
Yale University Human Research Protection Program

HRPP Policy 440: Collection and Banking of Data, Biological Specimens and other Materials in Human Research

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Scope

This policy applies to all members of the Yale University research community who intend to collect biological specimens (materials) and/or data derived from living human beings for the purposes of creating and maintaining repositories or banks to be used by themselves or others in the conduct of research.

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

Policy Statement

An Institutional Review Board (IRB) as designated by Yale University must review and approve, or otherwise acknowledge, as appropriate 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.

Reason for the Policy

The collection and use of biological specimens and data have proven valuable to researchers in making significant gains in the study of science and medicine. These materials may be prospectively collected or accessed from existing sources retrospectively. Repositories or banks allow materials and data to be stored and shared by investigators and accessed for multiple research projects, including those that were unknown at the time of data/specimen collection. The collection and use of data/specimens from a repository invokes unique ethical and regulatory issues that necessitate a distinct policy to facilitate proper management of these activities. The collection and maintenance of such materials in a repository and their subsequent distribution may itself be research that requires IRB approval *separate from* any subsequent study that may involve the use of the materials. This policy describes when Yale considers the collection or maintenance of materials to constitute research involving human subjects requiring IRB review and/or approval.

Definitions

Anonymous

Stripped of identifying information and of codes that could be used to link data or samples back to a specific individual. Although anonymous materials do not by definition contain linking codes, they need

not necessarily be de-identified (as defined below). Note that 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 and/or tissue/specimens collected and maintained for future research purposes. The bank should have written plans for distributing the stored data and/or specimens and may or may not intend to distribute the stored data and/or specimens to other research groups. Example a bank of biological specimens that are collected by clinicians within a department or section and used for their own research purposes.

Coded Material:

Data or specimens for which:

- (1) private information (such as name or social security number) that would enable the investigator to ascertain the identity of the individual to whom the data, specimens, records, or other materials pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- (2) a key to decipher the code exists, enabling linkage of the identifying information to the information or specimens.

Donor –Subject:

A living individual from whom materials are obtained either through clinical or research intervention or interaction with the individuals.

De-identified Material:

Data, biological specimen or tissue that cannot be linked to a specific individual by either:

- 1) not including any of the 18 identifiers specified by HIPAA or
- 2) if a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable: (i) applying such principles and methods, determines that the risk is very small 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; (ii) documents the methods and results of the analysis that justify such determination; and (iii) provides that documentation to the IRB.

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.

See also HIPAA Policy 5039, Use and Disclosure of De-Identified Information and of Limited Data Sets.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 and implementing 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 that 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 which is not reflected in all types of research. In some cases, the research volunteer is in fact more acted upon than truly having any sense of partnership in the research. Hence the term subject is considered more appropriate in such cases.

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) which removes all 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 also HIPAA Policy 5039, Use and Disclosure of De-Identified Information and of Limited Data Sets.

Materials

Data, films, biological specimens, or other recorded information that may be useful for research. Examples include vials of blood, medical records, tumor specimens, scans, and videotapes of interviews. Note that 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.

Recipient Investigator

A member of a research team who receives data and/or tissue/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.

Policy Sections

440.1 Banks or Repositories Requiring Review by the IRB

Collections, banks or repositories require review by a Yale IRB when:

- Specimens or data are collected prospectively and will be shared with other investigators for several distinct research projects, or stored for future research, whether or not individual identifiers are collected in the process; or
- Excess research materials that were collected as part of an IRB-approved protocol are stored for future research uses, or
- Existing individually identifiable clinical, historical or other collections are stored with the intent of being accessed for future research, or
- 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)
- 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

Collections involving only coded private information will not be considered human research by the IRB as defined in 45 CFR 46.102(f), and hence will not require IRB review when the following are both met:

- a. The private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; AND
- b. The investigator cannot readily ascertain the identity of the individual to whom the coded private information pertain because either:

- i. The key to decipher the code is destroyed before research began, or
- ii. The investigators and the holder of the key enter into an agreement, such as the Internal Data Use Agreement, prohibiting the release of the key.

440.2 Collection of Materials For Repositories/Banks Maintained Outside of Yale

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

440.3 Informed Consent/Authorization Required for the Repositories

Collection of materials (data/specimens) must be authorized by obtaining legally effective informed consent and authorization from each person (donor-subject) or their legally authorized representative unless waived by the IRB. (See IRB Policy 200: Informed Consent for Human Research).

