

# II3E PR2 Data Repositories and Banks: Collection, Banking and Use of Data and Specimens

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## Overview

The collection and use of data and biological specimens have proven valuable to researchers in making significant gains in the study of science and medicine. Repositories or banks allow data and biological specimens and materials derived from living human beings to be stored and shared or used by investigators for multiple research projects, including those that were unknown at the time the data and specimens were collected. Repository materials may be prospectively collected or accessed from existing sources retrospectively.

The collection and use of data, specimens or both from a repository invoke unique ethical and regulatory issues that must be addressed to facilitate proper management of these activities.

*Note: This policy does not apply to data, specimens or both that are collected and stored as part of routine clinical care or hospital procedures, such as blood banks, medical records or pathology specimens.*

## II3E1 Data Repositories: Collection, Storage and Use of Data and Specimens

### II3E1a Collection of Materials for a Repository

An Institutional Review Board (IRB) must review and approve the collection, maintenance and subsequent distribution of data and biological specimens in a repository; or determine that the proposed activities are exempt from IRB review or do not constitute human subjects research. Such activities include the *creation* of a repository or bank of data or biological specimens derived from human beings that is intended as a resource for research purposes.

### II3E1b Use of Materials from a Repository

IRB review and approval, or a determination of exemption or “not human subjects research” (whichever is appropriate for the circumstances) is required before investigators may conduct research using identifiable data and biological specimens when these are accessed from a data or biological specimen bank, repository or other collection.

*Note: Due to the specificity of research involving the creation and use of data repositories, the following key terms are defined in this procedure.*

## I13E1c Research Involving Data Repositories: Key Terms

### Anonymous

Data are stripped of identifying information and of codes that could be used to link the information or samples back to a specific individual. Although, by definition, anonymous materials do not contain linking codes, they may not be considered “de-identified data” (as defined below).

*Note: Materials containing certain demographic information may not be considered anonymous depending on the size of the population from which the materials or data are derived.*

### Bank or Repository

A collection of human data, tissue, and specimens collected and maintained for future research purposes. The bank should have written plans for distributing the stored data, specimens or both.

Data banks and repositories may or may not allow the stored materials to be distributed to other research groups. For example, clinicians within a department or section may maintain a bank of stored data, biological specimens or both collected by themselves for their own research purposes.

### Coded Material

Data or specimens for which all private information which would enable another person to ascertain the identity of the individual to whom the materials pertain (e.g., name, social security or telephone number) has been replaced with a code (e.g., numbers, letters, symbols or combination thereof) and a key to decipher the code or master list exists that would allow the identifying information to be linked to data or specimens.

### Donor-Subject

A living individual from whom information, specimens or tissue are obtained through clinical or research intervention or interaction.

### De-identified Material

Data, biological specimens or tissues that cannot be linked to a specific individual for the following reasons.

1. The materials do not include any of the 18 identifiers specified by HIPAA (see IRB Policy I13D Privacy in Human Subjects Research, Protected Health Information).
2. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable
  - applies such principles and methods to the materials;
  - determines that the principles and methods preclude possibility that the materials could be used, alone or in combination with other reasonably available information, by the researchers to identify an individual who is the origin of the materials;
  - documents the methods and results of the analysis that justify such determination; and

- provides that documentation to the IRB.

*Note: Materials are not considered de-identified if the researchers know that the materials could be used, alone or in combination with other information, to identify an individual who is the origin of the materials.*

## HIPAA

The Health Insurance Portability and Accountability Act of 1996 and implementation of the related privacy and security regulations.

## Human Subject or Human Participant

A living individual

- (1) about whom an investigator (whether professional or student) conducting research obtains either
  - (a) data through intervention or interaction with the individual; or
  - (b) identifiable private information; or
- (2) who is or becomes a participant in research involving drugs or devices, either as a recipient of a test article or as a control.

