UPMC
POLICY AND PROCEDURE MANUAL

POLICY: **HS-RS0004 ***
INDEX TITLE: **Research**

SUBJECT: **Research and Clinical Training Involving Decedents**
DATE: **November 10, 2016**

I. POLICY

It is the policy of UPMC that all research and clinical training involving human cadavers (inclusive of functioning human bodies following certification of death), cadaveric tissue, or decedent medical record information must be reviewed and approved by the University of Pittsburgh Committee for Oversight of Research and Clinical Training Involving Decedents (CORID). Immortalized cell lines derived from human decedent cells are exempt from this Policy.

Requirements for accessing decedent Protected Health Information (PHI) for research purposes are described in Policy HS-EC1602 Use and Disclosure of Protected Health Information, as well as in Policy HS-RS0005 Access, Acquisition, and Disposition of electronic Protected Health Information for Research Purposes.

Links to policies referenced within this policy can be found in Section VIII.

II. PURPOSE

The purpose of this policy is to advise individuals planning such research and clinical training activities for performance within UPMC entities and locations of the requirement for CORID approval and the procedures for securing such approval.

III. SCOPE

This policy applies to any United States based UPMC research and clinical training activity involving human cadavers, cadaveric tissue, or decedent medical record information which will be conducted within any UPMC entity or location. Please refer to UPMC Policies HS-EC1602 Use and Disclosure of Protected Health Information and HS-RS0005 Access, Acquisition, and Disposition of electronic Protected Health Information for Research Purposes with regard to disclosure of decedent PHI for research purposes.

IV. BACKGROUND

Consistent with the need to respect and protect the dignity of all decedents, research and clinical training on decedents require:

1. A review process to ensure the scientific or clinical merit of these activities,

2. Informed consent from the patient before death, the surrogate (usually the patient's next of kin) after death; autopsy authorization executed by the legal representative; or consent secured by approved external suppliers of tissue signed by the donor or legal representative.

3. Institutional oversight to determine whether such activities are within ethical and societal norms,

4. Institutional oversight to determine whether information derived from such activities may affect or harm the decedent's family, and

5. Procedures to minimize the time from obtaining consent to releasing a deceased patient to the family, should an activity require utilization of a functioning human cadaver in a clinical setting following certification of death.

Failure to satisfy these requirements may compromise patient and family rights, patient relations, the organ procurement program, and potentially give rise to abuse.

V. DEFINITIONS

The following are a list of terms and definitions applicable to this policy:

1. **Research activity**: Any investigation of *in situ* or *in vitro* cadaveric tissues, organs, or medical record information that is done with the express purpose of conducting research.

2. **Clinical training activity**: A course, session or lab conducted for the purpose of demonstrating and/or providing hands-on experience to physicians, trainees and other health care professionals in technical training and/or to enhance proficiency in procedural skills.

3. **Brain death:** Death using neurologic criteria, as defined in Policy HS-PS0502 Certification of Death in Adults.

4. **Cardiopulmonary death:** Death using criteria as defined in Policy HS-PS0502 Certification of Death in Adults.

VI. PRINCIPLES

1. It is imperative that all human cadavers and cadaveric tissue be handled and utilized respectfully and in an ethical manner. Thus, these principles apply whether the proposed activity is to be done on 1) whole cadavers or cadaveric tissue provided via the University of Pittsburgh, School of Medicine's Humanity

Gifts Registry Program or Department of Pathology, or through UPMC Autopsy Services; or, 2) cadaveric tissue procured via the Center for Organ Recovery and Education or an approved external tissue bank.

2. Research and clinical training activities utilizing the bodies or tissues of deceased patients or donors may be reasonable and scientifically or clinically important. Performing such research and clinical training has the potential to generate information, improve technical skills and enhance procedural proficiency without the significant risks that preclude activities from being ethically conducted on living patients or research participants.

3. Research and clinical training activities utilizing the bodies or tissues of deceased patients or donors may not be conducted without the prior consent of the patient, donor, or an appropriate surrogate.

4. If the decedent gave prior consent to organ donation and research or clinical training via an organ donor card or a living will document, such consent applies only to activities that fall within the scope of the ordinary understanding of "experimentation with human organs and tissue" unless explicitly stated otherwise.

5. If there is reason to believe that an activity is not within the scope of the ordinary understanding of "experimentation with human organs and tissue", such as research on a functioning human body following certification of death, the specific nature of the activity must be explained and the patient or surrogate must give permission for that particular activity.

