

University of Pittsburgh Research and Clinical Training with Human Cadaveric Material Policy Committee

I. Preamble

This body is called the Research and Clinical Training with Human Cadaveric Material Policy Committee ("Committee"). It is authorized by the Chancellor and will serve at the Chancellor's discretion. The Chancellor has authorized the Senior Vice Chancellor for the Health Sciences ("SVC-HS") to direct the operations of the Committee, consistent with the terms of this Charter. This Charter outlines the purpose, relevant background, scope, responsibilities, composition, and operations of the Committee, as well as the review process for any proposals generated by this Committee.

This document should be read in conjunction with University Policy AO 01, Establishing University Policies, and all other applicable University policies, protocols, and procedures.

II. Purpose

The Committee is created for the purpose of revising and replacing Interim University Policy RI 12, Research and Clinical Training with Human Cadavers, and its supporting documents (e.g., procedures and standards). Policy RI 12 governs the use of cadavers for research, education, and clinical training in any University facility.

III. Background

The University is committed to ethical practices in research and teaching, including research and teaching that involves the use of human cadaveric material. All human cadavers and cadaveric material must be handled and utilized respectfully and in an ethical manner. Accordingly, research, educational, and clinical training activities, including observational experiences, utilizing the bodies of deceased patients or donors, must be reasonable and scientifically, educationally, and/or clinically important.

In January 2023, the University established an Interim Policy to govern the use of cadavers provided to the University via the Pennsylvania Humanity Gifts Registry Body Donation Program. That Policy established the standard by which research and clinical training with cadavers must be conducted. It also identified the Office for Oversight of Anatomic Specimens ("OOAS") as the entity responsible for monitoring adherence to this standard and for reviewing requests from schools seeking access to human cadavers. Additionally, the Policy provided OOAS with the authority to remove human cadavers from a laboratory or other unit when a

violation of this Policy occurs. The Interim Policy RI 12 was intended to be in place temporarily until the University could develop a permanent policy on the topic. This Committee is now established in order to recommend a long-term or permanent set of requirements governing the use of human cadaveric material.

IV. Scope and Authority

The Committee will recommend a University Policy governing the use of cadaveric material for research, education, and clinical training in any University facility, and any necessary documents to support its implementation (e.g., procedures, guidelines), which will replace the Interim Policy found at University Policy RI 12. In doing so, the Committee must address the following topics in drafting the revised Policy:

- **Rules and Requirements.** Establish rules and requirements (including ethical principles) governing the use and observation of human cadaveric material at the University, including establishing the standard by which research and clinical training with cadavers must be conducted.
- **Compliance and Enforcement.** Articulate the process by which adherence to established standards will be monitored and enforced to include corrective action that may be imposed if compliance is not maintained. Any proposed rules and requirements must, at a minimum, comply with relevant research-related requirements and legal regulations.
- **Responsibilities.** Clearly define the responsibilities of those seeking to use human cadaveric material as well as those supervising that work or educational experience.
- **Scope.** Identify the appropriate scope of the Policy on the use of cadavers. Specifically, consider whether the Policy should be limited to a whole cadaver (as provided in the Interim Policy) or also include cadaveric tissue and cadaver specimens (i.e., human cadaveric materials) obtained from sources other than the Humanity Gifts Registry.
- Use Request. Clearly establish a process University members must use to request the use of human cadaveric material as well as a process by which such requests will be reviewed and approved.
- **Clarity.** Clearly define terms relevant to the proposed Policy so readers can easily understand parameters set forth in the Policy.
- **Training.** Develop and establish necessary training that will be required for complying with the proposed Policy.

V. Responsibilities

As provided above, the Committee is created to propose a revised University Policy on Research and Clinical Training with Human Cadaveric Material. To perform this function, the Committee has the responsibility to:

- Review the existing Interim Policy RI 12, and the processes by which it is implemented, to identify practices that should be retained as well as areas for revision and addition.
- Review examples of compliance and non-compliance with existing policies.
- Research and discuss best practices for similar policies implemented by peer universities and relevant organizations such as the Pennsylvania Humanities Gifts Registry.
- Discuss proposed requirements with interested stakeholders in the University community and potential external subject matter experts, in a manner consistent with this Charter and as authorized by the Committee.
- Recommend a draft Policy for review pursuant to the process described in Section VIII below and consider feedback received during that review.
- Develop any supporting documents needed for the effective and efficient implementation of the proposed Policy.

It is expected that the Committee will work in confidence to have a full and frank discussion of all options. Individual members should maintain the deliberations of the committee confidential and are expected to not discuss the content of the Committee's deliberations outside of the Committee, unless authorized to do so by the Committee. The broader community will have an opportunity to consider the Committee's proposals pursuant to the process described in Section VIII below.

VI. Composition

This Committee, at the direction of the SVC-HS and will be chaired by **Barbara Barnes**, Associate Vice Chancellor for Industry Relations and Continuing Education, Health Sciences; Associate Dean for Continuing Medical Education, School of Medicine; Vice President for Sponsored Programs, Research Support and Continuing Medical Education, UPMC. The Committee will include the following members:

- 1. Tanner Bartholow, Assistant Professor, Department of Pathology, School of Medicine
- 2. Betty Braxter, Associate Dean for Undergraduate Education, School of Nursing
- 3. Lisa Parker, Director, Center for Bioethics & Health Law; Professor of Human Genetics
- 4. Susan Sesack, Professor of Neuroscience and Deputy Research Integrity Officer
- 5. Jean Truman, Director of Nursing Programs, Bradford and Titusville campuses
- 6. **Seth Weinberg,** Associate Professor, Department of Oral and Craniofacial Sciences; Co-Director, Center for Craniofacial and Dental Genetics
- 7. **Bill Yates,** Vice Chancellor for Research Protections and Professor of Otolaryngology and Neuroscience

- 8. Andrea Hergenroeder, Associate Professor, Director of Undergraduate Program in Rehabilitation Sciences
- 9. Kristin Wannemo, GPSG Representative
- 10. Emily Dauria, University Senate Committee on Research representative

Brittany Conner, Policy Specialist, will help facilitate and support the Committee on behalf of the Office of Policy Development and Management.

Amy Lindenfelder, Assistant Legal Counsel, will support the Committee on behalf of the Office of University Counsel.

VII. Operations

The Committee will meet monthly, or more frequently as circumstances dictate, until the work set forth above is complete.

The Committee's proposed Policy on Research and Clinical Training with Human Cadavers will be submitted to the SVC-HS no later than the 2023-24 Academic Year. The SVC-HS may ask for interim status reports.

After the SVC-HS's review is complete, the proposed Policy will be submitted to the Office of Policy Development and Management ("Policy Office") to coordinate its review consistent with Policy AO 01.

VIII. Proposed Policy Review Process

The review process for the Committee's recommended Policy is as follows:

- University comment period;
- Council of Deans;
- University Senate's Committee on Research;
- Faculty Assembly;
- University Senate Council; and
- Administration Leadership.

The Committee will coordinate with the Policy Office to consider feedback provided throughout this process.

Once this review process is complete, the proposed Policy will be sent to the Policy Office for review and submission to the Chancellor in accordance with Policy AO 01.

IX. Amendment

Any amendments to this Charter must be made in accordance with Policy AO 01 and receive the approval of the Chancellor or designee.

This Committee shall expire on the publication of a new University Policy that governs Research and Clinical Training with Human Cadaveric Material unless otherwise directed by the Chancellor.