Genomics and Ethics in Research and Medical Decision-Making

Ethical Challenges of Biobanks in Research

Holly A. Bante, PhD, Moderator
10:00 to 10:40 am
Innovating consent: the case for theory-driven, interactive multimedia

Chris Simon, Ph.D., Bioethics and Humanities Program, Carver College of Medicine, University of Iowa

David Klein, Ph.D., Law, Health Policy & Disability Center, College of Law, University of Iowa

Helen A. Schartz, Ph.D., J.D., Law, Health Policy & Disability Center, College of Law, University of Iowa
Background

- Uncertainty and debate around informed consent (IC) for biobanking

- Biobanks required or electing to obtain IC will need to:
  - be efficient and cost-effective (Vaught 2011; Henderson 2014)
  - meet emerging ethical benchmarks (Beskow et al. 2014)
Electronic (e-)Consent

- E-consent is one option
- i.e., delivery of IC using digital technologies such as computers, tablets or smartphones to display slideshows, videos, digitized IC documents, or web pages.
Promising work in clinical research (e.g., Nishimura et al. 2013; Rowbotham et al. 2014)

Biobanks are interested in e-consent
- 48% of 70 genetic biobanks actively exploring e-consent (Simon et al. 2014)

A few have adopted e-consent systems (e.g., Marshfield Clinic, Vanderbilt)
Some Hurdles

- Proprietary e-consent costly, unproven
- Integration into research management systems is complex (Madathil et al. 2013)
- “Digital Divide” issues - low computer literacy and limited access to delivery technologies (computers, smartphones)
Our Program of Study

Goals:

- Develop an approach for educating and consenting people online
- Reduce costs and improve efficiency
- Enhance people’s understanding of biobank consent info. using low-tech, theory-based digital strategies
Randomized Trial

Compare a biobank’s standard, face-to-face (F2F) consent process to an electronic process using interactivity and multimedia on a wireless tablet.

NIH/NHGRI (R21HG006293)
Multimedia

- **Multimedia**: two or more media (e.g., text, graphics, photographs, video, audio)
- 9-page biobank IC document was organized into a slideshow, with graphics and audio narration
- Based on well-developed theories of learning and cognition (e.g., Paivio, 1990; Mayer, 2009; Schnotz & Kirschner, 2007)
Purpose of the Study

WHAT IS THE PURPOSE OF THE UNIVERSITY OF IOWA (UI) BIOBANK?

The purpose of the UI Biobank is to collect and store samples (such as blood, tissue, and saliva) and health information for use in research studies.
Interactivity

- **Interactivity in the IC process**: back and forth betw. a researcher or a proxy (e.g., computer) and a potential research participant.

- Interactivity in IC is not inherent and is typically infrequent.
We have operationalized (enhanced) interactivity:

- multiple choice questions – easy to study
- participant response to questions
- “researcher” feedback to response

Interactivity = Question $\rightarrow$ Response $\leftarrow$ Feedback
What is the main purpose of the UI Biobank?

1. To collect donations of blood to be used in surgical procedures.
2. To collect and store blood, saliva, and tissue and health information for use in research studies.
3. To collect enough of your tissue for analysis for your treatment so you don't have to return later to provide more.
What is the main purpose of the UI Biobank?

1. To collect donations of blood to be used in surgical procedures.

2. To collect and store blood, saliva, and tissue and health information for use in research studies.

3. To collect enough of your tissue for analysis for your treatment so you don't have to return later to provide more.

Correct. Your participation in the biobank enables researchers to do research that would be difficult for them to do otherwise.
What is the main purpose of the UI Biobank?