   Consent for research and clinical training after death confers a use right for the organization, not a property right. That is, UPMC does not own the cadaver, but it has the right to use it for purposes outlined within the consent.

6. If permission to obtain tissue from an individual following death is requested from that individual or his/her surrogate while the individual is still living, and if some pre-death screening or data collection procedure involving the individual is being performed for the purpose of research, then the usual Institutional Review Board (IRB) rules and jurisdiction apply. The IRB is responsible for supervising and regulating all research activities wherein an investigator conducting research obtains data through intervention or interaction with a living individual or obtains identifiable, private information about a living individual.

7. Organ procurement for transplantation saves lives. Therefore, any proposed activities on tissues or organs procured after death should not interfere with the efficiency or effectiveness of organ procurement for transplant.

8. Institutions engaging in research and clinical training activities involving decedents have the obligation to ensure that such activities have scientific or clinical merit. Therefore, all proposed activities involving decedents must be reviewed internally (school, department, or division) for their scientific or clinical merit prior to their submission to CORID. Approval requires affirmative answers to each of the following questions: a) Does the proposed activity address an important question or is it intended to provide required skills training?; b) Are the methods proposed likely to generate data that will contribute to answering the question or enhance skills proficiency?; c) Is the choice of subject appropriate?; and d) Is the intervention reasonable given the expected value of the data or training to be obtained?

9. Institutions engaging in research and clinical training activities involving decedents have the obligation to ensure that decedents as well as their families are protected from harm and that their privacy is respected. Therefore, an independent oversight entity must approve all proposed activities prior to their implementation.

10. Patient confidentiality is essential. Patients or their families may be harmed by disclosure of the information obtained from a research study. Therefore, information obtained as a result of the study that may be harmful to decedents or their families must be carefully protected. The procedures that will be utilized to maintain confidentiality of the study data must be addressed by the investigators, and reviewed by CORID.

11. Families may or may not want to be informed of the results of a research study (for example in research involving genetic testing). The appropriateness of revealing the results of the research to family members of the decedent must be addressed by the investigators, and reviewed by CORID. As part of the informed consent process, family members should be told whether or not investigators plan to disclose the results of the research. If disclosure is not planned, the reason for such non-disclosure should be provided to the family. If disclosure is planned and possible stress (e.g., results of genetic testing) or embarrassment (e.g., new paternity information) may be associated with such disclosure, the family members should be offered the option, in the informed consent process, to refuse disclosure. If the research involves genetic testing, the family members should be offered genetic counseling prior to deciding whether to receive the results and, if applicable, at the time of receiving the results.

12. A statement must be included in the consent which reads: "It is possible that the tissue provided may lead, in the future, to new inventions, discoveries or products that may be sold, licensed or patented. However, there are no plans to share with you any money or other rewards that may result from the development of those new products."

VII. PROCEDURES AND GUIDELINES

Research and clinical training activities using cadavers, cadaveric tissue, or decedent medical record information must adhere to the following guidelines and procedures.

1. Proposals should be submitted to CORID using an online application form. Submissions should include all required documents, such as a proposed consent form, Request for Access to Decedent Protected Health Information, if applicable. The Committee will review the application based upon guidelines set forward in this policy.

2. All applications submitted for review to CORID require prior review for scientific or clinical merit by the principal investigator's or course director's department. Written notification signed by the chairman of the departmental scientific or clinical review committee or the Department Chair or Division Chief indicating that such a review and approval has been completed is mandatory and must be submitted with the application to CORID for review.

3. CORID will inform the applicable UPMC Hospital Ethics Committee about any proposed activity to be performed on cadavers *in situ* at that facility and will carefully consider that Committee's suggestions and recommendations.

   The Ethics Committee of UPMC Mercy may, upon review of an applicable protocol and consent form, not approve the proposed study for performance at Mercy because of conflicts with Catholic moral teachings, inclusive of the Committee's understanding and implementation of the Ethical and Religious Directives, as well as other Catholic guidelines.

4. CORID may also inform and solicit recommendations from the applicable UPMC Hospital Ethics Committee about any proposed *in vitro* activity to be performed on tissues or organs from cadavers.

5. UPMC Hospital Ethics Committees may make policy recommendations to CORID. Final approval authority rests with CORID.

6. Decedents should be excluded if such activities would limit or interfere with organ procurement for transplantation.

7. Decedents should be excluded if the activity would interfere with an autopsy required to determine the cause of death.

