Consent and Stewardship:
Rethinking Strategies for Sustaining Public Trust

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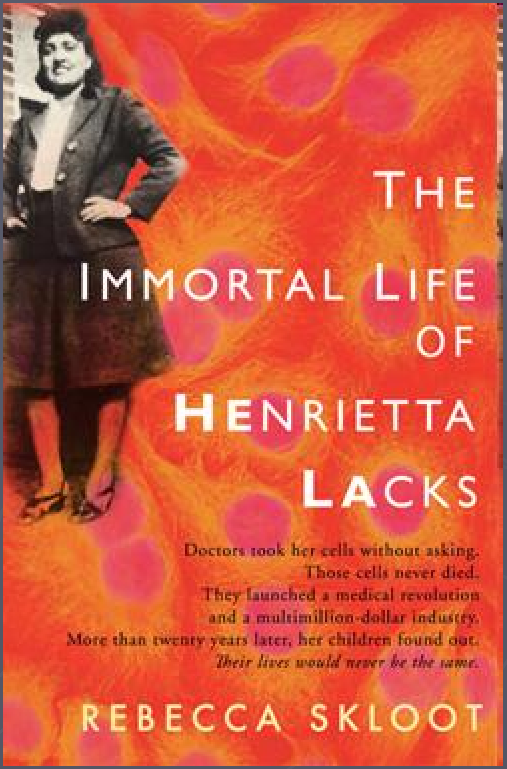
How to Proceed

- Thesis: Trustworthy practices in research are going to be critical to long-term success
- Problem: Regulatory and practice paradigms may no longer preserve public trust
  - Upfront review preferred
  - Heavy burden on consent procedures
  - Focus on individual privacy and identifiability
- Proposed Solution: Transformed oversight and research practices are needed

Current Public Climate for Research



THE

IMMORTAL LIFE

OF

HENRIETTA

LACKS

Doctors took her cells without asking.
Those cells never died.
They launched a medical revolution
and a multimillion-dollar industry.
More than twenty years later, her children found out.
Their lives would never be the same.

REBECCA SKLOOT

“Where did you go with my DNA?” - NYT

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

TIES

Trust, Integrity, and Ethics in Science

- Building and Sustaining Public Trust: Lessons from Industry and Input from Community
  - Relationships
    - Engage publics before starting to do a project
    - Identify concerns and opportunities
    - Educate about research processes, tech transfer
    - Establish communication channels (bi-directional)
  - Accountability
    - Develop mechanism for shared authority
    - Traceable samples so participants can learn who has their samples, for what purpose
    - Appreciate need for specific opt-out or withdrawal

Denver, 2005 & 2008; Yarborough et al. 2009

Unique Features with NBS

- ► Collected for public health purposes
  - § If intentions change, we have to keep people informed and up-to-speed.
- ► Bloodspots are finite resources
  - § We have to choose carefully how they are expended.
- ► NBS programs are run by DOH staff
  - § If research uses and requests begin to rise, we have to take into account burden on public health agencies.

Responsible Use of Public Resources

- Stewardship
  - Program-level decisions about who has access, for what purpose, relative to resource expenditure
  - Accountability for fair use, ethical practices, and follow-up with dissemination (where appropriate)
- Consent
  - Conveys respect by asking, inviting participation
  - Permits diverse beliefs, values, and preferences
  - Provides an opportunity for education and outreach

Stewardship: A Governance Model

- Stewardship is:
  - Taking responsibility for the survival and well-being of something that is valued
  - Responsibility for taking good care of resources entrusted to one.
  - Science, art, and skill of responsible and accountable management of resources (www.datagovernance.com)
- A steward:
  - Assumes responsibility for donor's intent, the manner resources are used, and the outcomes from their use (Jeffers 2001)

Consent Options

- Community consent
  - E.g. emergency medicine research, HapMap
- Blanket consent at birth
- Tiered consent at birth
- Waiver of consent
  - E.g. “anonymized” datasets
- Notification with opt-out or withdrawal options
- Re-consent for each research use

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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

Stewardship of Resources: Washington State Example

- Data release to researchers with written informed consent from parent and IRB approval from DOH/DSHS.
- Anonymous samples may be released if the department determines that the intended use has <u>significant potential health benefit</u> and that <u>each</u> of the following criteria have been met:
  - The investigation design is adequate to assure anonymity.
  - All newborn screening tests have been completed.
  - At least one fully adequate spot will remain after the anonymous sample has been taken.
  - Sufficient resources (personnel) are available for sampling.
  - The DOH/DSHS human subjects research review board has reviewed and approved the investigation.
    - http://www.doh.wa.gov/ehsphl/phl/newborn/privacy.htm

Washington State Experience

- Residual NBS bloodspot use for research:
  - Type 1 diabetes
  - Hearing loss
  - Maternal smoking
  - H1N1
  - Lysosomal storage diseases
- Participation rates as high as 90%

  (~104,000 of ~116,000 approached for Type 1 diabetes study)
- Fewer than 10 requests for destruction since 2004

  (out of ~450,000 births)

  - Weiss et al. 2010 Report

Conclusions

- We need to consider:
  - The consent process as an essential element in trust building
  - NBS programs must act as responsible stewards
  - We cannot anticipate harms for everyone
  - People will take risks if the payoff is worth it
- Residual bloodspot usage needs an approach that protects individual interests as well as promotes effective research.

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