. All these considerations are relevant for avoiding both deception and coercion. The proposal implies, furthermore, that individuals are offered 'simple and realistic ways of checking that what they consent to is indeed what happens and what they do not consent to does not happen';[37] and, if the latter, they can opt out. In addition to strengthening the basis for non-deception, this last point responds to the third issue, by securing the purpose of non-coercion, since it implies that participants need not continue in the research against their will.

We conclude, therefore, that an authorization which implies consent based on information about conditions for use of data in database research meets with the moral demands of respecting the person of research participants and supporting their autonomy. It does not manipulate, coerce or deceive participants but provides sufficient ground for voluntary choice and regulation which respects that choice. We reiterate, however, that we only have in mind participation in population databases intended for genetic epidemiological research. There may be types of research where consent is not necessary at all (because it involves minimal risk and perfect anonymity), but if consent is necessary, open consent cannot serve the moral purposes of informed consent, while authorization can. Therefore, even though it appears to be impossible to carry out database research of this sort while adhering to *standard requirements* for informed consent, we are not forced to choose between a commitment to such research and a commitment to the *moral purposes* of informed consent.

[37] O'Neill, 'Informed Consent and Genetic Information', p. 702.

Part V

Political considerations

24 The impact of biobanks on ethical frameworks

Ruth Chadwick and Mark Cutter

Alongside the extensive discussion that has taken place about the ethical, legal and social aspects of genetic databases and biobanks, it is also appropriate to step back and reflect on that discussion itself, and examine the ways in which scientific developments can affect ethical debate. There has been a certain amount of discussion about the implications of biobanks for ethics – concerning, for example, whether the ethical principles applicable to medical research as conventionally understood are appropriate in the era of population-based genomic research.[1] This has importance beyond the immediate context, as it raises theoretical issues about the nature of ethics, and more particularly bioethics, itself. It is our contention in this chapter, however, that different kinds of claims can be, and yet insufficiently have been, clearly distinguished in these debates. When thinking about the impact of biobanks on ethical frameworks, a number of different things might be at stake, so it is important to clarify what is meant by 'impact' in this connection. We suggest that there are at least four different possibilities:

1. the ways in which discussions have developed about ethics and governance in different countries which have biobank initiatives. Here, the 'impact' might simply be that as a matter of fact these initiatives have led to both academic and societal discussion about what governance arrangements can and should be put in place. This claim is most interesting from a social and legal, rather than an ethical, perspective.
2. the ways in which thinking about biobanks has led to the development of new models to deal with pressing practical problems. In this version the impact not only relates to the *fact* of discussion about governance arrangements but emphasizes *newness* or *novelty* in the models proposed – or at least modifications of existing models of governance.
3. the ways in which biobanks have highlighted questions about harmonization of ethics. This third version of impact arises from calls for

[1] R. Chadwick and K. Berg, 'Solidarity and Equity: New Ethical Framework for Genetic Databases', *Nature Review Genetics* 2 (2001), pp. 318–321.

harmonization between biobank initiatives, both at the scientific and at the ethical level. In other words, the suggestion might be that biobanks have provided a focus or at least a stimulus for discussion about international ethical governance. Discussion of the possibility of harmonization, however, raises a further question, concerning whether harmonization refers to agreement on pragmatic guidelines or to harmonization at a theoretical level – and whether the latter is even possible.

4. the ways in which the development of and operation of biobanks give rise to questions about the existing repertoire of ethical theories. This fourth and final possibility in our list concerns the discussion over the extent to which the ethical principles applicable in the context of medical research as conventionally understood might be considered inappropriate for the biobank context. Claims made under this heading have included suggestions of a shift from an individual-centred approach to one that is more community-centred. It is arguably this claim that is most interesting from an ethical point of view.

Before examining any of these different possibilities, however, there is another important preliminary point, and that is that in thinking about 'impact' it is important to avoid the suggestion that there is a straightforward linear progression from developments in science and technology to ethical impact. We are not putting forward a claim about causation here. There is a much more complex interplay between technological development and ethics to be addressed. The process of development both is itself 'framed' in ethical terms and may affect that framing. It is necessary also to be mindful of other factors at work, such as the background discussions both about genetic exceptionalism and about whether epidemiological research is itself a special case in terms of research ethics. The much-contested thesis of genetic exceptionalism holds that there is something special about genetics *per se* – not biobanks in particular – that makes certain medical ethics approaches inappropriate. Epidemiological research has also been regarded differently from other medical research, as regards the potential implications for the interests of participants. Research which involves a medical intervention, such as a drug trial, clearly has, potentially at least, a significantly different impact from research into frequencies of disease in the population. In the case of population biobanks for research, the combination of genomics with epidemiological research is facilitated – so it might be thought that a combination of genetic exceptionalism with epidemiological exceptionalism could produce 'biobank exceptionalism' – but we submit that genetic exceptionalism should not in this case be regarded as a primary explanation of what theoretical approach is appropriate. The thesis of

genetic exceptionalism has commonly been supported by purported characteristics of genetic *information* – that it is independent of time, predictive and shared between blood relatives. In relation to biobanks, it is surely not these features of genetic information that are appealed to in order to ground a claim of difference. Rather it is a question of the internal logic of biobanks, their rationale, which in turn determines their *modus operandi*, although as a matter of fact in both cases there is arguably a shift from the individual-centred to the community-centred ethic which may take subtly different forms.

In order to elaborate upon these points, we shall now consider the four categories in turn.

1. Ethics and governance

The presence of some form of ethical oversight at the institutional level is a feature common to all the biobank projects considered during the ELSAGEN study, as is the presence of some form of public ethical discussion. Thus it is possible to demonstrate, as a matter of fact, the setting up of ethical mechanisms to respond to biobank developments. However, the nature and efficacy of this oversight, and the form and intensity of the accompanying public discussion, are different in each project. The social context in which these developments occur, including expectations of and public trust in science, affects the form they will take.

One key distinction between projects is the relationship between the ethical frameworks associated with a specific biobank project and the legal system of the country in which it is based, and this is particularly significant in the case of larger scale projects. The Icelandic Health Sector Database and the Estonian Genome Project might be described as 'children of legislation' as their design and purpose is included within a specific piece or pieces of legislation. In contrast, UK Biobank, whilst created and funded in part by government funds, through the mechanism of the Medical Research Council (MRC), is not created by statute, but might be defined as 'self-creating' and more importantly self-regulating. The distinction between these two models of relationship is not insignificant as it gives rise to discussion of the efficacy of different ethical frameworks as a regulatory or governance tool. It is arguable that where a biobank, or similar project, is specifically born from some form of legislation or statutory instrument, and specific ethical parameters are identified within this legislation, then those ethical parameters or frameworks are in some way more enforceable, and perhaps take on the status or perception of being legal principles themselves. Where a project is created seemingly independently of legislation, on the other hand, there is the potential

perception that its ethical oversight mechanisms are somehow weaker, and less enforceable, than their legislatively created cousin.

The UK Biobank is governed by an Ethics and Governance Framework that was subject to a public consultation process, and this is in direct contrast to the Icelandic and Estonian initiatives that were created by statutory instruments, thus giving their guiding ethical principles some legal status and force. A potential problem for an initiative such as that in the UK results from the marriage of convenience which must take place between its ethical framework and pre-existing law. Just as it is possible for an individual or group to find itself faced with a conflict between law and ethics, so it is possible for the guiding principles of a project to be at odds with the law, as laws which predate the project's existence interact with it – examples might include laws which regulate data protection and intellectual property rights. The codification of ethical guidelines provides a certain element of stability for both those who choose to participate in the project and those who are conducting it. A synthesis of ethics and law potentially allows for a firm basis from which a project may be developed. Thus the possibility of the project team in some way altering the terms is reduced by the possibility of legal sanctions.

The essential point about impact here, then, is the fact that national biobanks have led to the need for discussion of alternative governance models, which are themselves a suitable topic for ethical assessment, in terms of the extent to which they are likely to serve the purpose for which they were established.

2. New models for specific issues

Stepping down from the question of overall governance to the level of debate about detail naturally leads to the focus on practical proposals surrounding arrangements for consent to participate in biobanks – and concerning arrangements for distributing the benefits. As regards consent, there has been considerable interest in the suggestion that individual informed consent at the very least needs to be rethought in the light of the nature of the research associated with biobanks and the long-term storage involved. The issues have included: opting in and opting out (as in the Iceland case); narrow versus broad consent (e.g., in the UK broad consent is to be sought to participate in the biobank); recontacting and reconsenting; individual or community consent; authorization as an alternative to consent. The adequacy or otherwise of these proposals is also related, however, to privacy protections and the arrangements for codification or anonymization of identifying information about individuals.

In other words, it is not only the fact that it is biobank research that is at stake, but also the precise arrangements in place, which influence the governance arrangements. What is technically possible regarding the holding and protecting of personal data does not only give rise to ethical issues, it also influences the parameters within which ethical solutions can be sought.

Where distribution of the benefits is at stake, it may make sense to appeal to the generic features of biobanks. If it is true, as suggested for example by the World Health Organization,[2] that the primary justification of a biobank is community gain, then the question arises as to *how* the benefits accrue to the community – and in what way is the gain to the community different from that arising from any other kind of medical research? For an attempt might be made to justify all *non-therapeutic* research, at least, on the grounds of benefit to the community rather than to the participants, so why the special focus on benefit-sharing? An appeal to the particular nature of health as a social good,[3] though important, is not a feature that distinguishes biobank from other medical research. There seem to be at least two factors that are relevant and important – public perceptions of what benefits there might be, and public *concerns* about commercial exploitation of participants (individuals and groups) who contribute samples to a biobank. It is partly a response to concerns such as this that underlies the emphasis on benefit-sharing in governance discussions – and also other proposals, including the development of the charitable trust model in regulation of biobank research.[4]

3. Harmonization

When we turn to harmonization it is important to have regard to the wider context of discussion about global bioethics, and the development of instruments such as the UNESCO Universal Declaration on Bioethics and Human Rights.[5] For present purposes, however, we should note the ways in which biobanks are likely to increase calls for harmonization.[6]

[2] World Health Organization, *Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights* (Geneva: WHO, 2003).

