Moving Beyond Consent: Deliberative Community Engagement as an Approach to Research Governance

Barbara A. Koenig, Ph.D.
University of California, San Francisco
Cincinnati, OH, March 13, 2015
The Bioethics Story
Premise

• Research is dynamic

• Rapid social transformations
  • data sharing
  • privacy
  • trust/trustworthiness
Rapidly Changing Research Environments in Genomics

Static Regulatory Systems!
We are in a “post-Belmont” world
Biobanks and tissue repositories present unique challenges to human subjects protection (“BIG DATA”):

• How much “work” can informed consent do?
• Should we rely more on “governance” and best practices?
• If so, how implemented?
The White House’s Precision Medicine Initiative
Overview

• Why I have concerns about over-reliance on informed consent

• Examples of Deliberative Community Engagement:
  • Mayo Clinic Biobank,
  • EngageUC (Biobanking),
  • Rochester Epidemiology Project
  • California Newborn Screening Policy (in process)
Genomics in translation

T0: Discovery to health application

T1: Health application to practice guidelines

T2: Practice guidelines to health practice

T3: Practice to population health

T4: Practice to population health

T5: Practice to population health
Moving Ethics Beyond Compliance!
Have We Asked TOO MUCH of Consent?
What I am NOT discussing

- Interventional research, such as phase 1 drug studies

- Physiological research with “normal” human subjects
• Bioethics, influenced by its American origins, has focused slavishly on the individual and individual choice in post-Belmont paradigms for the protection of human participants in research.
Has consent become the modern equivalent of a fetish?
We engage in the rituals of consent as though we were following the precepts of a sacred text.

Recitations of consent’s key components in consent forms and IRB protocols have a liturgical feel.
Research on Improving Human Research Protection Privileges Consent
The Paradox of Choice

• Preferences cannot be “biopsied”

• May be “generated” (constructed) through interaction
The Limits of Disclosure

• Conflict of interest in biomedical research

• Financial instruments/Mortgage Crisis?
The “Magic” of Consent
SACGT & Multi-plex testing
Studying Decisions about DNA Donation

What is the purpose of this research study?

Mayo Clinic researchers want to find out what people think about donating DNA for medical research. People have their own reasons for deciding if they want to donate DNA, and understanding these reasons will help Mayo Clinic researchers better address people’s concerns and values.

Why are we asking you to participate?

We want to talk to people who have made decisions about taking part in research studies. You have been asked to donate a DNA sample for research. We are interested in your thoughts, feelings, and beliefs about that research. We plan to have 75 people take part in this study.

What will happen if I participate in this study?

You will be interviewed by a member of the research team. The interview will take 30-60 minutes and will be recorded. If you do not want to be recorded, ask the interviewer to take notes instead. You don’t have to answer any questions that make you feel uncomfortable.

You will get $30 for being in this study.

Will my information be kept private?

Yes. All study information will be kept private. Only the researchers in this project will get to see this information. We will make a written copy of your interview and then destroy the recording. The copy will not contain personal information about you like your name, address, clinic number, or social security number.

Why would I want to participate?

Telling us what issues you think are important will help us to communicate better with future DNA donors. Your medical care will be the same whether you participate or not.

What are the risks of participation?

There are no known physical risks to taking part in this research study. Some questions may make you feel uncomfortable, but you can choose not to answer them.

Do I have to participate in this study?

No. You get to make this choice. There is no right or wrong answer. Your choice will not change the way anyone treats you. You can choose to withdraw from the study at any time.

For more information about this study, please contact:
Bioethics Research Administrative Assistant
(507) 284-1494
Data Sharing

When interviewed, most informants did not realize their data could be shared.

I: Do you think they might use [the data] for other kinds of health problems?”