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 can make an informed decision regarding agreement to allow materials to be stored in the repository. Investigators should note that a detailed use need not be identified, e.g., the study of Alzheimer's disease. Rather general or broad references, e.g., the study of human physiology and brain biology are considered specified future uses and are appropriate for consent purposes. Additionally, to qualify for approval by the IRB, 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 available for research indefinitely or for as long as the sample is available or until such time that the donor-subject revokes consent.

Researchers should use either a compound authorization form or consent and HIPAA authorization forms to comply with these requirements when the materials will include protected health information. 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 compound authorization form or consent form and HIPAA authorization form unless waived by the IRB.

A. Exceptions To Consent and Authorization

Prior consent and authorization may not be required when:

- It 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: 1) they contain no identifying information (i.e., subjects cannot be identified, directly or through identifiers linked to the subjects), or 2) are publicly available; or
- It 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); or
- The IRB waives consent and/or authorization in accordance with IRB Policy 200 and/or HIPAA Policy 5032 after considering whether or not the waiver of informed consent

would adversely affect donor-subjects and the waiver is 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 research entity, i.e, hospital different legal entity than “research” entity. In considering whether or not the waiver of informed consent would adversely affect donor-subjects, IRBs will consider at least:

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

B. Re-Consent and Authorization

Re-contacting of donor-subjects for new consent may be required by the IRB when any of the following conditions apply:

- a) The purpose of the collection and storage changes and is not consistent with the original purpose noted in the consent form used at the time the material was originally collected, or
- b) The purpose of the collection and storage falls out of society’s mainstream thinking as acceptable; or
- c) A donor-subject reaches the age of majority and the materials were stored by the donor-subject during his/her childhood,

If the IRB requires new informed consent/authorization, 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.

C. Consent Not Required

Informed consent may not be required for banking or future use purposes if the materials are truly unable to be tied to an individual.

440.4 Repository Procedures and Operations Required for IRB Approval

Repositories or banks of materials derived from human beings that are intended for future or secondary research must have a Yale University faculty/employee designated as the Principal Investigator. The Principal Investigator has the primary responsibility for the collection, storage and distribution of 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 440.5 below and in 440. PR1 Development of Repositories for Research to qualify for approval from the IRB.

In addition, the operation of the repository must be capable of:

- a. Identifying when the material is originally received and whether the person from whom the material was obtained signed a legally effective consent /gave authorization under HIPAA, if applicable.
- b. Identifying materials for which consent has been withdrawn and will ensure no future use.

- c. Restricting access to any identifiable materials to a limited number of repository staff. Accountability for controlling and monitoring access must be provided.
- d. A method to limit access to the coded material including computer security and material storage security measures must be provided.

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

440.5 Plans for Distributing Materials From Repositories For Future Research

A. Providing Access to Materials for Pre-Research Activities:

The Principal Investigator of the repository is responsible for receiving appropriate attestation by recipient investigators prior to permitting access to the database for activities considered preparatory to research. Appropriate attestations may be made using the Yale University/Yale-New Haven Hospital Request for Access to Protected Health Information for a Research Purpose Form.

B. Sharing Materials for Future Research

The distribution of materials that are stored in repositories for subsequent research is considered separately from the collection activity. 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 collection.

The repository protocol must include standard operating procedures for distributing 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 Yale 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 HRPP policies and the distribution processes of the protocol.

1. Requests to Use Identifiable and Anonymous Material

- Requests to use identifiable material require documentation from the recipient investigator that IRB review and approval has taken place.
- 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 Review of Research Policy 100.4) 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 does not require IRB review but HIPAA may apply, Appropriate attestations related to privacy of the information may be made using the Yale University/Yale-New Haven Hospital Request for Access to Protected Health Information for a Research Purpose Form.

2. Use of Coded Materials

Requests to use coded data sets warrant that someone other than the recipient investigator has reviewed the research and determined it not to be human research. This determination can be made by the IRB or a skilled member of the research team operating the repository or bank. It should be noted that IRB submission may be necessary should the investigator wish to publish research results in journals or other periodicals that require documentation of IRB review.

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

The repository may release coded data sets subject provided that

- a) the IRB or the repository team determines that the research does not involve “human subjects” as described in Section 400.1; and
- b) the recipient investigator will not be given the identifiable information linked to the material the material and signs an agreement not to access identifiers or attempt to ascertain the donor-subjects’ identity; and
- c) the Principal Investigator of the repository assesses that the proposed research is consistent with the scope of research described in the consent/authorization signed by the donor-subject at the time of collection.

