GENETIC RESEARCH: INFORMED CONSENT INFORMATION

Emory IRB

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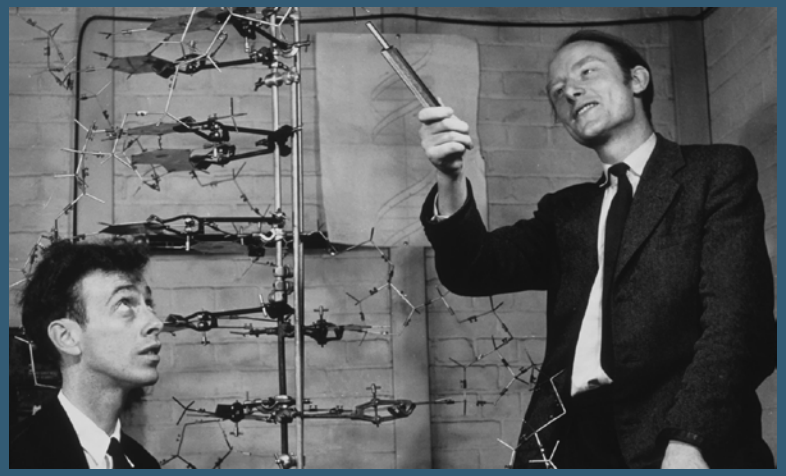
Overview

- Genetic Information Nondiscrimination Act
- Genome Wide Association Studies
- Genomic Data Sharing Policy
- Informed Consent Process and Document Considerations
- HIPAA Authorization Considerations

Overview

- Returning Results
- Differences between Individual Research Results and Incidental Findings
- Incidental Findings Management
- Research on Decedents
- Future Changes: NPRM



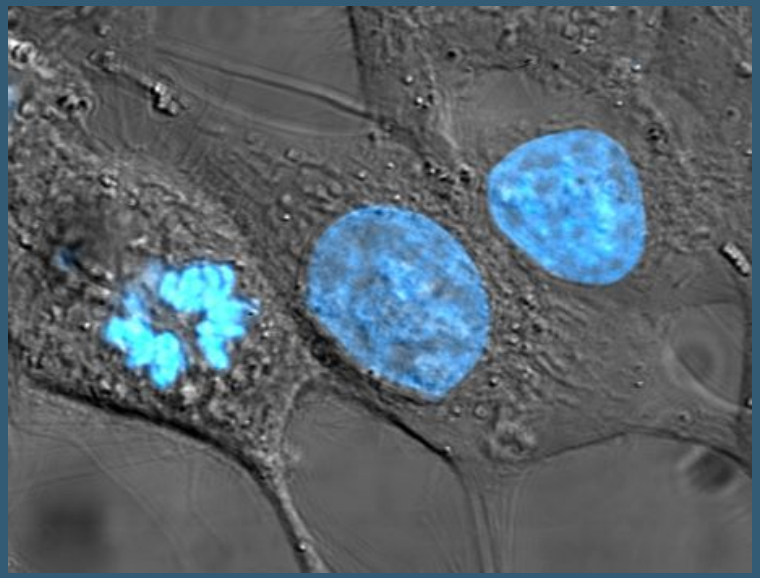
Genetic Information Nondiscrimination Act (GINA) 2008

- Genetic information protected by the law includes family health history, the results of genetic tests, the use of genetic counseling and other genetic services, and participation in ***genetic research***
- Prohibits health insurers and employers from requesting or requiring genetic information
- Provides legal protection against discrimination on the basis of genetic information
- Subjects should be informed about this protection, see our template language

Genome-Wide Association Studies Policy- 2008

- Policy that requires data from NIH-funded studies to be shared with the greater research community in the database of Genotypes and Phenotypes (dbGaP)
- The data is considered sensitive and is only accessed through a controlled access policy
- Requires that new research use of the data be consistent with the informed consent under which the data were originally collected