R: “I don’t think so.”
Empirical Studies


Context Matters

Rising Inequality

Market Assumptions
An Alternative: Stakeholder Engagement Based on Deliberative Democracy Theory
Deliberative events

- **BC Biobank deliberation**
  - Vancouver April/May 2007

- **Mayo Clinic, Biobanks**
  - September 2007

- **Rochester Epidemiology Project**
  - November 2011

- **Western Australia**
  - Stakeholders: Aug 2008
  - Public: November 2008

- **Salmon Genomics**
  - Vancouver November 2008

- **BC BioLibrary**
  - Vancouver March 2009

- **BC BioLibrary**
  - Vancouver March 2009

- **RDX Bioremediation**
  - Vancouver April 2010

- **Biofuels**
  - Montreal Sept/Oct 2012

- **Biobank Project Tasmania**
  - April 2013

- **California Biobanks**
  - LA: May 2013
  - SF: Sept/Oct 2013

- **Priority setting in Cancer Control**
  - Vancouver June, 2014
Mayo Clinic Biobank
Deliberative Community Engagement

DNA Biobanking in Olmsted County
A Deliberative Community Engagement

A project by the Mayo Clinic Bioethics Research Program in collaboration with the Center for Applied Ethics at the University of British Columbia

Funded by the Mayo Clinic Center for Individualized Medicine
Planning the Deliberation Methods

Nov. 2006

(with University of British Columbia Partners)
Key Questions in Event Design

- Who deliberates
- How selected
- Length of event
- Use of “experts”
- Background materials
- Use of visual aids
- Small vs large group time
- Specific questions (framing)
Deliberative Community Engagement

- Goal is not just to “inform” or “educate” the community
- Seeks genuine discussion among representative community members, and,
- Make recommendations about implementation, governance, & long term community oversight
Summary: Deliberative Community Engagement

- Key conditions for meaningful deliberation
  - Time
  - Information
  - Atmosphere of Mutual Respect
Procedures

- A "representative" sample of 21 Olmsted County residents deliberate over 2 weekends (4 full days)
- Two weeks before, they receive a mailing with basic information
- Website allows further interaction
- Experts available to provide their perspective and to answer questions
21 Demographically Stratified Participants

Pre-circulated website & materials

First Weekend Information
  Expert & Stakeholder Q & A
  Task: Identify the interests & values related to biobanking

Second Weekend Deliberation
  Task: Rank values, rate policy choices and identify persistent controversies

Website mediated dialogue & information

Media and Public Uptake
Reports, Print & online materials
Policy Uptake
DNA Biobanking in Olmsted County

A Deliberative Community Engagement

A project by the Mayo Clinic Bioethics Research Program in collaboration with the Center for Applied Ethics at the University of British Columbia

Funded by the Mayo Clinic Center for Individualized Medicine
Welcome!

Thank you for your interest in our community engagement on DNA biobanking in Olmsted County.

This event is run by the Bioethics research program at Mayo Clinic in collaboration with the Center for Applied Ethics at the University of British Columbia in Vancouver, B.C., Canada.

The purpose is to help people at Mayo Clinic develop the best possible policies about DNA research. To do this, we will be conducting a discussion about the collection, storage and use of human blood samples, DNA, and health information for research purposes. The technical term is "DNA biobanking," which means storing people’s blood samples to allow for studies of what causes disease, how best to treat it, or of things that keep people healthy. It is an important area of medical research today, but we don’t yet know what concerns people might have. That’s why we are interested in talking with.
Procedures

• Sample Selection
  • Main considerations: sex, age, educational level, race/ethnicity, religious beliefs, immigration status
  • Selected minorities (such as Native Americans) over-sampled
Key Feature: “Disinterested” (not uninterested)

• Legal Definition
Neutral, impartial; lacking a financial interest in, or other predisposition toward, a particular resolution of a controversy or issue.
The “Democratic” Deficit
Panel of Expert Speakers
Involvement of non-public “Expert Stakeholders”

• Stakeholders inform the debate but do not deliberate

• Avoid “hijacking” of the event to further specific agendas

• Speakers present a range of views about biobanking
Summary of Deliberation

• Participants compensated ($400.)

