

Guidance and Procedure: Data and Specimen Repositories

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- [Introduction](#)
- [UCLA IRB Oversight and Types of Repositories](#)
 - [Non-Research Repositories](#)
 - [Repositories Created for both Research and Non-Research Purposes](#)
 - [Research Repositories](#)
- [IRB Applications for Research Repositories](#)
- [Standard Operating Procedures](#)
- [Informed Consent Requirements](#)
- [HIPAA Requirements](#)
- [References](#)

Introduction

The terms *data and/or specimen bank*, *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. In this document, the term *research repository* will be used to refer to collections of data and/or specimens that are collected, stored and distributed for research purposes. The term *materials* will be used to refer to data and/or specimens collected from human subjects.

Figure 1: Schematic of Basic Repository



UCLA IRB Oversight and Types of Repositories

Based on whether or not they were created for research purposes, there are three major types of repositories:

- **Non-Research Repositories**

These are repositories that are created for non-research purposes and have identifiable data and/or specimens. Examples include, but are not limited to, university academic records, hospital medical records, or disease registries established by State law.

These types of repositories are not subject to IRB oversight, however, UCLA IRB approval or certification of exemption is required prior to acquisition or use of identifiable or coded materials for research purposes by a UCLA Investigator.

- **Repositories Created for both Research and Non-Research Purposes**

Some types of repositories are initially created for quality assurance, clinical care or other purposes, and are also designed to provide materials for research purposes. An example of this is a departmental bank that receives, analyzes and stores specimens for clinical as well as research purposes.

In this case, the repository would be considered to serve dual purposes. Since one of the purposes involves research, the operations of the repository would be subject to IRB oversight and require IRB approval. If the repository is at UCLA, it would require UCLA IRB Approval.

UCLA IRB approval is required for UCLA Investigators who access identifiable or coded materials from one these repositories.

- **Research Repositories**

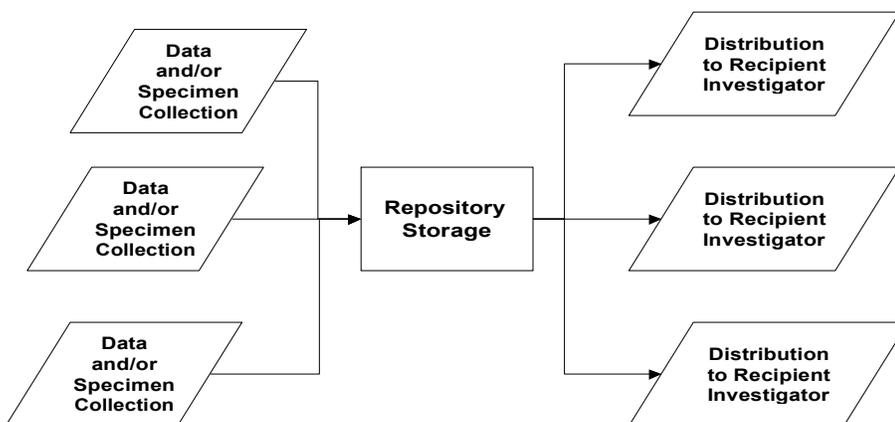
Many repositories are established specifically for research purposes. Examples include:

- **Outside UCLA:** Repositories managed by cooperative groups, government entities such as the Department of Education, National Institutes of Health, commercial entities, and other academic institutions.

UCLA IRB Approval is required for UCLA Investigators who access identifiable or coded materials from one of these repositories.

- **At UCLA:** Repositories may be created and maintained by individual investigators, research groups, programs, departments or institutes. A single investigator or group of investigators may wish to pool research data and/or specimens into a single repository that could be accessed by themselves or others for further research.
 - The operations of these repositories are subject to IRB oversight and require UCLA IRB approval if the materials are collected specifically for the research repository and/or are associated with identifiable information or coded.
 - UCLA IRB approval is required for UCLA investigators who access identifiable or coded materials from one of these repositories.
 - A [Material Transfer Agreement \(MTA\)](#) may be needed for data and/or specimens that are sent to another institution. Check with the [UCLA Office of Intellectual Property & Industry Sponsored Research](#) for further information.

Figure 2: Schematic of Repository Collecting Materials from Multiple Sites and Distributing to Multiple Investigators.



IRB Applications for Research Repositories

An IRB Application is required when an investigator plans on the following:

- Establishing a new repository, or
- Converting an existing database, collection of specimens, or non-research repository into a research repository for which research is one or the sole purpose of the repository.

