



**Policy options:
consent, privacy & research biobanks
Commentary from the International Perspective**

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- Member of the Sub-commission “biobanks” of the **Swiss Academy of Medical Sciences: guidelines on biobanks in Switzerland** (2003-2006)
- Member of the working group **Swiss Academy of Medical Sciences** and **Biobank Suisse** on general consent to biobank research at hospital admission (2007-present)
- Member of the **Swiss federal expert commission required by federal law (since 2007)** which is supposed to control the application of the Swiss federal law on genetic testing (2007 to present).

International research project

- Title: “Human Genetic Databases: Towards a Global Ethical Framework” (2004-2008)
- Collaboration between:
 - WHO (*Dep. of Ethics, Trade, Human Rights and Health Law*)
 - *University of Geneva, Switzerland*
 - *University of Zurich, Switzerland*



The international research project

- Research about the conditions under which genetic databases can be established, kept and used in an ethically acceptable way.

The international research project

- The study is explorative, probing the reasons for disagreement of those involved in the debate – scientists, biobankers, physicians, lawyers and ethicists from different parts of the world.

The international research project

- Book publication fall 2008: Ethical Issues in Governing Biobanks: Global Perspectives, Ashgate



The Ethics and Regulation of Human Genetic Databases Global Perspectives

Edited by
Bernice Elger, Nikola Biller-Andorno,
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- **Book
publication:
Ethical Issues
in Governing
Biobanks:
Global
Perspectives,
Ashgate 2008**

Policy brief by T. Caulfield and B. Knoppers

Commentary based on our experience (international research project):

- Our review of the literature and existing biobanks in order to identify controversial ethical issues in governing biobanks:
 - Does the **policy brief** present a well-balanced spectrum of plausible policy options for addressing them?
 - Did our international research project identify the same most relevant consent options?

Policy brief by T. Caulfield and B. Knoppers

Commentary based on our experience (international research project):

- Semi-structured interviews with 87 respondents worldwide (purposive sampling); different stakeholders (ethicists, ethics committee members, researchers, biobank managers, lawyers etc.)
 - Half of the experts were selected from around the world and stratified according to continents and socio-economic differences;
 - The other half were respondents working in the US at the time of the study, selected to include different ethical traditions.
- **Questions...**

Policy brief by T. Caulfield and B. Knoppers

Commentary based on our experience (international research project):

- Semi-structured interviews with 87 respondents worldwide:
 - Does the **policy brief** discuss in a balanced way the relevant ethical and legal issues associated with each policy option?
 - Are these issues in line with the ethical and legal concerns expressed by the experts from our international study?
 - Do the practical pros and cons identified in the **policy brief** reflect adequately practical considerations described by the experts who participated in our international study?

Policy brief by T. Caulfield and B. Knoppers

Commentary based on our experience (international research project):

- If international expert identified additional issues, are they relevant in the Canadian context? (yes, globalisation...)
- Future research questions to be addressed?

International commentary on the policy brief by T. Caulfield and B. Knoppers

- Did the international research project identify the same most relevant consent options?
- Overall on all evaluative questions the policy brief “scored” very well from an international perspective.
- We think two points might be worth to be added:
 - *we identified one more (a fourth) consent option which should be at least briefly discussed: multilayered consent.*
 - *we believe that the details of withdrawal of consent merit a somewhat more detailed discussion.*

International commentary on the policy brief by T. Caulfield and B. Knoppers

- A fourth consent option...

Consent: policy options

- For the biobank vignette used in our international study, four options of consent were proposed among which participants should choose:
 - **New informed consent:** For each new study not known at the time of recruitment, participants will be re-contacted and asked for their explicit consent.
 - **General consent:** Participants will be explicitly asked initially whether they agree to their samples and associated information being used for further yet unknown research projects.
 - **Presumed consent:** For each new study not known at the time of recruitment, participants will be informed and offered a chance to opt out.
 - **Multilayered consent:** The consent form should allow the participants to choose from the options mentioned above.

Consent: policy options

- The description of the ethical and legal as well as practical pros and cons of the **three** consent options in the policy brief corresponds mostly to the findings of our study.
- Although we think that the **fourth option, multilayered consent**, has serious shortcomings (impractical) and is not ethically indispensable, we think that this option should be mentioned in the policy brief:
 - because it has a long tradition, especially in North America (NBAC 1999 recommendations on research involving human biological materials)
 - because it is proposed regularly by some stakeholders worldwide and the arguments against and in favor should be discussed.

