Overview

This procedure provides information for researchers who wish to use data and/or 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 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 the collection or maintenance of the materials is designed for, or is specifically aimed at, creating a resource for future lines of scientific inquiry. 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.

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.

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 ensuring 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 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 under which the material is shared and distributed for future research projects.
Such a procedure should include whether 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. A statement regarding whether 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.

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. The Principal Investigator of the repository 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.

6. A statement regarding whether 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.

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

8. A description of the provisions under which the privacy of participants is protected

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.

Additionally, 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.
Obtaining Informed Consent and Authorization

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 (see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116 for further detail). 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;
2. The specific types of research to be conducted;
3. The conditions under which data and specimens will be released to recipient-investigators;
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, and to include 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 must prove that the research could not practicably be carried out without the waiver or alteration

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.
Revision History

September 27, 2012; January 18, 2014