Human Data and Biological Specimen Repositories Guidance

OVERVIEW
Human data and tissue repositories collect, store, and distribute human data and biological specimens. Repository activities involve three components: (i) collectors of biological specimens and data; (ii) repository storage and data management center; and (iii) recipient investigators, when research is involved.

Biological specimens are also often referred to as tissue- or biological- materials, samples or specimens. The terms data or tissue bank, repository, registry and database are often used interchangeably. These all involve the collection, storage and distribution of human data and or biological specimens.

Some repositories are created and maintained primarily for diagnostic or clinical purposes. Others are created specifically for research. Many serve more than one purpose. In any case, repositories (tissue banks), registries (data banks) and databases, comprise a vast resource that researchers can draw upon to address questions extending far beyond those envisioned when they were first created.

DEFINITIONS
Database: A collection of information elements (i.e. data) arranged for ease and speed of search and retrieval. Most databases are now maintained electronically, but the term can also be applied to paper record systems. Examples of databases include the following:
- A set of observations (i.e. data) resulting from a research study
- An electronic file of a medical provider’s patients
- A collection of diagnosis, treatment, and follow-up information for a hospital’s patients
- A file of outcomes information compiled for quality assurance activities
- A list of potential research subjects

De-identified: There is no identifiable information linked to the data/specimens and there is no code or code key that could be used to link the data/specimens, directly or indirectly, to specific individuals.

Under the HIPAA Privacy Rule, data are de-identified if either (1) an experienced expert determines that the risk that certain information could be used to identify an individual is “very small” and documents and justifies the determination; or (2) the data do not include any of the eighteen identifiers defined under the Rule (of the individual or his/her relatives, household members, or employers) which could be used alone or in combination with other information to identify the subject.

HIPAA: Health Insurance Portability and Accountability Act, passed by the U.S. Congress in 1996 which includes a number of measures designed to protect patient privacy. HIPAA contains very strict rules designed to protect patient privacy and to allow patients to control how and when information about them is released.

Individually identifiable: the identity of the subject is or may readily be ascertained by the investigator. According to the “Guidance on Research Involving Coded Private Information or Biological Specimens” OHRP generally considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.
Privacy Rule: The HIPAA Privacy Rule establishes national standards to protect individuals’ medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information (PHI), and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.

Protected Health Information (PHI): Individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records.

Registry: A registry or “data bank” is a collection of information elements whose organizers:

- Receive data from multiple sources
- Maintain the data over time
- Control access to and use of the data by multiple individuals and/or for multiple purposes, which may evolve over time

Repository: A collection of biological specimens is considered a repository or “tissue bank” when all of the following conditions apply:

- Specimens are received from multiple sources/persons
- The specimens are maintained over a period of time
- Access to and use of specimens controlled by multiple individuals and/or for multiple purposes, which may evolve over time.

Repositories usually include demographic and/or medical information about the individuals from whom the specimens were obtained. Repositories often maintain codes that link the information and specimens to their donor’s identity.

PROCEDURES

IRB Oversight

When the intended purpose of a repository containing identifiable private information or human specimens includes research, collecting, storing, sharing, and using the information are all considered human subject research activities and all require oversight by the IRB.

In addition to the information included in an IRB application and research protocol, the IRB expects that consent documents and the corresponding protocol for establishing and operating a research repository include at minimum, the following information:

- Name; Purpose; Location
- The general concept and purpose of repositories
- A specific description of what is being collected (types of data and/or specimens)
- If there is an allocation and/or advisory committee for distribution of the data and/or specimens, and if so, a description of this should be provided
- The conditions under which materials will be released to recipient investigators
- The populations from whom the materials will be collected
- If specimens are involved:
  - Indication of whether the specimens would be collected as part of a research or a clinical procedure, or specifically for the repository
  - If the specimens are collected specifically for the repository, the number of collections per person.
• Whether research participants would be asked permission to be contacted by the repository in the future, and if so, details regarding re-contact
• If the research participants would be able to withdraw their materials from further study
• Provisions for protecting the privacy of the research participants and the confidentiality of the materials
• Specific methods for assuring privacy and confidentiality include effective data security measure, limiting identifiable information retained by the repository to that needed for research use, confidentiality agreements with investigators, and use of firewalls
• Specific risks related to a breach of confidentiality related to the materials being collected
• How the repository will be maintained if the responsible investigator leaves the site

Additional considerations include:
• Inventory and/or database management procedures for the materials in the repository
• Quality assurance procedures
• A Certificate of Confidentiality is recommended, especially when genetic or potentially sensitive information is stored in the repository
• Where available, an application should include any information about the circumstances under which the data or specimens were originally collected.

Attachment A of the Application for Initial IRB review must also be completed. Attachment B must be completed if Genetic testing is to be part of the protocol.

Research repositories are routinely used for the purposes and in the manner specifically described in the IRB-approved protocol and informed consent document under which the information was collected. However, investigators wishing to use a repository for research that differs in any way from that described in a protocol approved by the IRB must submit a new or amended protocol for IRB review before initiating the new project.

Sometimes researchers wish to preserve or expand a research database so it can be used not for a specifically defined new project, but by multiple researchers and/or for multiple purposes, which may evolve over time. In such cases, one alternative is to submit a new or modified application for IRB review each time a new or revised project is defined. However, a more flexible and efficient alternative is to define, in relatively broad parameters, and operate the database as a repository.

REFERENCES
OHRP’s Issues to Consider in the Research Use of Stored Data or Tissues
OHRP’s Guidance on Research Involving Coded Private Information or Biological Specimens
OHRP Video - Research Use of Human Biological Specimens and Other Private Information