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PEARLS OF LABORATORY MEDICINE

Ethical Issues in Biobanking

Ann M. Gronowski & Gwen Clarke

Washington University, School of Medicine

On behalf of the IFCC Task Force on Ethics

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Biobank

Definition

- An entity that receives, stores, processes and/or distributes specimens, as needed. It encompasses the physical location as well as the full range of activities associated with its operation[1]

Types

- Medical & academic research
- Clinical studies
- Clinical laboratory collection
- Biotechnology domain
- Judiciary domain
- Commercial

Importance (examples)

- Discovery of heterogeneity of acute leukemias
- Breast cancer genes
- Association of *Helicobacter pylori* infection & gastric carcinoma
- Discovery of genetic basis of human blood group variability

[1] International Society for Biological and Environmental Repositories Best Practices for Repositories: Collection, Storage, Retrieval and Distributions of Biological Materials for Research. 3rd edition (2012) www.isber.org

Fundamentals of Biomedical Ethics

Respect for Persons:

Protecting the autonomy of all people & treating them with courtesy & respect & allowing for informed consent. Researchers and clinical laboratory professionals must be truthful and conduct no deception & tolerate no deception.

Beneficence:

Doing good. Maximizing benefits for the research project & minimizing risks to the research subjects and patients.

Non-maleficence = do no harm

Justice:

Ensuring reasonable, non-exploitative, & well-considered procedures are administered fairly — the fair distribution of costs & benefits to *potential* research participants and to patients — & equally.

Adapted from Gronowski AM. “Ethics in Laboratory Medicine” Pearl *http://media.aacc.org/Shows/Pearls/Gronowski_EthicsLaboratoryMedicine/player.html*

Why do Biobanks Cause Ethical Challenges?

- Specimens may be stored for long time
- Specimens may be used for multiple studies
- At the time of consent, unclear how many studies a specimen may be used for
- A multitude of private health information may be collected
- Depending on the biobank, specimens may be sold

Outline

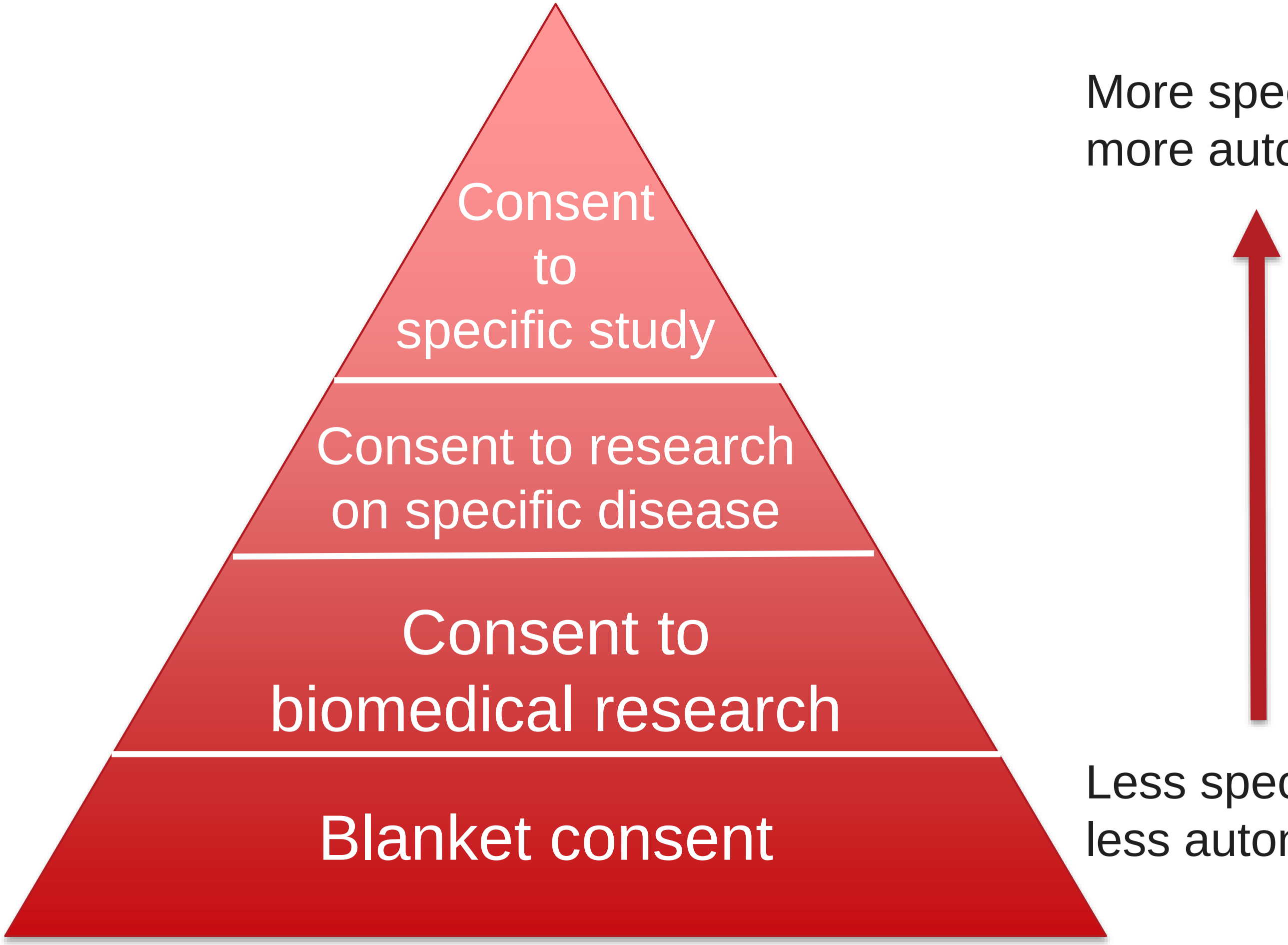
- Consent
- Privacy
- Return of results
- Governance & public trust
- Data sharing & exchange
- Ownership & commercialization

