

Biospecimen Banking	Effective Date	09.19.2014
	Revisions Date	11.1.2019

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for the submission of requests to create a local human biospecimen bank for research purposes.
- 2.0 Persons Affected:**
- 2.1** Individuals engaged in creating and managing a human research biospecimen bank
 - 2.2** University and Medical Center Institutional Review Board (UMCIRB) Chairperson (or designees) and members
 - 2.3** UMCIRB staff and administrators
- 3.0 SOP:** If a human research project specifically collects biospecimens for banking as its sole purpose or creates a biospecimen collection that will not be destroyed upon completion of the immediate research study, the collection must be presumed to constitute a human biospecimen bank maintained for possible future research projects. The IRB proposal for research for the creation and maintenance of a human biospecimen bank must include a robust description of the following components: (a) informed consent and collection of the biospecimens (creation of the bank); (b) maintenance and management of the bank; (c) access to biospecimen material in the bank for use in specific research studies; and (d) destruction or disposal of the specimens, as detailed below.
- 4.0 Definitions:**
- 4.1 Biospecimen:** a quantity of tissue, blood, urine, or other biologically derived material.
 - 4.2 Biobank:** A biobank is a type of biorepository that stores biological samples (human) for use in research. Biobanks have become an important resource in medical research, supporting many types of contemporary research like genomics and personalized medicine. May also be called biorepository or pathological banking/repository.
 - 4.3 Samples:** portions or aliquots of a biospecimen.
 - 4.4 Honest Broker:** A neutral intermediary (person or system) between the individual whose tissue and data are being studied, and the researcher. The honest broker collects and collates pertinent information regarding the tissue source, replaces identifiers with a code, and releases only coded information to the researcher. The role of the "honest broker" protects the tissue donors from any risks associated with the use of their private information and it allows the end-users (researchers who obtain de-identified samples/data) to (i) conduct research that does not constitute human subject research, thereby allowing the research to proceed without the need for an IRB approval or approval of an exemption request; and (ii) to conduct research without needing to obtain a specific informed consent or authorization, provided that all requirements of the Honest Broker system are met.
 - 4.5 Unlinked Samples:** sometimes termed "anonymized" because these samples lack identifiers or codes that can link a particular sample to an identified biospecimen or a particular human being.
 - 4.6 Coded Samples:** identifying information (such as name, medical record number or pathology number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

4.7 Identified Samples: supplied with a personal identifier (such as a name, medical record number or pathology number) that would allow the researcher to link the biological information derived from the research directly to the individual from whom the material was obtained.

4.7.1 A link to the list of the [18 HIPAA Identifiers](#) is located on the UMCIRB website.

5.0 Procedures:

5.1 The collection phase of the project involves issues familiar to IRBs in individual research studies that do not create banks, although human biospecimen collection involves several specific concerns that need to be considered and addressed, as applicable. For example, depending on the sources and timing in obtaining human specimens, there may be sensitive recruitment procedure issues. The protocol and consent should state whether the tissues will be screened for HIV, hepatitis, or other reportable diseases, and if so, to whom that information will be reported and what guidance will be provided to the participant.

5.1.1 The protocol for a biospecimen bank must provide justification for its existence based on good science but also requires specific issues be addressed:

5.1.1.1 A full description of the operation of the biospecimen bank including details about biospecimen collection or acquisition, storage, tracking, accessibility, and destruction.

5.1.1.2 Type and purpose of research to be conducted on the biospecimen with a discussion about future unspecified use (including potential for genetic research procedures) as applicable.

5.1.1.3 Risks related to collection or acquisition and how they will be minimized. The type and qualification of staff involved to collect, store, and transport biospecimens should be specified.

5.1.1.4 Discussion of anticipated research findings and circumstances under which participants will be notified of research results. Disclosures should be considered where findings are scientifically valid, have a significant implication on the participants health, and there is readily available interventions and treatment.

5.1.1.5 Identification of any plans to obtain access to and/or store medical record or other clinical information regarding the participant's samples/data.

5.1.1.6 Special safeguards in place to protect participant privacy and data confidentiality.

5.1.1.7 Discussion surrounding whether biospecimen and/or private data will be shared with other researchers, and, if so, what information will be obtained from the researchers about their research and how confidentiality will be protected for the sharing to occur.

5.1.2 The consent form must contain the essential elements of consent along with any additional elements as applicable and include the following specifically for banking of biospecimens:

5.1.2.1 Generally, in cases where the primary purpose of the study is to bank biospecimens, then the consent document will stand on its own. When biospecimen banking is adjunct to the main purpose of a study, the consent may be included as an addendum to the consent or included as a stand-alone document.

5.1.2.2 The consent form and process for maintaining human specimens in a repository for future research uses must inform the participants about the

basic operation of the bank, the known types of research to be conducted and explicitly about any unspecified possible future use of the specimens and related personal information that may be released.