*Note: Both “human subject” and “human participant” are used interchangeably in IRB policies and procedures. While the term “participant” conveys the voluntary nature of an individual’s agreement to participate in the research, it also can convey a sense of partnership that is not reflected in all types of research. In some research activities, a true sense of partnership may be lacking in which case “subject” would be the more appropriate term.*

## Individually Identifiable

The identity of the research participant is or may readily be, ascertained by the investigator or associated with the information.

## Limited Data Set

A subset of Protected Health Information (PHI) that do not contain any identifiers related to the individual who is the subject of the PHI, or of relatives, employers or household members of the individual except for one or more of the following: town or city, State, zip code, dates, including dates of birth, death, and services (see procedure I13D PR1 Authorization for Research Uses and Disclosures of Protected Health Information).

## Materials

Data, films, biological specimens, or other recorded information when, for the purpose of this policy, these are used for research. Examples include vials of blood, medical records, tumor specimens, scans, completed assessment instruments and videotapes of interviews.

*Note: Sources of information or data (e.g., facts) contained in articles or books are not affected by this policy because they do not identify any human subjects or contain PHI, or otherwise implicate any unique privacy concerns (e.g., the individual to whom the information pertains agreed to be identified).*

### **Recipient Investigator**

A member of a research team who receives data, tissue or specimens from a repository for a single and defined research purpose under an approved protocol or as otherwise permitted by this policy.

### **Research**

A clinical investigation or a systematic investigation, including research and development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

## **II3E2 IRB Review Requirements for Research Involving Banks or Repositories**

### **II3E2a Creation and Maintenance of Data Repositories**

Collections, banks or repositories require review by a University IRB under any of the circumstances described below.

1. Specimens or data are collected prospectively and will be shared with other investigators for multiple, distinct research projects; or stored for future research, whether or not individual identifiers are collected in the process.
2. Excess research materials that were collected as part of an IRB-approved protocol are stored for future research uses.
3. Existing individually identifiable clinical, historical or other collections are stored with the intent of being accessed for future research.
4. Collections of previously coded materials become individually identifiable. (e.g., an investigator requests the identities of the sources of coded tissue samples or of data previously considered anonymous.
5. The collection and storage is for the purpose of sharing with others, and that sharing is supported by an agency that requires IRB review, for example the Department of Health and Human Services.

### **II3E2b Data Repositories Involving De-identified Materials**

The creation of a data repository involving de-identified materials may not require IRB review and approval, or exemption or not human subjects research determination if the project does not constitute human subjects research as defined in 45 CFR 46.102(f). Determinations regarding whether the data, specimens or both are de-identified must be made by someone other than the principal investigator, such as IRB members or staff, or an individual with appropriate training and knowledge of the requirements for de-identifying or making data anonymous.

Collections involving only coded private information may not require IRB review and approval under the following conditions:

- the private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- the investigator cannot readily ascertain the identity of an individual to whom the coded private information pertain because either:
  - i. the key to decipher the code is destroyed before the research is initiated, or
  - ii. the investigators and the holder of the key enter into an agreement, such as an internal data use agreement, prohibiting the release of the key.

Principal Investigators should be aware that in some cases, journals or funding agencies may require documentation that the IRB, or someone other than the research investigator, has determined that the data, specimens or both are not individually identifiable or have been de-identified and therefore are not subject to IRB oversight.

### **I13E2c Research Uses of Materials from Repositories that Require IRB Review**

Use of materials from data repositories or banks requires IRB review and approval under the conditions itemized below.

1. Identifiable data or biological specimens stored in clinical, historical or other collections are used for research.
2. Identifiable information is seen by the investigator in the source record but is redacted or not recorded when the data are obtained or recorded for research purposes.
3. Materials are withdrawn from repositories as a limited data set.
4. Coded or anonymous materials become individually identifiable. (e.g., an investigator learns the identities of the sources of coded biological samples or data sets previously considered de-identified or anonymous).
5. Excess individually identifiable materials that were collected as part of the single IRB-approved protocol are used for a subsequent research project or secondary use not known when the materials were collected.
6. The utilization of de-identified, coded or anonymous materials for research is required by the repository retaining the material, or when the investigator believes journals or other publication entities will require proof of IRB review.