Consent

- According to Belmont Report & Common Rule, Subjects must be informed
- However, Biobanks are unique
- Impossible to fully “inform” subjects
  - Nature of future research unknown
  - Can’t consent for each & every future project

- Subjects have decreased autonomy

Continuum of Consent



Consent
to
specific study

Consent to research
on specific disease

Consent to
biomedical research

Blanket consent

More specific &
more autonomy

Less specific &
less autonomy

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Havasupai Tribe v. Arizona State University

Native American tribe donated samples for diabetes research. Samples were used for studies on schizophrenia, alcoholism & other.

Settled out of court. Arizona regents to pay $700,000 to tribe, and return blood samples.

The New York Times

U.S.

Indian Tribe Wins Fight to Limit Research of Its DNA

Jim Wilson/The New York Times

Edmond Tilousi, 56, who can climb the eight miles to the rim of the Grand Canyon in three hours.
More Photos »

By AMY HARMON
Published: April 21, 2010

SUPAI, Ariz. — Seven years ago, the Havasupai Indians, who live amid the turquoise waterfalls and red cliffs miles deep in the Grand Canyon,

CCTC Clinical Chemistry Trainee Council

Beleno v. Texas Dept of State Health Services

Parents sued state for use of residual samples collected for newborn blood screening & used in research for which parents had not given consent.

Settled out of court. State destroyed ~5 million residual specimens.

THE TEXAS TRIBUNE

TribBlog

Lawsuit Alleges DSHS Sold Baby DNA Samples

by Becca Aaronson | December 8, 2010

The baby blood battle continues with a second lawsuit against the Department of State Health Services for not only storing, but allegedly unlawfully distributing, baby blood samples. With the help of the Texas Civil Rights Project, two parents have filed a new class action lawsuit against DSHS and Commissioner David Lakey for allegedly selling, distributing and bartering blood samples collected from their children and others as part of the mandatory newborn screening program.

At a press conference in Austin today, plaintiff John Higgins and his attorney, Jim Harrington, accused DSHS of deception in selling blood samples to commercial pharmaceutical companies and sending blood samples to the Armed Forces DNA Identification laboratory. “My wife and I both were extremely upset when we found out about the data bank and the potential that [my daughter’s] DNA was going to be used or stored in some police, or military or Interpol, eventually, data bank,” Higgins said.

Carrie Williams, a spokeswoman with DSHS, said the agency has not yet seen the lawsuit. But based on what they're hearing, she said, the lawsuit is nothing new. "The Texas Civil Rights Project sued us before about bloodspot storage and use, and that issue was resolved and settled last year, with the Texas Civil Rights Project receiving funds for legal fees," she said. "...Unfortunately, based on media reports, it appears they have decided they want to double dip back into this issue with baseless assertions, including the false assertion that there is DNA in a federal database."

Consent

- Impossible to fully "inform" subjects
  - Nature of future research unknown
  - Can't consent for each & every future project

- Subjects in effect loose autonomy

- Right to withdraw-but may not be able to get samples already distributed

- Genetic information affects not only patient but also other people (relatives, spouses, etc)

Privacy

- Terms:
  - **Identified**-samples are linked to subject in a way that is immediately identifiable
  - **Coded** (traceable)-direct link to subject usually through random set of numbers
  - **Double code-**to link sample & data to individual requires 2 codes
  - **Encrypted**-further level of protection, code is transformed & requires a third party to link
  - **Anonymized**-link to subject has been irreversibly cut
  - **Anonymous**-there was never a link between subject and sample/data

Privacy

- Problem with genetic information is that it is always possible to identify donor & relatives
    - In 2008, geneticists showed that they could easily identify individuals within pooled, anonymized data sets if they had a small amount of identified genetic information for reference (N. Homer *et al*. PLoS Genet 4, e1000167; 2008).
- Confidentiality cannot be fully guaranteed despite all efforts
- Full confidentiality should never be promised

Return of Results

Incidental findings/individual research result

Has potential health importance & discovered in during research:

- & is in the stated aims of the research- **Individual research result** (IRR)
- But is unrelated to the research- **Incidental finding** (IF)[1]

However biobanks complex due to:

- Number of results very large
- Results generated over long period of time
- Actionable genetic results unclear
- Research labs often do not meet standards for clinical lab (e.g. CLIA)
- Genetic results very personal
- Genetic finding may have family implications[2]

[1] Wolf SM et al. Genet Med 2012;14:361-84

[2] Brothers KB. Personalized Medicine 2011;8:71-9

Governance & Public Trust

Who owns & finances the biobank?

