

440 PR.1 Development of Data Banks and Repositories for Research

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Overview

This procedure provides information for researchers who wish to use data and biological specimens (materials) in research or who intend to collect biological specimens 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.

Developing Banks and Repositories:

Key Consideration:

Collecting materials that could later be used for scientific purposes may or may not itself constitute human research; a key determinant is whether or not the collection or maintenance of the materials is *designed to*, or is specifically aimed at, creating a resource for future lines of scientific inquiry.

Ethical Considerations:

The person responsible for the collection should ask himself or herself whether any aspect of the activity would be done differently if the materials could not be used for any future scientific or research studies. In other words, if all future Research uses of the Materials were forbidden, would fewer materials be collected; would they be kept for a shorter period of time or held in a different fashion; or would they be organized differently or would faculty, medical staff or researchers have different access rights to them? If the answer to any of these questions is “yes,” then at least some portion of the activity of collecting or maintaining the materials would constitute research. If the answer to all of these questions is “no” – e.g., extra tissue is taken during a biopsy in case the first slides are inconclusive, or routine medical information is collected in a medical record that could later be accessed for research purposes but is not collected or maintained for that reason – then the activity would not constitute Research in its own right and would not require IRB approval; the activity, instead, would simply be required for the normal delivery of medical, clinical, or human services.

Creating Operational Procedures for the Bank or Repository to the IRB

A successful repository or bank should have an effective operational plan for specimen/data/record acquisition, handling, tracking, distribution and final disposition. A well developed operational plan will include written policies and procedures, as well as a secure system for managing records.

Repositories or banks of materials derived from human beings that is intended for future or secondary research must include the specific attributes to qualify for approval from the IRB. Some suggestions to consider for each area are shown as examples below.

- 1. A description of the types of future research to be conducted using the materials.**

Example: “The purpose of this study is to create a Yale School of Medicine Neuro-Oncology data bank that will be used for future research project involving the study of brain cancer biology and brain biology and related medical issues.”

2. A plan for the collection of material or the conditions under which material will be accepted.

Example: “The data bank will be created from adult patients (age >18) who are receiving ongoing care for brain tumors in the Departments of Neurosurgery, Radiation Oncology and Section of Medical Oncology.”

3. A description of the types of information and materials about the donor/individual contributors that will be entered into a database and the methods whereby confidentiality is upheld.

Example: The following information about subjects will be entered into the database that may be used for future research purposes: Name, age, medical record numbers, gender, the surgery date, the results of of clinical tests (such as MRI, laboratory tests and neuropsychological results), the duration of symptoms, any risk factors for tumors and other diseases, past medical history and other pertinent medical information.

4. The conditions or procedures whereby the material is shared and distributed for future research projects.

Such a procedure should include whether or not the material will be distributed for future research projects of the nature and purposes specified in the collection (repository protocol) and stated in the informed consent used for collection. The procedure should outline the conditions whereby materials are released, .e.g, after documenting proof of IRB approval, exemption determination, etc. . A statement regarding whether or not the data released to collaborators for IRB approved research will be directly identifiable or assigned a unique code should also be included.

- *Example:* Data released to collaborators for IRB approved research will be assigned a unique code, unless permission is granted by the IRB to include specific identifiers.
- *Example:* Requests by investigators for identifiable materials will be granted after receiving documentation of approval by the IRB.
- *Example:* Data will be distributed for research projects of the nature and purpose specified in this protocol and by the donor-subject in his/her informed consent document and HIPAA authorization documents.

In some cases, the Principal Investigator may wish to establish an oversight committee under the repository to evaluate each request for materials to see if the request is consistent with the protocol conditions for sharing materials as approved by the IRB. In most cases, however, the Yale IRB will perform this function when considering the secondary or future research project that is requesting to utilize samples stored in the repository/bank. However, while the IRB review and approval of such requests is encouraged, it is not always required. Requests for coded materials may be evaluated by the Principal Investigator of the repository if the recipient investigator has not received IRB review. In these cases, the Principal Investigator is responsible for evaluating the request to determine whether or not the research constitutes human research. Should the Principal Investigator make a not human research determination, then all requirements for the distribution of coded materials noted in Policy 440 HRPP Policy 440: Data and Biological Specimens in Human Research must be followed.

Recipient investigators who have had their research project exempted by the IRB may see direct identifiers, but they must not record them.

5. **A statement as to who is responsible for receiving appropriate attestation by recipient investigators prior to permitting access to the database for activities considered preparatory to research.**

Example: The Principal Investigator is responsible for receiving appropriate attestation by recipient investigators prior to permitting access to the database for activities considered preparatory to research. Investigators should complete and submit the Yale University/Yale-New Haven Hospital Request for Access to Protected Health Information for a Research Purpose Form.

6. **A statement regarding whether or not donor-subjects may withdraw their consent for the use of the materials at any time and the manner in which the request to discontinue use of the material is addressed in the data base and use of the material , e.g., will the material no longer be identifiable, or will it be destroyed.**

Example: Donor-subjects may withdraw their consent for the use of any data at any time. In this event, the Principal Investigator will indicate in the data base that consent from the donor-subject is no longer active and that data can no longer be used. However, data already distributed to recipient investigators or used in secondary research projects will continued to be used. (Note: Alternatively, the Principal Investigator may choose to destroy the material or destroy the link to any identifiers, making it de-identified and allowing for continued use.)

