
The Rise of Genetic Databases

Legal Concerns and Threats to Genetic Privacy

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Project Overview

- Personal (Protected) Health Information (PHI), is sensitive data that can be used to identify an individual
- Eg. birthdate, medical condition, and health insurance claims
- Although protecting the privacy of PHI has been a standard in healthcare for centuries, genetic data (most sensitive types of PHI) has not always received adequate protection
- recent technological advances, including the genomic revolution, have increased the reasons, ways, and opportunities to share genetic data with a variety of parties.



Significance

- The risk of deliberate and unintentional “oversharing” of genetic data has greatly increased.
- A new concept of privacy and confidentiality is required to protect increasingly available amounts of genetic data
- There is a responsibility to create legal guidelines that allow for the use of technology to improve public health without compromising privacy of genetic information and personal autonomy

Study Aims

This ongoing study will:

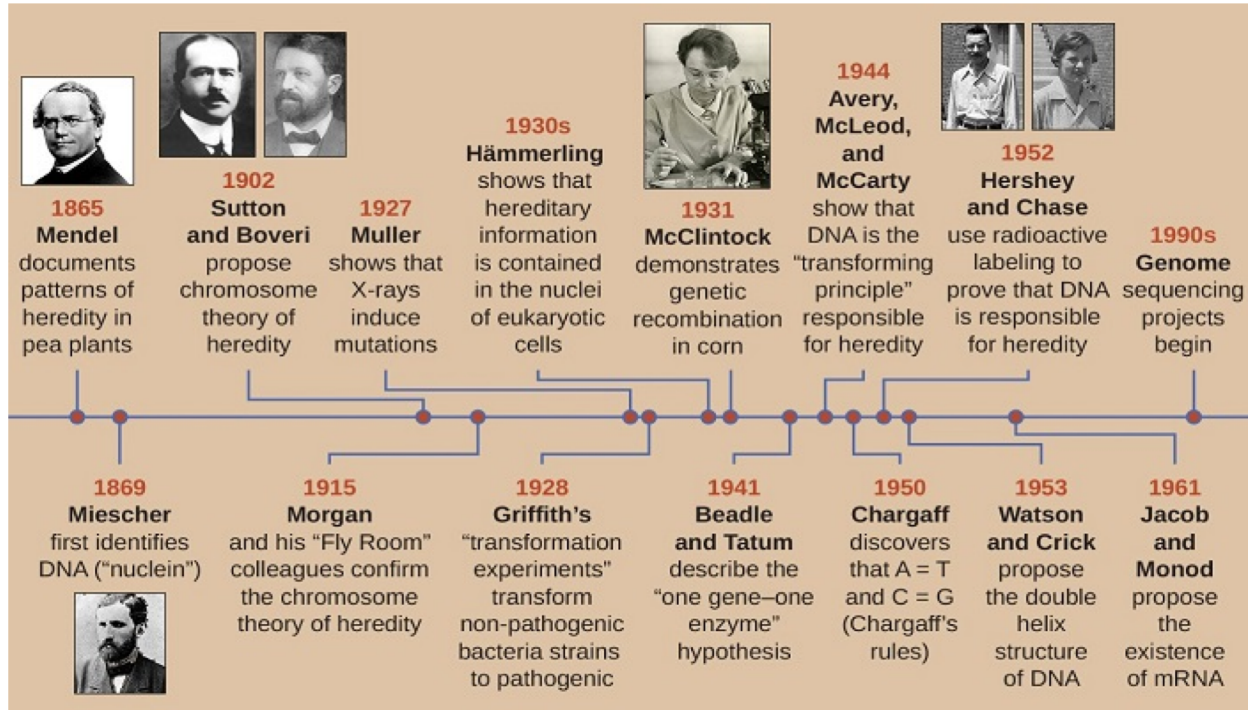
- A. describe privacy concerns resulting from increased genetic data testing and sharing
- B. explore the current landscape of genetic data privacy protections
- C. propose reform that protects consumers without hindering necessary research and medical advances



Background

- Genetic Timeline
- What are Genetic databases?
- What types of databases are available?
- What are some benefits ?

