

Principles and Practice in Biobank Governance

Edited by

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Published by
Ashgate Publishing Limited
Wey Court East
Union Road
Farnham
Surrey, GU9 7PT
England

Ashgate Publishing Company
Suite 420
101 Cherry Street
Burlington
VT 05401-4405
USA

www.ashgate.com

British Library Cataloguing in Publication Data

Principles and practice in biobank governance.

1. Biobanks--Management. 2. Biobanks--Moral and ethical aspects.

I. Kaye, Jane, 1962- II. Stranger, Mark.
576.5'0752-dc22

Library of Congress Cataloging-in-Publication Data

Principles and practice in biobank governance / [edited] by Jane Kaye and Mark Stranger.
p. cm.

Includes bibliographical references and index.

ISBN 978-0-7546-7825-0 (hardcover)

1. Tissue banks--Management. 2. Biobanks--Management. 3. Tissues--Collection and preservation--Government policy. 4. Biological specimens--Collection and preservation--Government policy. 5. Procurement of organs, tissues, etc.--International cooperation. 6. Bioethics. I. Kaye, Jane, 1962- II. Stranger, Mark.

[DNLM: 1. Biological Specimen Banks--standards. 2. Clinical Governance. 3. Public Policy. QU 23 P957 2009]

RD127.P76 2009

362.17'83--dc22

2009030145

ISBN 9780754678250 (hbk)

ISBN 9780754696193 (ebk)



Mixed Sources

Product group from well-managed
forests and other controlled sources
www.fsc.org Cert no. SA-COC-1565
© 1996 Forest Stewardship Council

Printed and bound in Great Britain by
MPG Books Group, UK

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Governing Biobanks: An Introduction

Mark Stranger and Jane Kaye

The collection and storage of human tissue for medical research is not a new phenomenon. Neither is medical research interest in genetic heritage new, although before the relatively recent advances in genetic science and technology this interest was expressed in terms of family history. A medical practitioner could expect questions about a patients' family medical history to be taken as a sign of their thoroughness and care. Such inquiries are perhaps accepted as benign or benevolent because they are like a natural extension of common civil greetings; such as 'How are you?' and 'How is your family?' But with the rapid advances in the human genetic sciences and the emergence of biobanks (and their potential links to other databases) the medical practitioner's inquiry could end up sounding more sinister.

*No don't talk. Just open your mouth wide while I take a swab.
I'll be able to find out all I need to know about your family history ...
and its future.*

A genetic test has none of the benign veil of civility that cloaked the intent of a trusted doctor's inquiry into our family's medical history, rather its shadow can loom large with the fear of discovering some dreadful and inevitable future, and the potential for discrimination.¹ The human genome's 'Book of Life' can be seen as just the introductory volume in an infinite series, where every individual has the 'Book of MY Life' written in their genes and awaiting publication. While the fear of uncovering indications of future diseases or disorders and concerns over the implications of acquiring this knowledge may lurk in the minds of the public, there is still a market for personal genetic information, as the emergence of direct to consumer testing companies demonstrate.

Rather than going through your local doctor, it is now possible to carry out a buccal swab test in the comfort of our own homes and log onto an internet account with a direct to consumer testing company. We can even have the results downloaded onto our iphones. The activities of direct to consumer testing companies are changing the landscape of genomics rapidly. Sequencing is no longer the exclusive domain of specialist scientists. These companies are here to stay, even if the information on risk that they offer is currently of limited clinical

1 <http://www.gdproject.org>.

utility. It is therefore more important than ever that the research community clearly articulate the principles that distinguish and underpin good practice in the field.