[3] See, for example, HUGO Ethics Committee, *Statement on Benefit-Sharing* (London: Human Genome Organization, 2000).

[4] D. E. Winickoff and R. N. Winickoff, 'The Charitable Trust as a Model for Genomic Biobanks', *New England Journal of Medicine* 349 (2003), pp. 1180–1184.

[5] UNESCO, Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO at its 33rd Session on 19 October 2005.

[6] See A. Cambon-Thomsen, C. Sallee, E. Rial-Sebbag and B. Knoppers, 'Populational Genetic Databases: Is a Specific Ethical and Legal Framework Necessary?', *GenEdit* III (1) (2005).

There are of course different kinds of biobanks. While those discussed in this volume are initiatives in different European countries, there are local, regional, ethnic and international developments in different parts of the world. The fact of different national initiatives, however, gives rise to the observation that comparability between the biobanks would add value to their capacity to generate research and other benefits – if only through enhancing statistical power. Harmonization at both a scientific and an ethical level might therefore appear to be a desirable goal and initiatives such as P3G (Public Population Project in Genetics) are pursuing this.

The extent to which harmonization is possible or desirable in ethics, however, is an important question. While we may seek and achieve agreement on a set of guidelines, and even on a number of principles, the underlying rationale for acceptance may be very different, and these differences may fail to appear. Autonomy, for example, may be accepted as an important value by people who start from very different philosophical positions, and they may interpret it very differently. Where biobanks may influence harmonization in ethics is in the mechanisms and standards for protection of information, rather than at a theoretical level.

4. Theoretical issues

The most interesting and yet difficult issues, however, concern the extent to which developments in ethical theory may be required. This might take different forms. One possibility might be that certain ethical traditions (which are not necessarily new) are more appropriate for addressing the relevant issues – for example, those which draw upon communitarian rather than individualistic theories. A more radical claim would be that we just do not have the ethical resources in current ethical theory to deal with some of the issues facing us right now.

The first possibility concerns the claim that there either has been or should be a 'communitarian turn' in ethical reasoning about genetics.[7] And yet one of the ironies of the current situation is that the rhetoric with which the purported benefits of population genetic research are promoted uses the language of individualization and personalization – in the form of future 'tailoring' of treatment and lifestyle advice.

One of us has argued elsewhere that new developments can have a 'value impact'.[8] This claim might be interpreted in a number of ways – it

[7] R. Chadwick, 'Genetics, Choice and Responsibility', *Health, Risk and Society* 1 (1999), pp. 293–300.

[8] R. Chadwick, *Concise Encyclopedia of the Ethics of New Technologies* (San Diego: Academic Press, 2001).

might refer to the potential of technology to facilitate (not necessarily *cause*) changes in the values that people actually hold (as claimed, for example, in empirical slippery slope arguments). Another interpretation, however, relates to the way in which technological development makes it impossible any longer to *think* certain things. The very boundaries of concepts can themselves be changed by new possibilities. Developments in embryology and cloning techniques, for example, have challenged the traditional understanding of the concept of embryo as the product of fertilization. Likewise certain ethical positions may become increasingly indefensible in the light of new understandings. This does not necessarily mean, however, that ethical theories themselves are challenged; what is at stake may be merely that their implications are different. Nevertheless as laws that predate technology are potentially unable properly to regulate the use of that technology, it is equally possible that ethical principles that predate technologies will be ill-equipped to mediate between the competing interests involved.

The question that must be addressed, however, is exactly what *is* new? The concept of collection of information into databases is not a new phenomenon; similarly, the collection and use of genetic information is not a new practice. The use of 'family history' in determining life insurance, assurance and relative premiums is well documented, as is its use in diagnosis during genetic counselling sessions. Equally the storage of human genetic material and information in the form of medical records is not unusual or new. Arguably, since Gregor Mendel's original experiments with the hereditary characteristics of pea plants, through to James Watson and Francis Crick's identification of the double helix of DNA, the biological sciences have been on a trajectory that seems naturally to culminate in the creation of human genetic research databases or biobanks. We then must contemplate what it is about biobanks, *if anything*, that causes them to be something special under this heading. The most promising explanation appears to be connected with their underlying rationale, which necessitates a revisiting of the individual–collective relation. The negotiation of competing interests between the individual and collective has always been a, if not the, central issue in public health ethics, but the interesting thing about population genetic research is that as the promises are increasingly individualized, collective action is ever more required, and there are implications for sub-groups of the population as well, in terms not only of health outcomes but also of group identity. So although there has been talk of the appropriateness of a shift from individual-centred ethics to a more community-focused approach, to which we have ourselves contributed in other work, it is actually more complicated than that. The negotiation of different

interests involved requires consideration not only of the rival claims of individuals and communities but also of purposes and benefits, the likelihood of achieving these (including statistical power), acceptability of requirements of participants, identity implications, the paradigms of medicine involved. It does seem to be clear that more is needed than a focus on individual privacy and informed consent; whether there will be significant developments in ethics in this particular case remains to be seen, but the interplay between science and ethics is an important topic for study in its own right.

25 Genetics, rhetoric and policy

Gardar Árnason

> By 2010, the [human] genome will help identify people at highest risk of particular diseases, so monitoring efforts can focus on them . . .
>
> In cancer, genetic tests will identify those at highest risk for lung cancer from smoking. Genetic tests for colon cancer will narrow colonoscopy screening to people who need it most. A genetic test for prostate cancer could lead to more precise use of the prostate specific antigen, or PSA, test by identifying those men in whom the cancer is most likely to progress fastest. Additional genetic tests would guide treatment of breast and ovarian cancer.
>
> Three or four genetic tests will help predict an individual's risk for developing coronary artery disease, thus helping to determine when to start drugs and other measures to reduce need for bypass operations.
>
> Tests predicting a high risk for diabetes should help encourage susceptible individuals to exercise and control their weight. Those at higher risk might start taking drugs before they develop symptoms.
>
> Scientists have a partial insight into the genetics of osteoporosis. With further research, Dr Collins said, 'you could imagine combining that kind of a test with a decision to start calcium and vitamin D therapy early on to try to prevent bone loss before it is clinically apparent, although we don't yet have evidence' that such therapy will benefit individuals at high risk for osteoporosis.[1]

The quote above is a journalist's paraphrase of the predictions of Francis S. Collins, who has led the Human Genome Project since 1993. It captures some of the rhetoric which has been used to justify not only the Human Genome Project, but also population-based human genetic databases. One of the main justifications for human genetic databases is indeed the possibility of producing the knowledge required for personalized medicine, that is, medical tests, drugs and therapies which are tailored to the genetic make-up of the individual patient. Admittedly,

[1] Lawrence K. Altman, 'Genomic Chief Has High Hopes, and Great Fears, for Genetic Testing', *New York Times*, 27 June 2000, p. D6. I thank Gudmundur Eggertsson for helpful comments on this chapter. Remaining errors and inaccuracies should be solely attributed to the author.

the Human Genome Project has given rise to stronger rhetoric than the databases, not least around the scientific breakthrough of the Human Genome Project which was fabricated for the media on 27 June 2000. When *Newsweek* published a story on the anticipated breakthrough, more than two months before it took place, it said: 'And science will know the blueprint of human life, the code of codes, the holy grail, the source code of *Homo Sapiens*. It will know, Harvard University biologist Walter Gilbert says, "what it is to be human".'[2]

The rhetoric used for justification of both the Human Genome Project and human genetic databases relies in large part on a very simplistic, deterministic view of genes, which developed alongside the rise of genetics in the twentieth century, but does not quite fit the view of genes in current science. The history of the concept of the gene is not very old. When Gregor Mendel published his laws of heredity in 1866 he called the carriers of hereditary traits simply factors.[3] While his paper lay largely unnoticed in *Verhandlungen des naturforschenden Vereines in Brünn*, biologists were observing for the first time curious threads in the cell nucleus when the cell is about to divide. Observations in 1877 of cell division, and of the formation of the ovum and the sperm cell, soon indicated that the threads were likely involved in carrying hereditary traits. The threads were called chromosomes. In 1892, the German physiologist August Weismann claimed in his *Das Keimplasma* that the chromosomes consisted of particles which were the carriers of hereditary traits. He called these particles *determinants*. Only in 1909 were the carriers of hereditary traits named *genes*, by the Danish Mendelian Wilhelm Johannsen,[4] although he did not think they were particles. And, as it turned out, no such particles exist.

Before the 1950s, the interior of the cell nucleus was not well understood. Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) had been identified in the late nineteenth century and a little later so were their four essential components (adenine, thymine, cytosine and guanine, better known by their initials A, T, C and G). The DNA was believed to be a repetitive and boring molecule, a 'stupid' molecule incapable of the complexity and diversity required for the carrier of hereditary traits.

[2] S. Begley, 'Decoding the Human Body', *Newsweek*, 10 April 2000, p. 52.

[3] Most of the historical material in this paragraph and the next is from Horace Freeland Judson, 'A History of the Science and Technology Behind Gene Mapping and Sequencing', in Daniel J. Kevles and Leroy Hood (eds.), *The Code of Codes: Scientific and Social Issues in the Human Genome Project* (Cambridge, MA: Harvard University Press, 1992), pp. 37–42.

[4] Jonathan Harwood, *Styles of Scientific Thought: The German Genetics Community 1900–1933* (Chicago: University of Chicago Press, 1993), p. 35.

