

WVU Specimen Bank Policy: May 16, 2011

1.0 Introduction

For purposes of this policy, the term, "tissue" includes any cell tissue, fluid, or excreta from which measures of normal or pathologic human physiologic function can be obtained. The term, "tissue" includes, but is not limited to pathological specimens, diagnostic specimens, hair and nail clippings, deciduous and permanent teeth, dental plaque and calculus, sweat, uncannulated saliva, placenta removed at delivery, amniotic fluid, cerebrospinal fluid, genetic material, urine, blood and other bodily fluids. First trimester fetal tissue may include additional guidelines.

2.0 Policy

Research using human tissue can be conducted, using the normal established guidelines for IRB review, as long as all tissue collected is either used for the purposes of the study described or discarded. If any tissue collected as part of an approved protocol, normal operating room procedure, or from a non-university affiliated institution **will be banked for future research investigations at West Virginia University or its affiliates**, the investigator must first register the tissue bank and then conform to the guidelines set forth in this policy for tissue banking. The policy is not directed at tissue banks that exist for other than research purposes, e.g., quality improvement or state reporting.

Registration

Individuals intending to create an on-site database or tissue bank utilizing clinical health information or authorized tissue specimens must complete and submit to the IRB office an "Application to Establish an On-site WVU Tissue Bank for Research or Database Development Involving Specimens Stored with or without Clinical Health Information" to register with the WVU Office of Integrity and Research Compliance. The form can be found on the IRB Forms & Samples page at http://oric.research.wvu.edu/human_subjects_research_and_the_irb/irb_forms_samples, and is listed as the Tissue Bank Development Form. Review and formal approval for the On-site WVU Tissue Bank application will be given by the ORIC Director and one of the IRB Chairs or Vice-Chairs. Once approved the form should be submitted as part of an IRB application.

Individuals intending to create an on-site database or tissue bank utilizing clinical health information or authorized tissue specimens from decedents must still register the bank with the IRB utilizing the aforementioned form. It is expected that proper informed consent from family members to have the decedent's tissue stored will be obtained and submitted with the registration application. **3.0**

Approval of Tissue Banking Protocols

3.1 Placement: Collection and placement of human tissue into a bank for research purposes can occur after completion and approval of an IRB protocol application. To establish an on-site Tissue Bank the approved Tissue Bank Development Form must be attached to the IRB protocol application. Human tissue, accompanied by a copy of an approved consent agreement signed by the donor, can be placed into an approved tissue bank for unspecified research purposes. Human tissue can be deposited as part of an IRB approved protocol: (1) following standard operating or delivery room procedures, (2) following standard diagnostic and treatment procedures (e.g., dental extraction,

collection of bodily fluids), and (3) from a non-affiliated institution that conforms to comparable standards for the protection of human subjects. An approved protocol is needed if human tissue is to be placed into a bank as part of an approved protocol for unspecified research purposes other than that outlined in that protocol, a separate consent form obtaining approval of the donor must be obtained.

a) *Surgical Consent Form*. If human tissue obtained through standard operating or delivery room (non-research) procedures is to be placed into a bank for potential research purposes, a separate consent form obtaining approval of the donor must be obtained in addition to the standard operating room consent form.

b) *Non-Surgical Consent Form*. If tissue obtained for purposes of standard medical or dental diagnostic and treatment (non-research) procedures is to be placed into a bank for potential research purposes, a separate consent form must be approved by the IRB for this purpose. For example, if a blood sample is obtained for standard clinical diagnostic purposes and then discarded without identifiers, no consent is required, unless the blood is analyzed as part of a research project prior to being discarded, in which case a standard approved consent form is required. If the remaining blood or components of blood from a standard clinical diagnostic test are banked for potential research use, a signed approved consent is required. Additionally, if the bank is on-site then the bank must be registered with the WVU Office of Research Integrity and Compliance.

c) *Tissue Acquired from a Nonaffiliated Institution*. If identifiable human tissue is acquired from an institution, laboratory, or company not affiliated with West Virginia University for the purpose of tissue banking for research, the tissue must be accompanied by an approved consent agreement signed by the tissue donor. The approved consent agreement must contain comparable language to the approved WVU tissue banking language, providing assurance that the tissue can be used without additional consent as long as donor confidentiality is maintained, that tissue can be used with subject identification with additional consent, and that financial considerations regarding the cost and potential financial advantage to institutions are enumerated. If CORE (Center for Organ Recovery and Education) is involved, their consent form may be substituted.

