



Title:	Research Tissue Banks/ Repositories
Department:	Human Research Affairs/Research Management
Policy Type:	<input checked="" type="checkbox"/> Partners System-wide <input type="checkbox"/> Partners System-wide Template <input type="checkbox"/> Partners Corporate <input type="checkbox"/> Partners Corporate Departmental <input type="checkbox"/> Entity
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH) and Massachusetts General Hospital (MGH)
Approved by:	Chief Scientific Officer
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Contact Person:	Director and Chair, Partners Human Research Committee

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the requirement for Partners Human Research Committee (PHRC) review and approval of Research Tissue Banks / Repositories and of the research use of identifiable tissue obtained from established Research Tissue Banks / Repositories.

This policy applies to Research Tissue Banks / Repositories established by BWH, FH and/or 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 / Repositories. 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.

DEFINITIONS:

Tissue means 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, or cell lines. Distant derivatives, for example, recombinant proteins, are not necessarily considered human tissue. The terms *tissue*, *specimens*, and *samples* are used interchangeably in this policy.

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

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

Directly identifiable tissue means tissue that is labeled with personal identifiers; for example, name, medical record number, social security number, laboratory accession number, or any elements of dates except dates limited to year alone. Any of the 18 personal identifiers specified under HIPAA constitutes a personal identifier. Refer to the Partners policy on identifiable health information.

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

Non-identifiable tissue means tissue that cannot be linked to a specific individual either because the existing link (such as a 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 of the 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.

POLICY STATEMENT:

The PHRC, i.e., the Institutional Review Board (IRB) for BWH, FH 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 PHRC 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. PHRC review will include consideration of the need for informed consent.

REQUIREMENTS:

1. Do all Research Tissue Banks require PHRC review?

YES. All research tissue banks require PHRC review.

2. 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, disbursed to other non-collaborating investigators, used repeatedly, or stored for future research uses; or
- Excess research samples collected as part of a PHRC-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 PHRC-approved protocol is not considered a Research Tissue Bank.

Investigators must submit a Research Tissue Bank application for PHRC 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.

3. 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. In addition, tissue specimen donors whose samples were collected when they were minors must be re-consented when they turn 18. If the individual cannot be located, the sample must be anonymized. This information should be included in the consent form. **NOTE:** Generally, the PHRC will 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 PHRC 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 PHRC will consider requests for a waiver of informed consent/ authorization for existing research specimen collections when seeking PHRC approval of a Research Tissue Bank / Repository.

Since many investigators perform genome wide association studies (GWAS) or large-scale gene sequencing on samples and send resulting data and samples to NIH or other central repositories, the tissue bank consent form should include the possibility of performing whole genome analysis and sending the results and samples to central repositories where they may be used by other researchers for genetic links to many diseases or conditions.

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

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

Researchers may submit the following requests to a tissue bank.

- 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 separate PHRC approval for a specific research protocol. As part of that review, the PHRC 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 PHRC 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 PHRC 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 bothersome if frequent. Advance planning and description of research plans at the time of initial consent may obviate these difficulties. If the PHRC 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.

- 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 PHRC 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.

- 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 fully anonymized by the tissue bank before release such that no link to the individual will exist) to the recipient researcher without PHRC review and approval. However, if the tissue was initially collected under a research 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 Partners Research Ventures and Licensing (RVL). 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 of Agreement templates and refer to Partners Policy on Transfers to Third Parties of Tissues, Other Specimens, and Data Obtained by Partners-Affiliated Providers from Patients and Research Subjects for more information.

OTHER APPLICABLE PARTNERS HEALTHCARE POLICIES:

Definition of Protected Health Information (PHI)
De-Identification Policy
Partners Policy on Transfers to Third Parties of Tissues, Other Specimens, and Data Obtained by Partners-Affiliated Providers from Patients and Research Subjects

REFERENCE:

Health Insurance Portability and Accountability Act (HIPAA)
OHRP Issues to Consider in the Research Use of Stored Data or Tissues
OHRP Guidance on Research Involving Coded Private Information or Biological Specimens

DEVELOPMENT AND CONSULTATION

Partners Research Management
Partners Research Ventures and Licensing
Partners Office of the General Counsel

Reviewed by:	Original Review Date:	Revision Approval Dates: