Biobank Governance

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Ethical Biobank Governance: Some Cautionary Tales and a Way Forward

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DOGBERT CONSULTS

Customer data is an asset that you can sell.

It's totally ethical because our customers would do the same thing to us if they could.

Sounds fair.

In phase one, we'll dehumanize the enemy by calling them "data."
What are we afraid of?

- Bad guys
- Data invaders
- Security breach
- Carelessness
- Forensic uses
- People doing things we do not agree with

“Usual” harms:
- Violation of privacy
- Discrimination

Less common harms:
- Tying up resources
- Self-concept damage
- Group stigmatization
- Perceived deception
- Lack of respect
- Lack of recognition
Public Narrative on Research

- Cells taken without her permission
- Researchers everywhere have profited from this
- Her family does not even have access to healthcare
Discarded Newborn Bloodspots

“The Government has Your Baby’s DNA”

- “I’m not much of a conspiracy theorist...I would have laughed if someone said the state has a multimillion-person DNA database and they’re sending samples to the U.S. military.”

- Parents’ lawsuit led to destruction of 5+million samples
“Where did you go with my DNA?”

Permission given for diabetes research; work on schizophrenia and population origins instead
Current Public Climate for Research

“Where did you go with my DNA?” - NYT
Perception of Risk

Risk = Hazard + Outrage

- P. Sandman, www.sandman.com
Lessons from these Stories?

► Regulations are the floor
  ▪ We may need other standards to guide us

► “Business as usual” practices can cause harm
  ▪ We cannot anticipate what “harm” looks like

► Engage the public
  ▪ Be transparent about research practices and intentions
  ▪ Communicate openly and clearly
  ▪ Ask permission before using samples if outside original scope or intentions
Traditional Systems for Managing Research Risk

► IRB Review
  ▪ Assess whether assumed risk is reasonable

► Consent
  ▪ Opportunity to voluntarily assume risks
    ▪ Implies being able to be informed about risks
    ▪ Implies being able to weigh those risks against anticipated benefits
    ▪ Implies there is a choice
    ▪ Implies a process or dialogue
Returning to Old Fashioned Research Ethics

► Respect for Persons
  ▪ How can our research processes enact respect?

► Beneficence
  ▪ How can we assure our research is achieving benefits? And clear benefits for whom?

► Justice
  ▪ How can we proceed equitably and fairly while addressing current injustices in the system?
Re-contact, Re-consent

We should explore new methods of re-contact (automated, electronic communication), which:

- Keep participants engaged and informed about research activities
- May contribute to science literacy
- Builds and sustains relationships, which are important to trust
- Creates good will in public programs and research enterprise
A research repository governance system will need to build in accountability mechanisms that:

- Track the research uses of repository samples and data
- Develop plans for risk management
- Establish recourse or consequences if breaches occur

Transparency about the systems for accountability will help enhance trust.
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