

# Consent, Privacy & Research Biobanks



Policy Brief No. 1

## Editor's Preface

*GPS: Where Genomics, Public Policy and Society Meet* is an Ottawa GE<sup>3</sup>LS Series led by Genome Canada to bring together leading researchers and senior federal policy-makers to explore options for addressing public policy issues at the interface of genomics and society. The resulting "Policy Directions Briefs" present the evidence base needed to support informed debate on a range of policy options, while deliberately stopping short of making any recommendations. Topics are selected on the basis of their broad societal importance, national interest, relevance to federal policy-makers, and "ripeness" for policy uptake.

Co-authors of the Policy Briefs are renowned leaders in the field, commissioned by Genome Canada to synthesize the current state of academic knowledge on a given topic and translate it into a format and language familiar to senior federal policy makers. Co-authors are asked to present a well-balanced range of feasible policy options, as neutrally as possible, and avoid favoring any particular position over another. The Policy Brief is not intended to reflect the authors' own views or opinions, nor those of Genome Canada.

The co-authors have benefited from valuable commentary of national and international experts and relevant stakeholders convened at a half-day event in Ottawa organized by Genome Canada and its Core Advisory Partners. In order to assure excellent quality, practical relevance and suitability for its intended purpose, the draft brief was then submitted to a small review committee in accordance with an explicit peer review process. The intent of these Policy Briefs is to provide a neutral, credible and legitimate source of information for policy-makers on important societal questions at the rock face of emerging genomics technologies and their applications.

- Patricia Kosseim

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## Executive Summary

In March 2009, Time Magazine picked biobanking as one of the TOP 10 Ideas changing the world right now. Indeed, large biobanks, linked with health, demographic and administrative data, are proliferating in countries around the world, not least of which is Canada. Scientists are poised internationally with an unprecedented ability to tease out complex interactions between genes and environment, enhancing our understanding of health and disease and paving the way towards a future of personalized medicine and public health. Meanwhile, existing legal and policy frameworks for personal data protection are founded on the concept of informed consent, the application of which has proven to be challenging for advancing biobank research and related scientific progress in Canada. This Policy Brief explores three possible policy options for implementing the concept of consent in the context of research biobanks: 1) specific and fully informed consent for each project; 2) broad initial consent accompanied by appropriate governance; and 3) opt-out model. The types of research biobanks being contemplated include: large population-based biobanks, disease-specific biobanks and biobanks created from left-over archival tissue originally collected in the context of clinical care.

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## I. The Context

The environment, socioeconomic status, diet, education, access to health care, gender, ethnicity and genetics are but a few of the complex, overlapping and inter-related factors known to contribute to health and disease. Given the innumerable variables involved, researching health issues can be a tremendously daunting task. Researchers need enough data to be able to understand the role and interaction of each potentially relevant contributing factor, including genetic factors. As such, biobanks are emerging as a common research tool for exploring the research questions. Indeed, in March 2009 *Time Magazine* picked biobanking as one of the Top 10 Ideas that are changing the world right now.

There has been growing interest in the development of large, population based, longitudinal research projects that include the collection, storage and long-term analysis of human tissue linked with a wide range of updatable health and demographic information, no longer limited to the clinical environment. Many of these population biobanks involve large numbers of participants (for example, the UK Biobank project is aiming for 500,000, see <http://www.ukbiobank.ac.uk/>). Just among the members of an international consortium (the Public Population Project in Genomics (P<sup>3</sup>G)), comprising 30 such biobanks from 47 different countries, there are an estimated 5 million participants whose data can be shared “virtually” on a large number of variables. In some jurisdictions, emerging biobanks are even being linked to existing tissue repositories and clinical data across borders (<http://www.bbMRI.eu/>).

The Canadian research community has made its own significant commitment to biobanking – investing millions of provincial and federal dollars in a variety of research initiatives. For example, large longitudinal studies such as the Canadian Partnership for Tomorrow Project (CPTP) and the Canadian Longitudinal Study on Aging (CLSA) are recruiting consenting volunteers across several provinces and involve the prospective collection of relevant health information and biosamples, with possible linkage to a range of other data sources (e.g., administrative health records). The hope is that these types of large, longitudinal databanks will provide an unprecedented ability to tease out the complex interaction between genes and environment and to better understand their impact on health or the disease process.

