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 databases 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?

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