

Ohio Administrative Code Rule 3349-1-143 Procedure for the request, use and disposal of cadaveric tissue on the NEOMED campus.

Effective: October 14, 2024

(A) Purpose

The purpose of this rule is to ensure the proper management and disposal of cadaveric tissue within the university.

(B) Scope

This rule governs the acquisition of cadaveric tissue to be used and disposed on the Rootstown campus as part of any research or educational presentation.

(C) Definitions

(1) "Cadaveric tissue" refers to tissue, including parts thereof, from a cadaver, or the dead body of an animal or human. Cadaveric tissues can be fixed or unfixed.

(2) "Fixative" refers to a substance that is added to products such as biological samples, or tissue to prevent decomposition by microbial growth or by undesirable chemical changes.

(3) "IACUC" refers to the institutional animal care and use committee.

(4) "Preservative" refers to a substance that is added to products such as biological samples, or tissue to prevent decomposition by microbial growth or by undesirable chemical changes.

(D) Procedure

(1) Notification and request to use procedures

(a) Any person seeking to bring non-human cadaveric tissue to the Rootstown Campus must provide



written notification to the institutional animal care and use committee (IACUC) regarding the acquisition of the cadaveric tissue before it is brought to and used on campus. The IACUC must also approve all cadaveric tissue requests, from both NEOMED and non-NEOMED individuals who wish to use tissue from cadavers of animals previously utilized in NEOMED research.

(i) Any individual intending to use non-human cadaveric tissue must inform the IACUC in writing of the plan to do so. This communication must contain the following information:

(A) Type of tissue to be acquired;

(B) Amount of tissue requested;

(C) Source of the tissue (Note: if an abattoir is to be used, please include the facility's United States department of agriculture registration number);

(D) Description of how the tissue is preserved (if applicable);

(E) Where the tissue will be used;

(F) Brief description of the proposed tissue use;

(G) How will the tissue be disposed of (coordinated via the safety office per paragraph (B) of this rule; and

(H) A statement must be included that states the animal were not euthanised specifically for the intended purpose.

(ii) The communication shall be addressed to the current IACUC co-chair via e-mail or written correspondence, with a copy sent to the regulatory affairs coordinator in the comparative medicine unit (CMU). All such communications should be forwarded to the regulatory affairs coordinator.

(iii) The IACUC co-chair will review the request and send their acknowledgment, or request for additional information, to the regulatory affairs coordinator. Once acknowledged, the regulatory



affairs coordinator will notify the requesting individual(s) in writing of the IACUC decision. A copy of the communication will be kept on file with the IACUC records. The CMU manager also will be notified of the tissue request and IACUC decision.

(b) Request for use of human cadaveric tissue shall be referred to the chair of anatomy and neurobiology for appropriate consideration and handling in accordance with university practices and the standards of the NEOMED body donor program.

(c) Request and use of any human cadaveric tissue related to an approved research project and unrelated to the NEOMED body donor program will be subject to the approval of the appropriate safety committee(s) and in accordance with regulations in place on the NEOMED campus that governs such use.

(2) Requirements for the safe use and disposal of tissue

(a) Personal protective equipment (PPE)

Any person handling of any form of tissue is required to wear steril gloves at all times. If a significant splash hazard exists, safety goggles or glasses are required. If the tissue contains a formalin-based preservative, additional PPE or controls may be recommended or required.

(b) Preservative (fixative)

Tissue must be preserved in a fixative that is free of any carcinogenic properties (i.e. formalin, formaldehyde, paraformaldehyde) if the tissue will be used or handled as part of a demonstration to minors. If a preservative is present, the chemical mixture of the preservative must be reported to the NEOMED safety office. Additional safety requirements may be applicable, particularly the tissue is preserved in a manner different than required by this rule.

(c) Waivers

Educational events for minors that utilize cadaveric tissue may require waivers, permission slips or additional requirements as determined by guidelines on waivers for minors by the office of the



general counsel.

(d) Request for supplies and/or disposal

(i) All disposal must be coordinated through the office of environmental and occupational health and safety.

(ii) To ensure proper disposal for tissue that is unrelated to an approved research project, a work order must be submitted to campus operations with the details of the event, including the following:

(A) Date and time of event;

(B) Date and time of pickukp of tissue or sharps for disposal;

(C) Location of event;

(D) Responsible person for event;

(E) Any supplies requested for disposal (sharps containers, tissue containers and regular trash cans for waste not otherwise regulated);

(F) An indication of whether the tissue (or any related sharps) used are infectious. The infectious nature of any tissue or sharps is determined based on the following considerations:

(i) Whether the sharps were used on people;

(ii) Whether the tissue was deliberately infected with an infectious agent or biohazard; and

(iii) Whether the tissue is human in origin.

(G) An index to which any fees for disposal or containers can be charged.

(iii) Disposal related to an approved research project will be subject to the appropriate safety



committees and regulations in place on the NEOMED campus that govern the disposal and will be subject to separate "lab disposal" requirements.

(iv) If the tissue is being purchased and utilized during an educational event provided on the Rootstown campus by a third party, the organizer of the educational event should address the appropriateness of the tissue being disposed of by the third party with the office of environmental and occupational health safety.