



HIPAA & Research: Certification for Research Using Decedent Protected Health Information # 2370.521

INITIAL EFFECTIVE DATE: December 31, 2017	LAST REVISION DATE: March 31, 2021	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT Office of Research and Economic Development
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POLICY STATEMENT

A Florida International University (“FIU”) covered entity may disclose protected health information (“PHI”) (except psychotherapy notes) to an investigator without patient authorization if the research is being conducted with PHI from decedents and the PHI disclosure request is authorized by the Covered Entity’s HIPAA Security Administrator in accordance with the Covered Entities’ internal procedures. The Covered Entity is required to protect PHI about a decedent for 50 years following the date of death of the individual.

SCOPE

University Community (faculty, staff and students)

REASON FOR POLICY

The purpose of this policy is twofold: to ensure that applicable FIU HIPAA policies regarding the protection of protected health information (PHI) apply to the PHI of deceased individuals and to establish standards for how a decedent’s PHI may be used for research purposes.

DEFINITIONS	
TERM	DEFINITIONS
Authorization	An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Privacy Rule, a covered entity may not use or disclose PHI for research purposes without a valid authorization.
Covered Entity	A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a healthcare transaction.
Decedent	An individual who is no longer living.



Disclosure (or Disclose)	The release, transfer, provision of access to, or divulging in any other manner of protected health information outside of the entity holding the information
Health Information	Any information, whether oral or recorded in any form or medium, that <ol style="list-style-type: none"> 1. is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and 2. relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
HIPAA	The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and implementing regulations (hereinafter "HIPAA" or "HIPAA regulations"). One such implementing regulation is the HIPAA Privacy Rule which may be found at 45 CFR Part 160 and Part 164, Subparts A and E.
Office of Research Integrity (ORI)	Is a unit within the Florida International University Office of Research and Economic Development.
Principal Investigator	The FIU employee who leads the FIU research project and bears the primary responsibility for the scientific, technical and fiscal administration of the research project.
Protected Health Information (PHI)	Individually identifiable health information that is: <ul style="list-style-type: none"> • Transmitted by electronic media; • Maintained in electronic media; • Transmitted or maintained in any other form or medium. • Protected health information specifically excludes: <ol style="list-style-type: none"> 1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g ("FERPA"); 2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and 3. Employment records held by a covered entity in its role as an employer.
Research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.
Use	With respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or



analysis of such information within the entity or health care component (for hybrid entities) that maintains such information.

ROLES AND RESPONSIBILITIES

All researchers are responsible for following the procedures stated in this policy. Prior to giving access to PHI belonging to FIU, the FIU health care component, FIU faculty, staff or workforce member must take reasonable steps to ensure that the procedures stated herein have been followed by the researcher.

RELATED RESOURCES

Policy 2370.510: HIPAA and Research Certification of Review Preparatory to Research

Policy 2370.515: HIPAA and Research Obtaining Authorization or Waiver of Authorization to Conduct Research

Policy 2370.520: HIPAA and Research Use of Protected Health Information for Research Purposes

Policy 2370.522: HIPAA and Research Limited Data Sets and Data Use Agreements

Policy 1610.010: HIPAA Privacy & Security: Responsibilities of University IT Security Officer & HIPAA Security Administrators.

45 CFR § 164.512(i)(1)(iii)

CONTACTS

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HISTORY

Initial Effective Date: December 31, 2017

Review Dates (*review performed, no updates*): January 29, 2024

Revision Dates (*updates made to document*): August 27, 2019; March 31, 2021.



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PROCEDURE STATEMENT

1. In order to obtain a certification that will allow a researcher to conduct research involving PHI of a decedent, the researcher must provide written documentation which shows:
 - a. That the use or disclosure sought is solely for research on the PHI of decedents;
 - b. Documentation, at the request of the covered entity, of the death of such individuals; and
 - c. That the PHI for which use or disclosure is sought is necessary for the research purposes.
2. The researcher must submit to a completed "Certification of Research on Decedents' Protected Health Information" form for review and approval
3. Such approval must first be obtained, in writing, from the Covered Entity's HIPAA Privacy Coordinator.
4. The researcher must provide a copy of the approved Certification of Research on Decedents Form to the Office of Research Integrity.