POLICY FOR IRB REVIEW OF PROPOSED RESEARCH INVOLVING TISSUE BANKING

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1. Introduction

1.1. This policy addresses research protocols that propose to collect human biological material (HBM) and store it in a repository for future research use. Such a repository is referred to as a “tissue bank” if the repository accepts and stores HBM for future research uses. The tissue bank may be located within Tufts University Health Sciences (TUHS)/Tufts Medical Center or at a remote location.

1.2. This policy also addresses information from medical records that could potentially accompany the HBM to be stored in a tissue bank.

2. Scope of Policy

2.1. This policy is intended to apply to situations in which research subjects are asked to consent to the collection of their HBM for transfer to a repository (tissue bank), regardless of the location of the tissue bank, for storage and future research use. The policy does not address the mandatory collection and transfer of HBM to a tissue bank as legally required under state law or regulation. The policy is limited to HBM collected from living persons and does not address the use of HBM obtained post-mortem.

2.2. The collection of gametes and fetal tissues raises special issues that are outside the scope of this policy.

3. Definitions: The following definitions will be used for the purposes of this policy.

3.1. A “human subject” is defined as: “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)).

3.2. HBM include a full range of specimens, from subcellular structures and cell products such as DNA, to cells, tissue (e.g., blood, bone, muscle, connective tissue and skin), organs (e.g., liver, bladder, heart, kidney, placenta), secretions, and waste (e.g., hair or nail clippings, urine, feces, sweat, or tears that often contain shed skin cells).

3.2.1. Classification of HBM: HBM may be classified according to whether or not the donor of the HBM can be identified. This document will use the following definitions:

3.2.1.1. Identifiable HBM:

3.2.1.1.1. This is HBM to which observable HIPAA-defined identifiers are attached (see Appendix). The HBM is associated with documented, unhidden individually identifiable health information in such a way that the Source Individual could be identified due to the presence of an unconcealed name, medical record number, clear pedigree location (i.e.: his or her relationship to a family member whose identity is known) or any other HIPAA-defined identifier.

3.2.1.1.2. HBM specimens whose HIPAA-defined identifiers have been replaced with a code that is linked to the specimen are considered identifiable HBM. Although readily recognizable information has been replaced by coded information, the presence of a link connecting the original specimen and its recreated (coded) identification could allow a tissue...
bank or investigator who obtained the code to identify the Source Individual. Thus, coded HBM that is linked to protected identifiers is considered identifiable HBM.

3.2.1.2. **Unidentifiable HBM**

3.2.1.2.1. HBM specimens whose associated, individually identifiable information was never collected or, if collected, was permanently removed and cannot be retrieved by the tissue bank or an investigator obtaining samples from the tissue bank are termed “unidentifiable”. Note: HBM from which identifiable information has been permanently removed is frequently also referred to as “anonymized”.

3.2.1.2.2. HBM whose individually identifiable information was replaced with a code is considered unidentifiable if the code was subsequently destroyed.

3.3. **Code**: A system of letters, numbers, or symbols into which normal language is converted to allow information to be hidden, concealed, or communicated secretly; any method used to transform data into an obscured form; the replacement of identifying information (such as name or social security number) with a number, letter, symbol, or combination thereof (i.e., the code)

3.3.1. **Coded HBM or coded medical record information (MRI)**: This term refers to HBM or MRI whose identifying information (such as name or social security number) has been replaced with a number, letter, symbol, or combination thereof (the code); and for which there exists a means or “key” to decipher the code. Deciphering the code would enable linkage of the HBM or MRI to the private information of the donor of the HBM (source individual).

3.4. **Tissue Bank**: An entity that receives, catalogues, and stores HBM, with or without associated MRI, with the intent of making the HBM available at some time in the future for research purposes.

3.5. **Tissue Banking**: Refers to the receipt, storage, and subsequent distribution or use of HBM (with or without HIPAA-defined identifiers) to investigators for research purposes.