Consent: policy options

- Arguments in favor of multilayered or at least two tiered consent:
 - Biobank participants have the option to choose at least to some extent the conditions of participation, i.e. it is not an all or nothing choice: “either you accept all conditions or you do not participate”. The latter could be considered to be creating pressure to participate under not completely accepted conditions simply because otherwise participation would not be allowed at all.

Consent: policy options

- Arguments against multilayered consent:
 - Psychology of decision-making: more options can also confuse participants and decrease autodetermination.
 - Multiple different consent options increase considerably administrative burdens of biobanks and could also create participation bias.

International commentary: consent

- The **policy brief** acknowledges correctly the controversy concerning consent.
- Indeed, responses in our international study varied considerably when it came to choosing the best policy for consent to research between the four options.

The burden of informed consent

(and of choosing between consent options...)

Preferences for different consent options of the international experts who participated in our study

Results from our international study

- The policy that was most frequently chosen and least frequently ruled out was **general consent**:
 - About 50% of the respondents from Europe and the US as well as from all remaining regions prefer this form of broad consent if research participants have been informed beforehand that their written consent covers further studies on other diseases.
 - More than 25% of the interviewees from outside the US and Europe, compared to less than 10% of respondents from the US and Europe, favored new informed consent for each future study.
 - Presumed consent was the option chosen least often, by only a handful of respondents.
 - More respondents from the US and Europe (one third) than from other regions (approximately one fifth) consider multilayered consent the best option.

Results: consent

Respondents who have used or stored samples

- preferred **general consent more often** than respondents without such prior involvement.
- they chose **new informed consent less often** than non sample users and indicated practical reasons, especially the disproportionate burden of this type of consent.
- for similar practical reasons, a substantial minority of them **criticized multilayered consent**.

These findings can be explained in several ways:

- **On the one hand respondents who used samples are in a better position to know about burdens they may have experienced themselves.**
- **On the other hand, as admitted by several respondents, researchers' attitudes reflect their own interests to avoid inconvenience for research, and they may see the balance with patients rights somewhat differently.**

International commentary on the policy brief by T. Caulfield and B. Knoppers

- Details of withdrawal of consent...

Results of the international study: withdrawal of consent

- The right to withdraw from a research project is a central feature of research ethics generally, but great controversy surrounds the question whether the donors of samples in genetic databases should always be able to withdraw their samples.
- In our study participants were asked to indicate which of four withdrawal policies would be the best and which policies they would rule out.

International study: four withdrawal options

- Concerning the options regarding withdrawal
 - the answers of respondents from Europe, North America and all other regions were similar and
 - no difference was found between the attitudes of respondents who have used or stored samples and those who have not been involved directly with samples

International study: four withdrawal options

- **Option (a) Withdrawal limited to future participation**
 - *limits the right of withdrawal to research participants' abstaining from providing any information and samples in the future. No right to withdraw exists for samples and associated information already submitted to the repository.*
- **Option (b) Withdrawal = anonymization**
 - *restricts the right to withdraw to requesting irreversible anonymization of samples and information. Research would be allowed to go on using the anonymized samples and information.*

International study: four withdrawal options

- **Option (c) Withdrawal = destruction of samples and data in the biobank**
 - *states that withdrawal implies the destruction of any samples and associated information contained in the biobank.*
- **Option (d) Withdrawal = destruction of samples and data in the biobank AND of samples given out to researchers**
 - *extends the destruction of samples and data further in order to include not only the material stored in the biobank, but also any samples and information provided to researchers. The latter will be obliged to destroy the samples and to remove sample information or associated information from any report of research that has not yet been submitted for publication.*

International study: four withdrawal options

- The policy most often chosen is destruction of all material including what has been sent to researchers (option d).
 - this option is favored by more than one third of respondents
 - but also ruled out by another third of interviewees.
- Destruction of all information in the biobank (option c) is the next most favored option.
 - It is preferred by one fourth of respondents and
 - is the policy that was ruled out the least often (by less than 20% of interviewees).