Current scientific opinion is divided over whether genetic information has any significance for many common diseases, as it is difficult to replicate findings and a lot more work needs to be done to determine the complex and subtle relationship between genotypes, phenotypes and environment (McCarthy et al. 2008, Ioannidis et al. 2009). The need for large sample sizes to understand and measure these complexities (Burton et al. 2009) has fuelled the drive to establish new biobanks, but also to link existing collections of samples and information. The perceived importance of biobanks is evidenced by the funding initiatives to develop infrastructure that can link and integrate biobanks and research collections. However, support of the public is essential, as it is only with continued donation of samples and data, and large-scale investment programmes that genomic research will continue. Good governance of biobanks is where we can first and most comprehensively address some of the fears and concerns of the public. It is well accepted that good governance structures for research have the potential to encourage greater public trust.

There are many different kinds of biobanks, both clinical and research focused, and these facilities can be called by different names (e.g. human genetic databanks, human tissue collections, biospecimen repositories, DNA Databases) (Tutton and Corrigan 2004, Cambon-Thomsen et al. 2007, Kaye 2006). In its most basic form, a biobank can be described as a collection of human tissue and the genetic information collected from that tissue. Combined with other sources of personal information biobanks can be used for different kinds of research by many different researchers. The value of the biobank is largely contingent upon being able to link the samples with donor information and its value increases with the depth and quality of the information. Biobanks can facilitate continuous collection of data and information over extended periods of time which maximizes the value of the existing resources and the potential to discover more about medical conditions. In an ideal world – for the researchers at least – the information linkages would include ongoing access to the donors’ medical records, and information about the environmental and behavioural risks that characterize their everyday lives. The list of potential contributing environmental and behavioural factors and combinations is endless. And so, it would seem, is the endeavour.

The term *governance* when applied to biobanks can have different meanings. When considered in terms of ‘corporate’ governance it relates to the business structures set up to manage the institution and ensure it achieves the desired outcomes within the relevant systems of regulation. Such governance frameworks have been described as, ‘... the agreements, procedures, conventions or policies that define who gets power, how decisions are taken and how accountability is rendered’ (Institute on Governance 2003 in Bédard et al. this volume). Therefore a governance structure is a combination of procedures declared through guidelines and policies, and enacted through decision-making bodies. The way that a governance structure is organized and where the control for decision-making

resides can fundamentally change the nature of a biobank, its priorities and the way the biobank interacts with the society of which it is a part.

It would be reasonable to assume that the primary focus for those wishing to establish biobanks is to create a system of governance that delivers in terms of outcomes: i.e. the quality of the collection and storage, its desirability as a research resource, the integrity of the system that manages access to specimens and data, and the efficiency and effectiveness of accountability, auditing and security mechanisms. This 'outcomes' focus is apposite to the model of corporate governance. Bioinformatics is considered key to achieving good outcomes-focused governance. However, the chapters in this collection demonstrate that a key concern of many governance structures established for biobanks is to ensure that research is carried out ethically, and research participants are not harmed by involvement in the biobank. But many of the governance systems in place do not involve research participants in decision-making.

As Gottweis and Petersen (2008: 8) point out, the use of the term *governance* represents a blurring of boundaries such that the regulation of biobanks is now an issue within the public arena. Biobank outcomes are contingent upon input in terms of tissue and data and donors must be forthcoming with deposits if the biobanks are going to be able to do their business. The link between donor participation, public trust and public consultation has been widely recognized and public engagement has been embraced as a necessary step in establishing a biobank (Weisbrot in this issue; Levitt and Weldon 2005, Stranger et al. 2005). Public engagement is considered the key to achieving good outcomes in this broader model of governance, and evidence of good corporate governance feeds into the communicative process. It is this broader sense of governance that engages ELSI scholars and is therefore the focus of this publication.

The enquiry into the ethical, legal and social implications (ELSI) of human genetic research and development has been a showcase for multidisciplinary collaboration. But it is a showcase that can never provide the kind of definitive outcomes that those wishing to establish biobanks might hope for. Despite the *need* for harmonization of governance structures in the global research environment (Bovenberg 2005), the 'Book of Life' is unlikely to be matched by the 'Book of Biobank Governance', at least not in the genre of a one-size-fits-all instruction manual. This, in the end, will be a political publication with multiple and varied versions.