3.5.1. **Tissue Banking is not Batch Processing**: The Institutional Review Board (IRB) of Tufts University Health Sciences (TUHS)/Tufts Medical Center regularly reviews research protocols that involve collection and analysis of HBM. Such collection and analysis frequently occurs periodically as the research study proceeds. In many instances, HBM is collected and preserved for analysis, usually with other similarly gathered HBM, at the conclusion of the study or at a convenient and economical point in time during the study. This HBM is either destroyed during the process of analysis or, once the study is concluded, is destroyed. This is the typical scenario when, for example, blood is drawn in conjunction with a research protocol to determine a subject’s serum lipid profile or a subject’s serum level of a particular drug being studied and the blood is set aside for future analysis. This is not tissue banking since the HBM (blood) is not being held in a repository for future research use, will not be subjected to testing outside the stated purpose and objective(s) of the original research protocol, and will not be disseminated to other investigators who are not part the original protocol.

3.5.2. **Tissue Banked Samples are not Protocol-defined Archived Samples**: A research protocol may clearly explain that some of the HBM acquired for purposes of the study will be archived for subsequent testing at some date in the future. Typically, these archived samples will be used to confirm tests that were
previously performed in the study on the same sample. These archived samples are not intended to be used by investigators other than those conducting the original research protocol, are not intended to be subjected to testing outside the stated purpose and objective(s) of the original research protocol, and will not be disseminated to other researchers who are not part of the original protocol.

3.5.2.1. **Archived Samples:** The collection, cataloging, and storing (archiving) of HBM for future analysis that is specifically described in the original research protocol is not “tissue banking”. Until the archived HBM are exhausted or the study is completed and will have no further need of the archived samples, the research study must be kept active and undergo IRB continuing review. Additionally, the expected length of retention of specimens is to be described in the protocol and the informed consent form (ICF).

3.5.2.2. **Retention of banked and archived specimens:** These are specimens that are being retained in order to be used for purposes other than tissue banking described in an IRB-approved study. The study must be kept active and undergo IRB continuing review until these activities are completed. These specimens are not to be retained past the conclusion of the study. The expected length of retention of specimens is to be described in the protocol and ICF.

3.6. **Research:** Is understood as defined in the Common Rule, that is, as a systematic investigation designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(d)).

3.7. **Genetic Testing** is the analysis of human DNA, RNA, chromosomes, proteins, and/or certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical or research purposes.

3.8. **HIPAA:** Is the Health Insurance Portability and Accountability Act of 1996 as amended and refers to Federal regulations that govern the use or disclosure of protected health information by covered entities (i.e., health care providers, health plans, and health care clearinghouses).

3.9. **A Cell Line** consists of cells of a single type (human, animal, or plant) that have been adapted to grow continuously in the laboratory and are used in research or industry.

3.10. **Medical Record Information (MRI):** Means information in any medium, including paper or electronic, that is derived from medical records maintained by Tufts Medical Center or Tufts University or from research records maintained by investigators, co-investigators, or other research team members in association with a clinical trial that has been reviewed and approved by the IRB.

3.10.1. **Classification of MRI:** MRI may be classified according to whether or not the patient or research subject to whom the MRI refers can be identified. This document will use the following definitions:

3.10.1.1. **Identifiable MRI:**

3.10.1.1.1. This is MRI containing unconcealed HIPAA-defined identifiers (see Appendix). Identifiable MRI includes readily observable protected information such that the Source Individual could be identified due to the presence of an unconcealed name, medical record number, clear pedigree location (i.e.: his or her relationship to a family member whose identity is known) or any other HIPAA-defined identifier.
3.10.1.1.2. MRI containing information that has been replaced with a code that is linked to the specimen is considered identifiable MRI. Although readily recognizable information has been replaced by coded information, the presence of a link could allow a tissue bank or investigator who obtained the code to identify the Source Individual. Thus, coded MRI that is linked to identifiers is considered identifiable MRI.

3.10.1.2. Unidentifiable MRI:

3.10.1.2.1. MRI from which identifiable information was permanently removed and cannot be retrieved by the tissue bank or an investigator is considered unidentifiable.