• Professional moderators (leaders)

• May use audience response to explore agreement/disagreement
Results of Engagement: Biobank Design
Mayo Clinic Biobank Governance Structure

**Institutional Review Board**
- Monitors Biobank policies, procedures, and written materials
- Approves or denies all research proposals at Mayo
- Evaluates and minimizes risk to research study participants

**Biospecimen Trust Oversight Group**
- Approves or denies research projects seeking access to Mayo's biobanks
- Creates and enforces Biobank policies regarding security and access
- Oversees donor recruitment and their on-going relationship with the biobank
- Consults and collaborates with various stakeholders

**Community Advisory Board**
- Reports to BTOG
- Provides community perspectives about Biobank policies, consent and recruitment documents, and potential research projects

**MAYO CLINIC BIOBANK**
Results of Engagement: Informed consent

• Format
  • simple language
  • multiple media
Results of Engagement: Disclosure

- Persistent disagreement over releasing to donor’s family
Results of Engagement: Access and sample control

- Control
  - oversight by Mayo Clinic regardless of where research is performed
  - return of excess to Mayo

- Establish a process for dealing with misuse of samples/data
Results of Engagement: Informing and involving the community

• Inviting community involvement
  • regular open forum
  • additional engagement events
What Worked Well?
Interim Community Advisory Board
Translation into Policy

• Reviewed long and short versions of informed consent forms, recruitment documents

• Unexpected feedback:
  • Favored omitting an opt-out regarding sample-sharing outside Mayo
  • Were comfortable with few details
Mayo Clinic Biobank
Community Advisory Board

• 20 members
• Meets every two months
• Half the members were deliberants
• Half chosen from the local community
• Co-chaired by an elected community member & a bioethics faculty member
Community Advisory Board

- Activities of CAB:
  - Advises on management and operation of biobank(s)
  - Reviews policies governing access to research samples
  - Evaluates patient materials
  - Suggests plans for community education
  - Considers complex policy decisions (such as return of results to participants)

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
“9. What if researchers discover something about my health?

- During individual studies, researchers could find out important information about your health. They might discover something about your health right now, or about your risk of getting sick in the future. **Researchers will not discover something about every donor, so you are not guaranteed to receive results.**

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
Excerpt from Biobank Consent form:

• Since decisions about health and disease are very personal, no one can predict which results donors will want in the future. One of the important jobs that BTOG has is to decide which research results, if any, will be returned to Biobank donors. They will make this decision for each individual study after consulting with the appropriate researchers, doctors, and the Community Advisory Board. Names will not be mentioned during this process.”

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
Process Used for Determining If/What Results are Returned

PROCESS SLIDES are courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
Biobank Access Process

1. Researchers fills out Access Request form

2. Researcher meets with Dr. Olson; Mses. Johnson and Kopp; Mr. Fredericksen

3. Request to full Access Comm. (CAB as needed)

4. Approve study. No results returned

5. Approve pending return of results discussion/plan

6. Deny/table
Biobank Access Process

1. Approve study. No results returned
   - Samples distributed
     - Study results deposited in Biobank database once complete

2. Approve pending return of results discussion/plan
   - Convene expert panel (CAB co-chair, Access Comm., subject experts MDs, PhDs) to discuss when to return results
     - Determine no return of results
     - Determine return of results necessary

3. Deny/table
   - Return of results plan developed by GC/Access Comm.
     - Modification and materials submitted to IRB for review
Return of Results Questions

• Convene an expert panel (locally) to consider:
  – Does the genetic finding:
    • have *important health implications* for the participant?
    • are the associated risks both *established* and *substantial*?
  
