

Biobanks and Consent Ottawa Policy Meeting

- 1) The three options:***
- a) Broad Consent***
- b) Specific Consent***
- c) Opt-Out***
- 2) Practical Considerations***

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Health Law Institute

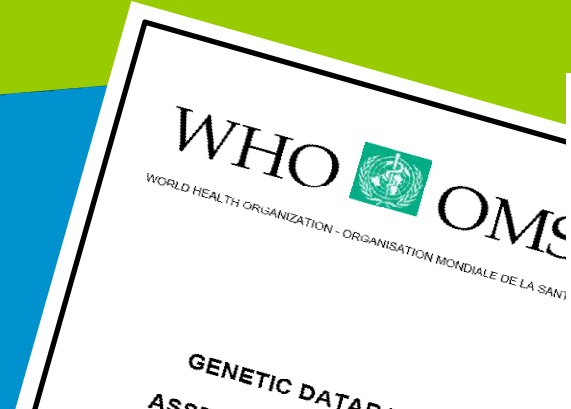
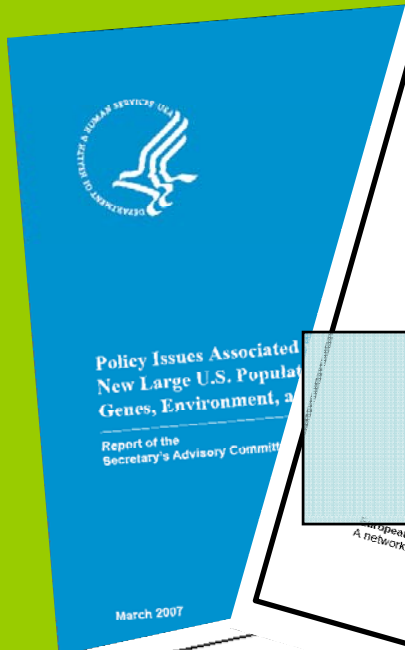


GenomeCanada

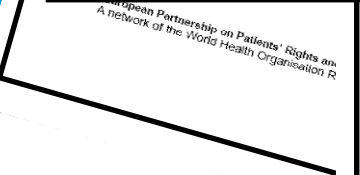
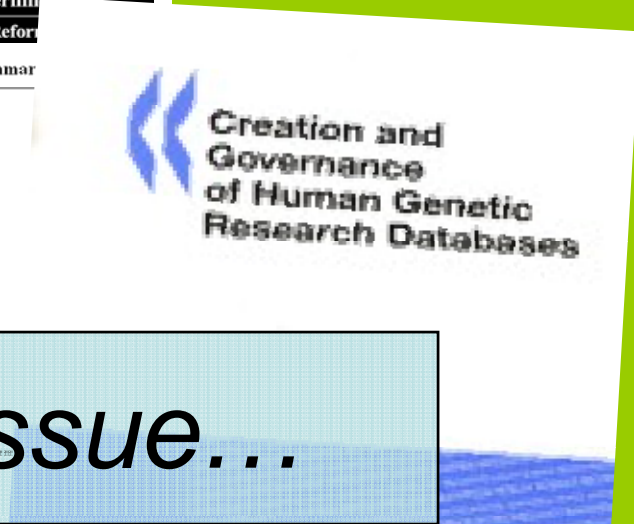
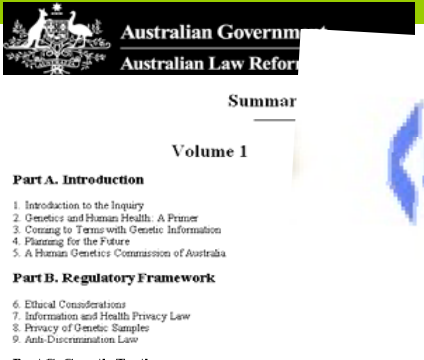


A H F M R

ALBERTA HERITAGE FOUNDATION
FOR MEDICAL RESEARCH



HUGE policy issue...



UK BIOBANK ETHICS AND GOVERNANCE FRAMEWORK
Version 3.0 (October 2007)

UK BIOBANK
Purpose and overview
Organisation and funding

I. RELATIONSHIP WITH PARTICIPANTS

A. RECRUITMENT

- 1. General principles 7
- 2. Selection and approach 8
- 3. Enrolment 9

B. UNDERSTANDINGS AND CONSENT

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- 3. Provision of health information to participants 9
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- 5. Expectation of re-contact 8
- 6. Right to withdraw 9
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- 8. Expectation of personal financial gain 10

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II. RELATIONSHIP WITH RESEARCH USERS 12

