



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

R&D 537/151  
April 13, 2011  
Version 3.6

**SOP: Tissue Banking  
Procedures  
At Jesse Brown VA  
Medical Center**

Please refer to the UIC policy and procedure *VA Research: Human Biological Specimens Collected, Used, and/or Stored from Veterans for Research* for more detailed information.

**POLICY**

Biological specimens collected during a VA research protocol must be banked at either a VA sponsored or VA approved tissue bank, if the specimens are collected and stored for future research purposes that are beyond the scope of work described in the original protocol and informed consent or those specimens collected under a protocol designed for banking of specimens are considered banked biological specimens. Human biological specimens collected under a VA-approved protocol are not considered to be “banked” specimens if they are used for only the specific purposes defined in the protocol and are destroyed either when the specific testing/use is completed or at the end of the protocol. If the specimens are sent to a non-VA institution for testing as defined in the protocol, once the specific analyses are performed, the remainder of the specimens must be destroyed or returned to the VA for destruction. If the specimens are destroyed at another institution, that institution must certify the destruction of the specimens in writing. [Note: If the protocol is 5 years or longer and the specimens are stored off-site at a non-profit institution until the end of the protocol, then the investigator must obtain a waiver from ORD. If the specimens are stored off-site at a non-academic, for-profit institution for greater than 3 months while awaiting analysis, a waiver must be obtained from ORD.]

If the tissue bank is not VA sponsored or VA approved, and the policy above indicates that the specimens are banked specimens, all new applications for VA approved tissue banks must be submitted to ORD by the Associate Chief of Staff for Research (ACOS/R) at the JBVAMC on behalf of the principal investigator. Applications cannot be submitted by non-VA investigators.

## **PROCEDURES**

- A. Investigators that will be banking biological specimens off-site are must clearly address the following points in a submitted memo:
- (1) The justification for establishing a tissue bank or for banking specimens at a non-VA repository.
  - (2) The benefits of the tissue bank to veterans, the VA investigator(s)' research program and the VA Medical Center.
  - (3) A description of the system used by the bank for the protection of veterans' privacy and confidentiality including protection of all clinical and personal data, the location and accessibility of the data, coding system utilized, and other important regulations.
  - (4) An assurance that the specimens cannot be linked to the veteran's social security number or name and that the code used to identify the specimen is maintained at the VA facility. (Under very rare circumstances, ORD may waive this requirement).
  - (5) A statement indicating whether the PI will transfer to the tissue bank any information from the patient's medical record and if such, an exact outline of the information.
  - (6) A statement indicating that all future uses of VA samples will be done through VA-approved protocols. If this cannot be assured, a clear description of the reasons and the mechanisms
  - (7) Used by the bank to distribute specimens to researchers, including a description of the oversight mechanisms protecting these specimens.
  - (8) A written assurance indicating that upon termination/closing of the bank, all veterans' biological specimens shall be destroyed or returned to the originating VA.
  - (9) A written assurance indicating that the specimens and all links to clinical and personal data can be destroyed upon the request of the donating human subject.
- B. Investigators must complete the JBVAMC Tissue Banking Application found within the JBVAMC R&D Protocol Submission Packet.
- C. Investigators must provide a copy of the completed JBVAMC Tissue Banking Application, the memo, the tissue bank manual or SOP, protocol document, informed consent document, and authorization form to the JBVAMC ACOS/R or designee. If the research has received IRB and R&D approval, these approval documents must be submitted as well. However, please note that ORD strongly recommends that the Off-Site Tissue Banking Waiver application be submitted prior to IRB approval as often elements are missing.
- a. A copy of the tissue bank manual or SOP. This manual, or SOP, should provide sufficient information regarding the bank's policy, mechanisms of tissue acquisition and redistribution, and all oversight mechanisms in place. If a tissue bank manual or SOP is not available, the "Tissue Bank Operations Sheet" (located on the ORD website:[http://www.research.va.gov/programs/tissue\\_banking/Tissue-Bank-Operations-Sheet.pdf](http://www.research.va.gov/programs/tissue_banking/Tissue-Bank-Operations-Sheet.pdf)) may be completed instead.

- b. The informed consent under which specimens are collected must meet all the requirements stated in VHA Handbook 1200.05 “Requirements for the Protection of Human Subjects in Research.” In addition, the consent form must clearly address the following points:

#### Specimen Storage at a Non-Profit Institution

- The types of specimens that will be stored and the name and location of the biorepository/tissue bank where they will be stored.
- The types of future research that the sample will be used for.
- If the specimen will be shared with other researchers for approved research protocols.
- The length of time the specimen will be stored.
- That the specimen will be labeled with a code that doesn't contain any personal identifiers (i.e., protected health information as defined by HIPAA) and if the subject's clinical data will be linked to the specimen.
- When and under what conditions research results will be conveyed to the subject, the subject's family, or the subject's physician. Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.
- The steps necessary for the subject to withdraw from the study and any future studies in which the specimens may be used. The consent must indicate what will occur to the data collected to that point and that the specimen and the code that links the subject's clinical data to the specimen will be destroyed.
- Disclose any potential commercial benefits and if the subject will receive money or other benefits.
- Disclose any intent to perform genetic tests.
- Disclose any potential risks to the subject or the subject's family. Potential risks may include breach of confidentiality, which may lead to discrimination in the areas of employment, insurability, social stigmatization, or psychological stress caused by disclosure of adverse information to the subject or the subject's family.

#### Specimen Storage at a For-Profit Institution

- The types of specimens that will be stored and the name and location of the facility where they will be stored.
- The types of analyses/studies that the biospecimens will be used for.
- The length of time the specimen will be stored.
- That the specimen will be labeled with a code that does not contain any personal identifiers (i.e., protected health information as defined by HIPAA).

- When and under what conditions research results will be conveyed to the subject, the subject's family, or the subject's physician. Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.
- The steps necessary for the subject to withdraw from the study. The consent must indicate what will occur to the data collected to that point, and what will happen to the samples already collected.
- Disclose if the subject will receive money or other benefits if a drug or product is marketed.

- D. Once the complete submission is received by the ACOS/R or designee, it will be forwarded to the ORD Tissue Banking Program.
- E. The ORD Tissue Banking Program will send a memo to the ACOS/R or designee listing the requested changes, if any, to the protocol and the supporting documents.
- F. Once the application is considered acceptable, the application will be approved; however, the approval of application will be contingent on IRB approval of the consent form. If the research has not received IRB and R&D committee approval, then the approval of the application would also be contingent on the final study approval by the IRB committee and R&D committee, or ACOS of R&D. Therefore, the applicable approvals will need to be sent to the ORD Tissue Banking Program.

# TISSUE BANKING APPLICATION

**STATION # 537/151**  
**Jesse Brown VA Medical Center**  
**820 S. Damen Avenue**  
**Chicago, IL 60612**  
**Tel. # 312-569-7441**  
**Fax # 312-569-8114**

Principal Investigator Last Name:
Principal Investigator First Name:
IRB Protocol #:
Project Title:

## CONTACT INFORMATION OF THE TISSUE REPOSITORY

Contact Last Name:
Contact First Name:
Full Address:
Telephone #:
Fax #:
Email address:

Principal Investigator's Signature:	Date:
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