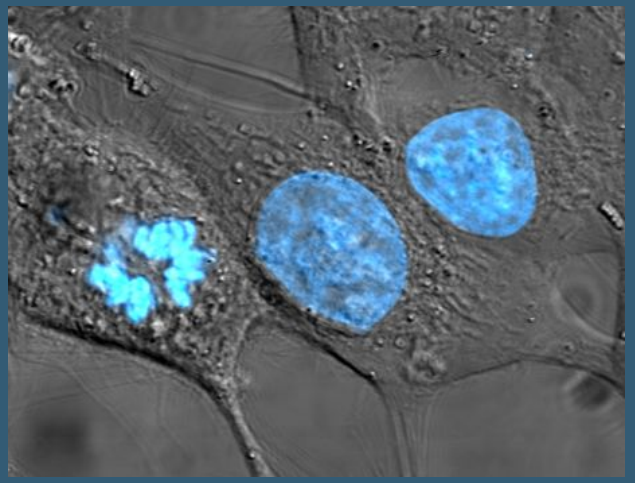
Genomic Data Sharing Policy



- NIH policy effective January 25, 2015
- Requires that investigators obtain consent for participants' data to be shared in data bases for future research use
- This applies to studies using genomic data from cell lines or tissue samples that were created or collected after the effective date
- Previous policy applies to samples/data collected before that date (consent just needs to be "not inconsistent" with sharing, not explicitly describe it)

Genomic Data Sharing Policy

- NIH grant proposals involving “large scale genomic analyses” need to include genomic data sharing plan
- Needs up-front IRB certification that consent(s) and protocol align with the policy
- IRB certification also required at time data is shared with NIH or other national repository – forms are confusing. Be prepared for some clarification with IRB.
- IRB NEEDS protocol, consent(s) that include future sharing, statement about when specimens were collected (i.e. before or after effective date of policy), and finally grant application



Informed Consent Process Considerations

- A flexible approach is necessary because of the challenges associated with explaining genetic research
  - For example, explaining how increased risk is different from a diagnosis or explaining risks associated with long-term storage and future use of data
- Scientific literacy and cultural expectations can vary greatly across subjects

Informed Consent Process Considerations

- Plans for measuring subject understanding should be made to ensure comprehension of complex topics
- Remote informed consent procedures might be appropriate in studies that require a large population

Informed Consent Documentation Considerations

- Modular consent language should be used to cover the following information, if applicable:
  - GINA and State of Georgia protections (or local protections if study is conducted in a different location)
  - Data/Specimen Sharing via Repository
  - Cell Line Creation
  - Returning Results

Topics that should be included:

- What samples/data will be shared
- How the samples/data will be stored and shared
- How the samples/data might be used in the future
- The risks (including privacy risks and psychosocial risks) and potential benefits of generating large-scale genomic data

Topics that should be included:

- If participants will be contacted in the future
- Whether participants will receive results from current or future studies using their samples/data
- What would happen if subjects decide to stop participating in the study or after they are deceased
- What happens if the repository closes

HIPAA Authorization Considerations

- Studies that do not involve treatment and electronic billing are not covered by HIPAA
- If any results are placed in the medical record, HIPAA will apply
- Researchers must still obtain HIPAA authorization or a waiver for use of identified samples from a repository

Returning Results

- The return of individual results is now more common due to decreased testing costs
- Returning results can lead to challenges, since there are differing opinions on whether individual results should be reported
- The only federal law requiring results to be returned is the Clinical Laboratory Improvement Amendment of 1988
  - Only results from CLIA-certified laboratories must be returned
- The informed consent document needs to detail whether results will be returned or not

Individual Research Results and Incidental Findings

- Individual research results-the results for a specific study participant
  - A particular gene variant under study
- Incidental findings- finding a potentially concerning result other than a gene variant being studied
  - A participant in a study investigating gene variants associated with Type 2 diabetes has a gene variant for Alzheimer's disease

Incidental Findings Management

- The scope of incidental findings should be disclosed during informed consent and subjects should be allowed to opt out of receiving results if they wish
  - Genetic counseling could be offered to recipients of incidental findings and coverage of costs for counseling should be included in the ICF

Incidental Findings Management

- An incidental findings management plan should be approved by the IRB
  - The plan could include verification of analysis and how results will be communicated

Research on Decedents

- Research on information or samples from deceased individuals who did not provide consent for genetic research presents ethical issues
  - Study teams should respect any known preferences of a participant, or the conditions described in the informed consent form signed by the participant

Future Changes- NPRM

- Changes might require upfront written consent for all future research on specimens/data
- Currently, research on existing specimens may be done without consent by stripping identifiers
- Proposed changes would create need for an open-ended consent for any future use of specimen
- Grandfather clause for existing specimens

Additional Questions?

- Please contact us at:
- Maria Davila, MD, CCRC, CIP
  Team Lead, QA and Education Consultant
  (404) 712-0724
- Shara Karlebach, WHNP-BC,CIP
  QA and Education Consultant
  (404) 712-0727
- Jessica Baker, BS
  QA and Education Research Protocol Analyst
  (404) 712-9698