In general, most in the scientific community seem to agree that large-scale biobanks have great scientific potential for understanding “genomic variation” and the “normal” distribution of health and disease. A recent European Science Foundation Report said biobanks are “indispensable” and will “play a key role in achieving the medical paradigm shift from ‘cure’ to ‘prevention’” (2008). However, it should be noted that these initiatives are not without their critics (Watts, 2006; Giles, 2006; Ghosh, 2003).

## II. The Issue

Biobanks present consent challenges. The issue is whether consent mechanisms can be developed to allow research access and use of biobanks to move forward but still respect participants' rights and interests.<sup>1</sup> This is not a simple task. As noted by Elger and Caplan: "The challenge produced by biobanks is immense: after more than 50 years of classical health research ethics, regulatory agencies have begun to question fundamental ethical milestones."

In general, traditional consent norms require researchers to get consent for each specific research project. However, large-scale, longitudinal population studies are designed to serve as long term research platforms and will receive access requests from thousands of research projects spread over many decades. On the one hand, getting specific consent for each project from each research participant would clearly meet traditional consent norms. On the other hand, doing so could entail prohibitively high costs, both in financial terms and research resources and may even contradict the wishes of participants who are willing to provide their samples for future, unspecified research and would prefer not to be re-contacted for every specific project.

In addition to longitudinal studies, there is a range of different biobanking practices. For example, researchers working on specific conditions have long collected data and samples. These disease-specific initiatives were (and are) often limited to narrowly defined areas or to specific genes. However, increasingly these resources are now being contemplated for studies on a broader range of related conditions. In addition, disease specific studies can evolve into studies that cover other biomedical issues. Whether research for other related (or unrelated) purposes fits within the scope of the original consent is often in issue.

There are also biobanks that contain tissues collected during clinical care, such as when tissue is removed for biopsy, surgery, diagnosis or follow-up. These archived tissues are not always destroyed and can serve as an important research resource years after their collection. Researchers may seek ways to retrospectively access these materials, but having to locate and re-contact individuals to obtain their consent in these contexts can be particularly challenging.

This policy brief explores three (basic) consent options for addressing these challenges. Longitudinal population biobanks are the primary scenario under study, but the discussion and proposed consent options touch upon and have relevance for the other types of biobanks as well.

## III. Legal – Policy Background

The issue of consent in the context of biobanking must be examined against the backdrop of Canadian consent case law, legislation and research ethics policy.<sup>2</sup> Canada has a rich legal tradition in the area of consent. While not pronouncing on consent in the research context, the Supreme Court of Canada has several decisions emphasizing the importance of informed consent (*Reibl v. Hughes* (1980); *Ciarlariello v. Schacter* (1993)). Likewise, the SCC has noted on several occasions that health information and tissue "remain in a fundamental sense one's own" (*R. v. Dyment*, (1988)) and that such information "goes to the personal integrity and autonomy" of the individual (*McInerney v. MacDonald* (1992)).

Most Canadian consent cases deal with personal information generated in the clinical setting, but the principles enumerated do not seem to be restricted to that environment. In total, this case law emphasizes the right of continuing control of personal information – generally through informed consent. And the obligations of consent are heightened further in the context of research. It has been called the most exacting duty possible (Picard and Robertson, 1996). This truism of consent in the context of research was recently reiterated in a report by UNESCO's International Bioethics Committee: "Informed consent is a fundamental principle that has marked the emergence of modern medical ethics based on personal autonomy" (2008).

While the obligation to obtain consent when using health and other personal information is a strong norm in Canada, other social goals, including the pursuit of research, have had an influence on Canadian consent laws. This balancing is most clearly reflected in provincial health information legislation which permits non-consensual exceptions for research (see Kosseim, Kardash, Penta, 2005). To cite just one example, Alberta's *Health Information Act* notes that researchers can use identifiable personal health information without consent (or with a modified consent), so long as certain

<sup>1</sup> By design, this policy brief is limited to the issue of consent. And this topic is largely explored from the context of law and existing research ethics policy. But we do not mean to imply that consent should be the sole focus of policy discussions in this context. Or that consent can address the myriad issues. On the contrary, the fostering of public trust, the need for public engagement and the development of independent governance are but some of the other approaches that need to be considered in the context of biobanks. There are also numerous consent issues that do not fall within the scope of this brief (see Archibald and Lemmens, 2008).

<sup>2</sup> There are a wide range of social norms, legal instruments and ethics policies relevant to biobanks (see Chart I). Here, we concentrate on Canadian policies and norms.

conditions are satisfied, including an approval by an ethics committee which must consider the public interest in the proposed research, the qualifications of the researcher, the privacy safeguards, and whether consent is not practical or feasible (s. 50). Other data protection laws across the country have similar exemptions, but differ in their criteria for application.