3.10.1.2.2. MRI whose identifiable information was replaced with a code is considered unidentifiable if the code was subsequently destroyed.

3.11. Source Individual: The living individual from whom the HBM and/or MRI is collected.

4. Type of IRB Review

4.1. Not Human Subject Research: Research conducted with unidentifiable HBM/MRI that were not collected specifically for the currently proposed research through an interaction or intervention with living individuals is not human subjects research and is not regulated by the Common Rule (See 16 October 2008 OHRP Guidance: http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf).

4.1.1. In order to deem a given research protocol exempt from IRB review, as defined in 45 CFR 46.101, the IRB must determine that:

4.1.1.1. The HBM/MRI to be used for tissue banking was collected as part of clinical care or as part of the primary clinical research, and

4.1.1.2. No additional volume of blood or tissue was obtained in order to provide HBM for tissue banking.

NOTE: Research protocols involving the collection, transfer to, and storage in a tissue bank of unidentifiable HBM/MRI must be initially reviewed by the IRB. It is the IRB – not the investigator - that must make the determination that a proposed study does not involve human research.

4.2. Exemption from IRB Review: Some tissue banking research may qualify for exemption from IRB review under 46.101(b)(4). To qualify for the exemption, specimens must be in existence at the time the exemption is applied for, and the information must be recorded by the investigator in a way that the subjects cannot be identified either directly or through identifiers linked to the subjects. The investigator must apply for and the exemption must be granted by the IRB before the research can begin.

4.3. Expedited Review: As defined by the Common Rule, all minimal-risk research involving HBM/MRI may be eligible for expedited review. (See: http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)

4.4. Convened Committee Review vs. Expedited Review: Research that is greater than minimal risk requires review by the convened IRB.

5. IRB Information Requirements: Before the IRB will consider proposed research involving the collection of HBM, with or without associated MRI, that falls within the scope of this policy, the Principal Investigator (PI) of the proposed research must provide the IRB with the following information:

5.1. The name and address of the tissue bank responsible for maintaining the HBM.
5.2. The names, telephone numbers, and e-mail addresses of the contact person(s) at the tissue bank.

5.3. The types of HBM to be transferred to the tissue bank, e.g., blood samples, tumor specimens, etc.

5.4. The manner in which the PI plans to collect the HBM.

5.4.1. The type and frequency of procedure used to obtain the HBM and the total amount of tissue removed for tissue banking must be stated in the protocol or in a site-specific protocol addendum. For example, the PI may plan to collect HBM by means of an additional procedure, e.g., an additional blood draw or biopsy, that is not part of clinical care or the primary research; or the PI may plan to use a blood draw that is scheduled as part of clinical care or as dictated by the research protocol.

5.4.2. The protocol or site-specific protocol addendum must specifically state whether an additional volume of HBM will be removed from the research subject for banking purposes and, if this is the case, the volume of the additional HBM to be removed.

5.5. Whether the HBM that the PI proposes to transfer to the tissue bank will be identifiable or unidentifiable.

5.6. If the HBM is to be coded and linked, the name, telephone number, and e-mail address of the person who is responsible for maintaining the link and their relationship to the study, i.e., principal investigator, co-investigator, etc.

5.6.1. The circumstances, if any, under which the code associated with the link may be revealed.

5.7. If it is planned that the tissue bank will distribute the HBM/MRI for research use by other investigators, whether the materials will be identifiable or unidentifiable when distributed to other investigators.

5.8. Whether the PI also proposes to transfer the Source Individual’s MRI to the tissue bank. If so, a detailed description of the specific information to be transferred must be included in the protocol or in a site-specific protocol addendum. Such information includes, but is not limited to:

5.8.1. Whether the MRI that the PI proposes to transfer to the tissue bank will be identifiable or unidentifiable.

5.8.2. Whether the information transferred to the tissue bank is

5.8.2.1. Limited to information that is available at the time the HBM is transferred to the tissue bank, or

5.8.2.2. To be provided on an ongoing basis or at predetermined times in the future. **NOTE:** Predetermined times may be defined in chronological terms (every 6 months) or expressed in terms of a triggering event (visit to an emergency room). In either case, the protocol (or site-specific protocol addendum) and the ICF must define the predetermined times and the duration of information transfer.

