Research Involving Human Genetic Data

Genetic information is considered to be **different** from other types of health information. Some reasons why include:

- Predicts future health conditions
- Has implications for family, children, and future generations
- Often contains uncertain information that is likely to change in future
- Is a unique identifier (that can, e.g., be used in paternity or forensics cases)

Research involving the collection, analysis, or storage of human genetic data requires special duties and obligations.

The Federal Human Subjects Regulations (2018) require the following in informed consent documents:

- Plans for storing and re-using genetic data or biospecimens for secondary research
- Whether research will, or may include, whole genome sequencing
- What, if any, clinically relevant research results, including individual research results, will be disclosed and under what conditions

The Genetic Information Non-Discrimination Act (GINA) is a federal law that prohibits discrimination based on genetic information in health insurance and employment. To comply with GINA informed consent documents should include:

- Risks of participation and a statement describing how confidentiality will be maintained

The Clinical Laboratory Improvement Amendments Act (CLIA) and the Health Insurance Portability and Accountability Act (HIPAA) regulate where testing is performed and the type of research information that can be returned to individuals.

Check with your IRB to determine what regulations apply and what results can be returned to research participants.

FURTHER RESOURCES: WU Human Research Protection Office https://hrpo.wustl.edu
Office for Human Research Protections https://www.hhs.gov/ohrp
National Academies' Report on Return of Individual Research Results https://doi.org/10.17226/25094

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