International study: four withdrawal options

The role of empirical questions:

- According to several respondents, before deciding on a policy regarding withdrawal, one needs first to evaluate how frequent withdrawal is. Since the following respondent thought it is probably infrequent according to empirical data, researchers could adopt policy (d).

– *“As long as it is likely to be infrequent, I think you can ask the researchers to do more so I would say [option] (d), and I don't think it's going to be burdensome because all the data suggest that this is not going to be a very common event”*

(#33 US, bioethics, medicine, government, A).

International study: four withdrawal options

The least often chosen options were anonymisation and withdrawal limited to future participation:

- **Anonymisation (option b):**
 - One fifth of respondents favor anonymisation of samples in the case of withdrawal,
 - but almost half of respondents ruled this policy out.
- **Withdrawal limited to future participation (option a):**
 - Less than 15 percent favor no right to withdraw samples and information that have been already provided to the repository
 - This option was the policy most often rejected (more than half of all respondents).

International study: four withdrawal options

Practical reasons against withdrawal:

- *“I would rather have a less comprehensive bank than trying to track and deal with withdrawals. I don’t think banks can be operated this way and deal with that [withdrawal of samples], people move and die and marry, change names...”*

(#98 US, philosophy, medicine, genetics, medicine, university, R/A/S).

International study: four withdrawal options

Attitude against too limited withdrawal - research participants should be allowed to change their mind:

- *“Informed consent has to allow for persons to change their mind, and option (b) does not allow it and option (a) [is] similar. If (a) and (b) are in the informed consent, it is still not acceptable because that presumes of course two things, one that it is perfect informed consent which never ever does occur—there is no such thing as perfect informed consent—and secondly, that things cannot occur temporarily that change a situation whereby a person could say: ‘under these conditions certainly I would consent; under these, no’ ”*

(#80 US, genetics, bioethics, philosophy, theology, university, R/A/S).

The policy brief in the context of the current international debate

Summary

And future research questions...

The policy brief in the context of the current international debate

- Consent

- The policy brief is in line with the answers of the interviewees in our study and reflects the various positions adopted in international guidelines. It is notable that one consent type proposed by the Human Genome Organisation (HUGO 1998), namely presumed consent, is clearly favored less often than the others.
- On the other hand, **general consent**, which remains controversial in many international guidelines on biobanks, is an acceptable option for half of the interviewees in our study. This “attractiveness” of general consent is acknowledged in the policy brief (although legal uncertainties persist regarding the use of this option in Canada).

The policy brief in the context of the current international debate

- Withdrawal

- Our international study demonstrates how important it is that questions about withdrawal are raised and more openly discussed.
- Many studies on biological material stored in biobanks grant the right to withdrawal without explaining what this means for the samples and related information.
- The **policy brief** acknowledges the importance of withdrawal as part of the governance framework including general consent. The silence on details of withdrawal could be simply a question of limited space.

Future research questions to be addressed?

- Withdrawal

- The **policy brief's** silence is in line with the silence of many research protocols and guidelines on details of withdrawal. This could mean that researchers and policy makers don't want to attract attention to this topic for fear of increasing the frequency of withdrawals, similar to the reasoning of one respondent in our study who recommended that biobanks permit withdrawal but avoid encouraging participants to request it.
- Withdrawal of consent is a key element in the justification of general consent. In our view how to frame withdrawal options is an important research question that should be addressed in the future in more detail.

Conclusions about the policy brief (1)

- The policy brief frames and synthesizes adequately the ethical, legal, and socio-economic issues related to consent options for biobanks.
- It summarizes appropriately the extent to which various policy options remain controversial in different parts of Canada as well as among experts of varying geographical and professional origin worldwide.
- In line with our findings the policy brief stresses the increasing support in favor of a governance framework involving general consent: a sizable sector of society is willing to participate in biobank research and to provide some type of broad consent.

Conclusions about the policy brief (2)

- It might be worthwhile to discuss in the policy brief a few additional issues such as multilayered consent and different forms of withdrawal of consent.
- Policy makers should acknowledge the specificities of biobank research and the need to create new legally acceptable frameworks beyond classical concepts of informed consent.
- The present policy brief is an important step in order to further reasonable consent policy for biobanks in Canada. This policy should be in line with international efforts to develop globally acceptable ethical and legal frameworks for research involving biobanks.



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