Consent Language Does Affect Your Ability to Share

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Today’s Discussion

• General Sharing Information
  • Protocol
  • Consent form
• NIH Genomic Data Sharing Policy
• Agreements and IRB Approvals
General Information
### Words Matter

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anonymous</strong></td>
<td>Data that at no time has a code assigned that would permit the data to be traced back to an individual.</td>
</tr>
<tr>
<td><strong>De-Identified</strong></td>
<td>Investigator cannot readily ascertain the identity of the individual.</td>
</tr>
<tr>
<td><strong>Coded</strong></td>
<td>Identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a code (number, letter, symbol, or any combination) and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.</td>
</tr>
<tr>
<td><strong>PHI</strong></td>
<td>Protected Health Information (as defined by the HIPAA Privacy Rule 45 CFR 164 § 501)</td>
</tr>
<tr>
<td><strong>Personally Identifiable Information (PII)</strong></td>
<td>(1) any information that can be used to distinguish or trace an individual’s identity, such as name, social security number, date and place of birth, mother’s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information.</td>
</tr>
<tr>
<td><strong>Sensitive Research Data</strong></td>
<td>when disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.</td>
</tr>
</tbody>
</table>

We always learned to share....

5.8
Will any individuals other than the investigators/research staff involved in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?

* Yes

OSIRIS 5.8 needs to be “yes”

- Another researcher or someone outside of RCCO MIGHT have access to the data (identified or de-identified)
- You MIGHT share with another researcher or someone outside of RCCO
We always learned to share….

5.8.1

Identify the 'external' persons or entity who may have access to research data/documents and the purpose of this access:

If Yes, describe how they will protect the confidentiality of the research data:

Address sharing when these may be involved:
- Multi-center or collaborative sites
- Ancillary labs, sites or individuals
- Results sent to sponsors
- National Repositories or other banks, registries or repositories
What About Specimens?

2.15 Does this research study involve the long-term storage (banking) of biological specimens?

* Yes

2.15.1 Broadly describe the intended future use of the banked biological specimens:
De-identified samples from mother (blood, urine) and baby (cord blood, placental block) may be used for future research about preeclampsia or pregnancy.

2.15.2 Indicate the planned length of storage of the banked biological specimens:
* Indefinitely

2.15.3 Will biological specimens be stored without identifiers or linkage codes?
If you answer Yes, the samples will not be stored with any identifiers or linkage codes and it is highly unlikely to be linked back to the individual.
If you answer No, the samples will be stored with an identifier or linkage code and can be linked back to the individual.
2. Describe where the specimens will be stored
3. How long will they be stored
4. How the specimens will be accessed and who will have access
5. List the data to be stored or associated with each specimen
6. Describe the procedures to release data or specimens, including: the process to request a release, who can obtain data or specimens, and the data to be provided with the specimens
We always learned to share...

Consent form needs to clearly state what will be shared, where, with whom and under what circumstances.
Specificity in Consent

Pre-2015: Silence

• **Silence**: Previously, CF neither permitted nor prohibited use

Post-2015: Specific permission

• **Specific Permission**: Now, CF must specifically dictate what will or MIGHT happen now or in the future

Turning point is NIH GDS Policy, January 25, 2015
IRB Verification

- Data submission and data sharing for research purposes are not inconsistent with informed consent
- Consideration given to the risks to subjects and their families as a result of the sharing
- Risks to groups or populations were considered, when appropriate
- The investigator has a plan for management and deidentification, consistent with GDS policy
General Summary

- Words matter
- Think broadly
- Future use is often unknown!
- Plan ahead, don’t restrict
- Become friendly with “may” or “might”
Imagine...

2001: Study X enrolls 1,000 subjects:

2018: HRPO gets a request from Study Y to use data & samples from Study X. Study X subjects must be re-consented for Study Y.
NIH Genomic Data Sharing Policy

NIH Policy: https://osp.od.nih.gov/scientific-sharing/policies/
HRPO Guidance: http://www.hrpo.pitt.edu/genomic-data-sharing
Genomic Data Sharing Policy (GDS)

January 25, 2015, issued by NIH

Requires broad sharing of genomic data

Applies to NIH-funded studies that generate large-scale human genomic data

4 Pieces of Information for Consent Forms

- Genetic Risk
- GINA
- Commercialization
- Sharing with Others and Federal Repositories
• Before joining the study, you may want to consider discussing your plans and this study with your family members.