Canadian researchers conducting research under the auspices of an institution receiving federal research funds must also comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998).<sup>3</sup> This document, which is Canada's de facto research ethics policy, can be viewed as supplementing the law (the law would be paramount if it is stricter than TCPS policy). Like the law, the TCPS emphasizes the importance of informed consent. However, the TCPS also contains an exception to the requirement to get specific consent, such as when, *inter alia*, the Research Ethics Board (REB) considers that the research is of minimal risk to participants, the consent waiver is unlikely to affect the rights and welfare of participants and the research cannot be practically carried out otherwise (Article 2.1). That said, the TCPS also re-iterates the importance of informed consent in the context of genetic research (Article 8.1) and, especially, in banking of genetic material (Article 8.6). Most significant, however, is Article 10, which seems to require quite specific consent for each research project involving tissue collection. Indeed, Article 10 states that research participants should be told, at a minimum, about the purpose of the research; the potential uses for the tissue including any commercial uses; the safeguards to protect the individual's privacy and confidentiality; identifying information attached to specific tissue, and its potential traceability; and how the use of the tissue could affect privacy.

In total, it can be said that Canadian law and ethics policy is built on a tradition of consent for specific research projects, with permissible exceptions under certain conditions. However, the application of existing law and ethics policy to biobanks is far from clear – as highlighted by the variability in existing laws and conflicting sections of the TCPS. As such, questions remain regarding whether existing law and policy would, for example, require researchers to re-consent all individuals who donated tissue for one specific purpose if the researchers wanted to use it, in a linked manner, for another purpose. Likewise, do Canadian consent norms require a

re-consenting of all individuals involved in a longitudinal population biobank for each research project? The fact that biobank research triggers this uncertainty about the application of policy frameworks highlights the degree to which various different kinds of biobanks can challenge the existing system. Indeed, it seems certain that the existing law and ethics policies were not developed with, for example, the large-scale biobanking in mind. In addition, there is no Canadian law directly on point.

#### IV. Consent Options

Given this policy dilemma, how best to move forward? Here, for purposes of discussion, we provide three options.<sup>4</sup>

##### **Option 1 – Require specific and fully informed consent for each project**

Because this is the most cautious and traditional approach, it would obviously satisfy existing consent norms and research ethics policy. It is a practice that works well for disease-specific projects that have a finite purpose (though, as noted, even these studies can evolve – perhaps even beyond the parameters of the original consent). However, this approach would do nothing to ameliorate the research efficiency concerns outlined above in relation to large population biobanks. Indeed, some (though not all) commentators are of the view that this approach would make many large-scale, longitudinal population biobanking projects too costly and cumbersome to undertake. Also, the approach does not respect the wishes of individuals who may want to be involved in biobanking initiatives/platforms, but do not want to be bothered with the re-consenting process. In other words, it could be argued that *requiring* another consent for each project does not respect the autonomous wishes of participants in longitudinal studies who have agreed to future research uses via the broad consent process and would prefer not to be re-contacted for each specific study. Finally, there is some concern regarding a possible “consent bias” that could have an adverse impact on research outcomes (Kho, et al., 2009).

<sup>3</sup> The TCPS is currently being revised. See <http://www.pre.ethics.gc.ca/eng/index/>. The new version of the TCPS may well change a number of the relevant provisions. Indeed, both the 2008 and 2009 drafts can be interpreted as not requiring ethics review or re-consent for secondary access where the researcher cannot reasonably re-identify the individual.

<sup>4</sup> This is not, obviously, a comprehensive review of all consent issues. Nor do the three options represent all possible approaches. However, these options help to illustrate and surface the relevant policy dilemmas and tensions.

