

FAQ: Banking of Human Biological Specimens for Research

Q: How do you define human biological specimens?

A: A 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.

Q: When are specimens considered to be banked specimens?

A: 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.

Q: Is all storage of human biological specimens considered banking?

A: 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.

Important Notes:

- 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.

Q: Is banking of bacteria or fungus samples obtained from human specimens considered tissue banking?

A: No, not as long as the human material has been removed.

Q: Does a VA investigator need approval from the Office of Research and Development (ORD) to establish a tissue bank on a VA campus?

A: No. A tissue bank established at a VA site by a VA-paid investigator does not require ORD approval. However, the ACOS/R should maintain records of all tissue banks within the facility.

Q: Does a VA investigator need approval to bank biological specimens collected from subjects at the VA Medical Center at his/her University affiliate?

A: Yes. If the specimens are banked at a site that is not on the VA campus, ORD approval is required.

Q: I am a Without Compensation (WOC) investigator at the VA. May I apply for a waiver for an off-site tissue bank or storage site?

A. Yes. If the PI on the study is WOC they may apply for a waiver, **but only if** they have a VA investigator, either part-time or full-time, take responsibility for the samples in the bank or at the storage site. The VA investigator needs to be located at the specific VA site that the application originates from. The VA investigator taking responsibility needs to send us a signed letter/memo indicating that they are taking responsibility for the samples on behalf of the WOC investigator for the study in question. The VA investigator does not need to be listed on the informed consent or protocol.

Q: My colleague received approval to bank specimens at off-site tissue bank XYZ. Do I need ORD approval to bank specimens there?

A: *Off-site tissue banks are approved on a per protocol basis* (with the exception of some NCI protocols listed in the answer to the next questions), so unless you are banking specimens for the same protocol as your colleague, you need ORD approval.

Q: Where can I find a list of VA-approved off-site tissue banks?

A: Tissue banks approved for *multi-site protocols* are listed below. This list is also posted on the VA R&D website.

The following banks are approved ONLY for the protocol listed:

| Protocol | Protocol Acronym | Tissue Bank Name and Location |
|---|------------------|---|
| Action to Control Cardiovascular Risk in Diabetes | ACCORD | Northwest Lipid Metabolism and Diabetes Research Laboratories, Seattle, WA |
| Chronic Renal Insufficiency Cohort | CRIC | CRIC Study Central Lab & Repository, University of Pennsylvania, Philadelphia, PA |
| Hepatitis C Long Term | HALT-C | SeraCare (formerly BBI Biotech), |

| | | |
|---|-------------------------|--|
| Treatment Against Cirrhosis | | Gaithersburg, MD |
| Alzheimer's Disease Neuroimaging Initiative | ADNI | National Cell Repository for Alzheimer's Disease (NCRAD), Indianapolis, IN |
| Protocol | Protocol Acronym | Tissue Bank Name and Location |
| Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes | AIM-HIGH | Northwest Lipid Research Laboratories, University of Washington, Seattle, WA |
| Lung Tissue Research Consortium | LTRC | Tissue Processing Distribution Center-Tissue Core Lab, University of Colorado Health Sciences Center, Denver, CO |
| Idiosyncratic Liver Injury Associated with Drugs: A Retrospective Study | DILIN-ILIAD | NIDDK Genetics Repository (Rutgers University Cell and DNA Repository) |
| A Multi-Center Longitudinal Study of Drug- and CAM-Induced Liver Injury | DILIN-CAM | NIDDK Genetics Repository (Rutgers University Cell and DNA Repository) |
| Action for Health in Diabetes | Look AHEAD | Look AHEAD Central Laboratory, University of Washington, Seattle, WA |
| Diabetes Prevention Program/Diabetes Prevention Program Outcomes Study | DPP/DPPOS | DPP/DPPOS Central Laboratory, University of Washington, Seattle, WA |
| Genetics of Endophenotypes and Schizophrenia | COGS | Rutgers University Cell and DNA Repository, Piscataway, NJ |