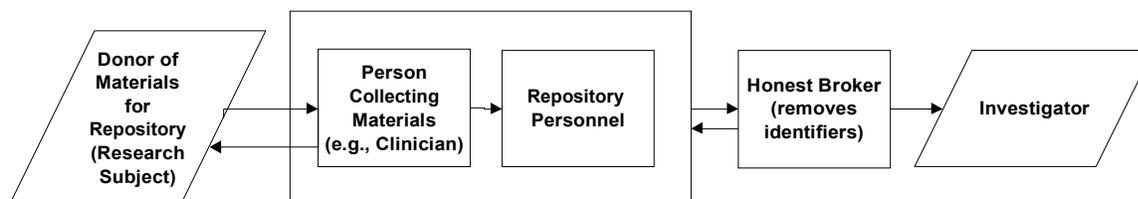
In addition to the information usually included in an application, the following information is required:

- **Standard Operating Procedures (SOPs)**

Standard operating procedures for the repository should be described in the IRB Application or in an attached document. At minimum, the information should include:

- Name
- Purpose
- Location
- If there is an allocation and/or advisory committee for distribution of the data and/or specimens, and if so, a description.
- The conditions under which materials will be released to recipient investigators
- The types of data and/or specimens
- The populations from whom the materials will be collected
- If specimens are involved:
 - Indication of whether the materials 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.
- Indicate how the repository will be maintained if the responsible investigator leaves UCLA.
- 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 measures, limiting identifiers/identifiable information retained by the repository to that needed for research use, confidentiality agreements with investigators, use of firewalls and/or use of an honest broker model (see figure below).

Figure 3: Honest Broker Model



The Honest Broker Model requires that a group or individual other than the investigator (i.e., the “honest broker”) protects the link between the materials and the subjects’ identities. This will allow

collection of follow-up information from the subjects, without revealing their identities to the investigator.

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.

Table 1: Is IRB Approval Needed for the Following Activities?

Type of Repository	For Collection of Materials that may be used for Research		For Repository Storage		By Recipient Investigator	
	Non-Research Purposes	Research Purposes	Non-Research Purposes	Research Purposes	Materials <i>do NOT</i> have identifiers	Materials <i>do have</i> Identifiers or Codes
Non-Research Repository	No	N/A	No	N/A	No	Yes
Repositories For Research & Non-Research Purposes	Yes		Yes		No	Yes
Research Repository	Yes		Yes		No	Yes

Informed Consent Requirements

• Non-Research Repositories

Research informed consent is not usually obtained for the initial collection and storage of materials in non-research repositories. Other types of consent, such as those used for clinical treatment, usually do not meet research regulatory standards. The following alternatives are available:

- The repository may release materials to investigators without identifiers, or if coded, with an agreement that the key to the code will never be released.
- The investigator may apply to the IRB for a waiver of consent, if:
 - The research involves no more than minimal risk to subjects;
 - The waiver would not adversely affect the subjects' rights and welfare;
 - The research could not practicably be carried out without the waiver; and,
 - Where appropriate the subjects will be provided with additional pertinent information after participation.
- The IRBs may require investigators to obtain the informed consent of subjects for research involving materials from non-research repositories.
- If the investigators wish to contact the subjects, the IRB may require that the repository obtain the permission of the potential subjects before releasing information to investigators for research recruitment purposes.

• Research Repositories

IRBs review the consent process and documentation for the initial collection of materials for repositories as well as the consent process and documentation for subsequent use of these materials. Unless waived by the IRB, the IRBs require that the informed consent documents

for collecting, storing and sharing materials for research purposes include a clear description of the following in addition to the other standard sections of the [consent templates](#):

- A statement describing the future use of specimens, if future use is currently unspecified, this should be stated in the informed consent.
- Likely areas of research to be conducted with the collected materials, at minimum, something such as “for health-related research.”
- Indication of whether subjects will be informed of any incidental or other findings related to the research.
- Indication of whether subjects may be re-contacted in the future for future research.
- The procedures for protecting the privacy of subjects and maintaining the confidentiality of the collected materials.
- Whether or not subjects may withdraw their data and/or specimens later and, if so, how they would indicate that wish.
- If human biological specimens are involved, a statement that the specimens may be used in research that may result in new discoveries and that the donor-subjects do not retain any property rights to their materials. Thus, they would not receive any financial benefits from these discoveries.

HIPAA Requirements

When identifiable materials are obtained in the course of providing healthcare services, all requirements of the [Health Insurance Portability and Accountability Act](#) (HIPAA) apply.

References

- [National Cancer Institute Cancer Diagnosis Program: 50-State Survey of Laws Regulating the Collection, Storage, and Use of Human Tissue Specimens and Associated Data for Research](#)
- [NIH: Research Repositories, Databases and the HIPAA Privacy Rule – January, 2004](#)
- [DHHS OHRPP: Issue to Consider in the Research Use of Stored Data or Tissues – November, 1997](#)
- [Report of the Public Responsibility in Medicine and Research \(PRIM&R\) Human Tissue/Specimen Banking Working Group – March 2007](#)