  – Is the genetic finding *actionable*?
    • Are there established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease?
Panel of Experts (Dominant Polycystic Kidney Disease) Discussion

• Does the genetic finding:
  – have important health implications for the participant:
    Yes
  – have established and substantial risks?
    Yes- genetic testing and management is undertaken routinely in clinic for this disease.

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
Panel of Experts Dominant PKD: Discussion

Is the genetic finding actionable?

– Are there established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease

Yes

• Medication to control high blood pressure
• Medication or surgery to reduce pain
• Antibiotics to resolve infections
• Dialysis to replace functions of failed kidneys, or kidney transplantation
• Management/Screening/surgery for aneurysms

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
PKD – Dominant Outcome

- Polycystic kidney disease: Dominant
  - Possible implications in Biobank participants:
    - 1 or 2 persons (if any) may be found to carry a gene mutation \textit{known to cause} Autosomal Dominant PKD
  - PROPOSED ACTION: Biobank would contact them to offer return of results (details provided later)

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
Discussion with Community Advisory Board

• January 27, meeting
  – Orientation to the specific disease
  – Small group discussion of return of results
  – Generally recommended return of results

• May 5, meeting
  – Reviewed first draft of letters to return results
  – Made many substantive suggestions

• September 8, meeting
  – Reviewed final draft of letters to return results

SLIDE Courtesy of Ms. Kiley Johnson, Mayo Clinic Genetic Counselor
CAB comments – hopes

• **Personal and family well-being/Advanced planning and Preparation**
  – Early detection: “If I was informed I had a gene with an unknown variation, I could watch my symptoms and possibly be diagnosed and receive treatment earlier.”
  – Family well-being: “Can help family members be aware of disease so they can be checked”
  – Reproductive planning and choices: “If I learned I was a recessive carrier. I could receive genetic counseling to possibly avoid having a child with Disease X and “[prevent] Pass[ing] this on to my offspring.”

• **Broad social benefit**
  – “I could get involved in the community or institution [as a research participant or disease advocate] that is interested to find a cure if any”
CAB comments – concerns

- **Personal and family well-being**
  - Undue stress and anxiety for both the individuals themselves and for their families.
    - “People might … overreact and overestimate the risk and obsess over it, and it could lower their quality of life even if they don’t have or may never get disease.”
  - Getting information about something for which they had little or no information.
    - “Some people don’t want to know.”
  - Concerns about discriminatory use of the research findings by insurance companies/potential employers:
    - “Results could impact patients future related to insurance…."

- **Logistical process of returning results**
  - Recognized struggles that researchers and policymakers would have to grapple with:
    - whether and what results to return
    - who makes the decisions and if returning findings does happen when, by whom, and how.
  - Cost
    - “If you tell someone they might have an increased risk or gene marker, they’ll need to be counseled about the implications – who, how or who pays?”
Process Proposed to Return Results
Flowchart of Biobank Return of Results (ROR)

Expert Panel Recommends Return of Results

Send R.O.R. letter

Patient wants more info?

- No response
- NO (Returns refusal letter)

Resend letter at 4 weeks

Yes

Record in database
1. Subject calls Biobank staff to set up 1st meeting with genetic counselor
2. **Phone call/meeting #1 with Genetic Counselor**
   a. Discusses pros/cons/background information on results
   b. **no results given**
   c. Ask if patient wants to set up meeting #2
3. Mail follow-up meeting summary & disease-specific pamphlets
4. Record call/meeting in Biobank database

Wants to continue?