A. STEWARDSHIP OF DATA AND SAMPLES 12

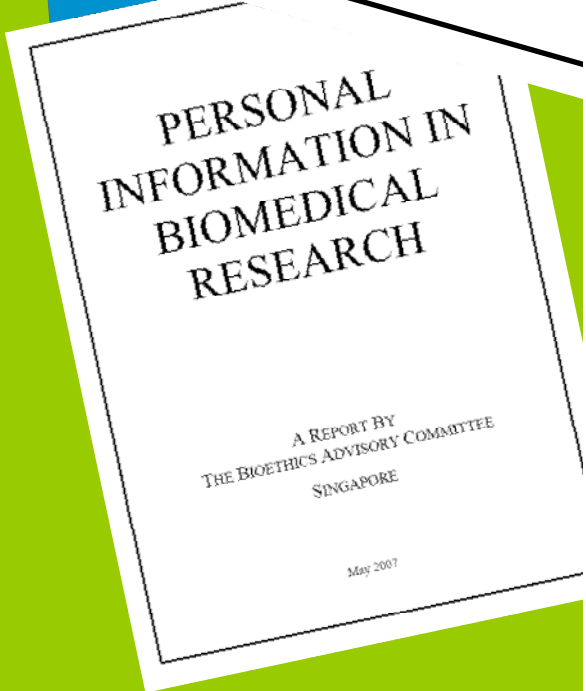
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- 1. General principles of access 12
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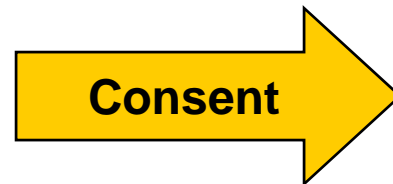
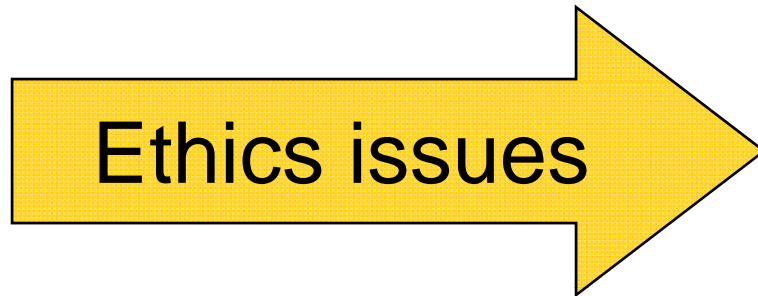
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- 2. Ethics and Governance Council 14
- 3. Steering Committee and International Scientific Advisory Board 15



Frame discussion



Consent can't do everything...

Broad Consent

UNIVERSITY OF
ACCEPTS COPY
RIGHT TO AGGREGATE
AND TO MOLECULAR
CHARACTERISTICS
ANY LOSS OF
RISK INFORMATION
OF TRAITS REMEMBER
A GENERATION
SEARCH FOR
GAGA REPEAT
ACCEPTANCE
ORDER PATIENCE
WISHES OTHER
TECHNOLOGY
OF THE FUTURE

Banking together

A unified model of informed consent for biobanking

Elena Salvaterra, Lucilla Lecchi, Silvia Giovanelli, Barbara Butti, Maria Teresa Bardella, Maria Teresa Moggio, Pier Alberto Bertazzi, Pier Alberto Moggio, Mario Nosotti, Silvano Bosari, Guido Coggi, Domenico A. Coviello, Faustina Lalatta, Massimo Moggio, Alberto Zanella & Paolo Rebutta

Pros:

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Giv

Broad consent is not truly informed consent, but rather is a generic authorization that sacrifices the right of the donor to self-determination in favour of research interests

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NO RESOLUTION!

International Bioethics
of UNESCO (IBC)
INSENT

biological research project
to give an overall prior
to any study that can be
material be irretrievably unlinked

have an consent process that is broad enough to take into account future uses, yet specific enough to address immediate study objectives. There is an ongoing ethical debate about the adequacy of consent when subjects are not provided with details about how their data and specimens will be used.

Specific Consent

UNIVERSITY OF
ACCEPTS COPY
RIGHT TO AGGREGATE
AND TO MOLECULAR
CHARACTERISTICS
ANY LOSS OF
RISK INFORMATION
OF TRAITS REMEMBER
A OPERATION AS
SEARCH FOR
GAGA REPEAT A
ACCEPTANCE HERSELF
CLINICAL AGGREGATE
DISORDER PATIENCE
WISHES OTHER TA
TA OF THE FUTURE

Pros:

Clearly conforms with existing principles.

Cons:

Doesn't address the challenges associated with re-consenting.

Consent bias?

Does not respect individuals' autonomy re broad consent.

Opt Out

UNIVERSITY OF
ACCEPTS COPY
RIGHT TO AGGREGATE
AND TO ANALYZE AND
DISSEMINATE CORRECT
GENETIC INFORMATION
AND TO TRAIT'S REMEMBER
A OPERATION AS
SEARCH FOR CANCER
GAGA REPEAT A
ACCEPTANCE HERSELF
CLINICAL AGGREGATE
DISORDER PATIENCE
WISHES OTHER TO
TAKE ACTION TO
PROTECT FUTURE

Pros:

Potentially the most efficient.

Work well for biobanks involving health system data/tissue.

Cons:

Most legally/ethical challenging.

