

PARTNERS HUMAN RESEARCH COMMITTEE RESEARCH TISSUE BANKS/REPOSITORIES

PURPOSE

The purpose of this policy is to define the requirement for Institutional Review Board (IRB) review and approval of Research Tissue Banks.

SCOPE

This policy applies to research Tissue Banks/Repositories established by BWH and MGH investigators for the purpose of storing tissue for future research use. It also applies to Partners-affiliated investigators who obtain tissue for research use from established Research Tissue Banks. This policy does not apply to specimens/data that are collected and stored as part of routine clinical care or hospital procedures, for example, blood banks or pathology.

POLICY

The Partner's Human Research Committee (PHRC), i.e., the Institutional Review Board (IRB) for BWH and MGH, must review and approve:

- the *establishment* of Research Tissue Banks/Repositories for research and
- the research use of *identifiable* tissue obtained from established Research Tissue Banks/Repositories.

Note that the IRB review of the bank will include a review of the procedures for placing tissues into the bank, as well as the procedures for release of stored tissues to investigators. IRB review will include consideration of the need for informed consent.

DEFINITIONS

For the purposes of this policy the following definitions are used:

Tissue: any biological specimen obtained from patients or human research subjects. This includes, for example, fixed, frozen or fresh pathology or autopsy specimens, blood, urine, saliva, CSF, semen, breast milk or other biological material, and any purified DNA, RNA, proteins, cell lines or clones. The terms *tissue*, *specimens*, and *samples* are used interchangeably in this policy.

Excess clinical/research tissue samples: tissue that was collected for clinical or research purposes and is no longer needed for the original purpose.

Research Tissue Bank (or Repository): an entity involved in procuring, processing, storing and/or distributing tissue expressly for use in research.

Directly identifiable tissue: tissue that is labeled with personal identifiers (e.g., name, medical record number, social security number, laboratory accession number, or any elements of dates except dates limited to year alone). Any personal identifier specified under HIPAA constitutes a personal identifier. (Refer to the [Partners policy on identifiable health information](#) – link on PHRC website).

Indirectly identifiable tissue: tissue that retains a link (or code) to identifiable information about the tissue donor.

Non-identifiable tissue: tissue that cannot be linked to a specific individual either because the existing link (such as code key) to the identity of the individual was destroyed (**de-identified** sample) or because a link was never created (**non-identifiable** sample). Non-identifiable tissue lacks all 18 personal identifiers specified by HIPAA. Information that cannot be used to identify the individual, such as diagnosis, age, and gender, may be recorded with or linked to the tissue.

Research: as defined by federal regulations 45 CFR 46.102(d), means a systematic investigation, including research development, testing, and evaluation, designed to contribute to generalizable knowledge.

Human Subject: as defined by federal regulations 45 CFR 46.102(f), means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

- (a) **Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.
- (b) **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Exempt Human Subject Research 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that

subjects cannot be identified, directly or through identifiers linked to the subjects. **Note:** The IRB must make the determination that the research activities are exempt from the regulatory requirements in the Common Rule (45 CFR 46).

A. Do all Research Tissue Banks require IRB review?

YES. The IRB is responsible for determining whether the tissue bank activities: (i) meet the regulatory definition of human subjects research and are subject to the IRB requirements set forth in the Common Rule (45 CFR 45); (ii) meet the definition of human subjects research but are exempt from the regulatory requirements in the Common Rule; or (iii) do not meet the regulatory definition of human subjects research.¹

B. When does the collection and storage of tissue samples for research become a Research Tissue Bank?

The collection and storage of tissue samples becomes a Research Tissue Bank when:

- Specimens/data collected prospectively or retrospectively will be shared by multiple investigators, used repeatedly, or stored for future research; or
- Excess research samples that were collected as part of an IRB-approved protocol will be stored for multiple future research uses by multiple investigators. The prospective collection and storage of samples for defined research purposes as part of a single IRB-approved protocol is not considered a Research Tissue Bank.

Investigators must submit a Research Tissue Bank application for IRB approval of existing collections of samples that were obtained and stored for future research use prior to the establishment of this policy (i.e., “historical” collections). Investigators may wish to build upon existing specimen collections by prospectively adding more samples. This may be accomplished by establishing a Tissue Bank that includes both the existing specimens and those added prospectively.

