

Biobank Governance

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Genetic Alliance

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.



Dilbert.com DilbertCartoonist@gmail.com

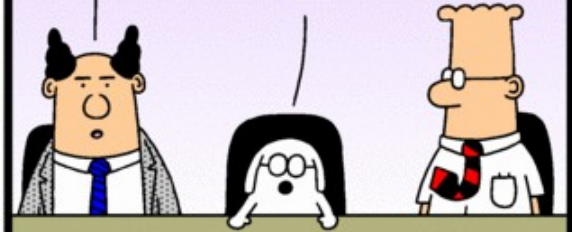
IT'S TOTALLY ETHICAL BECAUSE OUR CUSTOMERS WOULD DO THE SAME THING TO US IF THEY COULD.



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IN PHASE ONE, WE'LL DEHUMANIZE THE ENEMY BY CALLING THEM "DATA."

SOUNDS FAIR.



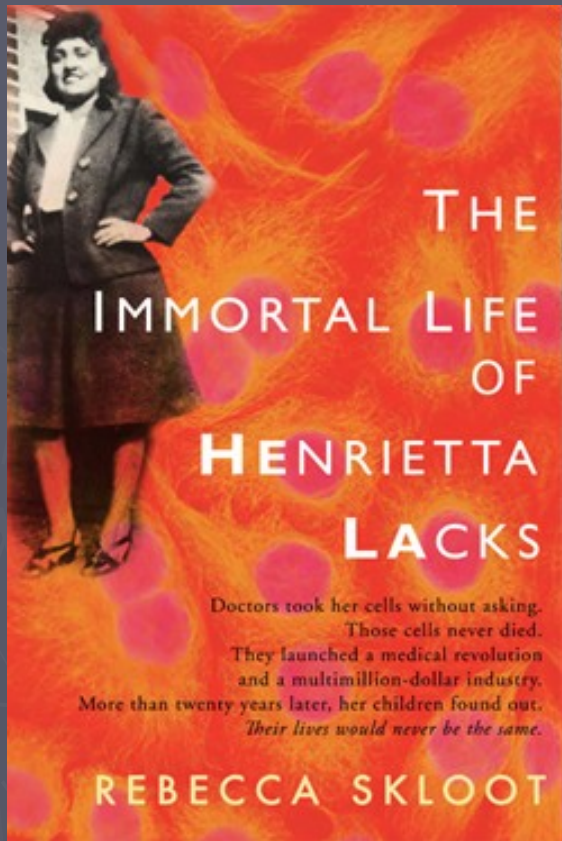
What are we afraid of?

- ▶ 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

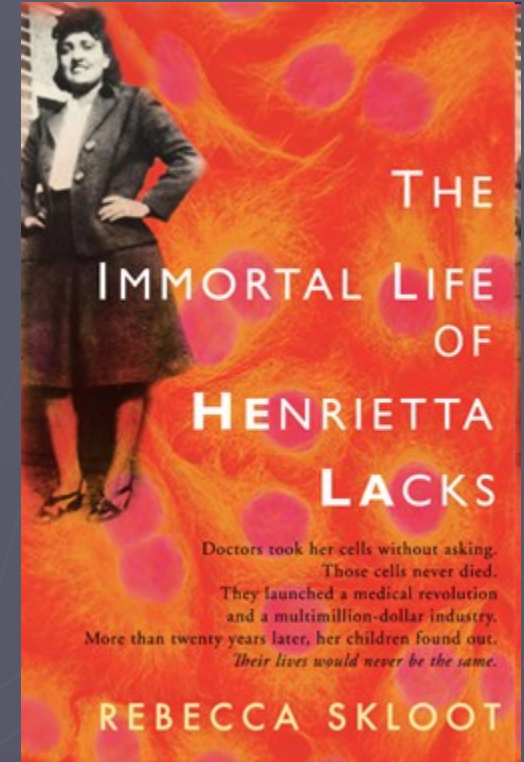


Havasupai- ASU Settlement

- ▶ “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

Accountability: Task for Stewards

- ▶ 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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