Public Perspectives on Informed Consent for Biobanking

Juli Murphy, MS, Joan Scott, MS, CGC, David Kaufman, PhD, Gail Geller, MHS, ScD, Lisa LeRoy, PhD, MBA, and Kathy Hudson, PhD

rations

Opinions



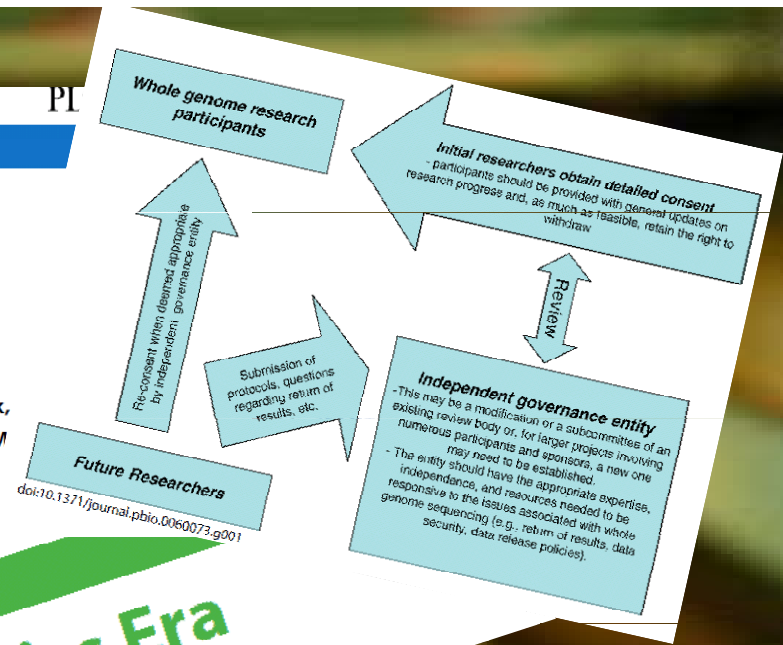
Recruitment experience with broad consent

Our research demonstrates that when considering participating in a genomic biobank, individuals want ongoing choices and control over access to their samples and information. (*Am J Public Health*. 2009;99:■■■■-■■■■. doi:10.2105/AJPH.2008.157099)

Note. Participants were asked if they agreed or disagreed with these statements about how they would feel if they had to give permission for researchers to use their samples and information before each new research project.

Research Ethics Recommendations for Whole-Genome Research: Consensus Statement

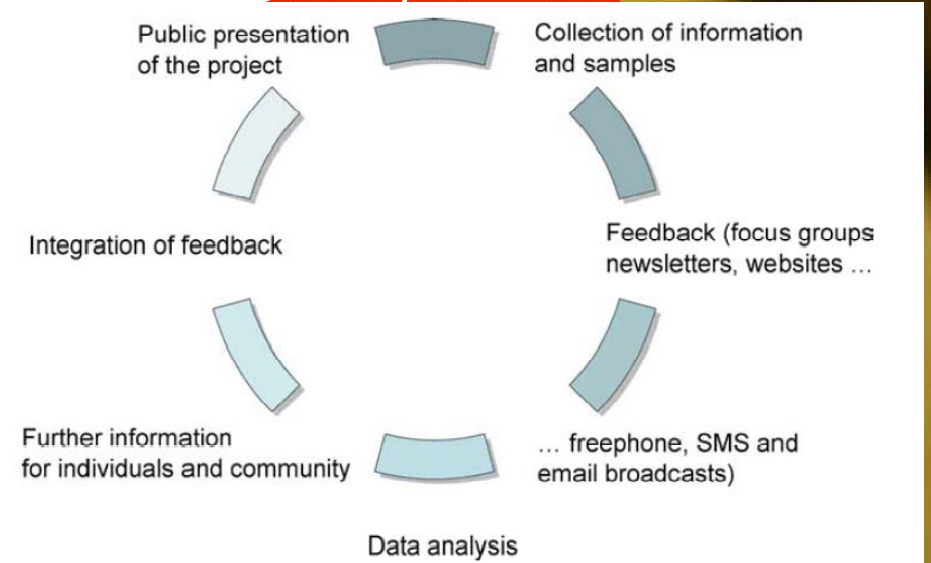
Timothy Caulfield*, Amy L. McGuire, Mildred Cho, Janet A. Buchanan, Michael M. Burgess, Ursula Danilczyk, Kelly Fryer-Edwards, Shane K. Green, Marc A. Hodosh, Eric T. Juengst, Jane Kaye, Laurence Kedes, Bartha M Trudo Lemmens, Eric M. Meslin, Juli Murphy, Robert L. Nussbaum, Margaret Otlowski, Daryl Pullman, Pete Jeremy Sugarman, Michael Timmons



options (re-contact, test

Informed Consent in the Genomics Era

Deborah Mascalzoni, Andrew Hicks, Peter Pramstaller, Matthias Wjst*



doi:10.1371/journal.pmed.0050192.g001

Figure 1. Informed Consent as a Process

Perspective



THANKS

ACCEPTS COPY
RIGHT TO AGGREGATE
AND TO MOLECULAR
BIOLOGICAL CORP
ANY LOSS OF
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