- 5.1.2.3 Clarify that there may be no direct benefit to the participant, as applicable.
- 5.1.2.4 A description of any information about the biospecimen source that will be maintained and whether or not it will include identifiers.
 - 5.1.2.4.1 If no personal identifiers will be used for labeling the stored biospecimen, i.e., if it is impossible to be linked with the participant, the consent form should so state.
 - 5.1.2.4.2 If personal identifiers are to be used that will allow future matching of the participant to the collected biospecimen, the consent form should describe how they will be used and how privacy and confidentiality will be protected.
- 5.1.2.5 Statement that previously unspecified future use of identified samples from the biospecimen will require separate IRB approval and participant consent.
 - 5.1.2.5.1 Future unspecified use of samples from the biospecimen would not be considered human subject research if de-identified by the honest broker prior to sharing or coded in a manner where the recipient cannot readily ascertain the identity of the individual from whom the sample came. **Please note:** the UMCIRB is of the opinion that any team member listed on the IRB application for the bank would be able to readily ascertain the identity of a sample and would always need to obtain IRB approval for previously unspecified future use.
- 5.1.2.6 A statement about any potential commercialization and whether there are plans for participants to share in financial proceeds that may accrue from products derived from the biospecimens.
- 5.1.2.7 A description of whether, how, and under what circumstance results from research studies using the biospecimens would be communicated to the participants and, where relevant, to their family members, primary physicians, or clinicians providing treatment.
- 5.1.2.8 If specimens are individually identifiable, a description of how the specimens and associated data may be withdrawn from the repository. If the specimens are not individually identifiable, include a statement that they may not be withdrawn for that reason. Biospecimens that have already been used and the data derived from their use cannot generally be withdrawn.
- 5.1.2.9 Description of any costs.
- 5.1.2.10 Description of who will have access to the specimen and any associated data.
- 5.1.2.11 Description of conditions and circumstances for sharing samples or data with other researchers including whether and how researchers may contact individuals whose specimens are in the bank.
- 5.1.2.12 Plans to destroy or discard specimens.
- 5.1.2.13 Disclosure of COI, when applicable.
- 5.1.2.14 Risks specific to genetics, if needed.

- 5.2 With respect to maintenance and management of the repository, the protocol should state clearly who will be responsible for the specimen repository. The IRB should receive the investigator's assurance that there has been adequate planning for the institutional resources required to perform the operations described for the proposed lifespan of the repository

- including any promised privacy/confidentiality protections, an adequate contingency plan for any institutional transfers of custody of the repository, and a plan for destruction of the biospecimens.
- 5.3** Access to material in the bank must include detailed procedures and information on how biospecimens will be transferred to other investigators.
- 5.3.1** The protocol should note whether actual samples will be shared with other researchers or only data obtained from the biospecimens.
- 5.3.2** The protocol should clarify whether the transfer/access procedures adequately provides for security and privacy protections; and
- 5.3.3** The protocol should address any restrictions on uses that were promised in agreements for establishing the repository. The relevant agreements may include one or more of the following: informed consent, waiver of informed consent, authorization or waiver of authorization, and/or any contracts with sponsors or agencies for creation or management of the specimen repository.
- 5.3.4** In cases where other researchers will be allowed access to biospecimen samples and/or data, the protocol should include a template application for other researchers to request those samples and/or data from the bank.
- 5.3.4.1** The application procedure should be described. The Honest Broker for the bank should verify whether any transfer/sharing agreements should be put in place prior to providing samples and/or data.
- 5.4** Investigators should make appropriate provisions for the disposal or destruction of biospecimens and describe this within the IRB application and protocol. These provisions should include procedures for maintaining the confidentiality of donors as well as for adhering to any guidelines related to the disposal of hazardous waste material.

6.0 Responsibilities:

- 6.1 Principal Investigators** are responsible for:
- 6.1.1** Developing a written protocol for the development of the bank.
- 6.1.2** Training study team members in proper conduct of their roles.
- 6.1.3** Describing, in detail, the biospecimen bank in the UMCIRB application.
- 6.1.4** Providing an appropriate consent document/HIPAA Authorization for participants to sign, based on accurate information.
- 6.1.5** Following the approved study procedures.
- 6.1.6** Ensuring an Amendment has been approved by the UMCIRB prior to making any changes to the bank.
- 6.1.7** Completing Continuing Reviews, as required, on time and providing accurate information on participants that have enrolled.
- 6.2 UMCIRB Chairperson (or designee)** is responsible for:
- 6.2.1** Reviewing and approving proposals involving requests to create a biospecimen bank.
- 6.2.1.1** Sending any research study to the convened UMCIRB if uncomfortable with approving in an expedited fashion or if some of the procedures or populations do not lend themselves to an expedited review.
- 6.2.2** Reviewing requests to use samples and/or data already within the biobank as applicable for studies that will meet the definition of human research and where the purpose of the research study is not specified in the protocol and consent, the Chair may consider topics such as:
- 6.2.2.1** What is the nature of the proposed secondary research?

- 6.2.2.2 Could it reasonably be understood to fall within the scope of research that was described in the consent form?
- 6.2.2.3 Does the new research use impose new or significantly greater risks (including privacy risks) not described in the initial consent form?
- 6.2.2.4 Are there known concerns of the study population(s) about the proposed new use?

6.3 UMCIRB office is responsible for:

- 6.3.1 Conducting a pre-review of the IRB submission and supporting documents to identify any regulatory issues or questions that need to be addressed prior to IRB review.
- 6.3.2 Providing education and guidance to investigators and study team members about biospecimen banking requirements for UMCIRB review.

7.0 Useful sources of information on human specimen repositories can be found at the following sites:

- 7.1 National Cancer Institute: “Human Specimens Resources”
https://cdp.cancer.gov/resources/human_specimen/organizational_operational_aspects.htm
- 7.2 International Society for Biological and Environmental Repositories (ISBER)
<http://www.isber.org/>

Revision History:

Date	Change	Reference Section(s)
11.1.2019	Updated name of office; minor clarifications; update Honest Broker definition	Throughout; 4.4

References:

Issues to Consider in the Research Use of Stored Data or Tissues. November 7, 1997
<http://www.hhs.gov/ohrp/policy/reposit.html>

FAQs, Terms and Recommendations on Informed Consent and Research Use of Biospecimens
The Secretary’s Advisory Committee on Human Research Protections (SACHRP). July 20, 2011
<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-d/index.html>