### Option 2 – Broad initial consent accompanied with appropriate governance

In this approach, participants are asked to provide broad consent for biomedical research generally,<sup>5</sup> even though details of all possible future research projects cannot be given. The consent process includes the provision of a wide range of information, including privacy issues, the nature and limits (if any) on the right to withdraw, what information will be fed back to the participants, and who will have access to the research data. By their nature, longitudinal biobanks foresee going back for repeat questionnaires and samples, thereby providing an opportunity for renewing consent and the right to withdraw through participant response over time. An independent oversight committee is established to which future research protocols are submitted for review and approval.<sup>6</sup> The committee would determine whether a given research project fits within the spirit of the initial broad consent. If not, re-consent would be required. The existence of this process for determining re-consent is an explicit part of the initial broad consent. Another common element of this approach includes the provisions of updates about the research to all research participants (which serves as a reminder of involvement and affords the opportunity to consider withdrawal). This approach attempts to strike a balance between respecting the rights and interests of research participants, while still allowing the research to move forward in a relatively efficient manner. As such, it is not surprising that broad consent with governance seems to be the emerging model within the population biobanking research community. That said, the appropriateness of a broad consent for future use is not universally accepted – primarily because some critics believe that one of the key elements of consent, that it be informed, cannot be satisfied (Salvaterra, et al., 2008; Mascalzoni et al., 2008; Takala, 2007; and Hofmann, 2009). As such, the legality of the approach remains an issue. Others argue that so long as the broad consent is thorough

and includes a discussion of the goals and relevant process, it is, in fact, informed (Nömper, 2005). This division in opinion can also be found in international policies. The recent UNESCO document (noted above), while not addressing biobanks specifically, rejects the idea of broad consent for unspecified future use (Article 54), but the OECD biobanking guidelines endorse the concept, so long as appropriate governance structures exist and the “use of human biological materials and data” is “consistent with the original informed consent” (2009).

### Option 3 – Opt-out model

This third option could be implemented by creating an opt-out scheme whereby individuals are notified that research is ongoing but are only required to explicitly express a desire not to be in a biobank initiative. In other words, individuals would be in the biobank (that is, their existing healthcare information and, perhaps, available genetic data) unless they made some kind of express pronouncement that they wished to remain out of the biobank. It would, of course, include some kind of notice regarding the existence and nature of the biobank. This approach has a precedent, at least in the context of access to healthcare data. Iceland’s DeCode biobanking initiative was created via national legislation and built around a presumed consent, or opt-out, strategy (the *Health Sector Database Act*). Likewise, Vanderbilt University has implemented an opt-out system (Pulley, 2007). While attractive from a research and efficiency perspective, the presumed consent strategy (which would likely require legislative amendments in each province) would cut against the well-established consent norms outlined above. Indeed, the approach used in Iceland received a great deal of criticism and was the subject of a successful constitutional challenge (see *Guomundsdottir v. Iceland*, 2003).

	Option 1: Specific Consent	Option 2: Broad Consent	Option 3: Opt-Out
<b>Possible Advantage</b>	Clearly complies with existing consent norms.	Allows future use while still providing an opportunity to consent.	Efficient and unambiguous for researchers.
<b>Possible Disadvantage</b>	Does not address the re-consent/future use dilemmas.	Some uncertainty about compliance with ethical and legal norms.	Challenges or (perhaps) conflicts with existing legal and ethical norms.
<b>Example Biobank Use</b>	Prospective, disease specific.	Large, population based longitudinal studies.	Biobanks that use tissues-data collected during care

<sup>5</sup> For some commentators, there is a subtle difference between “broad” and “blanket” consent – the former referring to consent that has some bounds (e.g., for a general area of research) and the latter referring to a consent that is completely open, a truly “blanket” consent.

<sup>6</sup> Appropriate governance mechanisms are important for a wide range of reasons, such as monitoring access to the biobank and public engagement. Governance goes beyond consent issues. But it is mentioned specifically in connection with option two because it is an explicit part of the consent process. Regardless of the consent approach taken, an appropriate governance strategy should be implemented. And the effectiveness of a governance strategy to mitigate consent challenges will also depend on the degree to which the governance scheme adheres to legal and administrative principles and is independent and trustworthy.

## V. Application

Naturally, different types of biobanks may trigger different consent issues and possible policy responses. One of the three proposed options (or a mix of all three) may be more or less appropriate depending on the nature of the biobank, as noted in the above table. For example, it could be argued (though not all would agree) that higher risk or controversial research may always require specific consent, but low risk work in non-controversial areas might lend itself to an opt-out approach. Moreover, there may be approaches more naturally suited for some forms of biobanks. For instance, the prospective creation of population biobanks generally requires at least an initial visit with participants (which can be quite extensive) in order to collect samples, ask socio-demographic related questions, etc.). Consent is necessarily obtained from research participants at the time data is collected, thereby rendering inappropriate any possible justification for the opt-out model in that context. Finally, these options are not necessarily discrete options and we do not pretend to cover all possible scenarios or possible consent approaches (e.g., see Mascalzoni, et al., 2008). For example, they do not include “multi-layered consent”, an approach that allows participants to choose from a range of different options, which may be suitable for disease-specific studies or residual archives, but far less workable in longitudinal population biobanks.