Proteins got everyone's attention, as they were known to have a complex structure. Then two things happened. First, Erwin Chargaff published a paper in 1950 in which he showed that DNA molecules could be 'as specific in sequence as proteins'.[5] Second, in the spring of 1953 James D. Watson and Francis Crick published their model of the structure of DNA, the famous double helix, suggesting that genes are a segment of DNA sequence and, furthermore, that the DNA both carries hereditary traits from parents to offspring and is the basis for their expression in the individual organism.

The gene, as a theoretical entity, kept changing as the theory of genes changed. The genes of molecular genetics are as far removed from the genes of classical genetics as the atoms of modern physics are from the atoms of Leucippus and Democritus. But what are genes today?

One of the most important books on the Human Genome Project, Kevles and Hood's *The Code of Codes*, defines in a glossary the term 'gene' thus: 'The fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides [A, T, C and G] located in a particular position [locus] on a particular chromosome. Each gene encodes a specific functional product, such as a protein or RNA molecule.'[6] This definition is commonplace and simple, but not without problems. Compare it with the definition of 'allele' from the same source: 'One of several alternative forms of a gene occupying a given locus on the chromosome. A single allele for each locus is inherited separately from each parent, so every individual has two alleles for each gene.'[7] According to the definition of a gene above, a gene is a sequence of nucleotides at a locus, but according to the definition of an allele, an allele is a sequence of nucleotides at a locus and a gene is a *type* of similar alleles (or a set of alleles defined by their function or locus). On the one hand we have the gene as an abstract entity and on the other its physical instantiation or encoding in an allele.

This ambiguous use of the term 'gene' is common in molecular biology. In population genetics, 'gene' is variously used to refer to an allele or a locus. This branch of genetics could easily do without 'genes' and refer only to alleles and loci.[8] Sometimes a gene seems to be determined by its function rather than locus or physical encoding in an allele. In a *Newsweek* article we read: 'Most women have two copies of the gene for HER-2 [a receptor protein found on the surface of breast cells], but roughly a

[5] Judson, 'A History of Gene Mapping and Sequencing', p. 53.
[6] Kevles and Hood, *The Code of Codes*, p. 379. [7] Ibid., p. 375.
[8] See Sahotra Sarkar, *Genetics and Reductionism* (Cambridge: Cambridge University Press, 1998), p. 6.

third of advanced breast-cancer patients have extra copies of the gene scattered about chromosome 17.'[9]

The ontology of genes does occasionally go beyond the ambiguous to the curious or downright bizarre, at least in popular accounts of genetic research. Consider cystic fibrosis, which is the most common hereditary disease in Caucasians. Francis S. Collins, Lap-Chee Tsui and Jack Riordan are often credited with having found 'the gene for' cystic fibrosis in 1989.[10] This 'gene' is a mutation called delta 508, it is found in 70% of cystic fibrosis patients and it consists of three base pairs (i.e., three pairs of nucleotides) that are *missing* from a locus on chromosome 7.[11] This gene is not a sequence of nucleotides, it is nothing physical at all. At most it is a locus where there *should be* three base pairs – which are not there. To be precise, there is a specific genetic explanation for 70% of all cystic fibrosis cases, namely that three specific base pairs are missing from a certain locus on both copies of chromosome 7. For the remaining 30% of cystic fibrosis cases, more than 350 pathogenetic mutations have been found.[12] Given all this, it does seem odd to speak of 'the gene for' cystic fibrosis. As far as inherited traits go, cystic fibrosis is simple. Each time when the disease is expressed in an individual it can be explained in terms of a single mutation, inherited in a Mendelian fashion from both parents (this applies at the very least to all cystic fibrosis patients who have one of the known mutations). Still, there is no 'physical and functional unit of heredity' which corresponds to 'the gene for cystic fibrosis'.

The concept of the gene is defined in many different ways depending on the purpose of the definition, and there is no single way to give a 'correct' definition of the gene. Furthermore, the gene as it was imagined in the early days of genetics, as particles or distinguishable units, simply does not exist. Despite all this, most people, including scientists, seem to believe that there are things in nature which we label 'genes' and that they do all sorts of things. A deterministic view of genes seems very common, except when philosophers and scientists seriously discuss genetic determinism, when no one will admit to holding deterministic views about

[9] Geoffrey Cowley and Anne Underwood, 'A Revolution in Medicine', *Newsweek*, 10 April 2000, p. 62.

[10] See, for example, Michael Legault and Margaret Munro, 'Gene Hunters Extraordinaire', *National Post*, 16 March 2000.

[11] Nancy Wexler, 'Clairvoyance and Caution: Repercussions from the Human Genome Project', in Kevles and Hood, *The Code of Codes*, pp. 211–243, at pp. 224–225.

[12] John C. Avise, *The Genetic Gods: Evolution and Belief in Human Affairs* (Cambridge, MA: Harvard University Press, 1998), p. 64.

genes. Let me now make five points about genes and the deterministic picture of them.

First, many Mendelian hereditary diseases can be explained by a genetic mutation leading to, for instance, an enzyme which does not function as it should. This can then lead to failures in the biochemistry of the body, which can be anything from harmless (like alkaptonuria, where the patient's urine turns black on exposure to air) to deadly. The English physician Archibald Garrod, who in 1902 first showed a human disorder, namely alkaptonuria, to be inherited in a Mendelian fashion, called such hereditary biochemical failures 'inborn errors of metabolism'.[13] This is a simple example of a genetic disease in a deterministic sense of 'genetic'. It has frequently been taken as the model for the genetic basis of disease, requiring only some adjustment to the complexities of diseases that are not strictly Mendelian.

Second, most interesting human traits, both those considered normal as well as those considered pathological, are much more complex than the relatively simple cellular production of proteins and corresponding failure in 'inborn errors of metabolism'. Geneticists like to say that such complex traits have both genetic and environmental factors, but this distinction between the genetic and the environmental (environmental as the remaining non-genetic factors) already gives the genetic factors too much credit in most cases. In a trivial sense, all traits have a genetic basis. They would not come about without the genes that control (in close interaction with the environment) the development of the human being from the fertilized egg to the embryo to the adult human. However, most complex traits, including behavioural traits, and most common diseases (pathological traits and deviant behaviours have been of particular interest) have not been found to have primarily a genetic explanation. Even the much-publicized breast cancer genes, BRCA1 and BRCA2, are thought to account only for about 7% of breast cancers, and scientists have estimated a woman's life-time risk of breast cancer given the presence of BRCA1 or BRCA2 to be anywhere from 20% to over 80%.

Third, even the simple biochemical traits discussed above are not merely caused by a gene – the gene does not cause the production of the protein it codes for. The gene does not do anything, it is just there. There is a complex mechanism that leads to the gene being read and expressed in a protein and this mechanism depends on other genes as well as the environment. A gene may not be expressed at all in an individual. The probability of a gene being expressed at all is called *penetrance*

[13] Judson, 'A History of Gene Mapping and Sequencing', p. 42.

(technically it is the probability of a phenotype *f* given the genotype *g* or P(*f*/*g*)). A gene may be expressed, but its degree of expression, or *expressivity*, can vary both because of other genes and because of non-genetic factors.[14] A gene may therefore not be expressed at all, or only to some degree, depending on other genes and the environment. It seems then of little explanatory value to say that the gene *causes* the trait when it is expressed, except when its expressivity is invariable and above zero (i.e., the allele is expressed in almost every individual who has the allele and to a similar degree in each individual). The allele may still play a part in the causal story, but not the only part.

Fourth, even if a gene is expressed in most individuals who have the gene, and to a similar degree in all individuals who have the gene, it is still not possible to say that the gene *genetically determines* the trait. In the most trivial case, the individual might die before the trait is expressed. It is of no use to add that the individual must develop normally, as that would introduce the environmental factors which genetic determination is supposed to exclude. Less trivially, no trait is expressed without cues from the chemical environment of the cell.[15] In the case of the more complicated, and more interesting, traits, like behaviour, it is clear that environmental factors cannot be excluded from an explanation of the trait. It is even questionable whether genes have any explanatory value at all in those cases.

Fifth, talking about genes, or alleles, causing traits or phenotypes, invites all the well-known philosophical problems with the concept of causality. I will not discuss these problems here. However, an evasive interpretation of 'the gene (allele) *x* causes trait *y*', would be that the gene (allele) *x* is the best explanation of trait *y*. In the case of cystic fibrosis, for instance, an allele pair, where both alleles contain the delta 508 deletion, is neither a sufficient condition nor a necessary condition for the expression of cystic fibrosis. It is not sufficient for the trivial reason that the organism requires all sorts of other alleles and the proper environment to develop in the first place and it is not necessary because at least 300 other mutations can lead to cystic fibrosis. Still, one might want to say that the best explanation for a particular case of cystic fibrosis is that the patient has the delta 508 mutation on both the relevant alleles (the disease is recessive, it will only be expressed when both alleles have the deletion). One might even want to say that a particular case of cystic fibrosis was caused by a pair of faulty alleles, faulty because three specific base pairs were missing from them. But it is slightly misleading to say that there is a

[14] My discussion here draws heavily on Sarkar, *Genetics and Reductionism*, pp. 125–126.
[15] Ibid., pp. 10–12 and 184.

gene that causes cystic fibrosis and completely wrong to talk about *the* gene for cystic fibrosis.

The idea of genetic determinism is clearly not tenable. Even the idea of genetic causes is rarely defended by philosophers or geneticists, but that idea, and even the idea of genetic determinism, constantly appears in not only popular writings on genetics, but also policy-related discussion – and generally in the non-scientific discourse on genetics.[16] Geneticists themselves usually speak of genetic components, factors and correlations, but outside the scientific context that is all too often translated into genetic causes and genetically determined traits.