7. **A data and safety monitoring plan and provisions for reporting serious and unanticipated adverse events, or unanticipated problems. Investigators should consult with the HIPAA Security policies and guidelines regarding appropriate protections for securing devices and databases containing protected health information (PHI). See <http://hipaa.yale.edu/security/index.html>**

Examples: loss of lap top, break-ins to data and servers.

In the unlikely event of a serious adverse event or breach in confidentiality, the event will be reported to the IRB within 48 hours of it becoming known to the PI.

The PI will periodically review the collection, storage and distribution practices associated with this data bank and determine whether or not changes to enhance confidentiality and privacy are required.

8. **A description of the provisions whereby the privacy of participants is protected**

Examples: Compound authorization form or consent and HIPAA authorization forms for banking activity that identify the conditions under which protected health information is shared.

If possible, compound authorization form or consent form and HIPAA authorization forms for secondary or future use.

9. **A description of the secure methods whereby materials are stored and shared**

Example: Information about the subjects will be maintained in password-protected computers and password-protected data files. Only researchers responsible for operating the data bank, will be provided with access.

Information resides on a server considered by ITS-Med to adhere to the HIPAA Security Rule.

Certificate of Confidentiality should be obtained to protect confidentiality should materials be identifiable.

Obtaining Informed Consent and Authorization the Bank or Repository to the IRB

Federal (OHRP) guidance for IRB review states that unless waived by the IRB, written informed consent should be obtained from each donor-subject, who will be asked to provide materials to the repository or bank. Informed consent should include the basic elements of informed consent including a clear description of the operation of the repository including;

1. A description of the nature and purposes of the collection;

Sample Language:

“You are invited to take part is a database that contains information from patients, like you, who have brain tumors. With your permission members of Yale University will keep and store information that we learn about you and your brain tumor into the database.The information will be used for future research projects involving the study of cancer biology and brain biology and related medical issues. ...used in studies intended to better understand and treat patients with brain tumors affecting the nervous system.

2. The specific types of research to be conducted;

Sample Language:

“The researchers who are responsible for entering and protecting your information in the database can use your information for the following purposes: future research projects involving the study of cancer biology and brain biology and studies intended to better understand and treat patients with brain tumors, and other types of tumors affecting the nervous system.”

Statements authorizing unlimited or unspecified future uses of the data do not meet the intent of the following consent form elements:

- an explanation of the purposes of the research
- the expected duration of the subject’s participation
- a description of the procedures to be followed
- identification of any experimental procedures

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

3. The conditions under which data and specimens will be released to recipient-investigators;

Sample Language:

“In most cases, the researchers will use your information in a de-identified manner. De-identified means that the researchers will use your information without knowing

who you are. In some cases they may use some identifying information about you for research purposes. This will only happen if the research has a protocol approved by an ethics board, which is known as an Institutional Review Board or IRB. At Yale, the IRB is known as the Human Investigation Committee (HIC). The HIC reviews, approves, and monitors human research.

Sample Language:

It is also possible that your information may be shared with other researchers who are not part of this research team. Your information may be given out to researchers who have 1) a research study approved by the IRB, or 2) a letter from the IRB stating that no review or approval is needed.”

4. Procedures for protecting the privacy of subjects and maintaining the confidentiality of data;
5. Where human genetic research is anticipated, informed consent information should include information about the consequences of DNA typing (e.g., regarding possible paternity determinations)

Informed consent form needs to be sufficiently detailed regarding potential future uses/commercialization. It would be acceptable for the consent to say that materials are to be used for research purposes. However, the word “donation” implies abandonment of rights to the “property.” 21 C.F.R. 50.20 prohibits requiring subjects to waive or appear to waive any rights as a condition for participation in the study. Language that has been deemed acceptable is, “Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.” Investigators collecting materials for repositories and banks should use a compound authorization form or consent and HIPAA authorization forms for banking activity. Investigators should use the Tissue and Consent for Banking and/or Secondary Uses Checklist found at www.yale.edu/hrpp/forms-templates when designing collection consent documents. If possible, a compound authorization form or consent form and HIPAA authorization forms should also be employed for future or secondary uses.

Requesting a Waiver of Informed Consent and Re-Consenting Donor Subjects

The Investigator may request and the IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent as per federal regulations and IRB Policy 200 Informed Consent for Human Research. Investigators should note however that in requesting a waiver, they would need to argue to the IRB that the research could not practicably be carried out without the waiver or alteration. In some instances, the IRB may find it is not impracticable but recognize that it may be burdensome. Thus investigators should plan research carefully so as to avoid having to obtain consent for future or secondary uses. It is recommended that researchers at the time the consent for the collection is taking place, use a compound authorization form or consent form and HIPAA authorization forms for anticipated future or secondary uses of the materials.

Re-contacting of donor-subjects for new consent may be required by the IRB when the intended research use of the material

- a) Is not consistent with the original purpose noted in the consent form used at the time the material was collected, or
- b) falls out of society’s mainstream thinking as acceptable.

The IRB may also require a new consent when 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 used for new research projects.

IRB Responsibilities in the Approval of Repositories and Banks

The IRB will issue an exemption determination for the collection activity and repository/bank operations (research), review the research pursuant to an expedited review procedure, 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. The IRB will ensure proper oversight of special categories of Repository Research in accordance with Section IV of this policy.