## **I13E3 Collection of Materials for Banks and Repositories Maintained Outside of the University**

Collections of identifiable materials, including those that are coded, for the purposes of storing the materials at a repository or bank located external to the University may require review by an IRB designated by the University. Under most circumstances, written informed consent from the donor of the material is required.

## **I13E4 Responsibilities of Recipient Investigators Utilizing Materials Stored in Repositories**

University investigators wishing to obtain materials from a repository must abide by the operating and distribution conditions specified by the repository and must use the materials solely for the purpose indicated in the IRB protocol and application or request for materials submitted to the repository. This requirement applies to repositories maintained by University investigators and those which are outside of the University. In the latter case, IRB review and approval of the research may be required by the IRB overseeing research activities for the organization that owns the repository.

## **I13E5 Informed Consent and Authorization Requirements for Data Repositories**

### **I13E5a Informed Consent for Collection of Materials for a Repository**

Collection of data, specimens or both must be authorized by obtaining legally effective informed consent and authorization from each donor-subject or her or his legally authorized representative unless waived by the IRB. (See IRB Policy I13F Informed Consent and procedure I13D PR1 Authorization for Research Uses and Disclosure of Protected Health Information).

The informed consent form must be sufficiently detailed to provide potential donor-subjects with adequate information on the types of potential future uses for which the materials could be used so that the donor-subjects may make informed decisions regarding agreement to allow materials to be stored in the repository.

Information about potential future uses may be provided in general or broad terms (e.g., the study of human physiology and brain biology) as opposed to in specific detail (e.g., the study of Alzheimer's disease). Such general uses are considered specified future uses and are appropriate for consent purposes.

To meet the criteria for IRB approval, the consent document must include a time frame whereby the materials will be retained and used for research. It is sufficient to say that the materials will remain in the repository and be available for research indefinitely or for as long as the sample is available or until such time that the donor-subject revokes consent.

When the materials include protected health information, investigators must also provide donor-subjects with a HIPAA authorization form to sign to document their agreement with the proposed future uses. Since HIPAA requires an authorization form be used for a specific purpose (e.g., banking) then secondary or future uses that are not consistent with the authorization will require a new HIPAA authorization form unless waiver of HIPAA authorization is approved by the IRB.

### **Exceptions and Waivers to Consent and Authorization for Collecting Data for a Repository**

Prior consent and authorization may not be required for research involving data and specimens under the conditions itemized below.

1. The research involves existing materials that have been collected, solely for non-research purposes such as medical treatment or diagnosis and these materials are transferred to the repository such that:
  - a. they contain no identifying information (i.e., subjects cannot be identified, directly or through identifiers linked to the subjects), or
  - b. are publicly available.
2. The research involves existing materials that have been collected for research purposes under another IRB-approved research study which did not obtain consent and authorization for future research use and these materials are transferred to the repository such that they contain no identifying information (i.e., subjects cannot be identified, directly or through identifiers linked to the subjects).
3. The IRB waives consent, HIPAA authorization or both in accordance with IRB Policies I13D and I13F, and related procedures after determining that the waivers would not adversely affect donor-subjects and the waivers are in accordance with federal regulations and local laws.

The IRB may waive informed consent and authorization when a researcher wishes to bank materials that are obtained from entities that are considered separate and apart from the University (e.g., unaffiliated hospital). In considering whether or not the waiver of informed consent would adversely affect donor-subjects, IRBs will consider whether

- the waiver would violate any state or federal law (e.g., HIPAA);
- the study will examine traits with political, cultural, or economic significance to donor-subjects; and
- the study results might adversely affect the welfare of donor-subject's community.

### **I13E5b Informed Consent for the Use of Materials from a Repository**

Consent for the use of materials stored in repositories must be consistent with the requirements noted in IRB Policy I13F, and if applicable, for authorization in procedure I13D PR1 for the research use of PHI. Consent and authorization for the use of the material may be obtained at the time the material is

collected. The IRB will approve the use of such a consent method for future research when the research aim of the individual research project is consistent with types of research described to the subject-donor at the time the material was collected and consent was obtained.