- University
- Government
- Industry
- Hospital

Who has access to the specimens and data?

What legal/ethical rules does biobank have to abide?

- Varies by country
- Varies by type of bank (identified, de-identified, residual etc)

Data Sharing and Exchange

- National laws and regulations
- Anonymization
- Informed consent
- Access to biobank
  - What conditions must be met
  - Fees required
- On line tools

Ownership and Commercialization

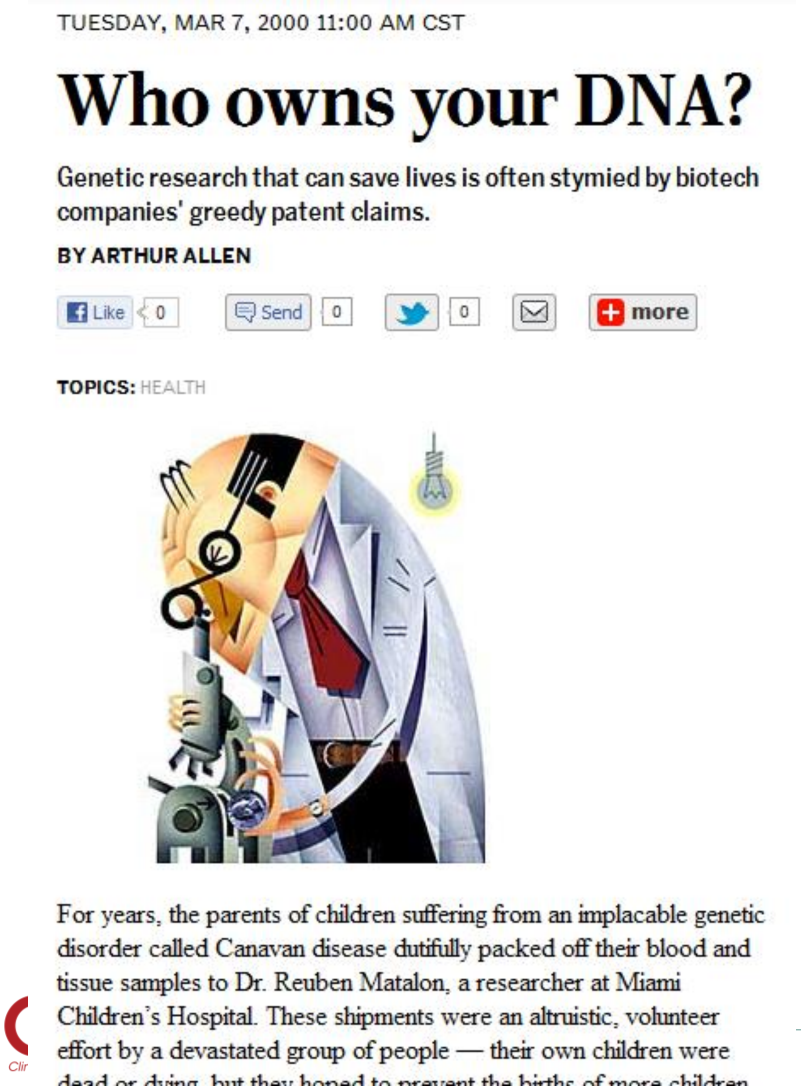
- Who can make money off specimens? Who has to pay for specimens?

- Should subjects be paid if researcher makes money

- General principle that subjects have no property in their samples (*res nullis*, ‘no one’s thing’)

- In a few cases this has been challenged

Greenberg v. Miami Children's Hospital Research Institute



TUESDAY, MAR 7, 2000 11:00 AM CST

Who owns your DNA?

Genetic research that can save lives is often stymied by biotech companies' greedy patent claims.

BY ARTHUR ALLEN

TOPICS: HEALTH

For years, the parents of children suffering from an implacable genetic disorder called Canavan disease dutifully packed off their blood and tissue samples to Dr. Reuben Matalon, a researcher at Miami Children's Hospital. These shipments were an altruistic, volunteer effort by a devastated group of people — their own children were dead or dying, but they hoped to prevent the births of more children

Donated samples that led to development of new diagnostic test. Sued after learning University licensed test.

Patients have no property right in tissue voluntarily donated for medical research.

Summary

In order to uphold principles of ethics, biobanks must:

1) Abide by all national/local laws & association guidelines & relevant standards
2) Obtain informed consent or use de-identified
3) Handle personal information safely & confidentially
3) Allow subjects to withdraw at any time
4) Require recipients of samples/data to undergo review by an ethics or human research protection committee

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