

STANDARD OPERATING POLICY AND PROCEDURE

SUBJECT: Biospecimen Request and Release

Policy Number: 500.0

Policy Date: 1/16/2009

Amendment Date: N/A

Revision Date: 5-3-2010

I. INTRODUCTION AND PURPOSE

The ethical use of stored biospecimen(s) of a tissue bank is dependent in part on the appropriate request and release of biospecimen(s). It is the responsibility of the Tissue Bank Director and Tissue Bank Committee that the release of biospecimen(s) for use by a researcher has met all federal, state and institutional guidelines for tissue release. This will occur, in part, through the SCI Use Agreement, as well as Institutional Review Board approval or exemption, where necessary.

Documentation of the request and the release process is required to establish that the biospecimen disbursement was conducted properly and that no biospecimen was released without prior documentation and approval.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for appropriately obtaining and documenting a biospecimen request, approval, and release.

2. SCOPE

This SOP applies to the activities involved in the request, approval for release, and the actual release of biospecimen(s) from the SCI Tissue Bank.

3. APPLICABLE REGULATIONS AND GUIDELINES

OHRP Guidance dated October 16, 2008	Guidance on Research Involving Coded Private Information or Biological Specimens (Replaces the August 10, 2004 Guidance)
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OHRP Guidance dated August 10, 2004	Guidance on Research Involving Coded Private Information or Biological Specimens
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OHRP Guidance dated November 7, 1997	Issues to Consider in the Research Use of Stored Data or Tissues
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OHRP Guidance dated March 19, 2002	Guidance for Investigators and Institutional Review boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-derived Test Articles
45 CFR part 46	Basic HHS Policy for Protection of Human Research Subjects
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
45 CFR parts 160 and 164	The Privacy Rule: Health Insurance Portability and Accountability Act of 1996

4. REFERENCES TO OTHER APPLICABLE SOPs

To be determined

5. ATTACHMENTS

- A. SCI Tissue Bank Application for Tissue Release and Use Agreement
- B. Tissue Release Form
- C. Specimen Request Checklist

6. RESPONSIBILITY

This SOP applies to those members of the SCI Tissue Bank involved in the request and release of biospecimen(s) from the SCI Tissue Bank. This includes the following:

- Tissue Bank Director
- Tissue Bank Committee
- Tissue Bank Technician

7. DEFINITIONS

- A.) The following definitions from the Guidance on Research Involving Coded Private Information or Biological Specimens (Replaces the August 10, 2004 Guidance) apply to this SOP.

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: 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.

Intervention: includes both physical procedures by which data are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Private Information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record).

Individually identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Coded:

- (1) Identifying information (such as name or social security 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 (i.e., the code); and
- (2) A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Investigator: Includes anyone involved in conducting the research, including those members of the Tissue Bank Committee who may be requesting biospecimens for their individual research projects.

B.) The following definitions from the International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline apply to this SOP.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Institutional Review Board (IRB): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

8. PROCESS OVERVIEW

- A. Obtaining written request from the researcher
- B. Review and approval of the biospecimen request
- C. Release of biospecimen(s)
- D. Documenting the request for biospecimen(s)

9. PROCEDURES

A. Obtaining Written Request from the Investigator

<ul style="list-style-type: none"> • Investigator 	<p>The investigator requesting the biospecimen(s) must fill out the SCI Tissue Bank Application for Tissue Release and Use Agreement.</p> <p>An Application and Use Agreement is considered valid once signed, and must be provided for each new biospecimen request.</p> <p>An Application and Use Agreement must be provided by all investigators even those serving on The Tissue Bank Committee.</p>
<ul style="list-style-type: none"> • Tissue Bank Director (Or Committee Designee) 	<p>In the header of the application write in the date the Application and Use Agreement was received in the Tissue Bank Office.</p> <p>If Human Subjects Approval (IRB approval or exemption) was received with the application fill this date in on the header as well.</p> <p>Determine if the investigator is requesting information related to the biospecimen outside of what is authorized for release as de-identified data. If the investigator is requesting additional information instruct the investigator to apply for an IRB approval of the project, which will be necessary prior to the release of the biospecimen with identifiers.</p> <p>If the Tissue Bank Director is the Investigator making the request, a Committee Designee should process the application.</p>