Human genetic databases are particularly concerned with the diseases that are most likely to kill those of us who live in developed countries, such as cancer or heart disease. Since these diseases have so far not been found to have a strong genetic basis, much of the genetic research focuses on finding alleles that are correlated to the disease, or the trait in question, in a statistically significant way (those are called allelic association studies). When an allele is associated with a disease, it is inferred that individuals who have the allele also have a higher probability, a greater risk, of developing the disease than those who do not have the allele. They are said to be genetically predisposed to the disease. It is then suggested that tests could be developed to identify those who carry the allele in question, those who are genetically predisposed to the disease (see the quote opening this chapter). Then the 'healthy ill', as Ruth Hubbard and Elijah Wald have termed them,[17] could at least minimize other known (environmental) risk factors. A person, for instance, who is diagnosed as a carrier of an allele associated with diabetes could change his or her diet, exercise and reduce cholesterol levels.[18]

Allelic association studies are correlation studies and inherit all their epistemic problems. Correlation is poor evidence of a causal connection as it may be the result of pure chance or the factors may be related in

[16] The most-quoted statement of genetic determinism is likely Watson's: 'We used to think our fate was in the stars. Now we know, in large measure, our fate is in the genes' (James D. Watson in *Time*, 20 March 1989; quoted, for instance, in Ruth Hubbard and Elijah Wald, *Exploding the Gene Myth* (Boston, MA: Beacon Press, 1997), p. vii), but genetic determinism is also apparent in metaphors (our genes as our essence, the human genome as 'the operating instructions for a human body'), idioms (the gene for . . .) and even book titles (Avise, *The Genetic Gods*).

[17] Hubbard and Wald, *Exploding the Gene Myth*.

[18] It is often taken as a given that knowledge about disease susceptibility is psychologically sufficient motivation for the patient to change his lifestyle. The existence of smokers seems to provide a strong counter-argument against that assumption. Furthermore, without knowledge about the magnitude of risk (in the sense of the probability of a specific harm), genetic disease susceptibility does not mean much.

much more indirect and complicated ways than simply as cause and effect. One way this can happen in allelic association studies is when an allele which is an actual genetic factor in a trait lies near an unrelated allele at a different locus on the same chromosome. The two alleles might occur more frequently than expected, for example in the case of genetic drift, in which case there would be a correlation between the second allele and the trait, although the allele plays no causal role in the origin of the trait.[19] Correlation could also be an artefact of the structure of the population, for example, if a part of a population has a higher than average frequency of a trait, then that trait can be associated with any allele that has also a higher than average frequency in that part of the population.

It has turned out to be difficult to replicate allelic association studies. The typical course of events is that first a study is published which finds a significant correlation between an allele and a trait (the front page headline in the newspapers will read 'the gene for *x* discovered' where *x* is the trait associated with the allele). Then a second study is published that does not find a correlation (the newspapers might have a brief note about it in the back of the paper), and finally a few more studies are published, some finding a correlation, others not. A common variation is a study that finds another allele associated with the same trait. This difficulty, together with the epistemic problems, should make us more cautious about reports of correlations between genes and traits, as well as scientific programmes promising to find genes associated with common diseases.

The rhetoric surrounding genetics is very powerful, but a basic understanding of the complexities of genetics goes some way towards deflating it. Still, the rhetoric is difficult to resist even for those with some basic understanding of the complexities of genetics. Reporters and journalists who question the rhetoric may seem like killjoys or party poopers,[20] and

[19] This example and the next is from Sarkar, *Genetics and Reductionism*, p. 134.

[20] At the press conference where Francis S. Collins of the US National Human Genome Institute and Craig Venter of Celera Genomics announced the completion of 'a working draft of the human genome', featuring inspired speeches by US president Bill Clinton and UK prime minister Tony Blair, a journalist asked: 'I am puzzled, you have mapped 97% of the genome, sequenced only 85% and just 24% are readable. Why are you giving a press conference?' (Ulrich Bahnsen, 'Im Dickicht der Proteine', *Die Zeit*, 13 July 2000; my translation from the German). The announcement was first page news, the journalist's scepticism was not. Toronto's *Globe and Mail* announced on the front page somewhat over-enthusiastically, 'The Language of God – Disclosed Yesterday in Washington, London, Paris and Tokyo' and the *New York Times'* front page headline read 'Genetic Code of Human Life is Cracked by Scientists'. Extensive reports in both papers failed entirely to explain what exactly the scientists had achieved, resorting to variously misleading metaphors: 'Two rival groups of scientists said today that they had deciphered the hereditary script, the set of instructions that defines the human organism', wrote the *New York Times* (Nicholas Wade, 'A Shared Success, 2 Rivals' Announcement Marks New

critical bioethicists may fear sounding like Luddites, trying to stop the progress of science and prevent the discovery of life-saving drugs. When it comes to policy issues regarding genetics, this rhetoric, and in particular that of genetic determinism, simply must be resisted – because it is so far from being justified. It is all too easy to use this rhetoric to present human genetic databases as promising revolutionary solutions to our medical problems. There are countless potential scientific projects, which may contribute to the progress of science and lead to medical breakthroughs, but we cannot have them all and we do not need them all. Human genetic databases will doubtless contribute to the progress of science and possibly lead to the discovery of new drugs, but science and medicine will also do very well without them.

Medical Era, Risks and All', *New York Times*, 27 June 2000, pp. A1 and A21) and the *Globe and Mail* reported: 'Hailing a milestone in the history of science, world leaders announced yesterday that an international team of scientists have completed their celebrated survey of the human genetic code and entered a brave new world of discovery' (Andrew Cohen, 'Scientific Team Crosses Genetic Frontier', *Globe and Mail*, 27 June 2000). Neither paper explained how much of the human genome had been mapped, how much sequenced and how much was ready for use.

26 Genetic databases and governance

Rainer Kattel

I

The publication of 'C. Elegans SGK-1 is the Critical Component in the Akt/PKB Kinase Complex to Control Stress Response and Life Span' in April 2004 received hardly any media attention.[1] *C. elegans* or *Caenorhabditis elegans* is a worm in which manipulation of a gene that produces enzyme SGK-1 stopped ageing processes. In other words, SGK-1-manipulated *C. elegans* is literally forever young. Human beings possess the gene for SGK-1 as well.[2] Longevity, living perhaps twice as long as we do today, seems to be around the corner. There are seemingly no limits to the biotechnology-induced development of modern medicine: 'precisely because modern medicine's unspoken goal is simply *more*, there are no limits to what can be hoped for and sought'.[3] The potential of transgenic enzymes and plants to transform traditional industries (such as production of paper, textiles and chemicals) and agriculture is similarly revolutionary. And it all promises to be huge business, too. In the chemical industry alone biotechnology could by 2010 account for $160 billion in sales.[4] Yet, 'despite such unquestionable success', writes Evelyn Fox Keller, 'biology is scarcely any closer to a unified understanding (or theory) of the nature of life today than it was a hundred years ago'.[5] In other words, we know fairly little what precisely we do with our biotechnological tools. Yet, the motives to use these tools more and more are so strong and obvious that it

[1] Part of the research for this chapter has been funded by the Estonian Science Foundation, grant no. 5780. The author would like to thank Wolfgang Drechsler for his help and critique.

[2] Maren Hertweck, Christine Göbeland and Ralf Baumeister, 'C. Elegans SGK-1 is the Critical Component in the Akt/PKB Kinase Complex to Control Stress Response and Life Span', *Developmental Cell* 6 (2004), pp. 577–588.

[3] Daniel Callahan, *False Hopes. Overcoming the Obstacles to a Sustainable, Affordable Medicine* (New Brunswick, NJ: Rutgers University Press, 1999), p. 52.

[4] Stephan Herrera, 'Industrial Biotechnology – A Chance at Redemption', *Nature Biotechnology* 22 (2004), pp. 671–675, at p. 671.

[5] Evelyn Fox Keller, *Making Sense of Life. Explaining Biological Development with Models, Metaphors, and Machines* (Cambridge, MA: Harvard University Press, 2003), p. 2.

is hard to conceive of a counterforce to these pressures that would let us govern these developments in a responsible manner.

It is this context that has led prominent writers like Francis Fukuyama and Leon R. Kass,[6] among many others, to stress the need and importance of action on the public policy level: 'Everything will depend, finally, not just on the possibility of choice, but on what is chosen.'[7] Yet, on what should the choice be based? How should a government agency determine whether a certain biotechnology research and development project is ethically and socially responsible and/or economically viable, and thus deserves funding? And, more importantly, if our future is at stake, should not we all have a say in this? It is thus perceived that there is a dire need to change the process of public policy-making itself: 'The call for greater participation and openness is one that challenges traditionally bureaucratic and technocratic approaches to policymaking in all areas.'[8] It is perceived that only with decisive participation of social actors and the business sector is there a chance of responsibly governing the development of biotechnology. 'The technology revolution', states the European Commission's *Life Sciences and Biotechnology – A Strategy for Europe*, 'calls for governance through inclusive, informed and structured dialogue.'[9]

This development coincides with the larger change in the nature and the role of the public sector in policy-making that began at the latest in the late 1970s. It was in particular in the 1990s that, in the search for a decidedly different approach to policy-making, a new conceptual development took place: the change of governing and government into governance. Governance, thus, is a mode of public policy-making that stresses the importance of co-operation of all three sectors (public, private and non-governmental) and of markets in shaping, implementing and evaluating public policies and steering a society.[10] The co-operation with

[6] Francis Fukuyama, *Our Posthuman Future. Consequences of the Biotechnology Revolution* (New York: Farrar, Straus and Giroux, 2002); Leon R. Kass, *Life, Liberty and the Defense of Dignity. The Challenge for Bioethics* (San Francisco: Encounter Books, 2002).

[7] Kass, *Life, Liberty and the Defense of Dignity*, p. 9.