Brief Genetic Timeline



The Human Genome Project

- International thirteen-year project that began in October of 1990 and ended in April of 2003
- The US Project was coordinated by the NIH and the DOE
- generated the first reference human genome
- Ushered in genomic revolution
- new phase of genetic exploration





What are Genetic Databases?

- collections of genetic samples and other health information
- May be accompanied by the storage of human biological materials such as extracted DNA, body fluids, cells and sections of tissue.
- may include molecular genetic data, standardized clinical data, genealogical data, and information on the health, lifestyle and environment of an individual

3 Main Types of Databases

1. Clinical

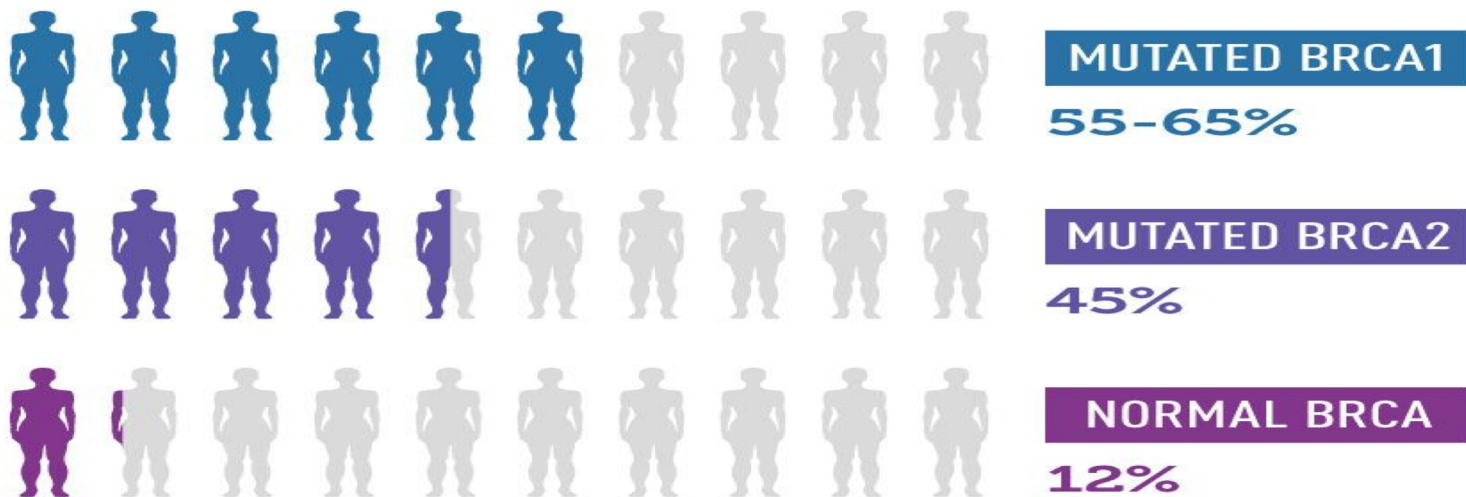
- Health care providers
- Examples: Mayo Clinic Biobank, Penn Medicine BioBank

Benefits:

- a. Offers a more precise diagnosis
- b. predict future health risks
- c. identifying defects pre-implantation or in utero
- d. gene therapy and gene repair (CRISPR)
- e. Predict individual responses to medications

NATIONAL CANCER INSTITUTE CHANCES OF DEVELOPING BREAST CANCER BY AGE 70

Specific inherited mutations in the BRCA1 and BRCA2 genes increase the risk of breast and ovarian cancers. Testing for these mutations is usually recommended in women without breast cancer only when the person's individual or family history suggests the possible presence of a harmful mutation in BRCA1 or BRCA2. Testing is often recommended in younger women newly diagnosed with breast cancer because it can influence treatment decisions and have implications for their family members.