8. As a general rule, investigators or course directors should refrain from participating in deciding whether a patient meets the criteria for death and in terminating life-sustaining treatments. In some situations, it may be unreasonable to separate the physician from such discussions and clinical determinations (for example when the investigator or course director is also the dying patient's

primary physician). In those situations, it is recommended that the physician/investigator request an ethics consult, or a consult from another physician to review the appropriateness of the process and decisions to forgo life-sustaining therapy. (Two physicians are already required for the determination of brain death). The involvement of the investigator or course director in such decisions must be addressed in the protocol submission to CORID, including a discussion of the steps that will be taken in the event that the investigator or course director is also the patient's primary physician.

9. CORID will review and monitor all activities using tissues of decedents. Since consent in accordance with the Uniform Anatomical Gift Act and as provided for on the UPMC Autopsy Authorization include consent for human tissue experimentation and medical education, no other consent document is necessary unless the proposed activity deviates from the scope of the "ordinary" understanding of "experimentation with human organs and tissue".

10. It is necessary to disclose specific information about the proposed activity to the appropriate decision-maker if the proposed activity deviates from the scope of the "ordinary" understanding of "experimentation with human organs and tissue", i.e., if it is unlikely to be considered an ordinary or conventional study or clinical training activity. In these cases, an informed consent document, detailing the study specific procedures, study duration, risks, and privacy and confidentiality protections must be reviewed and approved by CORID. The principal investigator, co-investigator or course director must discuss and obtain written consent from the patient's surrogate.

11. For all research and clinical training conducted following death, a written certificate of death is required before the activity may begin. This must be addressed in the application submitted to CORID.

12. In the case of CORID-approved studies of drugs or other therapies, any materials to be used must meet the same purity and production standards as would be required for an investigational new drug under the guidelines established by the Food and Drug Administration, unless exceptions have been specifically approved by CORID.

13. All procedures should be done in a respectful manner (i.e., cadavers should be treated in a manner that acknowledges that they once were the bodies of living persons).

14. Experiments, training and tissue procurement procedures should be designed to minimize the time required for their completion. The duration of the activity should be determined by scientific or clinical need and should be expressly stated when consent is obtained. The expected duration and its justification should also be addressed in the research protocol submitted to CORID.

15. All research or clinical training conducted after the death of a patient must be reviewed and approved by CORID prior to implementation of the activity. Reports of progress must be made to CORID annually, and at completion of the activity.

16. Prospective CORID approval is required for projects in which another research institution wishes to send human cadaveric tissue to the University of Pittsburgh for evaluation and testing by a University of Pittsburgh faculty member. An Incoming Material Transfer Agreement is required and the Office for Oversight of Anatomic Specimens (OOAS) will coordinate the submission of the paperwork through the University of Pittsburgh, Office of Research for approval.

17. Since the use of human tissue for experimentation or training may impact the organ procurement team(s), all protocols that may have such an impact need to be approved by the organ procurement team prior to their implementation. This approval should occur prior to submission to CORID. Operationally, to ensure minimal interference, this would entail having the investigator contact CORE, and through CORE, contact all teams (cardiac, thoracic, liver, kidney, skin, cornea, bone) whose efforts might be affected by the proposed activities. Included in this discussion is the time needed to procure the tissue and related measures that might delay returning the body to the family for burial. In addition, the investigators or course directors must coordinate with the organ procurement team on a subject-by-subject basis since inter-individual variations may make an approved project unfeasible in some circumstances.

18. Additional costs generated by maintaining some physiological functions(s) following death for research or clinical training activities must be addressed and accounted for in the application submitted to CORID.

19. Questions regarding this policy may be addressed to the Director, Office for Oversight of Anatomic Specimens.

VIII. POLICIES REFERENCED WITHIN THIS POLICY

HS-EC1602 Use and Disclosure of Protected Health Information (PHI) Including: Fundraising, Marketing and Research

HS-PS0502 Certification of Death in Adults

HS-RS0005 Research Using UPMC Electronic Protected Health Information (e-PHI)

SIGNED: Holly Lorenz, RN MSN
Chief Nurse Executive
ORIGINAL: October 10, 2011
APPROVALS:
Policy Review Subcommittee: October 13, 2016
Executive Staff: November 10, 2016
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SPONSOR: Vice President, Sponsored Programs, Research Support, and CME

*** With respect to UPMC business units described in the Scope section, this policy is intended to replace individual business unit policies covering the same subject matter. In-Scope business unit policies covering the same subject matter should be pulled from all manuals.**