Biobank Governance

October 26, 2010

Susan Brown Trinidad
Genetic Alliance

Genomic Research and Wide Data Sharing: Views of Prospective Participants

Susan Brown Trinidad, MA
Department of Bioethics & Humanities
University of Washington

October 27, 2010

Introduction: eMERGE

- **e**lectronic **ME**dical **R**ecords and **GE**nomics Network
- 4-year project funded by NHGRI to:
  - Explore methods for deriving reliable phenotypes from electronic medical records
  - Perform genome-wide association studies (GWAS) using previously collected data
- Participating sites:
  - Group Health / University of Washington
  - Mayo Clinic (Mayo Clinic Biobank)
  - Marshfield Clinic (Personalized Medicine Rsch Project)
  - Northwestern University (NUgene)
  - Vanderbilt University (BioVU)

Ethical, legal, social questions

- What do participants think about:
  - Wide data sharing (via dbGaP and other)
  - Return of research findings to individuals
  - Informed consent – when possible risks are unknown
  - Acceptable use of existing samples and data, re-consent
  - Research access to EMR data
- How can/should participant preferences be taken into account in developing research practices?
- What kind of relationship should there be between researchers and study participants?

Focus group composition

- 2 with ACT Study Participants
  - N = 18, avg age 80.4
- 2 with ACT surrogates/LARs
  - N = 16, avg age 59.5
- 2 with GH members age 18 – 34
  - N = 16, avg age 27.1
- 2 with GH members age 35 – 50
  - N = 14, avg age 42.8
- 2 with GH members age 50+
  - N = 15, avg age 62.7

General demographics

- Even participation by sex
  - 52% male, 48% female
- Limited racial/ethnic diversity*
  - 89% white, 10% Asian, 5% black
- Relatively high socioeconomic status
  - 42% report household income of $75k or higher
- Very well educated
  - 73% hold at least a BA/BS; 37% have advanced degrees
- 25% report prior research participation**

**includes double-counts* ***excludes ACT Study participants*

Acceptability of wide sharing

- Participants saw the scientific value of sharing data:
  - Strong support for enhanced efficiency and translation (shortening timeline from research → health benefit)
  - Wanted researchers to avoid wasting resources
  - "To me, the more information researchers have, the better, as long as you [can protect against discrimination]. I mean, that's what research is, and you're crippling it by not allowing them to share … they can advance quicker [if they share]."
- Wanted researchers to "make the most" of their contributions (tied to participants' altruistic reasons for taking part)

Who should have access

- Most considered within-GH investigators and other close collaborators acceptable data recipients.
- Non-profit, public-interest groups were also ok.
  - "More legitimate" because doing "pure science" directed at the common good
- For-profits were deemed untrustworthy by at least some participants in every group.
  - Perceived mismatch between participants' altruistic goals and corporations' profit motives.
- Concerns about Federal oversight (non-research use) expressed in every session.

Privacy & confidentiality

- Pervasive issue in all groups.
- Many believed that the benefits of wide data sharing outweigh the risks:
  - "I guess it comes down to a balance. How much good is expected from it, against the extreme risk that might – *might* – happen."
- Sense that unauthorized release is inevitable → skepticism regarding guarantees re privacy.
- "Safety in numbers" might reduce individual risk.
- Overall, not clear that risk of participation exceeds other normal risks in daily life (e.g., online banking).

Bonus round: re-consent

- For use of existing samples and/or data beyond the scope of initial consent
- Consent for pediatric participants who have turned 18
- Consent for adults who have experienced cognitive decline since study enrollment
- Can be challenging – even if not impracticable:
  - Locating participants can be difficult
  - State law may require consent from next of kin for deceased participants (unless IRB waives consent)
  - Reaching participants can be costly and is usually not budgeted
- *…and what if they say no?*

Re-consent process

- Original consent for the ACT Study cohort:
  - Dementia and “diseases associated with aging”
  - Did not contemplate broad sharing
- Group Health IRB required re-consent for dbGaP submission
- By mail (n=1340) or in person for those scheduled for study visit (n=353)
- 86% of cognitively intact participants contacted by mail agreed to have their de-identified data sent to dbGaP; 90% of in-person consents

Important considerations

- Improve patient care or treatment: 98%
- Group Health researchers are leading study: 98%
- Help increase knowledge for society: 96%
- ACT Study researchers are leading study: 95%
- Help me or someone close to me: 86%
- Concern about future kinds of research: 52%
- Concerns about for-profit use: 41%
- Privacy concerns: 33%

Alternatives to re-consent

	Completely unacceptable	Somewhat unacceptable
Opt-out (Let us know if you don't want your info shared)	19%	21%
Notification-only (We already shared it, fyi)	47%	20%
No consent, no notification	54%	16%

Acknowledgments

- Wylie Burke, MD, PhD, UW Bioethics & Humanities
- Stephanie M. Fullerton, DPhil, UW Bioethics & Humanities
- Evette J. Ludman, PhD, Group Health Research Institute
- NHGRI grant 1 U01 HG004610, Eric B. Larson, MD, MPH and Gail P. Jarvik, MD, PhD, co-PIs