2. Research

- Academic, government, research organizations
- Examples: NIH's All of US

Benefits:

- A. discovering disease etiology,
- B. identifying gene-environment interactions
- C. precision medicine



All of UsSM Research Program



WHAT IS IT?

Precision medicine is a groundbreaking approach to disease prevention and treatment based on people's individual differences in environment, genes and lifestyle.

The *All of Us* Research Program will lay the foundation for using this approach in **clinical practice**.

WHAT ARE THE GOALS?

Engage a group of **1 million or more U.S. research participants** who will share biological samples, genetic data and diet/lifestyle information, all linked to their electronic health records. This data will allow researchers to develop more precise treatments for **many diseases and conditions**.

Pioneer a new model of research that emphasizes **engaged research participants, responsible data sharing and privacy protection**.



Research based on the cohort data will:

- Lay **scientific foundation** for precision medicine
- Help identify new ways to **treat and prevent disease**
- Test whether **mobile devices**, such as phones and tablets, can encourage healthy behaviors
- Help develop the **right drug** for the **right person** at the **right dose**

WHY NOW?

The **time is right** because:

We have a greater understanding of human genes

People are more engaged in healthcare and research



We have the tools to track health information and use large databases

Research technologies have improved



Follow the Program's progress and be one of the first to join this landmark effort.

www.nih.gov/AllofUs-Research-Program

3. Proprietary

- For-profit companies
- Examples: AncestryDNA, 23andMe

Benefits:

- A. discovering genetic heritage
- B. finding lost relatives
- C. clarifying parentage
- D. finding perpetrators (even years after a crime)

Direct-to-Consumer (DTC)
Genetic Testing Companies



Risks and Concerns: Genetic Exceptionalism

New Concept of Privacy, Involving Genetic Relatives

- What does informed consent mean when genetic data involves so many parties?
- How do you protect your personal genetic data when your relatives could put you at risk?
- What are some potential risks involved?

Discrimination

- Potential use by employers and insurers (prohibited by GINA, but difficult to detect/enforce and exception for “voluntary” workplace wellness programs)
- Potential use by entities not covered by GINA (education, housing, life insurance, long-term care, mortgage lending, etc)
- Potential civil rights violations
- Threatens to create a “genetic underclass” (Roberts 2010), history of eugenics

Profit

- Personal data could be shared, sold, or used for profit without fair recompense to relatives (especially true if data provider does not approve of its uses)
- Potential exception in states with genetic property laws (which brings its own potential downside: less research to save lives)
- Profit by database owner not generally recognized as harm to subject

The Current Landscape of Genetic Privacy Protections

- 1. Health Insurance Portability and Accountability Act (HIPAA)**
 - Passed by Congress in 1996
 - Far-reaching Act that created national standards for the protection of personal health information, through what is known as the Privacy Rule.
- 1. Institutional Review Boards (IRB)**
 - began in 1974 with the National Research Act that created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
 - Type of committee formed to review and monitor biomedical research involving human subjects.
 - protects rights and welfare of human research subjects.

Current Landscape continued

3. Genetic Information Nondiscrimination Act (GINA)

- protects individuals from discrimination by health insurers or employers based on genetic information.

4. European Union's General Data Protection Regulation (GDPR)

- Harmonize data privacy laws across EU, protect EU citizens data privacy
- Reshape the way organizations across the region approach data privacy.

5. The California Consumer Privacy Act

- strong protection for individuals regarding their personal data and apply to businesses that collect, use, or share consumer data

Findings

What will happen to my samples and information when I die?

Once you die, your sample will be considered a gift to Mayo Clinic. That means Mayo Clinic can continue using it in the ways described in the consent form forever, even if your family wishes that you had not donated a sample to the Biobank.

Since your samples contain your genetic information, your family may want access to them after you die. On the consent form you can choose whether you would like to allow your next-of-kin access to your sample after you die.

Limitations

- GINA does not address wrongful publicity, unreasonable search and seizure, profit, or public trust
- GINA prevents unwanted access by employers or insurers, but not with respect to proprietary databases
- GDPR increases transparency, but requires well-informed and proactive consumers
- HIPAA applies to healthcare providers, IRBs regulate research, but no legal protections apply to proprietary databases, other than the terms of service.