1. To collect donations of blood to be used in surgical procedures.

2. To collect and store blood, saliva, and tissue and health information for use in research studies.

3. To collect enough of your tissue for analysis for your treatment so you don't have to return later to provide more.

Incorrect. Your participation in the biobank enables researchers to do research that would be difficult for them to do otherwise. Your samples will not be used for patient care.
# Randomized Trial – Design

<table>
<thead>
<tr>
<th>Standard Interactivity</th>
<th>Face-to-Face (F2F)</th>
<th>Multimedia (MM)</th>
</tr>
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<tbody>
<tr>
<td>Control</td>
<td>F2F Standard Interactivity</td>
<td>Multimedia Standard Interactivity</td>
</tr>
<tr>
<td></td>
<td><strong>No</strong> Embedded Questions</td>
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</table>

<table>
<thead>
<tr>
<th>Enhanced Interactivity</th>
<th>Face-to-Face (F2F)</th>
<th>Multimedia (MM)</th>
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</thead>
<tbody>
<tr>
<td>Embedded Questions</td>
<td>F2F Enhanced Interactivity</td>
<td>Multimedia Enhanced Interactivity</td>
</tr>
<tr>
<td></td>
<td>Embedded Questions</td>
<td>Embedded Questions</td>
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</tbody>
</table>
Stakeholder Involvement

Community and expert stakeholders were key to evaluating and refining the IM module over three rounds.

- Graphics
- Interactive questions
- Functionality – e.g., user controls
Study Sequence

University of Iowa Biobank Recruitment

Random assignment
One of four consent conditions

F2F S  F2F E  MM S  MM E

Assessment for understanding (electronic survey)

Answer any further questions

Completed experiment, final decision to enroll in Biobank
Results - Participants

- N = 200 (50 randomly assigned to each condition)
- Recruited by the Biobank from various sources
  - Dermatology, Rheumatology, Pulmonology and Family Medicine clinics,
  - ResearchMatch.org, mass e-mails to UI personnel and students, and posters)
Participants:
- Female (76%) and Caucasian (96%)
- mean 47 years (range 18-86)
- College educated (79% had at least college degree)

2% (4) chose not to enroll in the Biobank
Results - Understanding

- High overall understanding of the Biobank’s consent info (Avg. Understanding Assessment Score = 93.5 out of 100).*

- Interactivity and Multimedia associated with better understanding of Biobank IC info
  - Level of Interactivity \((F(1,196) = 7.56, p = 0.007)\)
  - Media \((F(1,196) = 4.27, p = 0.04)\)

Results – Understanding

Average Understanding Assessment Score*

Results – Understanding
Assessment Item on Biobank’s Data Sharing Policy

<table>
<thead>
<tr>
<th></th>
<th>Standard Interactivity</th>
<th>Enhanced Interactivity</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Correct</td>
<td>% Incorrect or Unsure</td>
<td></td>
</tr>
<tr>
<td>F2F</td>
<td>52%</td>
<td>48%</td>
<td>% Correct</td>
</tr>
<tr>
<td></td>
<td>18%</td>
<td>82%</td>
<td>% Incorrect or Unsure</td>
</tr>
<tr>
<td>MM</td>
<td>42%</td>
<td>58%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>14%</td>
<td>86%</td>
<td></td>
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</tbody>
</table>
## Results - Understanding

Assessment Item on Biobank’s Privacy and Confidentiality Policy

<table>
<thead>
<tr>
<th></th>
<th>Standard Interactivity</th>
<th>Enhanced Interactivity</th>
<th>Legend</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F2F</strong></td>
<td>44% 56%</td>
<td>26% 74%</td>
<td>% Correct</td>
</tr>
<tr>
<td><strong>MM</strong></td>
<td>26% 74%</td>
<td>22% 78%</td>
<td>% Incorrect or Unsure</td>
</tr>
</tbody>
</table>

Legend:
- **% Correct**
- **% Incorrect or Unsure**
Results – Participant Consent Time

- Interactivity and Multimedia took longer to complete.
  - Level of Interactivity ($F(1,196) = 32.32, p = 0.037$)
  - Media ($F(1,196) = 44.78, p = 0.021$)
Results – Participant Consent Time

Average Minutes to Complete Consent

Minutes from start of study to completion of consent.
Results - Summary

- Interactivity and Multimedia made the biobank consent process take longer for participants,

- but Interactivity and Multimedia resulted in better understanding.