5.9. A written explanation of the tissue bank’s policies that govern:

5.9.1. The types of investigators or entities to whom the HBM/MRI may be distributed, and

5.9.2. The types of research for which the HBM/MRI may be distributed, and
5.9.3. The measures taken to guard against disclosure of the Source Individual’s confidential information.

**NOTE:** A copy of the tissue bank’s written policies and procedures is preferred to satisfy §5.9.1 - 3 (above). In the absence of written policies, the PI may supply the IRB with a detailed written statement from the tissue bank that supplies the information requested in §5.9.1 – 3 above.

5.10. Whether or not distribution of HBM/MRI from the tissue bank to other investigators or entities is subject to oversight by an IRB or similar review body.

5.11. Whether or not the Source Individual can withdraw consent to research use of his/her HBM/MRI at any time, and the mechanism by which the Source Individual may effect withdrawal of such consent.

5.11.1. **NOTE:** The mechanism used to withdraw consent to research use of HBM/MRI should not be limited to written communication. The following example is usually adequate: “You may withdraw your consent to allow the use of your banked tissue at any time by calling Dr. _____________, the Principal Investigator, at xxx-xxx-xxxx or by making your request in writing and sending it to Dr. _____________ at Street Address; City, State, Zip Code.

5.12. Whether there are any circumstances under which the tissue bank or individuals or entities to whom the tissue bank distributes HBM/MRI might seek to contact the Source Individual.

5.13. Whether there exists a potential that the HBM may be subjected to genetic testing or used to create a cell line.

5.14. Whether there exists a potential that the HBM may be used in the development of commercial products and whether or not the Source Individual may share in any financial profit.

5.15. Whether the tissue bank proposes to pay money or other remuneration to Tufts Medical Center, Tufts University, or any member of the research team in connection with the collection or use of the HBM/MRI. If so, the nature and purpose of the remuneration must be described.

5.16. Whether the results of any research performed on the HBM/MRI will be conveyed to the Source Individual, or his or her primary or research physician, or placed in the Source Individual’s medical records.

6. **Policy for IRB Review:** The IRB will apply the following criteria when reviewing the proposed collection of HBM and, when indicated, associated MRI (“HBM/MRI”) for transfer to a tissue bank.

6.1. When a proposed research study involves tissue banking that is not a required component of the clinical trial (the “primary research or underlying clinical trial”) the collection, transfer, and storage of HBM/MRI for future research cannot be a condition for the subject’s participation in the primary research or underlying clinical trial, or any clinical trial.

6.2. If the proposed collection of HBM/MRI for tissue banking is a component of a research protocol (the “primary research or underlying clinical trial”) whose primary purpose is not the collection, transfer, and storage of HBM/MRI for future research, the use of a separate informed consent form (ICF) to allow the research subject to consent to the collection, transfer, and subsequent storage of HBM/MRI is recommended. This separate optional tissue banking consent form must meet all of the requirements for informed consent stated in 45 CFR 46.116.
6.3. If the primary purpose of the research protocol is to establish a tissue bank or specifically to collect HBM to be stored in a tissue bank, a separate ICF is not required. The protocol’s ICF will, by default, address tissue banking to the extent described in this policy.

6.4. The collection, transfer, or subsequent use of the HBM/MRI must not compromise the medical care or safety of the Source Individual.

6.5. In situations in which the IRB determines that there is a potential for compromise of care or safety, the IRB may impose conditions to eliminate or minimize this potential.

6.5.1. If, for example, the proposed research involves HBM that are “left over” after performance of diagnostic tests on a surgically removed tumor, the IRB may guard against removal of more than the usual amount of tissue by requiring that the surgeon not know if the subject has consented to the research use of any surplus materials.