## VI. Practical considerations

When considering one of the above options, several practical, legal and operationalization issues need to be considered. Some of the most pressing are set out below.

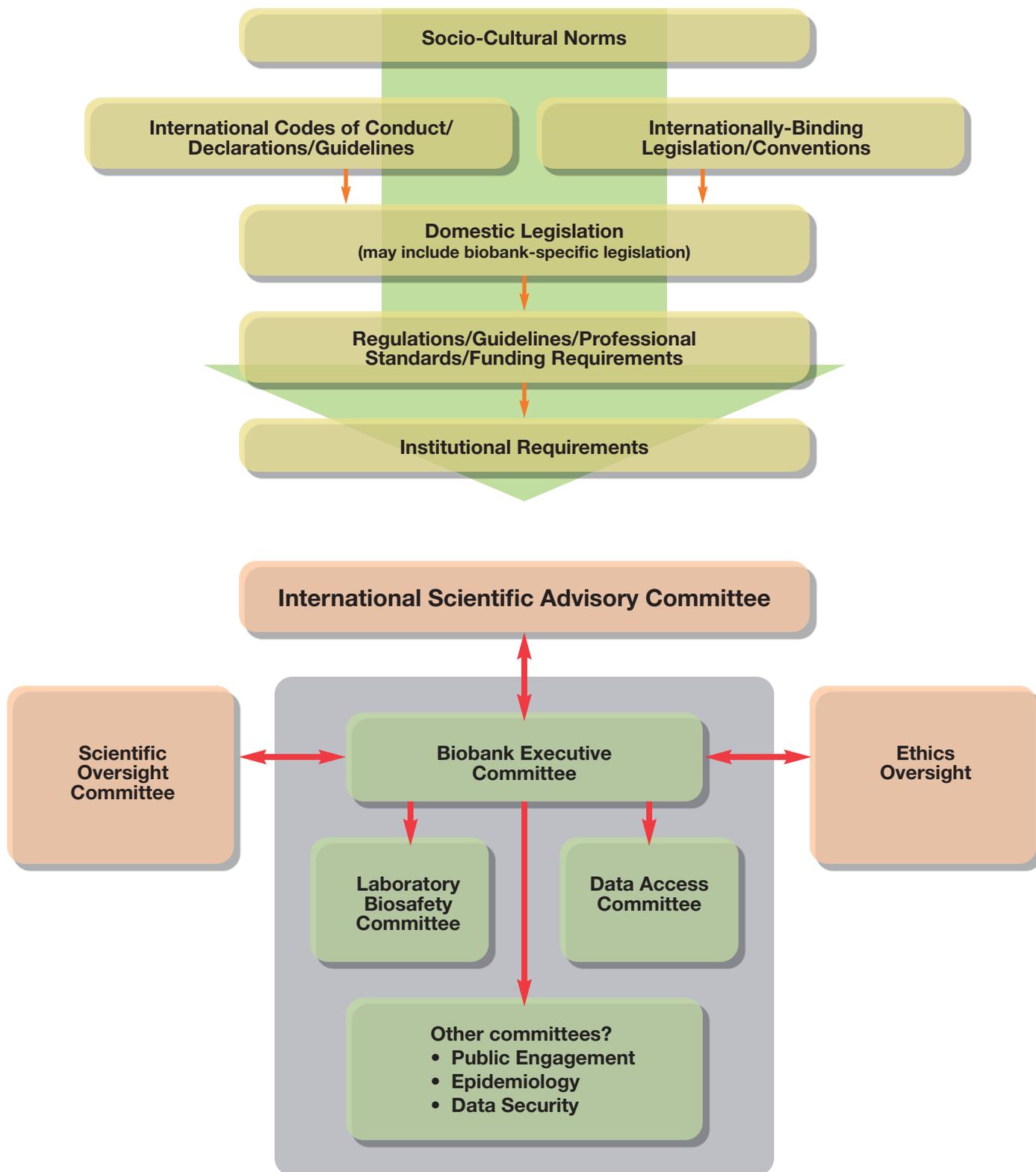
- **Research Ethics Board (REB) Approval and Variation.** As noted above, in Canada, REBs have much of the jurisdiction to determine the acceptability of a consent approach. This power comes via both the relevant health information legislation and existing research ethics frameworks. If a project is large and involves individuals from several provinces, numerous REBs can be involved. To complicate matters, there can be a great deal of variation in the ways in which REBs approach the relevant issues (Goodyear-Smith, 2002). In addition, in many Canadian provinces, the jurisdiction and scope of responsibility for REBs is not always clear, thus adding further uncertainty to the research ethics approval process.
- **Involvement of Pediatric/Incompetent Populations.** When pediatric or incompetent research participants are involved, the consent issues are magnified by issues of capacity (e.g., must you re-consent all minors when they gain capacity to decide for themselves? Must you withdraw biosamples of persons when they lose their mental capacity and there is no legally-recognized substitute decision-making process in place?).
- **Variation in Provincial Health Information and Privacy Laws.** Each province has relevant health information legislation that would need to be satisfied whenever health information is accessed – which will often be the case. In each province, slightly different rules and standards apply. Moreover, any policy action in this area will need to be sensitive to the federal/provincial dynamic. In general, consent is a provincial matter – as such, the provinces will need to be engaged in the policy debates.
- **Legal and Constitutional Uncertainty.** It is unclear how a Canadian court would react to Options 2 or 3. There are no Canadian cases on broad consent to research or on opt-out, but Canadian courts have generally put a heavy emphasis on consent and, in the clinical care context, have rejected the idea of broad consent. Courts have gone some distance to protect privacy (Gibson, 2003) and demand consent for access to personal information, even in the face of other socially laudable goals (*Cheskes v. Ontario* (2007)).
- **Cost and Resources Needed to Implement Governance Framework.** The need for a governance framework emerges in Option 2 but has relevance for all approaches to biobanking. In general, the governance structures that have been recommended are meant to be part of the overall consent and oversight system (e.g., see Caulfield, McGuire, and Cho, 2008). Will it be a challenge to obtain the resources and funds necessary to maintain an effective governance framework?
- **Public Trust and Perception.** There has been a good deal of interesting research on public perceptions (Burgess, et al., 2005) and on the issue of consent (Human Genetics Commission, 2001). For example, a recent study found that “when considering participating in a genomic biobank, individuals want ongoing choices and control over access to their samples and information” (Murphy, et al., 2009). However, as highlighted by recruitment efforts, there does appear to be a sector of society that is willing to provide broad consent (see, for example, <http://www.ukbiobank.ac.uk/>). Given the long-term nature of many types of biobanking initiatives (especially large scale population studies), understanding and responding to public perceptions will be essential. Also, it should not be forgotten that even one consent scandal can have a profound impact on public trust and biobank policy (Seale, et al., 2005). In addition, it has been shown that there are specific activities that can have a particularly profound adverse impact on public trust, such as the commercialization process. The involvement of the private sector in biobanking activities may impact the acceptability of various consent approaches. Certain scientific activities – rightly or not – may also trigger public trust issues (i.e., activities that the public views as particularly controversial). This is also true of certain types of data sharing.

