


<p>Name of Policy: Policy for research using cadaveric tissue.</p> <p>Policy Number: 3364-70-08</p> <p>Approving Officer: President</p> <p>Responsible Agent: Vice President for Research</p> <p>Scope: All University of Toledo Campuses</p>	 <p>Most Recent Revision date: November 23, 2011</p> <p>Original effective date: June 1, 2008</p>
<p><input type="checkbox"/> New policy proposal</p> <p><input type="checkbox"/> Major revision of existing policy</p>	<p><input checked="" type="checkbox"/> Minor/technical revision of existing policy</p> <p><input type="checkbox"/> Reaffirmation of existing policy</p>

(A) Policy statement

All research experiments or educational training programs that utilize cadaveric tissue must receive prior approval by the university Cadaveric Research Committee (UT-CRC). Noncompliance with the policies established in this document, and or other policies implemented by the UT-CRC, will prompt a review of the cadaveric tissue research or educational training program.

(B) Purpose of policy

To provide standards and defined procedures for all university research activities that utilize cadaveric tissue. This policy is designed to insure that cadaveric specimens are treated and maintained in a professional and respectful manner. This policy does not apply to the use of autopsy tissues by the Department of Pathology for the purposes of diagnosis, further elucidation of disease pathogenesis, or education of residents, fellows, and medical students.

(C) Definitions: cadaveric tissue

- (1) Cadaveric tissue is defined as any body, body part, organ, tissue, or prosthetic surgical device or implant that is part of the body at the time of death.
- (2) Cadaveric tissue may be derived from an embalmed or an unembalmed body.

(D) Source(s) of cadaveric tissue

- (1) Cadaveric tissue may be obtained from the University of Toledo College of Medicine and Life Sciences (UT-COMLS) Anatomical Donation Program, the anatomical donation program of another university or medical school, other organizations such as hospitals, pathology departments, or coroner's offices, or a commercial source.
- (2) Regardless of the source, all cadaveric tissue must be obtained from a donor source that has been documented to the UT-CRC and approved by the UT-CRC.

- (3) Regardless of the source, all purchases of cadaveric tissue must be coordinated with the UT Purchasing Department and all purchases made using the University of Toledo electronic purchasing system and procedures.
 - (4) Documentation must indicate that the approved use(s) of cadaveric tissue is consistent with the research or educational training proposed by university faculty principal investigators.
 - (5) The Principal Investigator must have documentation for each acquisition of cadaveric tissue from approved sources.
 - (6) It is a felony for any individual(s) working under an approved cadaveric tissue research project to sell, barter, trade, or give away cadaveric tissue.
- (E) Application for use of cadaveric tissue
- (1) All research experiments or educational training that utilize cadaveric tissue must receive prior approval by the UT-CRC.
 - (2) An application for research using cadaveric tissue must be submitted for review and approval by the UT-CRC before either the receipt or the use of any cadaveric tissue on university campuses by the principal investigator or other individuals.
 - (3) The principal investigator will assure that cadaveric tissues will be used only in the manner and for the purpose(s) described in the application.
 - (4) Any deviation from use(s) and purpose(s) for the cadaveric tissues described in the UT-CRC application must be approved in advance by the UT-CRC. Such alterations to the protocol application must be made in writing to the UT-CRC Chair, preferably by email.
- (F) Access to cadaveric tissue
- (1) Only individuals listed in the application for research using cadaveric tissue shall have access to cadaveric tissue. Any change in project participants involved in research using cadaveric tissue must be reported to the UT-CRC within 30 days as individuals either leave or join the project.
- (G) Labeling of cadaveric tissue
- (1) All cadaveric tissue must be labeled to maintain the identity of the donor of the cadaveric tissue. It is important to note that the “identity” of individual cadaveric tissue refers to a unique identifier (usually numeric, rather the name of the individual donor).
- (H) Storage of cadaveric tissue
- (1) When not attended, all cadaveric tissue must be stored in sealable, plastic bags or other suitable containers.
 - (2) The principal investigator will assure that the cadaveric tissue will be maintained and housed in a secure facility and that access to specimens will be only to those individuals involved directly in the project as described in the application.
- (I) Disposal of cadaveric tissue

- (1) Disposal of cadaveric tissue must be in accord with recovery instructions from the donor source.
 - (2) Cadaveric tissue obtained from the UT-COMLS Anatomical Donation Program must be returned to the Program for disposal at the time stated in the application for research using cadaveric tissue.
 - (3) Cadaveric tissue obtained from commercial source(s) must be disposed of at the time stated in the application for research using cadaveric tissue in accordance with the disposal policies of the donor source.
 - (4) If a donor source does not have an explicit disposal policy, the cadaveric tissue must be returned to the UT-COMLS Anatomical Donation Program for cremation (the cost of cremation will be covered by the research laboratory involved).
- (J) Inventory of cadaveric tissue
- (1) The Principal Investigator is responsible for maintaining a current inventory of all cadaveric tissue being used and/or stored in their lab (or affiliated labs). At the end of each year fiscal year (i.e., June 30), the Principal Investigator will submit a summary of the cadaveric tissues acquired and/or purchased and used during the previous 12 months, as well as any tissues remaining for ongoing or future research studies. These reports shall be submitted to the UT-CRC by August 31 of each year.
- (K) Inspection of cadaveric tissue research laboratories
- (1) Laboratories using cadaveric material on the university campuses are subject at any time to inspection by representatives of the UT CRC, or other designated officials.
 - (2) Non-compliance with the policies established in this document, and or other policies implemented by the UT CRC, will prompt a review of the cadaveric tissue research or educational training program.

<p>Approved by:</p> <p><u>/s/laj</u> Lloyd A. Jacobs, M.D. President</p> <p><u>November 23, 2011</u> Date</p> <p><i>Review/Revision Completed by:</i></p> <p><i>Vice President for Research</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none"> • <i>Previous 3364-70-08 , effective date August 19, 2011</i> <p>Initial effective date: June 1, 2008 Review/Revision Date: November 23, 2011 Next review date: November 23, 2014</p>
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