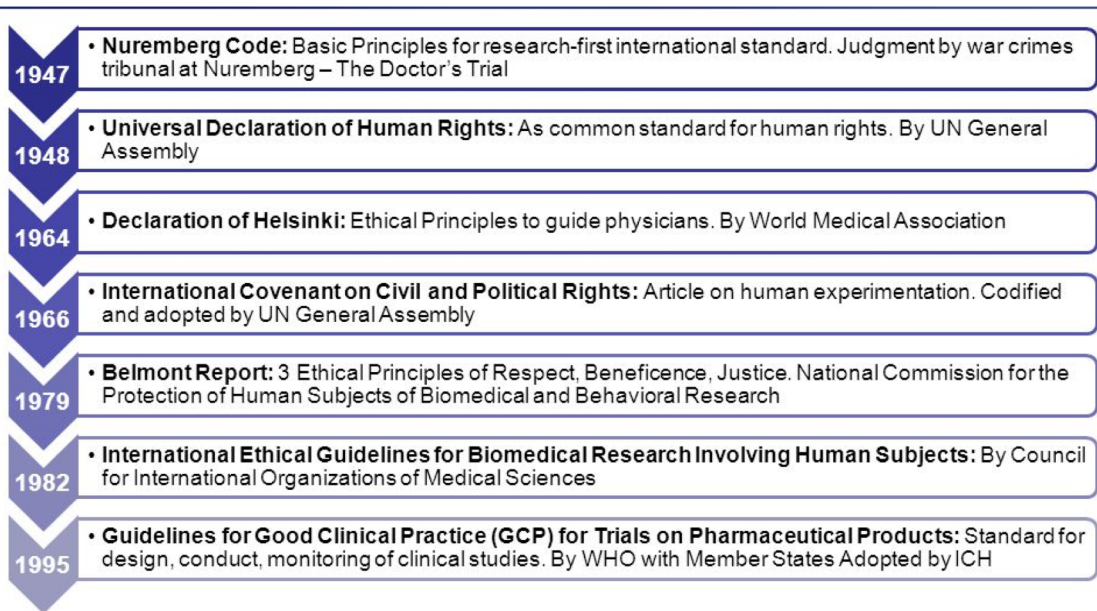
My Role/Methods

- Reviewed genetic databases, including clinical, research, and proprietary, and prepared spreadsheet with key information
- Found and summarized articles, academic reports, and other documents relating to:
 - genetic data privacy
 - current privacy policies of genetic databases
 - history of regulations and Institutional Review Boards (IRBs) / Limitations of IRBs
- Compiled references for law review paper

Proposed Safeguard: Data Protection Review Boards

- Goal: safeguard against potential harms without unduly suppressing opportunities for great medical and population health advance
- Modeled after IRBs and Data Access Committees that protect human subjects in research

History of Ethical Regulations/IRBs



Proposed Structure & Protections of DPRB

- Limiting the amount of data to be shared
- Requiring the data be destroyed after a specified amount of time
- Instituting data-handling protocols
- Implementing technological safeguards

Federal Oversight

- FDA for research related to pharmaceutical development
- FTC for other data sharing
- Possible new agency

Limitations of DPRBs

What DPRBs don't solve:

- Social and political misuse of data
- Follow-up contact of subjects and relatives with new findings
- Data ownership and right to proceeds of discoveries
- Ownership of designer genes

Conclusion

- Genomic advances have greatly improved the accessibility of genetic data and allowed for advances across all societal sectors.
- Like all other innovations, the rise of genetic databases comes with a price: privacy concerns.
- Through safeguards such as the proposed DPRB, the end goal is to protect consumers against potential harms without unduly suppressing opportunities for great medical and population health advances

What did I learn?

- A different style of research
- Problems that affect the health system as a whole
- The importance of being open to the opportunities that life affords you

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THANK YOU
