

**William S. Middleton Memorial VA Medical Center**  
2500 Overlook Terrace  
Madison, WI 53705  
(608)256-1901

Many human subjects research studies now include storage (“banking”) of human biological specimens (any material derived from human subjects, e.g., blood, sputum, hair, other tissue) from veterans as part of the protocol. All such material collected and stored for future research purposes are considered “banked” specimens. “Future” in this case means beyond the scope of the current project (some protocols request storage of biological specimens so that ideas that arise in the future can be tested using stored specimens).

All banked biological specimens should be stored at this VA hospital unless specific approval has been received from the VA Central Office in Washington.

Below:

- 1) What to include in a VA consent form when the banking of tissue is involved, irrespective of where the tissue is to be banked.
- 2) How to apply for VA-approval of a tissue banking site.

.....

**1) Language to be included in all VA consent forms in studies that include tissue banking**

In addition to the usual requirements (basic and additional elements for informed consent), VA regulations require that the consent form must clearly address the following points when tissue banking is involved:

1. Will the collected specimen be used for future research and if so, what kind of research (research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases; etc.)?
2. Will the specimen be used to generate a cell line or for genetic testing?
3. Will the specimen be stored without any identifiers (“deidentified”)?
4. Will the research results be conveyed to the subject and/or health care provider?
5. What is the disposition of the specimen after completion of the study or at the end of the banking period?
6. Will the specimens and all links to clinical data be destroyed or removed from the bank upon the subject’s request?
7. Will the subject be contacted after completion of the original study?

In addition: Describe any potential conflict of interest or financial gains for the investigator or the participating institution.

**2) How to Apply for VA-Approval of a Non-VA Tissue Banking Site**

Applications for the use of a non-VA tissue banking site must be approved by the VA Central Office prior to the use of that site. This includes the storage of tissue at any UW site. Application is to be made through the Madison VA Research Office in a letter addressed to the ACOS/R&D (Dr. Goodfriend).

All applications for VA-approved tissue banks must clearly address the following points:

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 coding system utilized, the location and accessibility of the data, etc.
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 cannot be re-linked to the veteran or the veteran's medical record **outside of the VA facility**. If the code is not to be maintained at the Madison VA hospital, a justification for locating the link outside the VA must be included.
5. A statement indicating whether the PI will transfer to the tissue bank ANY information from the patient's medical record and if so, 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 used by the bank to distribute specimens to researchers, including a description of the oversight mechanisms protecting these specimens?
7. A written assurance indicating that upon termination/closing of the bank, all veterans' biological specimens shall be destroyed or returned to the originating VA.
8. A written assurance indicating that the specimens and all links to the clinical and personal data can be destroyed upon the request of the donating human subject.

Please be aware that it is the policy of the Chief Research and Development Officer to **not** approve tissue banks requests from for-profit companies.