Conclusion

- Consent improvements need not be complex, but can be based on simple design strategies.
- Interactivity and Multimedia should be studied separately.
- Research is needed with more diverse populations, other interactive strategies, and other media.
Questions
The Finished Module

- Enhanced Interactive Multimedia Module
Biobanking at Birth: Parental Attitudes Concerning the Collection of Biospecimens in the Perinatal Period

Aaron Goldenberg, PhD, MPH
Assistant Professor of Bioethics
Associate Director, Center for Genetic Research Ethics and Law
Department of Bioethics
Background

- Increasing interest in using newborn’s biospecimens for research (ex genomics, epigenetics)

- Growing number of perinatal “biobanks”
  - umbilical cord blood stored in public banks
  - residual bloodspots from newborn screening programs
  - biospecimens collected as part of large longitudinal research programs (ex. National Children’s Study)

- Samples and data raises unique ethical, legal, and social concerns regarding the donors and their families.
Project Aims

• **Specific Aim 1:** To assess the attitudes and beliefs of expectant and new parents about the storage and use of biological specimens collected in the perinatal period for research purposes.

• **Specific Aim 2:** To analyze policies, educational materials, and consent documents from programs collecting biological specimens in the perinatal period.

• **Translational goal:** To explore whether the ELSI challenges raised by the growing use of samples and health data collected from newborns raises the need for new approaches to biobanking governance and human subject protections.
Methods

• The study was a qualitative study based on open-ended interviews with expecting and new mothers and partners.

• Participants were recruited at two Cleveland Areas OB/GYN practices representing both urban and suburban populations.

• A total of 129 participants were interviewed between January 2013 and April 2014.

• 87 (67%) prenatal vs. 42 (33%) postnatal
<table>
<thead>
<tr>
<th>Demographic Characteristic</th>
<th>Total N (%)</th>
</tr>
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<tbody>
<tr>
<td>Total Participants</td>
<td>129 / 100%</td>
</tr>
<tr>
<td>Mother or Partner</td>
<td></td>
</tr>
<tr>
<td>Mother</td>
<td>96 / 74.4%</td>
</tr>
<tr>
<td>Partner</td>
<td>33 / 25.6%</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
</tr>
<tr>
<td>White (non-Hispanic)</td>
<td>59 / 45.74%</td>
</tr>
<tr>
<td>Black (non-Hispanic)</td>
<td>58 / 44.96%</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5 / 3.87%</td>
</tr>
<tr>
<td>Other</td>
<td>12 / 8.29%</td>
</tr>
<tr>
<td>Total Household Income</td>
<td></td>
</tr>
<tr>
<td>≤$15,000</td>
<td>26 / 20.15%</td>
</tr>
<tr>
<td>$15,001 ≤ $35,000</td>
<td>27 / 20.93%</td>
</tr>
<tr>
<td>$35,001 ≤ $55,000</td>
<td>20 / 15.5%</td>
</tr>
<tr>
<td>$55,001 ≤ $75,000</td>
<td>12 / 9.3%</td>
</tr>
<tr>
<td>≥ $75,000 or No Response</td>
<td>44 / 34.1%</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>&lt; High School</td>
<td>8 / 6.2%</td>
</tr>
<tr>
<td>High School/GED</td>
<td>23 / 17.82%</td>
</tr>
<tr>
<td>Community College</td>
<td>24 / 18.6%</td>
</tr>
<tr>
<td>College/University</td>
<td>40 / 31%</td>
</tr>
<tr>
<td>Graduate/Professional School</td>
<td>34 / 26.36%</td>
</tr>
<tr>
<td>First Time Parents</td>
<td>58 / 44.96%</td>
</tr>
</tbody>
</table>
Results: Unique Factors Associated with Collecting Bio-specimens from Newborns

• The Uniqueness of Blood From Newborns: Blood taken from newborns was seen as a unique research resource because of its ‘newness,’ ‘freshness,’” or ‘untainted nature.’