The authors that have contributed to this volume range across disciplines and speak from scholarship and experience embedded in different cultures and politico-legal systems. These combined works present what we believe to be a snapshot of key principles and current practices relating to the governance of biobanks across the globe at this point in time. The governance structure of any biobank will be the result of political deliberations that reflect the cultural and political reality in which they are embedded. Any generic blue-print can only be in abstract terms. The best we can hope to offer is basic principles that can be adapted to suit the context. As will become clear, there is still plenty of room for debate around these principles

and how best they should be translated into governance structures, policies and guidelines. But this does not represent a failure on the part of ELSI scholarship. Ongoing debates around widely accepted principles and how they should be put into practice are surely indicative of some kind of end-point rather than inertia or confusion; they provide material for public political deliberation that must inform and, to a significant extent, *constitute* the governance of biobanks.

Themes and Chapters

The chapters in this book have been divided into four key themes; Benefit Sharing, Consent, Privacy and Access to Data, and Governing Bodies. What follows is a brief outline of the chapters as they appear, ordered under the themes that are their *primary* focus. As might be expected, given the contingent nature of the issues involved, individual chapters can also range across themes. The reader should therefore not consider the thematic ordering of the chapters as rigidly delineating all discussions of relevance to these topics.

Benefit sharing

Perhaps the notion of a common human heritage that became attached to the human genome has had some influence, but whatever the reasons, benefit sharing has emerged as a key theme in discussions about the governance of biobanks. The concept covers a fairly broad field, ranging from the individual to the global sphere; including ideas about benefits to donors, benefits to third world countries, and arrangements for sharing research data with other researchers. The principle involved here is that there should be some equity in the distribution of goods that accrue from the establishment of biobanks and the genetic research that they facilitate. It appears that we are not content to leave it to the invisible hand of the market to determine how the benefits are to be shared. How then might we best build mechanisms into the governance of biobanks that will help lead to the equitable distribution of benefits? The chapters in this section make a valuable contribution to our deliberations on this issue.

The findings of Nicol and Critchley's research (Chapter 1) show that Australians have clear expectations that there should be benefits to the broader community from their participation in a biobank. There is also a high level of support for: keeping research open, both by returning results to the biobank and by public dissemination; and ensuring that healthcare products developed using biobank resources are affordable to both the Australian and global community. The key conclusions that the authors make in this chapter are that people care about benefit sharing and want to know what benefit sharing arrangements are in place before deciding to participate in biobank research and therefore that as a matter of course, benefit sharing should be explicitly addressed in biobank governance frameworks. The warning for biobanks (especially for those with industry links) is that they

risk losing public support if benefit sharing is ignored. Further, the authors argue that public consultation is necessary ‘as it assists in understanding the motivations of members of the public to participate in biobanking and how regulatory and governance frameworks must be shaped to satisfy their needs and allay their concerns’.

In Chapter 2, Kanellopoulou provides the conceptual basis for empowerment that could underpin the empirical findings of Nicol and Critchley on benefit sharing. Kanellopoulou argues that the relationship between biobanks and their participants should not be founded solely on the basis of altruism and a gift model but that participants’ interests would be better served by the law if an approach was adopted that focused ‘on the nature of their interaction with researchers and describe it as an ongoing cooperation and dynamic relationship with special obligations for both sides’. She considers that this shift is necessary because of the increasing economic value of human tissue and commercialization, by both public and private institutions, and because of the long-term participation and commitment undertaken by participants. This requires a conceptual shift to recognize ‘the continuous nature of their relationship as dynamic and worthy of protection’. Under this approach, research gifts should be considered as conditional and regulated in accordance with requirements of reciprocity.

