

The following educational document was prepared by staff of the Cancer Diagnosis Program of the National Cancer Institute.

What Human Specimen Repositories Need to Tell Their IRBs: Points to Consider

Introduction and Purpose:

This document is an educational document intended to help individuals operating human specimen repositories provide the information their IRBs need to assess the protection of human subjects and compliance with federal human subjects regulations. It is intended to help repository developers/managers fully document repository operating procedures and policies. Effectively documenting procedures and policies should facilitate the IRB review and reduce the frustration of repository staff and IRB members. This document incorporates suggestions made by investigators, IRB members and federal program staff. Only fundamental items are listed. Additional information may be needed to demonstrate compliance with state and local laws, or the laws of other countries.

We have focused on repositories or collections of specimens that are used by multiple researchers with separate research projects. Several models exist for these repositories. For example, some repositories collect specimens specifically for distribution to researchers. Other repositories serve as central storage and distribution facilities for specimens collected specifically for individual research projects or clinical trials. Repositories may have a single collecting site or several collecting sites. This document is intended as an overview of the basic information repositories should provide to their IRB, regardless of the model. While this document is intended for repositories that provide specimens to multiple researchers, many points in the document are also germane to collections created for a single, specific, research project.

Information that Repositories Should Provide to Their IRBs:

Repository protocols should provide enough information to allow an IRB to assess compliance with the federal human subjects regulations (45CFR46), relevant medical records and privacy legislation, and state and local laws. The amount of information and level of detail required will vary depending upon the size of the repository, the nature of the research and the identifiability of the persons from whom the specimens were collected. In cases where specimens are collected as part of a specific research project, it may be desirable to submit a separate protocol for the repository operation. You should discuss this issue with your IRB. The following types of information should be considered in developing a repository's protocol for IRB review:

Purpose of the Repository

- What are the overall goals and purpose of the repository?
- What research will be conducted using the specimens and associated data? (Be as specific as possible).

Specimen and data collection procedures

- How will human subjects (specimen donors) be identified?
- From what populations are specimens obtained? Do the subjects have rare diseases or characteristics as individuals or groups that would facilitate identification? Are the subjects from special or vulnerable populations? Are specimens from a particular ethnic, racial or social group?
- What specimens will be collected?
- How will specimens be collected? For what purpose (e.g. research, medical care)?
- For specimens collected in the course of medical care, what procedures are in place to ensure that patient care will not be compromised as a result of specimen banking and distribution?
- What personal identifying information will be collected on the subjects? What other subject data will be collected?
- What are the procedures for data collection? Who will collect it?
- Will specimens and data be collected only once or will multiple specimens and/or data from the same subject be collected over time? Will individual subject data be updated?
- Which sites (hospitals, etc.) are collecting the specimens and associated data?

Informed Consent

- Will consent be obtained? From whom will consent be sought?
- What is the process for obtaining consent? (e.g. when will consent be obtained, who will obtain it, etc.)
- What procedures will be used to obtain consent or permission for individuals unable to consent themselves (e.g. children, cognitively impaired)?
- What consent form will be used? (attach a copy) What other educational tools (subject brochure, talking points, etc.) are used, if any? (attach copies)
- Will human subjects/research participants be specifically recruited? If so, what recruitment materials/advertisements will be used? (Attach a copy)
- What is the procedure for subjects to withdraw their consent?
- What happens to a subject's specimen if the subject withdraws consent? What happens to the subject's personal identifying data if the subject withdraws consent?
- If consent is not to be obtained, how can a waiver of consent be justified? (Justification should be based on the criteria for waiver of informed consent in the Common Rule, 45CFR46.116d)

Specimen and data storage/retention

- Are specimens and associated data linked in any way to subject identity? (e.g., can anyone trace the identity of the subject, including repository personnel?)
- Who will have access to subject identities or other personal identifying information?
- If specimens will be de-linked from subject identities, explain how this will be done (e.g. when is the de-linking performed, what entity performs the de-linking, and what identifying information is removed and how)

- How will specimens stored by the repository be identified (For example, a unique number assigned by the specimen repository)?
- State the physical location of the repository
- How will specimens and associated data be stored? Describe the procedures for secure storage of specimens and associated data
- How long will specimens and data be stored?

Specimen derivation and processing

- Will permanent cell lines be established?
- Will DNA be extracted from the specimens?

Specimen and data distribution

- What types of associated data will be provided to researchers with the specimen?
- What processes are in place for reviewing the appropriateness of the requests to use the specimens? How does the repository prioritize requests?
- Will the secondary distribution of specimens be controlled? How? (For example, is there a policy that forbids investigators from transferring specimens to third parties?)
- What is the repository's policy for providing specimens to commercial organizations?

Protection of subject autonomy, privacy and confidentiality

- What policies and procedures are in place to protect confidentiality? (e.g., employee confidentiality agreements, encryption techniques, Certificates of Confidentiality, "honest broker")
- What is the repository policy about releasing personal individual identifiers (e.g., medical record number, social security number, name, date of birth, etc.) to repository users? Under what circumstances, if any, will identifiers be provided with the specimen?
- Is there an agreement form that researchers and/or their institutions must sign before specimens and associated data are distributed? (Please provide a copy)
- What mechanisms are in place to assure that future uses of subject specimens are consistent with the informed consent?
- How will the repository comply with the requirements of the federal privacy legislation, "Standards for Privacy of Individually Identifiable Health Information," (<http://www.hhs.gov/ocr/hipaa>) and other applicable medical privacy legislation?

Return of Research Results

- What is the repository's policy concerning when, if ever, individual research results should be returned to subjects? (Be explicit about the processes proposed to evaluate the risks and benefits associated with the return of individual research results to subjects).

Repository Oversight

- What mechanisms are in place for the oversight of repository activities (e.g. IRBs, oversight committees, ethical advisory boards, etc.)?

Before preparing your documentation, it is recommended that you talk with your IRB chair to determine the specific requirements of your institution.