In addition, as a result of a letter of understanding with the National Cancer Institute (NCI), the following NCI-sponsored cooperative tissue banks, are designated as VA-approved if they are used for one of their protocols (for example, the SWOG-supported tissue bank can be used for SWOG protocols without ORD approval):

Clinical Trials Cooperative Groups Tissue Resources, which include
 American College of Surgeons Oncology Group (ACOSOG)
 Cancer and Leukemia Group B (CALGB)
 Eastern Cooperative Oncology Group (ECOG)
 Gynecologic Oncology Group (GOG)
 North Central Cancer Treatment Group (NCCTG)
 National Surgical Adjuvant Breast and Bowel Project (NSABP)
 Radiation Therapy Oncology Group (RTOG)
 Southwest Oncology Group (SWOG)

Cooperative Breast Cancer Tissue Resource
Cooperative Human Tissue Network
Gynecologic Oncology Group Tissue Network
Cancer Prevention Network
National Cancer Institute of Canada Clinical Trials Group (NCIC CTG)

Q: How do I apply for approval to bank or store biological specimens off-site?

A: **(Non-profit institution Application)** Complete VA FORM 10-0436
(<http://www.va.gov/vaforms/medical/pdf/vha-10-0436-fill.pdf>)

(For-profit institution Application) Complete VA FORM 10-0474
(<http://vaww.va.gov/vaforms/medical/pdf/10-0474-fill.pdf>)

The additional information requested on both applications can be scanned and attached to the pdf, which can be e-mailed to Marilyn Mason (offsite.tissuebanking@va.gov). Alternatively, the form and requested information can be mailed to the address given on the form. **Please note that we do prefer you to email the documents.** Please make sure that you send us the following documents that are listed on both applications. We cannot review your application until we receive the complete package.

- Research protocol
- Tissue bank manual or SOPs (if the bank in question has no manual or SOP's you can access the **Tissue Bank Operations Sheet** on the website)
- VA consent form
- HIPAA authorization

Q: How long does it take for ORD to process the application?

A: You will generally receive a memo within 2 weeks. Frequently, the memo will list issues found with the application, consent form, etc. and you will need to submit revisions.

Q: How difficult is it to get an application approved?

A: Most applications are eventually approved, but several revisions may be required. The most frequent problem is that required elements are missing from the informed consent and/or HIPAA authorization.

Q: Is there a list of elements that must be included in an informed consent when the protocol includes tissue banking?

A: Yes, they are posted on the VA website. There is a guidance document for both non-profit and for-profit sponsored studies.

Q: Does the informed consent need to narrowly specify the future uses of the banked specimens? (Non-profits only)

A: No, 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.

Q: Your tissue banking application requests a copy of the informed consent. Can I send it to you before sending it to the IRB for approval?

A: Yes, we would encourage you to do that. Often elements are missing, and we can point this out before you request IRB review. In addition, we can provide approval of your application that is contingent on IRB approval of the consent form. The approval of your application would also be contingent on the final study approval by the IRB committee and R&D committee, or ACOS of R&D.

Q: Why do we need the SOP’s for the tissue bank or storage facility? What if we don’t have them?

A: When we request to see the SOP’s of the tissue bank or storage facility, this is to make sure our veteran’s specimens are safeguarded. We do not need to know how tubes will be shipped or processed, but we do want to know if there is limited access to the specimens and power back-up for the storage units. If you don’t have banking SOP’s you can access the **Tissue Banking Operations Sheet** on the website, which can be saved and filled out using Adobe Reader. This form asks questions about specimen storage, facility security, and sample re-distribution. **Please note:** if your study is sponsored by a for-profit, the facility that is housing the specimens should have SOP’s or a laboratory manual.

Q: I have specimens that were collected for a protocol that will soon end. Can I use them for a different protocol or test them for something (protein, gene, etc.) not in the original protocol?