[8] European Commission, *Innovation Tomorrow. Innovation Policy and the Regulatory Framework: Making Innovation an Integral Part of the Broader Structural Agenda*, European Commission, Innovation Papers, 28 (Brussels: European Commission, 2002), p. 89.

[9] European Commission, *Life Sciences and Biotechnology – A Strategy for Europe* (Brussels: European Commission, 2002), pp. 17–18; further Brian Salter and Mavis Jones, 'Regulating Human Genetics: The Changing Politic of Biotechnology Governance in the European Union', *Health, Risk and Society* 4 (2002), pp. 325–339; for the discussion in the USA, see President's Council on Bioethics, *Beyond Therapy. Biotechnology and the Pursuit of Happiness. A Report by the President's Council on Bioethics* ((US) President's Council on Bioethics, 2003), p. 304.

[10] See, e.g., European Commission, *European Governance. A White Paper* (Brussels: European Commission, 2001).

business and non-governmental organizations has been pivotal for the success of the modern nation-state since its beginnings in the late Renaissance.[11] Democracy would be inconceivable otherwise as well. Yet, that business and non-governmental organizations should be equal partners to the public sector in policy-making was the key new element brought forward by the concept of governance in the 1990s. Indeed, perhaps one of the best-known slogans of governance is 'the new governance: governing without government'.[12] The second key element of governance is implementing markets or market principles in order to create a more accountable, cost-effective and transparent public sector. Privatizing public sector services (competition in service creation) and performance management for motivating and remunerating public servants (competition in service provision) has indeed become one of the hallmarks of governance.[13]

This is decisively changing the nature of the public sector: the need to constantly adjust and change is increasingly becoming one of the strongest characteristics of today's public sector.[14] However, this has severe dangers as well: it is still the government that carries the sole responsibility and duty of decision-making, yet it has fewer and fewer instruments with which to do so, as well as with which to resist too powerful interest groups. The public sector can lose its authority and legitimacy in implementing governance.[15] Thus, the public sector needs increasingly more resources

[11] Gustav von Schmoller, *Das Merkantilsystem in seiner historischen Bedeutung. Städtische, territoriale und staatliche Wirtschaftspolitik* (Frankfurt am Main: Klostermann, 1944 [1884]).

[12] R. A. W. Rhodes, 'The New Governance: Governing Without Government', *Political Studies* 64 (1996), pp. 652–667.

[13] For critical assessment of governance as well as new public management principles in public administration and government discourse, see Henry Mintzberg, 'Managing Government – Governing Management', *Harvard Business Review* 74 (1996), pp. 75–83; B. Guy Peters and John Pierre, 'Governance Without Government? Rethinking Public Administration', *Journal of Public Administration Research and Theory* 8 (1998), pp. 223–244; Klaus König, 'Good Governance – As Steering and Value Concept for the Modern Administrative State', in J. Corkery (ed.), *Governance: Concepts and Applications* (Brussels: International Institute of Administrative Sciences, 1999), pp. 67–93; Wolfgang Drechsler, 'Good Governance' and 'New Public Management', in Hanno Drechsler, Wolfgang Hilligen and Franz Neumann (eds.), *Gesellschaft und Staat. Lexikon der Politik*, 10th edn (Munich: Franz Vahlen (C. H. Beck), 2003); on global governance institutions, see Keith Griffin, 'Economic Globalization and Institutions of Global Governance', *Development and Change* 34 (2003), pp. 789–807; on governance and good governance, see Wolfgang Drechsler, 'Governance, Good Governance, and Government: The Case for Estonian Administrative Capacity', *Trames* 8 (2004), pp. 388–396.

[14] Allen Schick, 'The Performing State: Reflection on an Idea Whose Time Has Come but Whose Implementation Has Not', *OECD Journal on Budgeting* 3 (2003), pp. 71–103.

[15] See Ezra Suleiman, *Dismantling Democratic States* (Princeton: Princeton University Press, 2003).

and capacities to coordinate policy-making and problem-solving. Governance brings, perhaps paradoxically, the need for better government in order to resist the inherent dangers in the concept of governance: loss of governmental authority, legitimacy and responsibility.[16]

It is this particular and historic change in the nature of public policy-making that is becoming the key element in the debate on the future of biotechnology.[17] Can governance, as a transformed mode of policy-making, deliver responsible biotechnology? This will be examined below using the case of genetic databases as an example. Genetic databases are perhaps the most advanced institutionalized forms of biotechnological development that have been created already using elements of governance: for instance, public–private partnerships for commercialization of research results, ethics and science committees and various oversight bodies representing various social and economic interests as well as different scholarly disciplines.

II

A genetic database or gene bank 'can be defined as a stored collection of genetic samples in the form of blood or tissue, that can be linked with medical and genealogical or lifestyle information from a specific population, gathered using a process of generalized consent'.[18] There are currently at least nine gene banks in the world: in Iceland, the United Kingdom, Estonia, Latvia, Sweden, Singapore, Quebec (Canada), Minnesota (USA) and Wisconsin (USA).[19] The projects are in very different development phases, ranging from plans to actual storing of samples.

[16] See Francis Fukuyama, *State Building. Governance and World Order in the Twenty-First Century* (London: Profile Books, 2004), pp. 9–25.

[17] See Francis Fukuyama and Caroline S. Wagner (eds.), *Information and Biological Revolutions: Global Governance Challenges, Summary of a Study Group* (RAND MR-1139-DARPA, 2000); European Commission, *Life Sciences and Biotechnology*. Johns Hopkins University hosts a web forum with a newsletter on 'Human Biotechnology Governance Forum' at http://www.biotechgov.org.

[18] Melissa A. Austin, Sarah Harding and Courtney McElroy, 'Genebanks: A Comparison of Eight Proposed International Genetic Databases', *Community Genetics* 6 (2003), pp. 37–45, at p. 37; see also Paul Martin, 'Genetic Governance: The Risks, Oversight and Regulation of Genetic Databases in the UK', *New Genetics and Society* 20 (2001), pp. 157–183, at p. 164.

[19] Melissa A. Austin, Sarah Harding and Courtney McElroy, 'Monitoring Ethical, Legal, and Social Issues in Developing Population Genetic Databases', *Genetics in Medicine* 5 (2003), pp. 451–457; and Austin, Harding and McElroy, 'Genebanks'. See also Hans-E. Hagen and Jan Carlstedt-Duke, 'Building Global Networks for Human Diseases: Genes and Populations', *Nature Medicine* 10 (2004), pp. 665–667, who list among such databases also various collections of data from twins; on small-scale European human biobanking, see Isabelle Hirtzlin, Christine Dubreuil, Nathalie Préaubert, Jenny Duchier,

Yet, none of the gene banks has yet reached full operational capacity. Those in Estonia, Iceland and Sweden are probably the most developed, with actual samples stored.

The rationale behind establishing genetic databases is in all cases similar: to improve research into diseases and thus eventually further medical therapy. That this research can also be economically very lucrative and thus positive for economic development is explicitly advertised (Iceland and Estonia) or at least implied.[20] Thus, genetic databases should primarily be in the public interest and supported accordingly. Yet, all proposals to establish a gene bank have been met with some form of protest and discussion. There are generally three areas of concern that have been brought up so far in the discussion around gene banks: *Privacy* – who has access to stored data, how and why; is the data linked to other databases; and is the data anonymous or can it be linked to the donor? *Consent* – is it an opt-in or opt-out consent, and is it specific for each further research question or general for any research? *Solidarity* – who gets to benefit from the research in gene banks, will there be a personalized medicine, community-specific research or general research for the benefit of mankind?[21]

The common denominator of these concerns is the fundamental uncertainty as to what the data and the research results can be used for in both a negative and a positive sense.[22] However, as long as this uncertainty persists, the genetic databases are inherently – notwithstanding their

Brigitte Jansen, Jürgen Simon, Paula Lobato de Faria, Anna Perez-Lezaun, Bert Visser, Garrath D. Williams and Anne Cambon-Thomsen, 'An Empirical Survey on Biobanking of Human Genetic Material and Data in Six EU Countries', *European Journal of Human Genetics* 11 (2003), pp. 475–488. Plans to establish a gene bank in the Kingdom of Tonga were cancelled after initial protests (Austin, Harding and McElroy, 'Genebanks').

[20] Only the Genome Institute of Singapore will avoid 'any commercialization of the project' (Austin, Harding and McElroy, 'Genebanks', p. 40). This, of course, does not prevent anybody else commercializing the results of the project.

[21] See Martin, 'Genetic Governance', pp. 172–174; generally Henry T. Greely, 'Human Genomics Research: New Challenges for Research Ethics', *Perspectives on Biology and Medicine* 44 (2001), pp. 221–229; and, from the legal perspective, Jane Kaye, Hördur Helgi Helgason, Ants Nõmper, Tarmo Sild and Lotta Wendel, 'Population Genetic Databases: A Comparative Analysis of the Law in Iceland, Sweden, Estonia and the UK', *Trames* 8 (2004), pp. 15–33.