6.6. The IRB may approve proposed research that involves the collection and transfer of unidentifiable HBM/MRI to a tissue bank, provided:

6.6.1. The protocol and any additional descriptive materials (protocol addenda; site-specific amendments) include the information specified above in §5 (IRB Information Requirements);

6.6.2. Informed consent will be obtained in accordance with the policies in §7 (Informed Consent Form Policy);

6.6.3. If the tissue bank plans to distribute HBM/MRI to other investigators, the tissue bank must provide the IRB with its written policies that govern:

6.6.3.1. The types of investigators or entities to whom the HBM/MRI may be distributed, and

6.6.3.2. The types of research for which the HBM/MRI may be used, and

6.6.3.3. The tissue bank’s practices regarding IRB and/or ethics committee review of research for which the tissue bank may release HBM/MRI, and

6.6.3.4. The measures taken to abide by HIPAA regulations\(^4\) to protect the confidentiality of the Source Individual.

**NOTE:** A copy of the tissue bank’s written policies and procedures is preferred to satisfy §6.6.3.1 - 4 (above). In the absence of written policies, the PI may supply the IRB with a detailed written statement from the tissue bank that supplies the information requested in §6.6.3.1 - 4 above.

6.7. The IRB may approve proposed research that involves the collection, transfer, and storage of identifiable HBM/MRI in a tissue bank, provided the protocol or site-specific protocol appendix include the information specified above in §5 (IRB Information Requirements), and

6.7.1. The HBM/MRI are coded, and

6.7.1.1. The key to the code remains within the exclusive possession and control of a designated individual or individuals at Tufts Medical Center/Tufts University, and

6.7.1.2. An agreement is created between the PI and the tissue bank that the key to the code will never be shared with the tissue bank, secondary recipients of the HBM, or with anyone else except pursuant to IRB approval or as necessary for an audit to ensure that written informed consent was obtained;
**NOTE:** Sometimes a tissue bank may send HBM/MRI to the PI who initially collected and submitted the HBM/MRI to the tissue bank. To protect against loss of confidentiality in a situation in which the investigator who initially collects HBM/MRI for the tissue bank subsequently receives a distribution of those same materials from the tissue bank, the IRB may consider requesting that investigators, co-investigators, research coordinators and other research team members not be the custodian of the key to the code. The IRB must rely on the PI to recognize the potential for this occurrence and to appoint a custodian of the key who is not a member of the research team.

6.7.2. The protocol or site-specific protocol appendix identifies a secure location in which the designated individual(s) will keep the key to the code and identifies the procedures to assure its privacy;

6.7.3. Written informed consent will be obtained in accordance with the policy in §7 (Informed Consent Form Policy);

6.7.4. The Source Individual is able to withdraw consent at any time to the future use of HBM/MRI that have been transferred to the tissue bank, except where it is impossible to achieve the withdrawal because:

6.7.4.1. The tissue bank has already distributed the HBM/MRI to other investigators/entities, or

6.7.4.2. The HBM has been completely exhausted; or

6.7.4.3. The code is no longer available.

6.7.5. The research protocol or site-specific protocol appendix identifies whether or not the results of research performed on HBM/MRI that have been transferred to the tissue bank will be communicated to the Source Individual, to the individual’s attending (research) physician, to the individual’s primary physician, or placed in the individual’s medical record.

6.7.5.1. If results are to be transferred to any of the above-cited individuals or to the medical record, the PI must provide a justification in the protocol (or in a site-specific protocol addendum) for such transfer and the planned transfer must be approved by the IRB. If approved, the subject must be informed in the ICF of the proposed transfer of research results and the potential benefits and risks of the information to be transferred.