3.2 Removal: Removal of human tissue from a bank for research purposes.

Human tissue can be removed from an approved tissue bank for research purposes with an approved protocol using the normal established guidelines for NHSR (Not Human Subjects Research), exempt, expedited, or quorum review. All researchers must apply singly for an IRB approval for each individual research project utilizing tissue from a Tissue Bank.

a) *NHSR*. If human tissue is totally de-identified (stripped of all 18 Protected Health Information Identifiers) so that the researcher cannot trace the tissue back to the donor, then it is not human subjects' research (NHSR). The researcher must submit an NHSR application to the IRB for acknowledgement

b) *Exempt Research*. If identifiable human tissue is removed from a bank for research purposes, but the researcher records the data without identifiers, the project qualifies as "exempt research."

c) *Expedited or Quorum Review*. If identifiable human tissue is removed from a bank for research purposes and information is provided to the investigator in such a manner that human subjects can be or are identified, and the researcher uses the identifiers, the research project must follow the procedures for Expedited Review or Quorum Review.

d) *Tissue Sent to a Nonaffiliated Institution*. If identifiable human tissue is removed from an approved bank at West Virginia University and sent to an institution, laboratory, or company not affiliated with West Virginia University for purposes of research, the investigator must conform to the IRB Guidelines for the Protection of Human Subjects by obtaining approval through an approved protocol from their institution.

4.0 Approval of Tissue Banking

4.1 Policy: All research conducted on banked human tissue at West Virginia University must be obtained from an IRB-approved tissue bank.

4.2 Requirements: Requirements for IRB-Approved Tissue Banking.

- a. All WVU Tissue Banks must have biosafety approval from the Institutional Biosafety Committee (IBC) before the IRB will approve the protocol.
- b. Storage of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined through the IBC Guidelines.
- c. Disposal of tissue must be conducted in a manner conforming to the appropriate care and handling of biological specimens as outlined through the IBC Guidelines.
- d. This identification number assigned by the tissue bank will be the only method of linking the specimen, the Specimen Record, and the Donor Record. The Donor Record and the Specimen Record will be housed in separate files.
 - **The Specimen Record.** The Specimen Record includes demographic and medical information from the patient's medical or research record which does not identify the patient. Variables like age (< 90), medical diagnosis, and laboratory values can be included in the Specimen Record. Variables like date of birth, hospital record number, or phone number cannot be included in the Specimen Record.

- **The Donor Record.** Any information identifying the donor, including a copy of the approved consent agreement signed by the donor, shall be kept in the Donor Record.
- e. Deposits of banked specimens must conform to the IRB-approved guidelines for conducting research on human tissue. All specimens in a tissue bank must be accompanied by a copy of the consent agreement signed by the donor.
- f. Removal of banked specimens or portions of banked specimens must conform to the IRB guidelines for conducting research on human tissue. No tissue can be removed for research purposes without an approved IRB research protocol or IRB acknowledgement of a protocol involving de-identified samples.
- g. All tissue deposited and/or removed from a tissue bank must be logged using a Tissue Bank Log which will include date and time of deposit or removal, specimen number, the approved IRB protocol number, name(s) of investigators making the deposit or removal, and name of the tissue bank personnel responsible for completing the transaction.

4.3 Monitoring of IRB-Approved Tissue Banking: The IRB has the authority to suspend or terminate any or all research being conducted through a tissue bank that is not in compliance with IRB Guidelines. Tissue banks are subject to periodic audits.

5.0 Pre-Existing Specimens

5.1 Policy: The IRB acknowledges that there may be specimens that were collected prior to the development and enforcement of the approved policy for conducting research on human tissue, and that records accompanying these specimens may not be in compliance with these IRB Guidelines. Whenever possible, it is the duty of the tissue bank to bring records from pre-existing specimens into compliance with IRB Guidelines (e.g., obtaining copies of consent forms to accompany specimens, separating the Specimen Record from the Donor Record, completing a Tissue Bank Development Form to register an on-site Tissue Bank).

5.2 Grandfather Clause: All tissue deposited or removed from a tissue bank after 1 January 2011 must conform to the IRB Guidelines for Tissue Banking. Any tissue banked after 1 January 2011 must conform to the IRB Guidelines for removal of tissue from a tissue bank. As it may be impractical to obtain consent for many specimens deposited before 1 January 2011, the tissue bank will not be required to demonstrate evidence of informed consent for specimens collected prior to this date.