Winickoff, in Chapter 3, advocates the notion of ‘partnership governance’ for biobanks. He argues that biobanking projects are likely to fail both as a normative and practical matter without greater attention to issues of procedural justice: in particular, the constitution of distributive agency over resources for genomic research. For Winickoff partnership governance ‘presents a productive avenue for achieving a normative shift from “benefit sharing”, a distributive value, to “power sharing”, a procedural one’. He asks why the ‘principles and legal forms derived from charitable trust law and corporate governance, such as trusteeship, fiduciary duties and shareholding’, should not be brought to bear in the realm of charitable biobanking. His idea of ‘partnership governance’ does not mean exclusive ownership by volunteer individuals, nor does it allow self-interested action. Rather, partnership governance is based on an idea of cooperative human relations forming and acting out different parts of a complex governance structure for public benefit. ‘If implemented, partnership governance would empower participants to exert a share in distributive decision-making in return for contributing to the economic and social capital of the project’ and ‘go further than existing mechanisms of “community consultation”, by implementing a share of control at the level of the research participant collective’. Winickoff draws on legal principles and norms from charitable trust law and corporate law to help arrive at partnership governance.

Consent

A requirement for informed consent is regarded as a fundamental principle in medical research ethics. However, biobanks raise considerable difficulties for

the practical application of this principle. In particular, problems arise because the samples being donated can remain in storage as a valuable resource for future research unimagined at the time of donation. In practice, the idea of being adequately informed has always been problematic, and in the context of biobanking it is clearly even more so. Given the potential benefits that could be gained from biobanks and the difficulties involved in following the conventional model of informed consent, different approaches have been considered, ranging from forms of re-consent through broad consent and alternative governance mechanisms, and combinations thereof.

In Chapter 4, Gundermann and Stockter argue that at a minimum, broad consent has to be obtained from the donor before their tissue and related data can be processed, but this must wherever possible be accompanied by the possibility that donors can exercise ‘co-determination’ as a means of safeguarding their autonomy. ‘Co-determination’ has its origins in German labour law and denotes ‘the transfer of democratic decision making processes into private or public management structures’. In the case of biobanking, Gundermann and Stockter regard that ‘co-determination’ would entail the possibility of donors exerting influence on the precise use of their data and tissue in a biobank and particularly in a population biobank. They argue that the original consent could still be broad and open regarding research uses, but co-determination does however require transparency for donors: ‘they must be kept updated on current and envisaged future use of the material’. In this conceptual framework the donor is not considered as ‘an indifferent supplier of research tissues but as a partner, who by his or her donation enables research’. Gundermann and Stockter see that the principle of co-determination drawn from law would require the biobank to keep the donors informed about these new developments. This approach is very similar to Winickoff who uses corporate law models of shareholders to argue for greater rights for biobank participants.

In Chapter 5, Otlowski argues in favour of a broad consent for biobanks, by proposing a hybrid model that involves ‘informed and specific consent for the collection and storage of samples and information, and broad consent for future use for presently unspecified research’. She argues that consent needs to be reconceptualized in the context of biobanks. She says that although all future research projects cannot be specified at the time samples and information are collected, the core principles consent aims to uphold can and must be protected. When being asked for a broad consent individuals must have ‘enough information to understand the general nature of what the research is about’. Otlowski believes that broad consent operates best in ‘a well regulated and protective environment augmented by a strong governance regime: indeed, it would be a mistake to rely on consent as the sole basis of protecting research participants’.

In the new Spanish law on biobanks, as described in Chapter 6 by Casado da Rocha and Etxeberria Agiriano, there has been a move towards a ‘flexible, middle way’ in between a broad consent and informed consent. This Act allows for the possibility that individuals might give explicit consent to the use of their samples for one kind of research project and then consent to further unspecified uses of

the samples in projects that are related to the original research project, whether by the same team or another. It is up to a Research Ethics Committee supervising the biobank to make the decision on the unspecified research on the donor's behalf. Although this 'governance-by-committee' approach is still being developed, there are already many exceptions to consent for biobanks in the new Spanish law, and Casado da Rocha and Etxeberria Agiriano have concerns that it might prove to be a slippery slope whereby the requirement for consent is progressively eroded away.

