

Research Using Decedent PHI	Effective Date	6/17/2021
	Revised Date	

1. **Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for the use or disclosure of decedents' Protected Health Information (PHI) for the purpose of research.
2. **Persons Affected:** Individuals undertaking research involving PHI of decedents.
3. **SOP:** This SOP outlines the requirements for the use of decedent PHI under 45 CFR 164.512. Research on identifying information of decedents does not meet the definition of human subjects research according to 45 CFR 46 and is thus not under the purview of an institutional review board. However, the HIPAA Privacy Rule includes a provision extending some protections for the use and disclosure of individually identifiable health information for 50 years following the date of the death of an individual.
4. **Definitions:**
 - 4.1. **HIPAA Privacy Rule:** establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information without patient Authorization. The Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.
 - 4.2. **Protected Health Information (PHI):** individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act (FERPA), as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
5. **Procedures:**
 - 5.1. Under 45 CFR 146.512, covered entities are permitted to use and disclose decedent PHI for research as long as the covered entity obtains from the researcher:
 - 5.1.1. Representation that the use or disclosure sought is solely for research on the protected health information of decedents;
 - 5.1.2. Documentation, at the request of the covered entity, of the death of such individuals; and
 - 5.1.3. Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.
 - 5.1.3.1. Unlike requests for waivers or alterations of authorization, there is no requirement for the review or approval of requests for the use or disclosure of PHI for research purposes by a Privacy Board under the Privacy Rule. As such the UMCIRB (acting in the role of the Privacy Board at East Carolina University) does not review or approve these requests when the sole target of the research is decedent PHI. Nor will any date stamp be affixed to any document requesting the use or disclosure of decedent PHI.
 - 5.1.3.1.1. When submitted as part of a larger research study that does involve human subjects, the UMCIRB will review these requests as part of the submission. Date stamps will be applied to these documents as they are with other HIPAA related documentation associated with human subjects research.

Revision History:

Date	Change	Reference Section(s)

References:

Privacy Rule. Code of Federal Regulations:

<https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>