PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Title:	Research Tissue Banks/ Repositories
Department:	Human Research Affairs
Policy Type:	☑ Partners System-wide ☐ Partners System-wide Template ☐ Partners HealthCare ☐ Partners HealthCare Departmental ☐ Institution
Applies to:	Employees, Professional Staff or Other Agents of Brigham and Women's Hospital (BWH), Faulkner Hospital (FH), Massachusetts General Hospital (MGH), McLean Hospital (McLean), and North Shore Medical Center (NSMC)
Approved by:	Chief Academic Officer
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Contact Person:	Director, Human Research Review and Compliance

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 Partners 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. Lastly, this policy or parts of it, may also apply to PHS specimens or data stored in external 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:

The Partners Human Research Committee has developed the following definitions of terms commonly used in tissue research in order to provide clarity and avoid confusion.

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.

Individually identifiable tissue means the identity of the subject is or may readily be ascertained by the investigator. Tissue that is labeled with or linked to a Limited Data Set (data set that only includes HIPAA identifiers dates and/or zip codes/city/town name) may or may not be considered individually identifiable. The tissue repository administrator, in conjunction with the PHRC, will make this determination.

Directly identifiable tissue means tissue that is labeled or released to researchers with *personal identifiers*; for example, name, medical record number, social security number, laboratory accession number, etc. *Personal identifiers* include any of the 18 personal identifiers specified under HIPAA. While HIPAA regulations do not apply to tissue samples, they do apply to health information linked to the tissue. Of note, use of any part of an identifier, e.g., patient initials, in combination with code numbers, is also considered an identifier under HIPAA.

Indirectly identifiable (coded) tissue means tissue that retains a link (or code) to information about the tissue donor that includes any of the 18 HIPAA *personal identifiers*.

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 or because a link was never created or retained. 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.

NOTE: Avoid use of the terms "anonymous" or "anonymized" when describing the status of tissue or data as these terms are interpreted differently by different investigators. The PHRC considers "anonymous" samples to be "non-identifiable" as defined above. If a key to the code linking the sample to the tissue donors exists anywhere, the samples are not "anonymous."

POLICY STATEMENT:

The PHRC, i.e., the Institutional Review Board (IRB) for BWH, FH, MGH, McLean, and on occasion other Partners sites must review and approve:

- the *establishment* of Research Tissue Banks / Repositories for research;
- the research use of *identifiable* tissue obtained from established Research Tissue Banks/ Repositories; and
- The research use of banked tissue that is not consistent with the scope of research (nature and purpose) described in the tissue bank consent form.

Note that PHRC review of the bank will include a review of the procedures for placing tissues into the bank and the procedures for release of stored tissues to investigators.

REQUIREMENTS:

1. Do all Research Tissue Banks require PHRC review?

YES. All research tissue banks established by employees, professional staff, or other agents of Partners HealthCare 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 or 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, and does NOT require submission of a separate tissue bank application.

Investigators must submit a "Tissue or Sample Repository" 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 in November 2005 (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 samples obtained solely for research (research samples). In such cases, the responsible principal investigator or tissue bank director/designee must obtain informed consent/authorization from each tissue specimen donor or their authorized representative. In general, tissue specimen donors whose samples were collected when they were minors must be approached for consent when they turn 18. If the individual cannot be located, the sample may be rendered non-identifiable (see above) and continue to be used in ways consistent with consent provided by parents or guardians. This approach should be described in the consent form for parents.

NOTE: Generally, the PHRC will NOT grant waivers of consent/authorization for prospective collection of directly or indirectly identifiable samples in tissue banks.

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. New informed consent/authorization may not be required for existing tissue collected prior to January 1, 2006. The PHRC will consider requests for a waiver of informed consent/ authorization for existing, archival research specimen collections, i.e. "grandfathering" of existing samples collected in the distant past.

Since many investigators perform genome wide association studies (GWAS) or large-scale gene sequencing on samples and send resulting data and samples to NIH-sponsored 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.

As of January 25, 2015, investigators conducting new or ongoing NIH-funded research that generates or uses for subsequent research large-scale human or non-human genomic data must include language in the consent form that addresses future research uses and broad sharing. See NIH Genomic Data Sharing (GDS) Policy and Other Applicable Partners HealthCare Policies for more information.

Note that FDA regulations define clinical research differently than the Common Rule, and FDA standards for research tissue banks remain unclear. The PHRC will determine how to address tissue banking questions in FDA-regulated studies.

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 scope of research (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 broad 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.

- 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 individually 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 or a HIPAA Limited Data Set, if the information released cannot be used to "readily ascertain" the identity of the individual from whom the tissue was obtained. When applicable, a HIPAA LDS Data Use Agreement must be signed.

- Recipient researcher requests tissue with **no** 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 the tissue donor, OR is fully anonymized by the tissue bank before release such that no link to the tissue donor 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, and the transfer must be coordinated with Partners Innovations). 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 between academic researchers. 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
NIH Genomic Data Sharing (GDS) Policy

DEVELOPMENT AND CONSULTATION

Partners Research Management
Partners Innovations
Partners Office of the General Counsel

Reviewed by:	Original Review Date:	Revision Approval Dates:
Dennis A. Ausiello, MD, Chief Scientific Officer	December 16, 2010	
Anne Klibanski, MD, Chief Academic Officer		May 5, 2015