Hens and Dierickx question whether children should be excluded from genetic research and the storage of their samples in pediatric biobanks. In Chapter 7 they acknowledge that the storage of tissue from minors and subsequent research conducted using this tissue, raise ethical issues that do not arise for adults. In particular: (1) the question of consent; (2) the strict requirement in pediatric research that research should pose no more than minimal harm; and (3) that there should be direct benefits to either the child or the group to which he or she belongs. Hens and Dierickx argue that with proper policies and procedures that take these issues into account, there is no need for a ban on involving children in biobanks or genetic research.

In Chapter 8, Cadigan and Davis present findings from a study of healthy volunteers who were approached to enrol in the Environmental Polymorphisms Registry (EPR), based in North Carolina in the US. What is particularly interesting about this study is that it involved interviews both with people who had agreed to enrol in the study, as well as those who had declined to be involved. The chapter discusses the importance of financial incentives and existing governance mechanisms to those who chose to donate a sample of blood to the biobank. However, for those who chose not to participate in the EPR, financial rewards and knowledge about governance safeguards, such as research ethics committee approval, Certificates of Confidentiality, and institutional reputation, did little to allay their concerns about privacy and involvement in a longitudinal genetic research study.

Privacy and access to data

Ensuring the privacy of donors, their relatives and genetic communities, remains a central issue for the governance of biobanks. Regardless of where we might stand on the uniqueness of genetic information and the privacy rights of individuals versus more utilitarian principles, the potential for donors to be harmed through the disclosure of sensitive genetic information is widely accepted. The principle driving developments in this area then is not simply the protection of individual privacy *per se*; it is fortified by the principle that donors and their genetically significant others should be protected from harm *caused* by breaches of privacy. The problem of protecting these people from harm is compounded by the need for samples to be identifiable and linked to other personal information. Providing researchers with access to samples and data in a form that is both useful to them

and protects the privacy of donors is problematic; it is further complicated when the researchers work under different governance structures and within different regulatory frameworks. The chapters in this section explore a range of problems and potential solutions associated with the protection of privacy in biobanking.

Townend, Taylor, Wright and Wickins-Drazilova report on some of the preliminary findings from the PRIVILEGED Project. The project is looking at the ethical and legal interests in privacy and data protection in relation to biobanks and genetic databases. In Chapter 9 they discuss the results of a review of research literature from across Europe looking at the public's attitudes and opinions in relation to genetic databases and biobanking. Townend et al. conclude that while there are typically majority positions, these are expressed within a wide range of attitudes and opinions. Simply allowing the majority views to dictate policy for biobank governance, they suggest, would result in the alienation of significant minorities, and that this could undermine the potential value of biobanks. While they recognize the impossibility of encompassing all opinions within a regulatory framework, they maintain that 'an iterative process can be imagined that would, if undertaken, progressively identify the widest range of options for participants consistent with effective research'.

In Chapter 10, Skene considers 'the nature, extent and enforceability of the legal duties' that custodians of biobanks, researchers and other biobank users may owe to donors and perhaps even their relatives, in the case of 'significant findings'. She regards significant findings as those where: '(1) the risk for disease is significant; (2) the disease has important health implications (i.e. fatal or substantial morbidity); and (3) there is a proven therapeutic or preventative intervention available'. Skene discusses Australian law and whether an obligation of feedback exists under statute, contract law, the duty of negligence, the doctrine of confidentiality, privacy statute or property rights. She concludes that it is unlikely that a legal obligation would arise, though she believes that a biobank would have a duty to consider how to make information available under the National Health and Medical Research Council guidelines, rather than to directly warn research participants at risk.

The chapter by Zarabzadeh, Watson, Bradley, and Grimson (Chapter 11) describes the measures that have been put in place for the Irish Prostate Cancer Research Consortium (PCRC) biobank. The PCRC research biobank stores tissue, blood urine and DNA that has been used for diagnosis and determining clinical care. The biobank's infrastructure enables research to be carried out using the samples and information held within the consortium. This is an example of where the divide between the clinic and research has been bridged for the benefit of cancer patients and the wider community. Zarabzadeh et al. maintain that infrastructure design and the standard operating procedures have been developed in accordance with data protection principles, in an effort to ensure the highest standards of confidentiality. The PCRC biobank is said to provide a model that could be used for biobanks elsewhere in order to enable researchers to make greater use of such resources.