6.8. In specific circumstances, the IRB may approve proposed research that involves the collection and transfer of HBM/MRI that have not been stripped of all HIPAA-defined identifiers, provided requirements 5.11, 5.12, and 5.16 of the immediately preceding § are met; and

6.8.1. The protocol and associated materials are well designed as determined by the Tufts Medical Center and TUHS Scientific Review Committee (SRC); and

6.8.2. The intended research uses of the HBM/MRI cannot reasonably be carried out if all identifiers are removed; and

6.8.3. The PI names or describes the specific identifiers that are necessary to the proposed research uses in:

6.8.3.1. The protocol or in the site-specific appendix, and

6.8.3.2. The Research Authorization Form (RAF), and

6.8.3.3. The ICF.

6.9. All other identifiers must be removed prior to transfer of HBM/MRI to the tissue bank;
6.10. The privacy risks to the Source Individual are reasonable in relation to the
importance of the knowledge that may be developed through the research uses of
the HBM/MRI;

6.11. The tissue bank will only allow use of the banked HBM/MRI pursuant to an IRB-
approved research protocol;

6.12. **NOTE:** If the tissue bank is a covered entity under HIPAA, the PI or the tissue bank
must provide certification to the IRB that any subsequent release of HIPAA-identified
materials from the tissue bank to researchers will be in accordance with the
requirements of HIPAA.

6.13. IRB approval of the provision of HBM-associated MRI to the tissue bank may include
MRI that is available at the time the initial HBM is transferred to the tissue bank or
may include MRI generated subsequent to that date, or both.

6.13.1. If the PI wishes to provide MRI to the tissue bank subsequent to the original
submission, the PI must provide the IRB with justification as to why the
provision of additional MRI is necessary along with the frequency and duration
of such subsequent submissions. The IRB must then determine whether or
not the proposed multiple submissions of MRI is within the scope of the
proposed research. **See also: Informed Consent Form Policies below.**

6.14. No HIV-test information may be disclosed to a tissue bank unless the Source
Individual has provided the specific consent for disclosure of such information that is
required under Massachusetts law.

6.15. The IRB may require the tissue bank to provide written assurance that it will not
make any attempt, through use of other databases or other means, to ascertain the
identity of the Source Individual, and may require the tissue bank to agree to return
to Tufts Medical Center/Tufts University any HBM/MRI that are inadvertently
transferred to the tissue bank with identifiers.

6.16. The IRB may, with respect to specific proposed research, impose any other conditions
that it deems necessary or advisable for the protection of human subjects. For
example, if the written policies of the tissue bank do not describe with sufficient
specificity the research purposes for which the HBM may be used, the IRB may
condition approval upon written assurance that the tissue bank is subject to oversight
by an IRB, ethics committee, or similar body, and that the recipient investigators are
bound to abide by the conditions specified by that IRB.

6.17. The IRB may submit to the relevant legal office for its review any research protocol
that involves the transfer of money or other remuneration from the tissue bank to
Tufts Medical Center, Tufts University, or the principal investigator in connection with
the use of the HBM. The IRB will not consider the research protocol for final approval
until the IRB receives written notification from the legal office that all legal issues, if
any, have been satisfactorily resolved.

7. **Informed Consent Form Policies:** The following information must be included in the ICF.

7.1. A description of the HBM to be collected.

7.2. A description of the manner in which the HBM will be collected. In particular, whether
the involvement of the tissue bank will necessitate the performance of procedures in
addition to, or taking of materials in a greater volume than, that which would
otherwise be done as part of the underlying clinical trial.

7.2.1. If the collection of HBM involves the performance of procedures in addition to
those that would be performed as part of the underlying clinical trial, or
involves the collection of materials in a greater volume than would be collected
as part of the underlying clinical trial, an explanation of the associated risks, if any.

7.3. If associated MRI will also be collected, a detailed description of the specific information involved as well as the frequency of its collection and transfer to the tissue bank.

7.4. A statement that the Source Individual’s agreement to collection of HBM/MRI for transfer to a tissue bank is not a condition for enrollment in any research trial or for future care or treatment at Tufts Medical Center or Tufts University.

7.5. A description of the measures that will be taken to guard against loss of confidentiality.

7.6. A description of (a) the types of investigators/entities to whom the HBM/MRI may be distributed, and (b) the purposes for which the HBM/MRI may be used. The ICF is to describe the intended purposes for the future use of the materials with as much specificity as possible.