- NO: Record in database
- YES: Continue process
Second call/meeting #2 with Genetic Counselor

1. Return results
2. Recommend CLIA confirmation
3. Mail follow up meeting summary to patient and M.D. if requested
4. Record in database
5. Clinical follow-up as appropriate
Stakeholder Engagement on “Biobanking in California”
1) Public 2) Biobankers 3) IRBs

NIH/NCATS
UL1TR000004-07S2
Project Goal: Ethical, Efficient, & Sustainable UC Biobanking System

• Ethical
  – Aim 1, Stakeholder engagement with the public
  – Gain insights on consent and governance

• Efficient
  – Aim 2, Clinical trial to compare methods for obtaining consent (underway)

• Sustainable
  – Aim 3, Policy translation
  – Inform system-wide policies & action
  – November “stakeholder” meeting
Conducting a Bilingual (Spanish/English) Engagement

• Design decisions:
  – Why Spanish?
  – Create a Spanish-speaking small group
  – Use simultaneous interpretation in large group
  – Include educational presentations in both languages
## EngageUC Participant Demographics

<table>
<thead>
<tr>
<th></th>
<th>LA (n=26)</th>
<th>SF (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>14</td>
<td>10</td>
</tr>
<tr>
<td>Female</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td><strong>Age (mean)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21-38</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>39-56</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>57+</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td><strong>Language Preferred</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>18</td>
<td>26</td>
</tr>
<tr>
<td>Spanish</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>16</td>
<td>12</td>
</tr>
<tr>
<td>Black</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Native American</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Ethnicity = Latino</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;HS</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>HS</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Some College</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>AA degree/vocational</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>College or &gt;</td>
<td>9</td>
<td>18</td>
</tr>
</tbody>
</table>
Deliberative Community Engagement: Recommendations & Persistent Disagreements

• Most deliberants want legacy samples retained and used for medical research even if samples were collected without consent or with less-stringent consent;

• Views were divided about the need for re-consent and/or re-contact for future uses
Deliberative Community Engagement: Recommendations & Persistent Disagreements

• Deliberants support sharing data to advance research
  – but many are concerned about sharing overseas
  – some are concerned about sharing with government
After the deliberation:

• Continuing public engagement
  – Convened LA/SF deliberants & other stakeholders to discuss community role in biobank governance

• Compare methods to obtain consent
  – Pre/post test of newly-developed consent methods in diverse clinical and research settings
Rochester Epidemiology Project

A Deliberative Community Engagement

November, 2011
REP: Why unique?

- “Unconsented”; Researchers, once approved, have full access to medical records
- Supported by NIH for five decades
- Planned expansion throughout SE Minn.
- Link to biobank (?????)
Newborn Screening Policy in California

- R21 from AHRQ
- Julie Harris-Wai, PI
- Ideal topic for deliberative community engagement
- Public health context
“Adaptive” Governance

Consent to be governed
Adaptive Governance in Action
Topics Addressed by Mayo CAB

• Hands on role in creating trustworthy practices
• Voice in “access committee”
• Data sharing
• Return of results
Emerging Issues

• Whole genome analysis?

• Responsibility for reanalysis?

• Sequencing of deceased participants?

• Obligations to family?
Challenges

• Current U.S. legal/regulatory framework does not encourage innovation or community-based approaches
  • Focus remains on the individual

• Deliberative Engagement is expensive & time-consuming

• Techniques of evaluation are emerging
Deliberative Community Engagement in Diverse Communities

- Can the technique be adapted for diverse, multi-lingual communities such as California?
Deliberative Community Engagement in Diverse Communities

- Challenges:
  - Assumptions about need to target CE according to race/ethnic groups.
Summary

The ritual of informed consent oftentimes masks the very thing it purports to enact.
Alternative View

• Consent is not abandoned

• Deliberative community engagement can:
  • help determine which choices actually matter
  • can guide policy makers in setting defaults
Acknowledgements

• NIH

• Michael Burgess, Kieran O’Doherty, Holly Longstaff

• Marguerite Robinson, Walter Rocca, Jen McCormick, Ellie Garrett

• Dan Dohan, Arleen Brown, Sarah Dry, Elizabeth Boyd, Jen Hult, Jessaca Machado, Megan Dowdell, Blanca Corea, Arturo Martinez, Stefanie Vassar

• Julie Harris, Roberta Ryan
Thank you!

QUESTIONS????

barbara.koenig@ucsf.edu