In Chapter 12, Rial-Sebbag, Mahalatchimy, Chartier, and Cambon-Thomsen report on an internet-based research tool called hSERN. This tool is designed to provide researchers with the information required to transfer human biological materials (HBM) between France and the United Kingdom (to be extended to other European countries). ‘While biobanks are designed to make HBM more accessible to a large number of researchers, they do not necessarily address the procedural issues of how to transfer HBM between biobanks located in different countries’. hSERN came out of the recognition that regulations affecting the movement of HBM across national borders can be a major stumbling block to research progress. hSERN enables researchers to collaborate and can underpin biobanking activities. The different legal requirements that apply within Europe are a serious obstacle to the network of biobanks described by Kaye (following chapter). This tool has the potential to bring significant benefits to researchers, the development of infrastructure as described by Zarabzadeh et al. and the networking of biobanks in general.

In Chapter 13, Kaye starts to explore the issues raised by the development of European infrastructure that will lead to large-scale linkage and sharing of samples and information that are held in biobanks. Such infrastructure, that are still in the process of being developed, would enable researchers to be able to access a number of biobanks at the same time through one portal rather than approaching each biobank for access individually. Kaye sees this as the next logical step from the development of common standards and procedures by organizations such as the Public Population Project in Genomics (P³G). However, such initiatives create a number of challenges, particularly for the protection of privacy and informed consent. The difficulty with such proposals is that the legal framework and the governance bodies are nationally based and are currently unable to govern infrastructure of this sort.

Governing bodies

While we strive towards some level of standardization, the governance structures of biobanks are necessarily context specific. As each new biobank is established those involved in its development can draw on the experiences of those before them, adopting and adapting principles and practice that suit the particular aims of their facility and the legal, social, cultural and political environments in which they will operate. As noted above, this environment will increasingly include networking between biobanks and even across national borders. But the governance of biobanks is not restricted to the in-house mechanisms of the facilities. It also reaches out into the community in various ways – through ethics committees, public engagement mechanisms and regulatory bodies. A key role of governing bodies is to interpret accepted principles through policies and guidelines, and ensure they are put into practice. The chapters in this section provide an overview and critique of some of the models of biobank governance emerging around the globe.

The chapter by Bédard, Wallace, Lazor and Knoppers (Chapter 14) discusses a study of governance systems for population biobanks that were a part of the P³G consortium. The research was conducted in order to provide a basis for the design of the governance structures for the CARTaGENE population biobank in Quebec, Canada. This study shows that these biobanks are embedded in a complex regulatory framework involving six ‘elements’ or sets of governance procedures: (1) scientific evaluation; (2) ethics evaluation; (3) data protection and public health laws, and laws on statistics; (4) bio-security standards for laboratories; (5) guidelines for research with human participants; and (6) professional guidelines. Despite these common elements, the study found that there were also significant differences between the governance structures that reflected the particular context in which the biobanks operated. Bédard et al. concluded that ‘[n]o one governance framework could be determined that would fit all biobanks’. However, they suggest that in the future it may be possible to arrive at an ‘optimal governance framework for a population biobank’.

In Chapter 15, Richards, Hunt and Laurie provide a description of the UK Biobank’s Ethics and Governance Council (which is one of the committees included in the study conducted by Bédard et al.). This Council was established as an addition to the existing UK research governance and regulatory systems because of the nature of UK Biobank as a very large scale and complex project with very broad purposes and long-term aims. Unlike research ethics committees it can undertake continuing monitoring. And the Ethics and Governance Framework with the independent Ethics and Governance Council as its guardian provide a further safeguard and a foundation for trust. According to Richards et al. ‘a body such as the EGC can add value to a governance model by actively monitoring and developing alongside the scientific project’. In the case of the EGC, it has taken on a number of different tasks, such as commissioning research, tracking the concerns of research participants, and providing ethical advice to the UK Biobank.

