

November 6, 2000

BANKING OF HUMAN RESEARCH SUBJECTS' SPECIMENS

1. PURPOSE: This Veterans Health Administration (VHA) Directive implements a new policy related to human biological specimens collected for research purposes and stored for possible later uses, including genetic studies. It also addresses the collection and storage of clinical data that may be linked to the human biological specimens.

NOTE: For the purpose of this Directive, the term human biological specimens is defined as any materials derived from human subjects, such as blood, urine, tissues, organs, hair, nail clippings or any other cells whether collected for research purposes or as residual specimens from diagnostic, therapeutic or surgical procedures.

2. BACKGROUND

a. The availability of human biological specimens for research purposes is crucial for the advancement of medical knowledge and in understanding, diagnosing, and treating diseases that affect the veteran population.

b. With the advent of new technologies and their abilities to uncover information that may adversely effect the donor in anticipated or unanticipated ways, it is imperative that all ethical and legal issues related to the use of these specimens and, if collected, their linked clinical data be identified and understood.

c. It is imperative that human research subjects donating the specimens receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research subject.

d. The use of Department of Veterans Affairs (VA)-sponsored tissue banks will facilitate the protection of an individual's rights without compromising the advancement of medical science. Further, it will allow investigators to pursue research projects that have been subjected to scientific merit review and the Institutional Review Board, to assure compliance with all applicable Federal regulations such as Title 38 Code of Federal Regulations (CFR) 16, and 45 CFR 46.

NOTE: For the purpose of this Directive, a VA-sponsored tissue bank is defined as a tissue bank in VA facilities or approved off-site locations that operates in accordance with VA guidance and regulations.

3. POLICY: It is VHA policy to ensure that human biological specimens, 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 at VA approved tissue banks. *NOTE: This policy 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.*

THIS VHA DIRECTIVE EXPIRES OCTOBER 30, 2005

VHA DIRECTIVE 2000-043

November 6, 2000

4. ACTION

a. Effective on this date, all new projects collecting and storing human biological tissue specimens shall utilize VA-sponsored tissue banks. These tissue banks may also serve as the repository for the clinical data that have been collected and that may be linked to the specimens.

b. All previously established projects must develop plans to either obtain approval or to move specimens and linked clinical data to VA-sponsored tissue banks and begin implementation of these plans as soon as feasible.

NOTE: Failure to comply with the policies stated in this Directive could result in immediate withdrawal of VA research funding for the programs in question and/or suspension of the research program.

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: The Office of Research and Development (12) is responsible for the contents of this Directive. Questions may be referred to 202-408-3614.

7. RESCISSIONS: None. This Directive expires October 30, 2005.

Thomas L. Garthwaite, M.D.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 11/8/2000
FLD: VISN, MA, DO, OC, OCRO, and 200 - FAX 11/8/2000
EX: Boxes 104, 88, 63, 60, 54, 52, 47 and 44 - FAX 11/8/2000