### **Consent Not Required**

Informed consent may not be required for materials when the materials cannot be linked, either directly or indirectly, to an individual.

## **II3E5c Re-Consent and Authorization for Collection and Use of a Data Repository**

The IRB may require the investigators to re-contact donor-subjects for new consent under any of the conditions itemized below.

1. The purpose of the collection and storage, or proposed use of the data or specimens changes and is no longer consistent with the purpose noted in the consent form used at the time the material was originally collected.
2. The purpose of the collection and storage, or proposed use of the data or specimens falls out of society's mainstream thinking as acceptable;
3. A donor-subject reaches the age of majority and the materials were stored by the donor-subject during her or his childhood.

*Note: If the IRB requires new informed consent, authorization or both, and the original informed consent does not include the donor-subject's permission for future contact, the materials cannot be distributed for new research projects.*

## **II3E6 IRB Requirements: Repository Procedures and Operations**

### **II3E6a Investigator Responsibilities for a Overseeing a Data Repository**

Repositories or banks of materials derived from human beings that are stored for future or secondary research must have a University or affiliate faculty or staff designated as the Principal Investigator. The Principal Investigator has the primary responsibility for the collection, storage and distribution of the materials. The repository operation must comply with all applicable laws and policies regarding establishment, maintenance and use of databases containing personal identifiers including obtaining IRB approval. Repositories or banks of materials must include the operational procedures described in Section II3E-1E below.

The repository must be established in such a way that the operators are able to

- identify when the material is originally received and whether the person from whom the material was obtained provided legally effective consent and authorization under HIPAA, as applicable;

- identify and ensure no future use of materials for which consent has been withdrawn;
- restrict access to identifiable materials to a limited number of repository staff and provide evidence that safeguards exist to insure access is adequately controlled and monitored; and
- limit access to coded material through implementation of computer security and material storage security measures and provide evidence of same.

A Certificate of Confidentiality is recommended, but not required, as an additional protective measure.

## **I13E6b Distributing and Accessing Materials from Repositories for Future Research**

### **Distribution or Access for Pre-Research Activities**

#### ***Distributing Investigator***

The Principal Investigator of the repository is responsible for receiving appropriate documentation of attestation by recipient investigators prior to permitting access to the database for activities considered preparatory to research.

#### ***Recipient Investigator***

Investigators wishing to access materials or databases for activities considered preparatory to research, for example, to determine a sufficient statistical base, are required to provide an appropriate attestation of the activity to the Principal Investigator of the repository.

### **Sharing Materials for Future Research**

The distribution of materials that are stored in repositories for subsequent research is a separate activity from the collection of the materials. The distribution activity has a unique research purpose and aim that differs from the collection objective of the repository protocol. As such, the distribution process and the research that utilizes the materials may require additional review by the IRB. However, the distribution process whereby the repository distributes materials to recipient investigators for future research may be incorporated into the IRB approval for the collection activities.

The repository protocol must include standard operating procedures for distributing the materials to recipient investigators. The operating procedures should note that research activities that utilize materials withdrawn from the repository require a separate protocol that may warrant review by a University IRB.

Materials released to recipient investigators for IRB-approved research will be assigned a unique code, unless permission is granted by the IRB to include specific identifiers. Prior to releasing materials from a repository, the Principal Investigator is responsible for receiving appropriate documentation from recipient investigators that IRB review of the research has taken place in accordance with University policy and the distribution processes of the repository.

## Requests for Use of Identifiable and Anonymous Materials

### *Distributing Investigator*

Requests to use identifiable material require documentation from the recipient investigator that IRB review and approval has taken place.

### *Recipient Investigator*

Investigators should be prepared to provide documentation of IRB review and approval or exemption or not human subjects research determination to the Principal Investigator or other person operating the repository when requesting to access or obtain materials.

Requests to use anonymous materials when the requestor will have access to individual identifiers, but not record them, may qualify for an exemption determination from the IRB (see IRB Policy I12 IRB Review of Research Protocols). Recipient investigators who have access to directly identifiable materials and who have been granted an exemption from the IRB are prohibited from recording the direct identifiers.