A: If banking was not included in the original protocol and informed consent, then in order to use the specimens, you would need to re-consent the patients, or an IRB would need to waive consent, if applicable. If approval is obtained from subjects or the IRB waives consent, the samples would be considered banked samples. All new uses of the samples would have to be approved by the IRB and R&D Committees. If approval is not obtained, then the samples would have to be destroyed.

Q: Our pathology lab has paraffin-embedded specimens that it plans to destroy. Can we use the specimens for research, including genetic testing?

A: Your IRB must make that determination. Please note: clinical samples may NOT be transferred to a commercial (for-profit) entity for research purposes.

Q: Can we bank DNA/blood at a for-profit sponsor's site?

A: Currently, we are not permitting off-site tissue banking at for-profit entities, with the exception of NIH-sponsored banks, such as those at Coriell and ATCC. However, specimens may be stored at a commercial sponsor's site for up to 3 months while waiting for analyses/tests specified in the protocol to be performed. If the analyses/tests cannot be completed within the 3-month limit, a waiver must be obtained from ORD. *This waiver will allow specimens to be stored for up to 1 year past study completion date.*

Q: I am applying for a waiver and the study is sponsored by a for-profit company, but the protocol involved includes many study sites, not just VA. Is it possible to have the protocol document amended in order to incorporate specimen storage elements if ORD determines that information to be lacking?

A: Even if the protocol covers many study sites (including non-VA) an amendment can be included, and only refer to VA subjects that are enrolled/enrolling. We have had many sites request that the sponsor amend the protocol in order to incorporate details about specimen storage. We do not usually approve the study if these changes cannot be made.

Q: If I want to store specimens off-site for a multi-site clinical trial where several VA's are participating, how do I know that one of the other sites has not submitted an application for an off-site waiver? (For-profits only)

A: If you are not sure what other VA sites are involved, or have no communication with them, you can contact us anytime in order to make an inquiry. For a multi-site clinical trial study we usually accept one application from one site. If the waiver is approved we then send out a contingent approval which would apply to any other sites involved. Please do not assume that one of the other sites has submitted an application. If you have any hesitation, please contact us. If another site has already submitted, but you would like for us to look over your individual informed consent or HIPAA documents, we are more than willing to review them.

Q: With the new ORO guidance on VA sensitive information, and specifically the statement, “Thus, with a valid HIPAA authorization (or IRB approved waiver of authorization), the subjects’ PHI stored on the affiliate’s servers not considered “VA sensitive information” under VA Handbook 6500 because the data no longer belongs to the VA. According to OGC a VA CIO waiver is not required under these circumstances,” do I need the database, that may contain patient identifiers, to be FIPS 140-2 encrypted?

A: If your database is housed on the affiliate’s server it does not need to be FIPS 140-2 encrypted as long as the HIPAA authorization is adequate (refer to VHA Handbook 1605.1, section 14 “Authorization Requirements”). If your study was initiated pre-HIPAA the database does not need to be encrypted as long as the consent form states that data will be stored. We will make this determination.

Q: You have an agreement in place with NCI regarding the use of tissue banks that they sponsor. What about other NIH Institutes?

A: Each NIH Institute sets its own policies regarding the repositories it sponsors, and our only agreement to date is with NCI.

Q: I am a VA-paid investigator and would like to bank blood for a study, but our VA Medical Center does not have the facilities to do that. Is there a VA-approved tissue bank that I can use?

A: You may bank samples at any VA Medical Center that has an established tissue bank. Alternatively, you could also use the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) core laboratory at the Boston VA. It serves as the Cooperative Studies Program (CSP) Genetic Tissue Core Laboratory. The laboratory provides both local and national VA researchers a convenient, high-quality, low-cost mechanism to include biological specimen handling, storage and analysis in clinical studies. Laboratory capabilities include: coordination of collection, processing, shipment, and storage of serum, plasma, buffy coats and other biological specimens; extraction of DNA from blood, tissue, or serum buffy coat; extraction of RNA; and genotyping. See <http://www.csp.research.va.gov/boston.cfm> for contact information.