# Decedent Research

## Overview:

Research that uses ***only*** human cadavers, cadaveric tissue, decedent medical record information or discarded decedent specimens from clinical use is not subject to prior review and approval by the University of Pittsburgh IRB. There are, however, ***ethical*** issues associated with research that uses decedent tissue, specimens or data. To address these ethical issues, all University faculty, students and trainees conducting this type of research must submit an application to the University of Pittsburgh Committee for Oversight of Research and Clinical Training Involving Decedents (CORID) [Reference UPMC policy *HS-RS0004 Research and Clinical Training Involving Decedents*].

According to Federal policy, research involving deceased individuals is not considered human subjects research and hence does not require IRB oversight **unless the research study includes both living and deceased individuals.**

> **45 CFR 46.102(f):** *A "Human Subject" is a **living** (emphasis added) individual about whom an investigator conducting research obtains:*
>
> - *data through intervention or interaction with the individual, **or***
> - *identifiable private information.*

For studies that involve **BOTH** living subjects and human decedents (cadavers, tissue or medical record data, including the use of fetal tissue), the IRB is the institutional committee with jurisdiction for oversight and approval. Therefore, a research study must be submitted to the IRB for review and approval before the study can be initiated.

Note that the use of protected health information (PHI) is regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. Thus, per UPMC policy *HS-EC 1602*, research involving the medical records or specimens of a deceased patient is subject to one of the following:

- Secure a valid research authorization signed by the administrator or executor of the decedent's estate or the person listed as next-of-kin, ***or***
- Obtain the approval of a Request to Access Decedent Protected Health Information (PHI). Additionally, all research involving UPMC electronic protected health information must be conducted in compliance with UPMC policy *HS-RS0005 Research Using UPMC Electronic Protected Health Information (e-PHI)*

If you are unsure whether your project requires IRB review, email us askirb@pitt.edu.

## Accessing Decedent Medical Records:

If the medical records and/or specimens of the deceased will be requested from a UPMC facility, approval from the UPMC Office of Sponsored Programs and Research Support (OSPARS) is required.

If the medical records and/or specimens will be requested from a non-UPMC facility, it is the investigator's responsibility to obtain the proper authorization (usually from the next of kin) or a waiver of authorization (from the site privacy office) to access the records (PHI). The Pitt IRB cannot grant a waiver for non-UPMC facilities.

**UPMC Request Process**

To obtain approval for use of decedent records, complete the "Request to Review Decedent Protected Health Information for Research" form [available at OSPARS share point].

- Submit the completed request form to OSPARS@upmc.edu
- Upload the approved form (with a signature from UPMC OSPARS) into OSIRIS before submitting to the IRB for review.

**Note**: Investigators with Pitt email addresses will need to request access to UPMC OSPARS share point/forms. Access to the share point can be requested by emailing OSPARS@upmc.edu.

## Federal Regulatory Requirements (included in the request to review decedent PHI):

PHI of Decedents {45 CFR 164.512(i)(1)(iii)}

§ 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

(iii) Research on decedent's information. The **covered entity** obtains from the researcher:

(A) Representation that the use or disclosure is sought is solely for research on the protected health information of decedents;
(B) Documentation, at the request of the covered entity, of the death of such individuals; and
(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

## Considerations:

The Pitt IRB may grant access to and permit researchers to record the PHI or collect specimens of deceased individuals, held by a UPMC entity, under the following conditions:

- If the information is de-identified by an honest broker service or,
- If pursuant to a valid research authorization signed by the administrator or executor of the deceased individual's estate or the person who is listed as next of kin, or
- If a request for access to decedent records is approved by the UPMC Privacy Office and (for living subjects) a waiver of HIPAA Authorization is approved by the IRB

## Additional Information:

CORID: http://www.ooas.pitt.edu

Code of Federal Regulations (Definition of Human Subjects):
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102

IRB Policies and Procedures: http://www.irb.pitt.edu/pandp/default.aspx

Office of Sponsored Programs and Research Support (OSPARS):
https://spis.upmc.com/corporate/Finance/ospars/default.aspx

UPMC Policies: http://infonet.upmc.edu/Policies/systemwide/Pages/default.aspx

- HS-EC1602 Use & Disclosure of Protected Health Information (PHI) Including: Fundraising, Marketing and Research
- HS-RS0005 Research Using UPMC Electronic Protected Health Information (e-PHI)
- HS-RS0004 Research and Clinical Training Involving Decedents