- **Withdrawal of Consent.** While beyond the scope of this document, the challenges surrounding the withdrawal of consent are worth noting. Virtually all research ethics policy statements endorse the idea that individuals can withdraw consent at anytime without providing a reason. For example, the Helsinki Declaration states that the withdrawal of consent can happen “[a]t any time without reprisal” (see also UK Biobank explicit policy: <http://www.ukbiobank.ac.uk/faqs/consent.php>). However, while possible for samples in most cases, operationalizing this right in respect of data may be far more difficult due to aggregation and dissemination.

## VII. Future Research Questions

All of the practical issues raise interesting and important research questions. For example, how will the existing provincial laws and ethics policies be applied and, if necessary, reconciled? What are the effective and most legally appropriate governance structures? How best to engage the public and maintain public trust? Will increased linkages between biobanks and other sources magnify the legal/ethical challenges? If re-consent is needed, what triggers the need: a new project; a linkage to a new databank or other data source; or a controversial application? Will emerging technological advances allow for more ongoing participant contact and participation, thus moderating the re-consent challenge (Kohane, et al, 2007)? At the same time, will technological advances make it increasingly difficult to maintain and “promise” the confidentiality of data? How will “security sustainability” be maintained if a biobank goes bankrupt or loses the necessary funding? And, finally, is an entirely new legal consent framework required?

## Appendix 1: Example Model of Biobank Policy/Oversight



## Further Reading

### Example Policies and Law

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002 and 2005 amendments).

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