“Collecting the sample from a newborn would be totally different from an adult because I guess when you’re probably getting them at the first cycle of their life, you probably could find out more things about them now you know before they occur in their life. So I’m thinking it’ll be more useful.”
Results: Uniqueness of Blood cont.

“They have not been affected by all the environmental factors that we have.”

“I think their blood is kind of untainted and hasn’t been touched or you know injected with needles and all that stuff yet.”

“You know it’s real fresh though…They’re not born with so many problems and diseases.”
Results: Avoiding Additional Blood Draws

• Many parents also shared that they would not participate in research if their newborn had to endure an additional blood draw.

“So if it was an additional blood draw, I probably would not do that as a newborn in the hospital because it hurts them. They don’t know what’s going on, so I wouldn’t do that just for research.”

“I’m not gonna be possessive over blood that was already drawn, you know. They can have it…but I wouldn’t want the baby to get pricked and in pain. They don’t understand. You know they’re just little and I know they can calm down easily, but you know it’s trauma to them.”
Results: Avoiding Additional Blood Draws

“You don’t want to harm a child, and taking their blood could possibly harm them, but you know the more people understand that taking a little bit of blood is not gonna harm a child and it’s [research] gonna be great, not just good, but it could be you know potentially earth shatteringly great for our species. Not just this town, this community, but the entire human race.”
Results: Health of the newborn

- The health status of their newborn was also a big factor for many parents in deciding to donate.

“If the baby’s healthy, 100% healthy, then I wouldn’t have a problem with it, but if she’s like having problems and stuff, I think I’d be so stressed out that I wouldn’t be willing to [donate].”

“I guess it would depend on how much and what kind of condition my newborn was in, if I had a healthy newborn baby, you know and it depends on how much [blood]. I might say okay, but if there were any health concerns or anything like that, I wouldn’t want to jeopardize the baby”
Results: Vulnerability

• Expectant and new parents both discussed the vulnerability of their newborn, as well as the vulnerability they feel as new parents impacts their decisions about research participation.

“I think they’re just very sensitive about a newborn baby. You know they go through a lot in those first couple of days.”

“Being a parent, you know I have responsibility for how my son’s information is distributed and how it’s used by others, and I would wonder if he would, in my instances, want me to have given that information out.”

“I think the fact that a child is so vulnerable and you know it can’t really defend itself. You have to provide care and protection for the child”
“As a new, especially first-time mom and a new parent you’d just be like you don’t want anything to happen to them. You don’t want them to get poked and anything like that.”

“The size of infants and how delicate they are and how you don’t really know their health history and what they’re susceptible to makes a lot of people I would say more nervous to donate, as you know opposed to an older adult who you know is healthy”
Preliminary Discussion

• Parents are generally supportive of research using their newborns samples

• Many parents do see a newborn sample as unique when compared to other types of specimens

• Expectant and new parents seem to utilize a decision-making model that balances the risks and benefits of participating in research, mediated by
  • The vulnerability of their newborns
  • Feeling vulnerable themselves as new parents
Parental Willingness to Allow a Newborn's Blood Sample to be Used in Research

**Personal Values**
- Beliefs about Research
- Health Status of Newborn
- Privacy and Impact of Results

**Study Conditions**
- Potential Benefits
- Return of Results
- Study Risks
- Need for Blood Draw

**Vulnerability of Newborns and New Parents**
The Newborn Screening Saves Lives Reauthorization Act

• Provides Federal support for Newborn Screening Programs

• **Section 12:** Defines bloodspots collected during Newborn Screening as human subjects

• Does not allow for a waiver of consent

• Does not allow for any alteration to the traditional consent components
Acknowledgements

• Thank you to Laura Morello, Roselle Ponsaran, and Venessa Marshall

• I wish to acknowledge my gratitude to all the parents who participated in our in-depth interviews

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