Requests to use anonymous materials when individual identifiers are not viewed by the requestor may not require IRB review but HIPAA may apply. Investigators may wish to discuss such requests with an IRB Program Manager.

## Requests for Use of Coded Materials

Investigators wishing to withdraw coded materials from repositories should be knowledgeable as to whether or not the repository requires review of the project by an IRB. Documentation of IRB review may be required by some repositories or for publication in certain journals or other places.

When the recipient investigator is also a member of the research team that operates the repository, the IRB may approve the secondary or future use of the materials in a coded or anonymous manner at the time the collection protocol is under review. Such IRB approval is only applicable to secondary and future research activities that are consistent with the purpose outlined in the collection protocol. The repository operator (i.e., Principal Investigator on the collection protocol) will be responsible for ensuring compliance with HIPAA policies related to the use of the material.

The conditions under which the repository may release coded data sets are similar to those for the collection of the data:

1. The private information was not collected for the currently proposed research through interaction or intervention with living individuals and the identities of the individuals to whom the data pertain cannot be easily ascertained.
2. The IRB or the repository team determines that the research does not involve “human subjects” as defined above.

3. The recipient investigator will not be given the identifiable information linked to the material and signs an agreement not to access identifiers or attempt to ascertain donor-subjects' identities.

*Note: The release of coded materials that retain a link (i.e., code) to identifiable information about the donor-subject requires the Principal Investigator of the repository to verify that the proposed research is consistent with the scope of research described in the consent and authorization signed by the donor-subject at the time of collection.*

### **Requests for Use of Limited Data Sets**

Requests to withdraw limited data set materials from repositories must be reviewed and approved by the IRB. The IRB will review the proposal and make an appropriate determination in accordance with other IRB review policies. The IRB will consider whether or not waiving consent and using limited data set identifiers for the proposed research is consistent with the permission provided by the donor-subject at the time of collection.

University investigators wishing to obtain limited data sets containing PHI from databases and repositories owned by the University or its agents, or repositories that are external to the University, must submit a data use agreement as required by the repository.

### **No Identifiers Requested**

Research in which investigators request only de-identified materials do not require documentation of IRB review or approval, or exemption or not human subjects research determinations because the project does not constitute human subjects research (e.g., bench research).

## **I13E-1F IRB Review of Repositories**

The IRB will review the protocols describing the collection activity and repository or bank operations protocols in accordance with the guidelines set forth in IRB Policy I12 Review of Research, and will approve the research or issue an exemption or not human subjects research determination as appropriate for the proposed research activities. The IRB will also require investigators to obtain consent from subjects, or may waive or alter applicable informed consent and research authorization requirements.

To ensure that the rights and welfare of donor-subjects are upheld and protected, the IRB must review the procedures for placing materials into the bank or repository; for release of stored materials to recipient investigators; and donor-subjects to withdraw consent, authorization or both.

The IRB may approve a collection protocol that contemplates unspecified future uses when the donor-subject is so informed. However, new IRB review and consent and authorization, or waivers or alterations may be required before the investigators may initiate any such future research.

## **II3E-1G Ownership and Transfer of Repository Materials**

Materials acquired during clinical investigations or research activities at the University are considered University property.

Investigators wishing to transfer materials retained in repositories and banks operated by the University must consider the rights of other investigators who assisted in the research and remain at the University. Requests to transfer materials must comply with IRB Policy II5 IRB Requirements for Record-keeping, and Biological Specimen Retention and Transfer.

Investigators who are permitted to take such materials elsewhere must provide an attestation that they will treat and work with the materials only in accord with the original consent and HIPAA research authorizations, grants and IRB-approved protocols. The transference of biological specimens may also be subject to Material Transfer Agreements.

Investigators bringing in research materials collected at another institution and intended for future research purposes are required to establish a repository or bank subject to University IRB review and approval.

If the Principal Investigator of a repository or bank leaves the University, she or he must identify a successor Principal Investigator for the repository or bank and submit an amendment to the related protocols for IRB review and approval.