[22] It is not clear in what terms one should conceptualize the ownership of DNA samples: different legal contexts and cultures give different answers, and thus it is not clear in most genetic databases who is the owner of the samples and what the owner can do with the samples (Kaye et al., 'Population Genetic Databases', pp. 17–19). Indeed, one can conclude that 'the UK, Swedish and Icelandic regulators have left the issue of the ownership of DNA samples in an uncertain state unless this is determined through individual contracts . . . It is only in Estonia that this has been expressly stated that both the DNA sample and the health status description as single items belong to the chief processor of the biobank' (ibid., pp. 19–20).

possible future benefit and gain – endangering the basic freedom of the modern democratic state: not only freedom of an individual to participate in governing but also his or her freedom towards and against the state and democratic processes of the society as such.[23] To counterbalance precisely this problem, various elements of governance – for instance, setting the research agenda before lay panels,[24] checking upon research via ethics commissions,[25] public–private partnerships for commercialization of research results – have been introduced into the set-up of genetic databases.[26] The elements introduced vary between databases, but perhaps the most common element is the use of various committees and commissions to enable strong stakeholder and donor participation in governing genetic databases as well as in economic benefit-sharing.[27] However, this participation-oriented set-up of gene banks rests on two assumptions: first, that it is new technology that creates new markets, products and industries, and thus wealth and benefits to share; second, that with control over technology development one can control also economic development and benefits. The history of capitalism, however, tells us the opposite: it is the market, or more precisely the entrepreneur, that in the search for new opportunities takes up new technological solutions and creates innovative products or services, and thus gains market share up to a monopoly (e.g. Microsoft's Windows today).[28] This very understanding is, in fact, reflected in how most gene banks envision how commercially viable research should come about: they rely on some form of public–private partnership for their respective commercialization efforts. This is in effect distribution of benefits as well. Such commercialization

[23] Ernst-Wolfgang Böckenförde, 'Die Bedeutung der Unterscheidung von Staat und Gesellschaft im demokratischen Sozialstaat der Gegenwart', in E.-W. Böckenförde, *Recht, Staat, Freiheit* (Frankfurt am Main: Suhrkamp, 1991), pp. 209–243, at p. 226; Harvey C. Mansfield Jr, *Taming the Prince. The Ambivalence of Modern Executive Power* (Baltimore: Johns Hopkins University Press, 1993), p. xxiv; on biotechnology in this context, see President's Council on Bioethics, *Beyond Therapy*, pp. 283–285.

[24] See discussion in Derrick Purdue, 'Experiments in the Governance of Biotechnology: A Case Study of the UK National Consensus Conference', *New Genetics and Society* 18 (1999), pp. 79–99.

[25] Richard Tutton, Jane Kaye and Klaus Hoyer, 'Governing UK Biobank: The Importance of Ensuring Public Trust', *Trends in Biotechnology* 22 (2004), pp. 284–285.

[26] See also Austin, Harding and McElroy, 'Monitoring Ethical, Legal, and Social Issues in Developing Population Genetic Databases', p. 452.

[27] On the level of theory this is best expressed in the idea of community consent: see Ruth Chadwick and Kåre Berg, 'Solidarity and Equity: New Ethical Framework for Genetic Databases', *Nature Review Genetics* 2 (2001), pp. 318–321; Jane Kaye, 'Genetic Research on the UK Population – Do New Principles Need to be Developed?', *Trends in Molecular Medicine* 7 (2001), pp. 528–530; Kaye et al., 'Population Genetic Databases', pp. 26–27.

[28] Joseph A. Schumpeter, 'The Economy as a Whole. Seventh Chapter of *The Theory of Economic Development*', *Industry and Innovation* 1/2 (2002), pp. 93–145.

agreements represent cases of privatization of a specific function of an otherwise public gene bank, i.e. a classical tool of governance. The lack of direct participation in benefits of donors is compensated by involving representatives of the public/donors in governing bodies of genetic databases (e.g. ethics and scientific commissions). This should deliver control over technological development (what research is allowed to begin with) and thus render market pull or demand into a secondary role. Thus, governance of genetic databases tries to solve the dilemma of controlling technological development in terms of ethics, and yet developing commercially viable technology at the same time. This, however, seems not to work.

III

Three of the gene banks – in Iceland, Estonia and Sweden – have or have had explicit and exclusive agreements with private companies for commercialization of research results in return for significant funding by those companies (deCODE genetics, EGeen Inc. and UmanGenomics, respectively);[29] others rely on public organizations or are undecided.[30] In all three of the agreements with private companies there have emerged serious problems. In Estonia the original agreements on how data is gathered (what questions are asked of donors) and for what purpose (general research vs. specific disease research) were significantly altered in early 2004.[31] In Sweden, the initial agreements, motivated by community consent ideas, and the nature of the company ownership (51% belonged to a public university, Umeå University) were changed in 2002, and public access to the database was limited.[32] In Iceland, the exclusive access rights granted to deCODE severely limit possible

[29] However, in Estonia 'the chief processor is co-owner of any intellectual property created by its private funding partner' (Kaye et al., 'Population Genetic Databases', p. 21). The exclusive agreement with EGeen Inc. was terminated in early 2005 due to differences about the substantial activities of the gene bank; the future financing scheme of the Estonian gene bank is unclear. In Sweden, UmanGenomics is granted exclusive commercial rights to results. deCODE has exclusive access rights to the Icelandic database.

[30] Austin, Harding and McElroy, 'Genebanks', p. 40.

[31] See Rainer Kattel and Riivo Anton, 'Estonian Genome Foundation and Economic Development', *Trames* 8 (2004), pp. 106–128, at p. 120.

[32] Hilary Rose, 'An Ethical Dilemma. The Rise and Fall of UmanGenomics – The Model Biotech Company?', *Nature* 425 (2003), pp. 123–124; Klaus Hoeyer, ' "Science is Really Needed – That's All I Know": Informed Consent and the Non-Verbal Practices of Collecting Blood for Genetic Research in Northern Sweden', *New Genetics and Society* 22 (2003), pp. 229–244, at pp. 231–232.

research options.[33] In all cases the scientific and commercial developments in genomics – what can be scientifically done now and what is commercially viable – have put considerable pressures on the respective public–private partnerships and changed the nature of gene banks from what was originally intended. From the economic point of view, such behaviour from private investors is highly logical and predictable since this is what private entrepreneurs do: they try to run profitable companies. However, this means that purely scholarly research that is guided by whatever happens to interest a scholar is almost impossible under these circumstances. The same is true as far as community-specific research is concerned – in the case of Estonia and Iceland, domestic markets are clearly too small, and the entire population of each country is not enough to carry out third-phase clinical trials as well,[34] which makes community-specific commercialization almost impossible.

Thus, these three gene bank projects which were initiated in the public interest may not necessarily reflect the public interest any more, but rather specific interests of a private company that has to follow the rule of the market: profitability. In this change rests perhaps one of the most pronounced dangers of today's science and research: the rise of McScience, where scholarly standards are lowered or bent because of possible future commercial success (e.g. selectively reporting results of clinical trials).[35] It is precisely this risk that has been brought into genetic databases via exclusive commercialization agreements. Moreover, as all three cases show, this danger cannot be counterbalanced by other governance structures such as ethics, scientific and general oversight commissions because these are too weak (or in inner conflict) to resist or, as in Estonia in 2004, in fact take the side of the private company. It is very difficult, if not impossible, for the public sector (the Ministry of Social Affairs in the case of Estonia) to resist such coalitions without jeopardizing the entire project. To repeat, the private companies have behaved in these situations as they were expected to behave. It is the public sector that has been caught unawares and has needed to adjust but has not been up to the task.

In other words, in all three cases the public sector has come to rely on the private sector not only so far as commercialization is concerned (creating benefits), but also in large part as to what kind of research is carried

[33] See Jon F. Merz, Glenn E. McGee and Pamela Sanker, ' "Iceland Inc."? On the Ethics of Commercial Population Genomics', *Social Science and Medicine* 58 (2004), pp. 1201–1209.

[34] I owe this observation to Tiit Talpsep.

[35] Richard Horton, 'The Dawn of McScience', *New York Review of Books* 51 (2004), 11 March; Marcia Angell, 'The Truth About the Drug Companies', *New York Review of Books* 51 (2004), 15 July.

out (controlling technology). The latter was supposed to be decided by different governance structures, namely by ethics, scientific and general oversight commissions, and not by the market. The opposite is the case.

IV

Harvey and McMeekin describe a race between two public–private partnerships to sequence the genome of *A. tumefaciens*, where in both cases academic pressures to publish the results were counterposed with entrepreneurial tactics of protecting the results via patent. The race ended in back-to-back co-publication (triggered by a public funding agency, the US National Science Foundation) of the results. Only then did it become clear that the two teams had come to rather different scientific results, reflecting the existence of considerable genetic variation that needed further research.[36] By its nature science does not have final answers; yet this is what the market demands: clear answers and predictable use.[37] This undermines basic scientific principles of openness and trust.[38] Modern science seeks this trust, perhaps paradoxically, in the process of blind peer-review. Yet, it is precisely the anonymity of peer-review that can maintain trust in impartial science that is not run by commercial or, for that matter, social standards.[39] Innovation, on the other hand, does not necessarily include any science or discovery at all; innovation can also use *existing* knowledge in the economic process.[40] This means that policy instruments that should trigger innovative activities of private entrepreneurs do not need to enter the field of science. As the goal of innovation is to disguise

[36] Mark Harvey and Andrew McMeekin, 'Public–Private Collaborations and the Race to Sequence *Agrobacterium Tumefaciens*', *Nature Biotechnology* 22 (2004), pp. 807–810.

[37] Martin Lindner, 'Im Supermarkt der Biotechnik. Eine Reportage', *Gegenworte. Hefte für den Disput über Wissen* 13 (2004), pp. 30–35, at p. 35.

[38] Angell, 'The Truth About the Drug Companies'; Steven Shapin, *A Social History of Truth. Civility and Science in Seventeenth-Century England* (Chicago: University of Chicago Press, 1994), p. xxvi.

[39] See also Martin, 'Genetic Governance', p. 178.