<ul style="list-style-type: none"> • Tissue Bank Technician 	<p>Review the application to ensure that the required information has been adequately provided. Once the information has been deemed to be adequate the biospecimen database will be queried to determine that tissue fitting the request description is available.</p>
<ul style="list-style-type: none"> • Tissue Bank Technician • Tissue Bank Director (Or Committee Designee) 	<p>Using the Specimen Request Checklist ensure that all documentation needed for a request review has been provided by the investigator and that specimen is available. If the information is incomplete notify the investigator of that information which remains outstanding. Once all information has been received as complete, notify the investigator that specimen(s) meeting the request criteria are available within the bank and that the request will be forwarded to the Tissue Bank Committee for review and approval.</p>

B. Review and Approval of the Biospecimen Request

<ul style="list-style-type: none"> • Tissue Bank Director (Or Committee Designee) 	<p>The appropriate forms and documentation will be scanned in as a pdf document and an email generated to the committee outlining the request. An attachment with all applicable documentation will be sent to the committee. Use the Specimen Request Checklist to ensure that all the appropriate information is sent to the committee.</p> <p>If the Tissue Bank Director is the Investigator requesting biospecimen release, the Tissue Bank Technician must approach a Tissue Bank Committee Member not involved in the research project for review of the Application and associated documentation for forwarding for review by the committee.</p> <p>If any member of the Tissue Bank Committee is requesting specimen release or is directly involved in the research project utilizing the tissue requested, that committee member will be excluded from both the review and vote for approval of specimen release.</p>
<ul style="list-style-type: none"> • Tissue Bank Committee 	<p>The Tissue Bank Director (or designee) must receive 4 of 5 votes for approval for release before an application may be signed as approved for release. The approvals must be confirmed either with emails or as documented meeting minutes with a vote count. Each reviewer has 5 business days to respond to the email. If the required number of email votes cannot be obtained for approval, a Tissue Bank Committee meeting must be convened for review of the request.</p>

<ul style="list-style-type: none"> • Tissue Bank Director (or Committee designee) 	<p>Once the request has been approved indicate the date of approval in the header of the application and sign and date in the blue box at the end of the application form.</p> <p>Attach any email correspondence pertaining to the request or approval to the application.</p> <p>The Tissue Bank Director or designee will forward the approved request to the Tissue Bank Technician.</p> <p>The original signed request application must be kept on file. Upon release of the specimen(s) provide the documentation to the clinical research office for filing.</p>
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C. Release of Biospecimen(s)

<ul style="list-style-type: none"> • Tissue Bank Technician 	<p>Once the Tissue Bank Technician has received the approved request the corresponding specimen release may be fulfilled. The Tissue Bank Technician will notify the researcher of the approval and arrange for specimen pick-up or shipping.</p> <p>Indicate in the header of the application the date the request was added to the release list.</p> <p>Use the Specimen Request Checklist to ensure that the proper information and material are provided to the researcher. A copy of the approval and corresponding de-identified information will be released to the investigator upon payment.</p> <p>Information to be released with specimens includes age, gender, and tissue pathology. Tissue pathology includes any and all information on the surgical pathology report excluding direct identifiers such as dates of service, donor name, accession numbers, and medical record numbers. Examples of information to be released include tumor characteristics, additional staining or biomarker reports, microscopic diagnosis, clinical diagnosis, description of the surgical margins and gross description of the surgical specimen. General prior treatment information such as radiation, surgery, chemotherapy or biologic therapy may be given upon request. Identifiable information, as defined by the Privacy Act, will not be provided without a separate IRB review.</p>
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<ul style="list-style-type: none"> • Tissue Bank Director • Tissue Bank Technician • Clinical Research Office Manager 	<p>If an investigator has requested identifiable information related to the specimens and has provided the proper IRB approval documentation, coordinate the release of such information (e.g. patient names) with the clinical research office and provide to the clinical research office the specimen ID key to match to the identifiers.</p>
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D. Documenting the Request for Biospecimen(s)

<ul style="list-style-type: none"> • Tissue Bank Director • Tissue Bank Technician 	<p>Prior to the release of the specimen(s) a Tissue Release Form must be filled out with the appropriate information. Once the release Form has been filled out it must be filed with the Corresponding Collection form for that particular specimen.</p>
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