• Because certain conditions and traits run in families and are inherited through genes, this study is recruiting biologically–related family members. This study will compare family members who have [disorder] and family members who do not have [disorder].

https://www.genome.gov/27559024/
• The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization.

• You may learn something about your genome that relates to the health of your relatives. If so, your relatives might want to know so that they can decide whether to get tested or follow up in other ways. It is also possible that they might not want to know.

https://www.genome.gov/27559024/
Genetic Information Nondiscrimination Act of 2008: Prohibits discrimination in health coverage and employment based on genetic information

- Only covers genetic testing of diseases and disorders that have not yet manifest

- **Sample Language:** A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance

Subjects should be told whether there may be any future commercial use of their samples and what will happen with products that are eventually developed and sold for commercial purposes.

- **Pitt Language**: Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

• Give subjects information related to storing, sharing and future use of data and samples

• Language will be dependent on what takes place in the study and for what purpose
  • Convey that data, samples and genetic data will be shared with others and federal repositories, de-identified
  • NIH expects that permission for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.

Sample Language:

• We will store your samples and data indefinitely. Information will be shared with other researchers in the future but those researchers will not be able to identify you. Your data and samples may be used in any type of research. Your samples, data and genetic data generated from the samples may be shared with others, federal repositories and will be shared without identifiers.

Consistency is Key

**Study Purpose:**
Your blood samples will be used by researchers to do research on neurological conditions. Those researchers will not have access to your identifiable information.

**Who will have access to my information:**
Study investigators may send your deidentified study results to the NIH. Other researchers nationwide can ask the NIH for access to your deidentified study data for research purposes. Experts at the NIH who know how to protect this information will look at every request carefully to minimize risks to your privacy.

**Where will my information be stored:**
Your coded information and samples will be sent to the Data Archive at Lead Site University. If you decide that you do not want to share your information, contact the investigator of this study and they will request that your samples be destroyed. Previously shared information cannot be returned.

**Will this study use or disclose my medical information?**
In addition to the investigators listed on the first page of this form and their research staff, others may have access to identifiable information related to your participation in this research study. Your research data may be provided to secondary investigators for the purpose of conducting additional analyses about neurological or other conditions.
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Your coded information and samples will be sent to the Data Archive at Lead Site University. If you decide that you do not want to share your information, contact the investigator of this study and they will request that your samples be destroyed. Previously shared information cannot be returned.

Now What?

Will this study use or disclose my medical information?
In addition to the investigators listed on the first page of this form and their research staff, others may have access to identifiable information related to your participation in this research study. Your research data may be provided to secondary investigators for the purpose of conducting additional analyses about neurological or other conditions.
Agreements

Contact Pitt Office of Research Clinical & Corporate Contract Services

http://www.research.pitt.edu/processing-teams/clinical-and-corporate-contract-services
Data Use Agreement (DUA)

• Contractual document for transfer of data between organizations
• Assures that data is being used in accordance with the applicable laws and regulations
• Administered by Office of Research through MyRA
What is Data?

Any research data

Lab notes, methods, experimental data

Human data

Non-human data
DUA Establishes:

• Document data being transferred
• Ownership/stewardship of data
• Permitted uses and further distribution
• Publication of results
• Compliance with applicable laws
• Liability
• Term
Material Transfer Agreement (MTA)

• Contractual document for transfer of biological and research materials between organizations
• Memorializes transfer of material
• Defines rights and responsibilities
• Administered by Office of Research through MyRA
What is Material?

- **Biological Materials**
  - Cell lines
  - Tissue
  - Vectors

- **Pharmaceutical drugs or compounds**

- **Chemicals**

- **Software**

- **Other physical material**
MTA Establishes:

- Permitted uses of material
- Further distribution
- Ownership
- Publication of data and results
- Compliance with applicable laws
- Liability
- Term
Data and materials can only be transferred AFTER all parties have signed and approved
When is a Protocol Needed to Receive Specimens:

**Data: It Depends**
- De-identified data from another university: no
- DbGap, publicly available – only need one if the funding agency requires it

**Specimens: Always, unless:**
- Commercially purchased cell line
QUESTIONS?