[40] Joseph A. Schumpeter, *Business Cycles. A Theoretical, Historical and Statistical Analysis of the Capitalist Process* (Philadelphia: Porcupine Press, 1939), pp. 58–61. Much of the current 'entrepreneurial university' rhetoric rests on the linear assumption that basic research is followed by innovation in industry. Stating, as for instance Henry Etzkowitz does, that the linear model should be complemented by a reverse linear model ('moving from problems in industry and society and seeking solutions in science') assumes again – as with the case of community consent discussed above – that it is technology that creates markets and not *vice versa* (Henry Etzkowitz, 'The Evolution of the Entrepreneurial University', *International Journal of Technology and Globalisation* 1 (2004), pp. 64–77, at p. 69). See Tomes' critique of recent UK science policy (Anne Tomes, 'UK Government Science Policy: The "Enterprise Deficit" Fallacy', *Technovation* 23 (2003), pp. 785–792).

and protect the source of itself, i.e. to create a monopoly,[41] it becomes clear that innovation policy measures may not actually enter the field of science, particularly not in the case of biotechnology because of such great uncertainties. As the sequence of the human genome is publicly available to all, so, it seems, should be all genetic databases (with anonymous data), as, for example, is the case with the planned UK Biobank.

In the case of genetic databases, market-based co-operation between public and private sectors seems to be particularly ill-advised because of the great uncertainties that surround genetic databases and because solutions provided so far for eliminating these uncertainties seem only to make the uncertainties stronger.[42] However, the main problem highlighted by the cases of Estonia, Iceland and Sweden is the weakness of the respective public sectors. There is a clear need in governing genetic databases to enhance public sector capacities.

V

Can governance deliver responsible biotechnology? The case of genetic databases, in particular those in Estonia, Iceland and Sweden, seems to suggest a negative answer. The contradictory efforts to try simultaneously to control the technological development via governance (ethics, scientific and general oversight commissions) yet to unleash it by using exclusive commercialization agreements have significantly changed the nature of these genetic databases. In fact, they have become more or less private ventures, where future public benefits have become much more obscure than initially planned or agreed. This, in turn, is compounding the original problem of genetic databases: endangering freedom of an individual in and against the state and society he or she lives in. Genetic databases are inherently endangering this freedom because of fundamental uncertainty so far as their possible future (ab)use is concerned. The use of governance approach in building up genetic databases only compounds the original problem. Governance demands a highly competent public sector. This seems not to be the situation in the cases discussed above. It is, thus, highly advisable, first, to raise the level of public sector control (via enhancing the capacities and competencies) over genetic databases; second, not to have exclusive commercialization agreements, but rather to create competition for scientific results (after mandatory publication of all research results), and not in generating those results.

[41] Schumpeter, *Business Cycles*, pp. 58–61.
[42] See also Merz, McGee and Sanker, ‘ “Iceland Inc.”?’, p. 1206.

Part VI

Conclusion

27 Bioethical analysis of the results: how well do laws and regulations address people's concerns?

Matti Häyry and Tuija Takala

People have concerns, and in democratic societies we expect these concerns to be somehow addressed by the public authorities.[1] In this chapter, we propose to answer two questions. First, in the light of the sociological studies conducted by the ELSAGEN team,[2] what are the main concerns that people in Estonia, Iceland, Sweden and the United Kingdom have regarding large-scale human genetic databases? And secondly, in the light of the research of the legal team,[3] how well have the authorities of Estonia, Iceland, Sweden and the United Kingdom addressed these concerns? After these main considerations, we will conclude by presenting some remarks concerning the limitations of our brief analysis.

[1] See Matti Häyry, 'Can Arguments Address Concerns?', *Journal of Medical Ethics* 31 (2005), pp. 598–600.

[2] Külliki Korts, Sue Weldon and Margrét Lilja Gudmundsdóttir, 'Genetic Databases and Public Attitudes: A Comparison of Iceland, Estonia and the UK', *Trames* 8 (2004), pp. 131–149; Külliki Korts, 'Introducing Gene Technology to the Society: Social Implications of the Estonian Genome Project', *Trames* 8 (2004), pp. 241–253; Mairi Levitt and Sue Weldon, 'Genetic Databases and Public Trust', in Gardar Árnason, Salvör Nordal and Vilhjálmur Árnason (eds.), *Blood and Data: Ethical, Legal and Social Aspects of Human Genetic Databases* (Reykjavík: University of Iceland Press and Centre for Ethics, 2004), pp. 175–179; Sue Weldon and Mairi Levitt, 'Public Databases and Privat(ized) Property? A UK Study of Public Perceptions of Privacy in Relation to Population Based Human Genetic Databases', in Árnason, Nordal and Árnason, *Blood and Data*, pp. 181–186; Külliki Korts, 'Becoming Masters of Our Genes: Public Acceptance of the Estonian Genome Project', in Árnason, Nordal and Árnason, *Blood and Data*, pp. 187–192; Anna Birna Almarsdóttir, Janine Morgall Traulsen and Ingunn Björnsdóttir, ' "We Don't Have That Many Secrets" – The Lay Perspective on Privacy and Genetic Data', in Árnason, Nordal and Árnason, *Blood and Data*, pp. 193–200; the contributions in part II of this volume.

[3] Jane Kaye, Hördur Helgi Helgason, Ants Nõmper, Tarmo Sild and Lotta Wendel, 'Population Genetic Databases: A Comparative Analysis of the Law in Iceland, Sweden, Estonia and the UK', *Trames* 8 (2004), pp. 15–33; Ants Nõmper, 'What is Wrong with Using Anonymized Data and Tissue for Research Purposes?', in Árnason, Nordal and Árnason, *Blood and Data*, pp. 121–126; Hördur Helgi Helgason, 'Informed Consent for Donating Biosamples in Medical Research – Legal Requirements in Iceland', in Árnason, Nordal and Árnason, *Blood and Data*, pp. 127–134; the contributions in part III of the present volume.

Trustworthiness as the main concern

It appears from the ELSAGEN work that people's main concerns in all four countries centre on the *privacy* of the citizens and on the *trustworthiness* of genetic-database operators in serving a valuable social function. As far as we can see, however, a felt need to strike a balance between these private and public concerns tends to make, on the whole, trustworthiness the primary issue. Respect for privacy can be seen as one of the criteria for assessing the goodness and reliability of the activity.

According to the sociological surveys of the ELSAGEN team, people's general attitudes towards genetic research and large-scale genetic databases are not particularly hostile. Especially in Estonia, optimism about science can be seen as a prominent force. The vast majority of those interviewed seem to think that the benefits of genetic research outweigh the risks and that the information collected and stored in genetic databases will in the long run come to profit individuals as well as businesses. People appear to have confidence in both scientists and database controllers. In the other three countries, mindsets are slightly more cautious, but not by any means overtly cynical. Icelanders do have their doubts about items stored in the Health Sector Database, but they are also technologically well motivated. Swedes want genetic-data handling to be securely under state control, but their stance is otherwise pragmatic. And although people in the United Kingdom are suspicious of idly curious scientists tampering with nature, they nonetheless support genetic research and data collection as parts of the contemporary healthcare system.

In all four countries, the groups and individuals studied have concerns regarding privacy, consent and confidentiality. Two-thirds of the Estonians interviewed worry about leaks of information; nine out of ten Swedes stress the need for explicit individual consent and strict confidentiality; and comparable anxieties and attitudes are also registered in Iceland and the United Kingdom. On the other hand, however, none of these requirements seems to be categorical in the public consciousness. It is widely recognized that genetic databases can serve useful diagnostic, medical, scientific and forensic purposes. The use of genetic records for criminal investigation by law enforcement officials in particular seems to have almost universal appeal among the studied populations.

This is where the requirement of regulation and control enters the stage. People want to support the establishment of genetic databases, but they also want the collections to be run by dependable organizations, and to be used only for good causes. While Estonians and Icelanders appear to be reasonably content with private companies being in charge, Swedes insist and Britons expect that the sample and information

collections are publicly owned and handled. Definitions of good causes vary among the populations, but the evil purposes that are condemned include genetic discrimination in employment, insurance and reproduction; science purely for its own sake; and the accumulation of obscene profits. People want trustworthy institutions to run and control genetic databases in order to keep discrimination, unfairness and violations of privacy at bay while allowing the public interest to be protected against preventable crime and diseases.

Alternative and complementary concerns

On the surface, then, the sociological work of the ELSAGEN team seems to convey the message that trustworthiness is the primary concern that people in Estonia, Iceland, Sweden and the United Kingdom have regarding large-scale human genetic databases. However, while this is the general drift of the studies, it is based on assumptions that can, to a certain extent, be contested. Alternative analyses reveal other important concerns, which should also be addressed.

The primacy of trust rests on two beliefs. The first is that majority opinions are paramount in public decision-making. This reflects the democratic view that our leaders should make decisions which in conflict situations respect the views of the many rather than the views of the few. The point of social studies is, within this model, to inform the authorities of the direction of the majority opinion. The second belief is that members of the public are entitled, and perhaps obliged, to adjust their spontaneous attitudes in the light of information provided by the authorities. This notion draws a line between immediate emotional reactions and more considered attempts to take into account the feelings of others. Citizens are expected, for instance, to revise their own views on privacy if these are incompatible with public hopes concerning crime and disease prevention.

An alternative to this 'majority approach' is deliberately to seek areas in which a considerable minority disagrees with the rest of the population. With the findings of the ELSAGEN team, this is not particularly difficult. A third of those interviewed in Estonia thought that the risks of genetic research outweigh the benefits, and the same proportion feared that scientific advances will lead to a brave new world of discrimination. The latter concern was even more prevalent in Sweden. Every sixth Icelander opined that the Health Sector Database is a bad idea, and in the United Kingdom one in three people felt uneasy about geneticists tampering with nature.

Another feasible option is to read the majority's views on privacy and trustworthiness in the reverse order. The moral of the story will then also be upturned. The starting point is that people would indeed, hypothetically

speaking, support human genetic databases if they felt that they could trust those running and controlling them. The truth of the matter is, however, that this assumption of trust can be challenged. Less than half of the studied population in Iceland had confidence in their Minister of Health and in the pharmaceutical industry – surely important players in the issue. The situation seems to be roughly similar in Estonia and the United Kingdom (although not in Sweden). This could be seen to imply that the majority of people who have concerns about privacy and confidentiality in these countries would not, on reflection, support genetic databases.