C. When is informed consent/authorization required for the collection and storage of tissue in tissue banks?

Informed consent/authorization is required for the collection and storage of directly or indirectly identifiable excess clinical samples AND for collection and storage of any tissue obtained solely for research (research samples) in a tissue bank. In such cases, the responsible principal investigator or tissue bank director/designee must obtain informed consent/authorization from each tissue specimen donor. **Note:** Generally, the IRB will

¹ FDA regulations define clinical research differently than the Common Rule, and FDA standards for tissue banks remain unclear. In the interim, if a tissue bank raises a clear question under the FDA's rules, the IRB will determine how to address it in the particular case.

NOT grant waivers of consent/authorization for long-term storage of directly or indirectly identifiable samples in tissue banks.

New informed consent/authorization may not be required for existing tissue collected prior to January 1, 2006. The IRB recognizes that identifiable, existing, and sometimes very old and valuable tissue may have been collected prior to recent federal guidance on requirements in this area. Therefore, the IRB will consider requests for a waiver of informed consent/authorization for existing research specimen collections when seeking IRB approval of a Research Tissue Bank.

D. How may researchers access tissue from the tissue bank or repository?

Researchers may submit the following requests to a tissue bank.

1. **Recipient researcher requests tissue with identifiable information (directly identifiable tissue):** The tissue bank can only release tissue with identifiable information to researchers who have obtained IRB approval for a specific protocol. As part of that review, the IRB must determine whether or not the original consent/authorization signed by the subject covers the proposed use.

If the original informed consent/authorization does not cover the proposed use (nature and purpose), the IRB may require the researchers to obtain separate informed consent/authorization for this new study or may waive the requirement for informed consent/authorization depending on the specific circumstances. In general, the IRB recommends seeking consent at the outset, when tissues are collected, for the expected research. Although re-contact of subjects for new consent is not impossible, nor prohibited, it may be impractical and annoying if frequent. Advance planning and description of research plans at the time of initial consent may obviate these difficulties. If the IRB requires new informed consent/authorization, and the original informed consent does not include the subject's permission for future contact, the tissue **cannot** be used for these new studies.

2. **Recipient researcher requests coded tissue with no identifiable information (indirectly identifiable tissue):** The tissue bank may release tissue that retains a link (code) to identifiable information about the tissue donor without additional IRB review if the following conditions are met:
 - a. the recipient researcher will **not** be given the identifiable information linked to the tissue, and agrees in writing (signs an agreement) **not** to access identifiers or attempt to ascertain the tissue donor's identity; **and**
 - b. the proposed research is consistent with the scope of research described in the consent/authorization signed by the tissue donor.

If these conditions are not met, then the requirements for release of tissue with identifiable information must be followed.

*Note: The tissue bank **can** release information, such as diagnosis, age, or gender, if the information released could not be used to “readily ascertain” the identity of the individual from whom the tissue was obtained.*

3. **Recipient researcher requests tissue without any identifiers or codes (non-identifiable tissue):** In accordance with the Common Rule, the tissue bank can release non-identifiable tissue (i.e., tissue that is **non-identifiable** because it never retained a link to a person, OR is **de-identified** by the tissue bank before release) to the recipient researcher without IRB review and approval. However, if the tissue was collected with informed consent/authorization, the tissue can only be used for the scope of research described in the consent/authorization signed by the tissue donor.

Reminder: If tissue will be sent to a for-profit or commercial collaborator outside of Partners, a Materials Transfer Agreement (MTA) is required, so the transfer must be coordinated with the Partners Office of Corporate Sponsored Research and Licensing (CSRL). Partners does not normally require an MTA for tissue sent to not-for-profit academic collaborators; these may be sent with a simpler “Letter of Agreement.” See letter templates, and refer to the [Partners Policy on Tissue Transfer](#) for more information.

For more information on tissue banking activities, refer to:

[PHRC Guidance on Genetics Research](#)

[Partners Policy on Tissue Transfer](#)

[OHRP Guidance on Tissue Repositories](#)

Or contact Elizabeth L. Hohmann, M.D., Director and Chair, Partners IRBs