In Chapter 16, Lemmens and Austin discuss how a combination of various developments makes it increasingly difficult to protect privacy through informed consent procedures alone. They discuss how the concept of Fair Information Practices (FIP) offers an interesting model for a more coherent governance system of health information. This model has already been introduced in the context of research by various Canadian provinces. They say that the promotion of the integration of FIP into the existing system of research ethics review has been done ‘without appropriate recognition of the structural weaknesses of the current regulatory regime surrounding research’. This development is particularly important in the context of biobank governance as health information privacy legislation will govern many of the aspects of the collection, use and disclosure of information associated with these biobanks. These privacy statutes do not provide a detailed regulatory framework for the research ethics boards that have to promote and enforce the Fair Information Practices. Lemmens and Austin argue that research ethics boards, as currently regulated, are inappropriate to carry out this activity because the existing ethics review structure does not fulfil established

minimum criteria for good governance. They go on to describe an alternative governance model that has been developed in British Columbia (Canada), involving Data Stewardship Committees. These committees have a number of lay representatives, a legislative base and are clearly accountable to the government.

Weisbrot's Chapter 17 demonstrates the important role of government bodies in carrying out community consultation exercises and how these exercises provide a basis for the development of recommendations to government. This chapter provides an insight into two successful public consultation processes held in 2003 and 2008, conducted by the Australian Law Reform Commission that dealt directly with the ethical, legal and social implications of human genetic research and the governance of biobanks. The consultation processes identified a range of concerns that fell into four broad categories: ethical oversight; biobank governance; commercialization, access and equity, and benefit sharing; and genetic discrimination. He argues that 'policy-makers must address the associated, and very legitimate, concerns expressed by members of the community, or else risk a backlash that would dramatically set back all such research, however well-designed and intentioned'. Weisbrot concludes that there is a clear need for openness and transparency if biobanking and population genetics initiatives are to benefit from public confidence. He says experience to date clearly shows that taking ethics and governance seriously is essential for achieving public acceptance and legitimacy, and inherent in this is engaging in community consultation early and on an ongoing basis.

Conclusion

As biobanks flourish across the globe in response to the demands of research and commerce, they do so largely ahead of adequate regulatory frameworks, transcending national borders, pushing the boundaries between public and private enterprise models, pioneering new forms of governance, and embracing the *need* for public engagement (if not the democratic principles behind it). It is essential that those of us engaged in the ELSI of biobanks keep abreast of these global developments. It is to this end that this volume and others like it serve as an important resource.

The themes that have given a framework for the discussions presented here represent key areas around which basic principles for biobank governance have been forming. While debates continue to define and refine the principles in abstract, biobanks themselves are shaping them through practice.

Advances in technology and the momentum towards the integration of collections, and the sharing of data and tissue between biobanks, research teams and across legal jurisdictions, all contribute to an evolving research environment. Governance structures risk becoming redundant if they fail to incorporate mechanisms that facilitate timely adaptation to changing circumstances. Well designed and implemented public engagement processes (as opposed to public

relations programs) that are integrated into governance structures, have the potential to function as mechanisms for adaptation.

Public engagement should not be considered as simply a necessary step on the way to establishing a biobank – a box to be ticked and move on – rather it is essential that it becomes an integral part of the overall governance structure of the biobank. This is especially the case given the rapidly evolving nature of the science and research environment and the fluid societies in which they operate.

A biobank governed by regulations, policies and guidelines (informed by public consultation), that is engaged in open ongoing dialogue with its publics, stands the best chance of fostering and maintaining the public trust and support necessary for its successful operation. But even given this ideal, the governing bodies involved will need to steer a path through sometimes competing principles – the principles of good science and those of a liberal democracy are not always in harmony. The chapters that follow do not provide definitive answers to the problems of biobank governance, but they do contribute substantially to the ongoing dialogue that must accompany the organic process that is biobank governance.

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