7.7. If the HBM/MRI will be coded, a statement that the Source Individual is able to withdraw consent at any time to future use of the HBM/MRI, except where it is impossible to achieve the withdrawal because the tissue bank has already distributed the HBM/MRI, the HBM has been completely exhausted, or the code is no longer available.

7.8. If the HBM/MRI will be coded, a statement indicating that the PI is the person to contact if the source individual wishes to withdraw consent to the future use of the HBM/MRI.

7.8.1. **NOTE:** the mechanism used to withdraw consent to the research use of HBM/MRI should not be limited to written communication. The following example is usually adequate: “You may withdraw your consent to allow the use of your banked tissue at any time by calling Dr. _____________, the Principal Investigator, at xxx-xxx-xxxx or by making your request in writing and sending it to Dr. _________________ at Street Address; City, State, Zip Code.

7.9. A statement that a risk of participation includes the possible loss of confidentiality and, if genetic testing is part of the protocol, a statement to the effect that the results of genetic tests, if inadvertently disclosed, could negatively affect access to insurance or employment, or could have an impact upon family or social relationships.

7.10. A statement that the Source Individual will not be contacted by the tissue bank or by secondary recipients of HBM/MRI distributed by the tissue bank. If the IRB allows such contact, the ICF must state the circumstances under which such contact may occur.

7.11. A statement, if applicable, that the HBM will or may be used in the development of commercial products, including the development of cell lines and whether the Source Individual will receive any benefit or monetary gain from such development.

7.12. A statement addressing whether or not the Source Individual will receive any direct benefit from participation in the tissue banking component of the research protocol.

7.13. A statement describing whether or not, once the Source Individual’s HBM have been transferred to the tissue bank, the results of research performed on those materials will be communicated to the Source Individual or to the individual’s attending (or research) physician, the individual’s primary physician, or placed in the individual’s medical record.
7.13.1. If research results are to be communicated to the Source Individual’s attending (research) physician, the Source Individual’s primary physician, or placed in the Source Individual’s medical records, the potential benefits and risks of such transfer and placement of information must be stated in the ICF.

7.14. An explanation, if applicable, that Tufts Medical Center, Tufts University, or a member of the research team will receive money or other remuneration from the tissue bank for the collection or use of the HBM. No explanation is necessary if the remuneration is intended solely as reimbursement for the direct costs of the collection of the materials and transfer to the tissue bank.

7.15. If the IRB approves a research protocol that allows identifiable MRI to accompany the HBM supplied to a tissue bank, the ICF must include each of the following additional elements:

7.15.1. An expiration date or expiration event for the potential research to be performed on the Source Individual’s HBM/MRI;

7.15.2. A statement that once MRI is disclosed to the tissue bank, subsequent release of MRI by the tissue bank may not be protected by the federal privacy rule;

7.15.3. A statement that the Source Individual may inspect or copy the medical record information to be disclosed to the tissue bank; and

7.15.4. A statement describing the particular identifier(s) that will be disclosed to the tissue bank (for example, date of birth, zip code, etc.).

7.16. If it is anticipated that the Source Individual’s MRI will be supplied to the tissue bank on an ongoing basis, the ICF must:

7.16.1. Explicitly disclose that MRI will continue to be collected from future medical records on an ongoing basis and transferred to the tissue bank; and

7.16.2. State any risks associated with supplying the Source Individual’s MRI to the tissue bank on an ongoing basis; and

7.16.3. Describe the specific information to be disclosed, the frequency of its disclosure, and the time period during which it will be disclosed; and

7.16.4. State that the ongoing disclosure of medical record information will terminate once all research on the individual’s HBM has been completed; and

7.16.5. State that the individual can, at any time, revoke permission for the ongoing collection of information from his or her medical records and include the mechanism for doing so. (See §7.8 above)
APPENDIX

Identifiers:

An Identifier is any one of the following types of information about the individual (or the relatives, employers, or household members of the individual) from whom the HBM are collected:

1. Name
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
   b. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of date (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying characteristic.

Exemption from IRB Review:

45 CFR 46.101(b)(4):
(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from [IRB review]:
(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic 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.
REFERENCES:


