FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

HIPAA & Research: Use of Protected Health Information for Research Purposes # 2370.520

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

POLICY STATEMENT

Any FIU Workforce Member who intends to use protected health information for FIU research purposes shall abide by the requirements of the Health Insurance Portability and Accountability Act of 1996 (hereinafter "HIPAA" or "HIPAA regulations") and its implementing regulations and shall also comply with the terms and conditions of this policy.

Research is subject to HIPAA if:

1. It uses protected health information ("PHI") obtained from, or maintained by, any of the health care components within FIU;
2. It uses PHI obtained or maintained by the hospitals and physicians having an affiliation agreement with FIU;
3. It uses or seeks to use PHI obtained from other covered entities such as health plans, health care providers, physicians, hospitals and nursing homes that are not affiliated with FIU. In that case, use of PHI will be governed by this policy as well as any HIPAA policies of such covered entities as determined by the Institutional Review Board/Privacy Board reviewing and approving the research.

SCOPE

University Community (faculty, staff and students)

REASON FOR POLICY

The purpose of this policy is to set forth the requirements that are applicable to research activities that involve the use or disclosure of protected health information which is subject to HIPAA.

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 HIPAA 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.
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 Care	care, services, or supplies related to the health of an individual, including (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual that affects the structure or function of the body; and (2) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription. 1. Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and 2. A government-funded program (unless otherwise included at section 160.103 of HIPAA) whose principal purpose is other than providing, or paying for the cost of, health care or whose principal activity is the direct provision of health care to persons or the making of grants to fund the direct provision of health care to persons.
Health Information	Any information, whether oral or recorded in any form or medium, that 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.

Hybrid Entity	A single legal entity:
	• That is a covered entity;
	  ○ Whose business activities include both covered and non-covered functions; and
	  ○ That designates as health care components those units of the business that perform the function of a health plan, health care clearinghouse, or health care provider who transmits health information in electronic form in connection with a transaction.

Individually Identifiable Health Information	Information that is a subset of health information, including demographic information collected from an individual, and
	1. Is created or received by a health care provider, health plan, employer, 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; and
	  a. That identifies the individual; or
	  b. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Institutional Review Board (IRB)	An IRB can be used to review and approve a researcher's request to waive or alter the Privacy Rule's requirements for an Authorization. The Privacy Rule does not alter the membership, functions and operations, and review and approval procedures of an IRB regarding the protection of human subjects established by other Federal requirements.
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: • Transmitted by electronic media; • Maintained in electronic media;

	• Transmitted or maintained in any other form or medium. • Protected health information specifically excludes: 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.
Transaction	The transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions: • Health care claims or equivalent encounter information. • Health care payment and remittance advice. • Coordination of benefits. • Health care claim status. • Enrollment and disenrollment in a health plan. • Eligibility for a health plan. • Health plan premium payments. • Referral certification and authorization. • First report of injury. • Health claims attachment. • Other transactions that the Secretary of Health and Human Services may prescribe by regulation.
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.
Workforce (or Workforce Member)	Part-time, full-time and temporary faculty and staff, students, volunteers, trainees, and other persons whose conduct, in the performance of work for the University, is under the direct command of the University (regardless of whether or not they are paid by the University.

ROLES AND RESPONSIBILITIES

All researchers are responsible for following the procedures stated in this policy.

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 2370.521: HIPAA and Research Certification for Research Using Decedent Protected Health Information

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

45 CFR 164.501; 45 CFR 164.508; 45 CFR 164.512(i); 45 CFR164.532

CONTACTS

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HISTORY

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Review Dates (*review performed, no updates*): N/A
Revision Dates (*updates made to document*): April 6, 2020; March 31, 2021

FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY PROCEDURE

HIPAA & Research: Use of Protected Health Information for Research Purposes # 2370.520a

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

PROCEDURE STATEMENT

The Principal Investigator must obtain an authorization in the form approved by the IRB from each research subject or the research subject's personal representative to use or disclose the participant's protected health information, unless the IRB has determined that a waiver of authorization is permissible for the research study or disclosure is otherwise permitted or required by federal and/or state law.

Special rules apply to research involving psychotherapy notes. Use or disclosure of psychotherapy notes for research is permissible only if the individual signs an authorization that encompasses only psychotherapy notes and no other PHI.

Informed consent is not the same as a HIPAA authorization. All projects with informed consents must also include: a HIPAA authorization if they involve the use or disclosure of PHI or a waiver of one or more elements of an authorization. The HIPAA authorization form or waiver of authorization, as applicable, must be approved by the appropriate IRB.

In certain situations, the IRB may waive the requirement that research subjects sign a HIPAA authorization form. A waiver of HIPAA authorization does not mean that the research is otherwise exempt from HIPAA requirements; it only means that a HIPAA authorization form or one or more elements of such form does not need to be obtained from the research participant. In order to qualify for a waiver of HIPAA authorization, the researcher must demonstrate to the satisfaction of the IRB that the proposed research meets the criteria for such waiver.