Department of
Veterans Affairs

MEMORANDUM

Date: March 28, 2001

From: Chief Research and Development Officer (12)

Subj: VHA Directive 2000-043: Banking of Human Research Subjects' Specimens

To: ACOS/Coordinators for Research and Development (151)

1. VHA Directive 2000-043: Banking *of* Human Research Subjects Specimens was published on November 6, 2000. In an effort to assist all facilities in complying with this Directive, a VHA Handbook entitled "Requirements for the Collection and Banking of Human Research Subjects' Specimens" will be published in the near future. In response to requests from the field for additional guidance in the interim, the Office of Research and Development has prepared this memorandum.

2. All new proposals must comply with the guidance detailed In this memorandum. All previously established projects must develop plans to come into compliance with VHA Directive 2000-043. The plans should be developed as the principal investigator develops the continuing review submission for the IRB. Once published, the Handbook will supercede this memorandum.

3. For purposes of this memorandum, the following three terms are defined: human biological specimens, VA-sponsored tissue banks, and VA-approved tissue banks.

a. Human biological specimens are any material derived from human subjects, 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.

b. The definition of a 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,

c. A 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. The following guidance is applicable to all VA-approved research protocols that collect, use, or store human biological specimens.

a. Human biological specimens collected under a VA-approved protocol are not considered to be "banked" (stored) specimens if the specimens 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/use 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.

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b. Specimens collected and stored far future research purposes are considered "banked" specimens. These specimens must be banked in a VA-sponsored or VA-approved tissue bank. Reuse of the specimens must be consistent with the consent under which they were collected, and the reuse must only occur through a VA-approved protocol.

If the protocol requires that the specimens be analyzed/used at a non-VA institution, a written understanding between the VA investigator and the non-VA institution must specify the analysis/use as defined in the protocol. The agreement must also specify that any remaining quantities of the specimens shall be either destroyed or returned to the VA. If the remaining quantity is destroyed, that institution must certify the destruction of the specimens in writing. The remaining quantity may not be retained and/or stored by the non-VA institution.

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.

c. 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.

d. The informed consent under which the specimens are collected must meet all the requirements in draft Handbook 1200.5. In addition, it must clearly state:

(1) If the specimen will be used for future research and allow the subject the choice of how the specimen will be used (any research, research by the PI or other researchers, genetic analysis, research related to a specific area, etc.).

(2) If research results of reuse of the specimen will be conveyed to the subject.

(3) If the subject will be re-contacted after the original study is completed.

(4) If the subject requests, the specimen and all links to the clinical data will be destroyed.

e. The ACOS/Coordinator for R&D shall maintain records for all new banks within the facility. These records will include the location of the bank and the name of the investigator responsible for the oversight of the bank.

5. If you have any questions, please contact Dr. Michael Cohen, Deputy Director, Medical Research Service, Office of Research and Development, at (202) 408-3608.