

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP # 15

May 7, 2007

DNA RESEARCH AND TISSUE BANKING

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to complying with the VHA Directive 2000-043 that mandates the human biological specimens that are collected for research purposes and stored for possible later uses, including genetic studies, as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, are maintained in VA-approved tissue banks. This TVAMC HRPP standard operating procedure (SOP) is the written policy and procedure regarding the banking of human subjects' specimens and is applicable to all research projects that are conducted by VA investigators in VA facilities or approved off-site locations, whether the research is funded or unfunded, and regardless of the source of funding.

The TVAMC conducts research involving the collection of human subjects' specimens for DNA research and tissue banking in VA-approved tissue banks. However, the TVAMC does not conduct the actual DNA research itself, i.e. does not conduct laboratory research using recombinant DNA. Should such research needs arise in the future, the TVAMC HRPP would develop an SOP regarding DNA laboratory research that includes a chemical hygiene plan and other safety protocols for research staff involved in hazardous materials.

2. RESPONSIBILITIES

TVAMC Director is responsible for assuring that all VHA Directives are followed by the TVAMC HRPP, including mandates for tissue banking.

Coordinator of Research and Development (C/R&D) and R&D Administrative Officer are responsible for assuring that policies and procedures are operational and complied with, including those SOPs regarding tissue banking of human subjects' specimens.

R&D Committee is responsible for final approval or disapproval of IRB reviewed and approved studies involving tissue banking.

The Institutional Review Board (IRB) is responsible for reviewing all research activities involving tissue banking for compliance with all applicable regulations, policies, and guidelines.

The Investigator is responsible for adhering to this HRPP SOP in regards for obtaining proper approvals (IRB, R&D, and if applicable, ORD) for tissue banking in VA-approved tissue banks.

3. DEFINITIONS

Human biological specimen is any material derived from a human subject—such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids—whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.

Banked specimens are biological specimens collected and stored for future research purposes that are beyond the scope of work described in the original protocol and informed consent or those collected under a protocol designed for banking of specimens are considered banked biological specimens.

Stored Specimens (Not Considered Banked): 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.

VA-Sponsored Tissue Bank is a tissue repository or storage facility at a VA facility or approved off-site location that operates in accordance with VA regulations. It contains human biological specimens collected under VA-approved research protocols that are under both VA ownership and VA control.

VA-Approved Bank differs from a VA-sponsored tissue bank in that an approved tissue bank is located at a non-VA facility and has the appropriate approval from the Chief Research and Development Officer. It must also meet safeguards similar to those required for a VA-sponsored tissue bank. Non-VA sites that may not be acceptable include non-academic, for-profit institutions, such as pharmaceutical companies.

4. PROCEDURES

- a. **IRB and R&D Approval:** All research involving tissue banks (involving DNA research or other future uses) must obtain TVAMC IRB and R&D approval. Research involving use of stored DNA specimens and DNA analysis requires a separate DNA consent form and full IRB submission and approval, using identical procedures for initial and continuing review (HRPP SOP#3 and SOP#6).
- b. **On-Site VA Tissue Banks:** A tissue bank established at a VA site by a VA-paid investigator does not require Office of Research and Development (ORD) approval. However, the C/R&D should maintain records of all tissue banks within the facility.
- c. **Off-Site Tissue Banks:** A VA investigator needs ORD approval to bank biological specimens collected from VA subjects and maintained on an off-site tissue bank, such as a University affiliate. A part-time or full-time VA-paid investigator on a non-VA tissue bank study team must submit a tissue bank application. The VA-paid investigator has ultimate responsibility for VA specimens in that off-site tissue bank. Off-site tissue

banks are approved on a per protocol basis (with the exception of some National Cancer Institute protocols listed on the VA web site).

- d. Application for Approval to Bank Human Biological Specimens in Off-Site Tissue Bank:** The investigator must apply for approval from ORD by completing VA form 10-0436 (<http://www.va.gov/vaforms/medical/pdf/vha-10-0436-fill.pdf>), which is a fillable pdf. The additional information requested on page 5 of the application can be scanned and attached to the pdf. The form and requested information can be mailed to the address given on the form. The documents requested include the
- Biographical sketch of the PI
 - Research protocol
 - Tissue bank manual or SOPs
 - VA consent form

All new applications for VA-approved tissue banks must clearly address the following points in the 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 that all future uses of VA samples will be done through VA-approved protocols. If this can not be assured, a clear description of the reasons and the mechanisms used by the bank to distribute specimens to researchers, including a description of the oversight mechanisms protecting these specimens.
6. A written assurance indicating that upon termination/closing of the bank, all veterans' biological specimens shall be destroyed or returned to the originating VA.
7. 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.

The front page of the application must state the name of the Principal Investigator, the name, number and address of the VA Medical Center, the title of the project collecting/banking specimens, the name of the tissue repository and contact information for the PI. The biographical sketches of the PI and all co-investigators shall be appended after the front page. A copy of the research protocol, the manual for the tissue bank, and the IRB and R&D committees' approval letters must be appended to the application after the biographical sketches section. In addition, the application must also include the IRB approved and stamped consent form. The consent form under which specimens are collected must meet all the requirements stated in VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research".

In addition, the consent form must clearly address the following points:

- If the collected specimen will be used for future research and provide a choice for the type of research (research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases; gene testing; etc.).
- If the specimen will be stored without any identifier or if the subject's identifier and clinical data are linked to the specimen.
- If the research results will/will not be conveyed to the subject and/or health care provider.
- If the human subject will be contacted after the completion of the original study.
- If the specimens and all links to clinical data are destroyed or removed from the bank upon the subject's request.
- The disposition of the specimen after completion of the study or at the end of the banking period.
- Any potential conflict of interest or financial gains for the investigators or the participating institution.

The statement about future uses does not have to be very specific. If it is not specific, in the consent form or during the consent process, the PI should explain what such phrases as "related diseases" or "unspecified research" means for the use of the sample and the impact on the subject.

ORD generally processes the review and approval/disapproval within 2 weeks and communicates via memo. The memo may list issues found with the application that need clarification or revision. The most frequent problem is that required elements are missing from the informed consent.

The investigator storing the banked specimens must maintain a copy of the original consent under which each specimen was collected, a record of the use of the specimens, and the protocols under which they are used.

Linking of the data generated by the specimens and the clinical data should occur within the VA and by VA investigators whenever possible. When this is not possible, the minimal amount of clinical data necessary should be shared with those doing the statistical analysis. The clinical information that is shared should not contain any unique identifiers.

5. REFERENCES

VHA Directive 2000-043
VA Memorandum from ORD, dated March 28, 2001

6. ATTACHMENTS

None

7. **RESCISSIONS**

IRB Standard Operating Procedures dated July 1, 2004.

8. **REVIEW DATE**

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development