

Title:	Research Tissue Banks and Repositories
Department:	Human Research Affairs
Policy Type:	Mass General Brigham System-wide
Applies to:	Employees, Professional Staff or Other Agents of Mass General Brigham
Approved by:	Chief Academic Officer
Original Approval Date:	November 9, 2005
Original Effective Date:	November 9, 2005
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Current Revision Effective Date:	December 1, 2020
Next Review Date:	January 15, 2022
Contact Person:	Director, Human Research Office

KEYWORDS:

IRB, Institutional Review Board

PURPOSE:

The purpose of this policy is to define the requirement for Mass General Brigham IRB review and approval of Research Tissue Banks and Repositories and of the research use of identifiable tissue obtained from established Research Tissue Banks and Repositories.

This policy applies to Research Tissue Banks and Repositories established by Mass General Brigham investigators for the purpose of storing tissue for future research use. It also applies to investigators who obtain tissue for research use from established Research Tissue Banks and Repositories. Lastly, this policy or parts of it, may also apply to Mass General Brigham specimens or data stored in external repositories. This policy does not apply to specimens or data that are collected and stored as part of routine clinical care or hospital procedures, for example, blood banks or pathology.

DEFINITIONS:

See Definitions in Human Subject Research

POLICY STATEMENT:

The IRB must review and approve:

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

The IRB 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 IRB review?

YES. All research tissue banks established by employees, professional staff, or other agents of Mass General Brigham require IRB 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 an IRB-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 IRB-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 IRB 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 and HIPAA authorization required for the collection and storage of tissue in tissue banks?

Informed consent and HIPAA 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 IRB will NOT grant waivers of consent/authorization for prospective collection of directly or indirectly identifiable samples in tissue banks.

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. New informed consent and HIPAA authorization may not be required for existing tissue collected prior to January 1, 2006. The IRB will consider requests for a waiver of informed consent and HIPAA 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.

Note that FDA regulations define clinical research differently than the HHS Common Rule, and FDA standards for research tissue banks remain unclear. The IRB 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 IRB approval for a specific research protocol. As part of that review, the IRB must determine whether or not the original consent and HIPAA authorization signed by the subject covers the proposed use.

If the original informed consent and HIPAA authorization does not cover the scope of research (nature and purpose), the IRB may require the researchers to obtain separate informed consent and HIPAA authorization for this new study or may waive the requirement depending on the specific circumstances. In general, the IRB recommends seeking consent for all future uses 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 IRB 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 and HIPAA 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 (LDS), 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 further IRB review and approval. However, if the tissue was initially collected under a research informed consent and HIPAA authorization, the tissue can only be used for the scope of research described in the consent and HIPAA authorization signed by the tissue donor.

REMINDER: If tissue will be sent to a for-profit or commercial collaborator outside of Mass General Brigham, a Material Transfer Agreement (MTA) is required, and the transfer must be coordinated with Mass General Brigham Innovations. Mass General Brigham 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 Mass General Brigham Policy on Transfers to Third Parties of Tissues, Other Specimens, and Data Obtained by Mass General Brigham-Affiliated Providers from Patients and Research Subjects for more information.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES:

Definition of Protected Health Information (PHI)

De-Identification Policy

Mass General Brigham Policy on Transfers to Third Parties of Tissues, Other Specimens, and Data Obtained by Mass General Brigham 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:

Mass General Brigham Innovation

Mass General Brigham Research Management

Mass General Brigham Office of the General Counsel