Giving some extra weight to majority views, we can say that the main concerns that public authorities ought to address in our present context are, in receding order of political importance, the following:

- Human genetic databases should be run and controlled by trustworthy institutions. These should respect the demands of privacy and confidentiality and contribute only to socially valuable goals such as health promotion and crime prevention – not to dubious side-effects of the use of genetic information like discrimination and economic injustice.
- Human genetic databases should not promote idle scientific curiosity, encourage reckless attempts to tamper with nature, or clear the path for the division of human beings into genetic 'superiors' and 'inferiors'.
- Human genetic databases should not violate the privacy and rights of those who do not go along with the majority opinions encapsulated in the public-interest-in-health-and-crime-prevention view.

It would seem that if lawgivers and policy-makers can successfully address these concerns, their democratic duty to their constituencies is performed. So the question is, can they?

Laws, regulations and majority concerns

Public authorities have at least five strategies by which they can try to take into account people's opinions regarding activities in the social arena. They can leave things as they are and assume that market forces and common decency will keep the activities in question under control. They can encourage the self-governance and professionalism of the parties involved in the practice, and hope that their business sensitivity and integrity prevent immoralities and damage. They can regulate the activity by policies which make it profitable for the entrepreneurs to respect majority opinion. They can find guidance in the existing body of law, and inform all those involved of the probable legal consequences of malpractice. Or they can create new laws, either to clarify the legal situation or to develop completely new rules to regulate the activity. The choice of the strategy should, in democratic societies, reflect the views prevalent among the population.

On this general level, the legislators of Estonia, Iceland, Sweden and the United Kingdom have, arguably, risen to the challenge reasonably well. People in these countries recognize that the market is probably the driving force behind technological advances; yet their trust in private enterprise is weaker than their confidence in academic scientists and the public authorities. This indicates that some subsidiary measures ought to be taken by the governments to strike the right balance between private and public involvement in the running of population-level human genetic databases. In all four nations such measures have been taken in various ways, and in none of them has this been done in a manner that would obviously jeopardize the expected benefits of the associated scientific and economic advances.

All the countries have chosen slightly different approaches to the level and extent of regulation. Estonia has specific legislation which includes rules concerning issues like ownership, consent, feedback and third-party access. Iceland also has a specific law which addresses some of these issues. Sweden and the United Kingdom have regulations that cover medical research in general, with the United Kingdom approach tending to favour self-governance by the operators and to rely on general principles of law. The public authorities of all four nations have stressed the health aspects of the databases and they have enabled, in one way or another, police access to genetic information when this has been considered relevant to the investigation of serious crimes. Legislation, regulations and moratoriums have been enacted to prevent the use of genetic information by employers and insurers.

As the lawyers of the ELSAGEN team have repeatedly pointed out, the current laws and regulations on human genetic databases contain many gaps and some confusing contradictions. The issues that population genetic databases present are not addressed in the same way across all jurisdictions. For instance, the ownership issues are largely unresolved; requirements for consent, especially for secondary research purposes, remain erratic; different legal systems allow and require different degrees of feedback for the participants; and the rules concerning third-party access are in some cases unclear. But this is not necessarily dangerous if the point of the exercise is to accommodate the majority views of the populations. (We will return to the 'if' clause in the final section of this chapter.) People's concerns are by no means well defined, and there is variation from jurisdiction to jurisdiction. It can be argued that as long as the lawgivers address, to some degree, the main issues, there is no acute need for immediate harmonization or strict consistency. The important thing is that people's trust is maintained by public-spirited, if at times slightly haphazard, regulative activity.

Laws, regulations and alternative concerns

One potential problem with this policy is that it seems to leave the concerns of many minorities unaddressed. What about the anxiety that nature will be tampered with and horrible new worlds will emerge? Some of this unease is soothed by well-targeted and well-publicized prohibitions on high-profile activities like human reproductive cloning, but other fears stay intact. And what about the individuals who still worry about possible leaks of information, and remain sceptical regarding the benefits of human genetic databases? Existing regulations may go some way to protect privacy and confidentiality, but there are no guarantees in individual cases.

If these residual qualms are seen as practically unanswerable, and if all concerns must be addressed by laws and regulations (this is another 'if' clause that we will revisit in our closing section), a universal ban on population-level human genetic databases could be the only sufficient response to them. But this would probably be an unpalatable response for the governments of Estonia, Iceland, Sweden and the United Kingdom. These nations are strongly committed to the pursuit of genetic knowledge and technological advances, partly due to the expected public health benefits, partly because science and industry are seen as good forces. To go against majority opinion, or what is seen as majority opinion, in this matter could spell political trouble. Besides, the solution would be self-defeating. In an attempt to accommodate the views of the few, public authorities would now disregard the views of the many.

Consequently, the governments of many countries have decided to tackle the 'horror' concerns and 'individual' fears by launching science education campaigns directed at the general public. The logic here is that only lack of knowledge can prevent lay people from seeing the overwhelmingly useful and beneficial nature of genetic research and population databases. Media releases and public-awareness programmes have been geared towards softening people's attitudes to new scientific developments. The messages conveyed include, although often only implicitly, notions like 'There is nothing unnatural about advances in genetics – only opponents of progress can stand in their way', 'The strict rules of consent are a thing of the past – we cannot be forever held back by the ghosts of Nuremberg' and 'Individual privacy and confidentiality should give way to national security and public interest – those who disagree should learn to be more altruistic.'

It is difficult to judge how successful these campaigns have been in addressing people's concerns. The majority opinion is consistent with their ethos, but minorities are either patronized or ignored by them.

And the fact remains that in many cases less than half of the population actually trusts the authorities issuing the reassurances. In the end, the final assessment depends on our idea of democracy. If it is sufficient that the concerns of the majority are, by and large, adequately addressed, then the present legal situation is acceptable. If, on the other hand, the views of minorities should also be taken seriously, ways should be explored to incorporate them into the regulatory system.

Some methodological reflections

It remains to be noted that we have, in this chapter, presented only one possible interpretation of the findings of the ELSAGEN team. We have done this by starting from two premises: firstly, that people have concerns; and secondly, that it is of paramount importance that laws and regulations address these concerns. Both premises are certainly a part of the democratic rhetoric of our time.

We have, by focusing on the opinions and anxieties presented by the members of the general public, implicitly rejected an alternative approach, which would stress the importance of 'issues' (objective problems identified by experts and politicians) over 'concerns' (subjective or intersubjective irritations felt by lay individuals and groups). This rejection has been deliberate. For the purposes of this account, we have assumed that issues in and by themselves should have no privileged status in ethico-legal discussions. They are either constructions based on public concerns (as we have hypothesized in our chapter on the 'mezzanine rules' of genetic databanking in this book) or subjective concerns held by the experts and politicians who draw attention to them (due to professional or ideological commitments). The more objectivist line has been taken in many other parts of the book, including the legal analyses.

It is quite feasible, however, that the concerns registered by social studies and recognized by public authorities have less to do with people as individuals than they have with cultural narratives and specific interest groups. Ideologies, religions, works of art and the mass media direct our attention to particular issues and patterns of thought, and it is arguable that surveys and interviews catch the 'general ethos of the time' more effectively than the unadulterated feelings and attitudes of individual citizens. The argument can also be made that the only voices public authorities hear are the voices of interest groups from either side of the debate, or those of the 'chattering classes'. These potential limitations do not unduly influence the results of our surface descriptions of stock similarities in popular attitudes. But they would impede any attempts to expose the deeper, and in many senses more interesting, differences of

opinion between nations and cultures as well as between age, gender and income groups. Some of these aspects have been made more visible in the detailed sociological studies of this book.

Another question raised by our approach is that the proper role of laws and regulations may not be the reactive accommodation of majority – or minority – views in the first place. According to a more authoritative view, the role of law is to provide an acceptable standard of what is considered lawful and what is not, so that people know what they should do. It is important, within this model, that law embodies one definite view instead of many outlooks. Proceeding from this notion, the legal situation in the four countries studied by the ELSAGEN team is less than ideal. The laws on population genetic databases do not address all the relevant issues, nor are they consistent throughout jurisdictions. This is a problem, for instance, in the concrete case of sharing data and samples across national borders. It is also a problem from the more abstract viewpoint of 'European justice'. If Europe is to be seen as a political entity with a certain degree of unity, then it can be argued that everybody in the continent should be governed by the same rules and to the same standard. The other side of this coin, however, is that if the standards are oppressive or detrimental to human good, it would presumably be better to have variety than to stick to one bad set of rules, however consistent and coherent that might be.

Yet another qualification to be made is that we have described the arguments that public authorities could give to those who want laws and regulations to address people's concerns, not the actual causal connections between popular worries and legal rules. It is almost certain that the lawgivers of Estonia, Iceland, Sweden and the United Kingdom have not deliberately kept the regulations muddled and inconsistent to respond in the best possible way to the muddled and inconsistent hopes and anxieties of their citizens.

The analysis given in this chapter does not cover all the aspects mentioned here. More stringent accounts of both the sociological studies and the legal research of the ELSAGEN team can, however, be found in the preceding chapters. We hope that our brief overview has provoked some new thoughts concerning the complexities of social concerns and regulatory responses.[4]

[4] Our thanks are due to Kjell E. Eriksson and Jane Kaye for their critical but constructive comments on the first draft of this chapter. Most of the qualifications that we list in the last section have been inspired by their words, although any responsibility for the views expressed in that section, as well as in the other sections, is, of course, entirely ours. Our thanks are also due to Peter Herissone-Kelly for checking our English.

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