Operators of repositories or data management centers are prohibited from releasing the key to recipient investigators under any circumstances, until the individuals are deceased, or IRB approval is obtained for releasing the identifiable information.

3. Limited Data Sets

Requests to withdraw limited data set materials from repositories must be reviewed by the IRB. The IRB will review the proposal and make an appropriate determination in accordance with other IRB review policies. The IRB will also 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.

Requests to use limited data sets containing protected health information (PHI) from databases and repositories owned by Yale University or its agents must utilize an Internal Data Use Agreement. Requests to use limited data sets containing PHI from researchers who are external to Yale, must be accompanied by a Data Use Agreement as provided by Yale or the repository institution.

4. No Identifiers Requested

Requests for de-identified materials do not require documentation of IRB review, approval, exemption or not human subject determination because the project is not human subject research, i.e., bench research.

440.6 IRB Review of Repositories

The IRB will review the collection activity and repository/bank operations (research) and issue an exemption determination or approval of the research, waive or alter applicable informed consent

and research authorization requirements, or otherwise assess the research in accordance with the guidelines set forth in IRB Policy 100 Review of Research Protocols. A review of the procedures for placing materials into the bank/repository, as well as the procedures for release of stored materials to recipient investigators and donor-subject withdraw of consent/authorization must be considered by the IRB to ensure that the rights and welfare of the donor-subject are upheld and protected. The IRB review will include consideration of the need for informed consent. See 440.PR1 for operational procedure requirements for repositories.

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 or waiver) may be required before initiating any such future research.

440.7 Ownership and Transfer of Repository Materials

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

Investigators wishing to transfer materials retained in repositories and banks operated by Yale University must consider the rights of other investigators who assisted in the research and remain at Yale. Therefore requests to transfer materials must comply with Policy 730 Human Research Record and Biological Specimen Retention and Transfer.

Investigators who are permitted to take such materials elsewhere must provide an attestation that they would 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 previously collected at another institution and intended for future research purposes are required to establish a repository/bank subject to Yale IRB review and approval.

If the Principal Investigator of a repository or bank leaves Yale University then a successor Principal Investigator must be identified and made known to the IRB.

Related Information

440 PR 1:

Data Use Agreement –<http://info.med.yale.edu/hipaa/forms/index.html>

Yale University Internal Data Use Agreement

Yale University Material Transfer Agreement

Yale University Research Authorization Form

Yale University/Yale-New Haven Hospital Request for Access to Protected Health Information for a Research Purpose Form.

Yale University IRB Application to Involve Human Subjects in Research; Biologic Material and/or Data Repository, www.yale.edu/hrpp

Yale University IRB Policy 200 Informed Consent for Human Research, www.yale.edu/hrpp.

Yale University IRB Checklist for Banking of Data and Biologics for Future Use, www.yale.edu/hrpp

Contacts

Questions can be addressed to:

Subject	Contact	Phone
Submitting protocol-specific conflicts of interest (Biomedical Research)	Human Investigation Committee	203.785.4688 www.yale.edu/hrpp
Submitting protocol-specific conflicts of interest (Social and Behavioral Research)	Human Subjects Committee	203.436.3650 www.yale.edu/hrpp

Roles and Responsibilities

[Human Investigation Committee](#)

The HIC I, HIC II, HIC III and HIC IV serve as the Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

[Human Subjects Committee](#)

The HSC is responsible for the review and oversight of social and behavioral research involving human subjects.

References:

National Heart, Lung and Blood Institute; Guidelines for Human Tissue Repository
<http://www.nhlbi.nih.gov/funding/policies/repos-gl.htm>

DHHS, Office for Protection from Research Risks (OPRR), Issues to Consider in the Research Use of Stored Data or Tissues, November 7, 1997
<http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>

DHHS, Office for Human Research Protections (OHRP), Guidance on Research Involving Coded Private Information or Biological Specimens, October 16, 2008
<http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>

Mark Barnes and Kathleen T. Uscinski, Secondary Uses of Data, PRIM&R Annual Conference, October 2004

Lawrence H. Muhlbaier and Kathleen T. Uscinski, Primer on Data and Specimen Repositories: How to Establish, Manage, and Be HIPAA Compliant. PRIM&R Annual Conference, November 2007

Partners Human Research Committee Policy on Research Tissue Banks/Repositories, November 9, 2005
 PHRC Policy on Research Tissue Banks/Repositories

UCSF Guide for the Research Use of Human Biological Specimens: Collecting, Banking and Sharing Specimens, May 2005

Revision History