DNA RESEARCH AND TISSUE BANKING

1. POLICY

The Birmingham VA Medical Center (BVAMC) Human Research Protection Program (HRPP) is committed to complying with the guidance set forth from the Office of Research Oversight (ORO) http://www.research.va.gov/programs/tissue_banking/default.cfm 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 (click http://www.research.va.gov/programs/tissue_banking/approved.cfm for a complete listing). This BVAMC 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.

2. RESPONSIBILITIES

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

Chief of Staff, Research and Development (ACOS/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**

See HRPP SOP #24 – HRPP Definitions

4. **PROCEDURES**

a. **IRB and R&D Approval:** All research involving tissue banks (involving DNA research or other future uses) must obtain BVAMC 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 ACOS/R&D should maintain records of all tissue banks within the facility.

c. **Off-Site Tissue Banks:** A VA investigator must request 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 1200.05 “Requirements for the Protection of Human Subjects in Research”.

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

**Non-Profit Organization:**

- 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 share with other researchers for approved research protocols.
- The length of time the specimens 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.
- 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.
• The IRB approved wording notifying potential subjects of the Genetic Information Nondiscrimination Act (GINA).

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.
  o 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.
• Disclose any intent to perform genetic tests
• If genetic analysis will be performed, 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.
• The IRB approved wording notifying potential subjects of the Genetic Information Nondiscrimination Act (GINA).

The statement about future uses should be 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.

Once approved by ORD for offsite tissue banking the investigator must send a copy of the approval letter to the IRB office to be filed with the study.

5. REFERENCES

- http://www.research.va.gov/programs/tissue_banking/default.cfm
- http://www.research.va.gov/programs/tissue_banking/approved.cfm
- VA Memorandum from ORD, dated March 28, 2001 - Banking of Human Subjects Specimen

6. ATTACHMENTS

None

7. REVISIONS


8. REVIEW DATE

January 2021.

Louis Dell'Italia, MD
ACOS, Research and Development