FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

University Community (faculty, staff and students)

SUBJECT (R*)	EFFECTIVE DATE (R*)	POLICY NUMBER (O*)
HIPAA & RESEARCH: USE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES	December 31, 2017	2370.520

POLICY STATEMENT (R*)

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 PHI created by a researcher conducting research on behalf of FIU;
4. 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.

REASON FOR POLICY (O*)

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

RELATED INFORMATION (O*)

45 CFR 164.501; 45 CFR 164.508; 45 CFR 164.512(i); 45 CFR164.532
HIPAA & Research: Certification for Research Using Decedent Protected Health Information, Policy No. XXX;
HIPAA & Research: Certification of Review Preparatory to Research, Policy No. XXXX.
HIPAA & Research: Obtaining Authorization or Waiver of Authorization to Conduct Research, Policy No. XXXX

DEFINITIONS (R*)

"Authorization" means 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" means 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" means 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" means 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.

HIPAA means 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" means 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" means 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 HIPAA Privacy Rule's requirements for an Authorization. The HIPAA 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 or "ORI" is a unit within the Florida International University Office of Research and Economic Development.

"Protected health information" or "PHI" means 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" means 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" means 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" means 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.

"Waiver of authorization" means the documentation that the covered entity obtains from a researcher or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the HIPAA Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

"Workforce members" means 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.)

PROCEDURES (O*)

1. No protected health information ("PHI") may be accessed by, or disclosed to, a researcher or research team except in the following limited circumstances:
   A. Research conducted pursuant to an Institutional Review Board ("IRB") waiver of authorization
   B. Research conducted pursuant to an authorization that meets the HIPAA requirements
   C. Reviews Preparatory to Research
   D. Research on Decedent Information

2. Not all individually identifiable health information is subject to HIPAA. Research that involves health information that is not obtained by or from a covered entity may not be subject to HIPAA. However, it is established that there are other federal and state laws that apply to safeguard the privacy and confidentiality of individually identifiable health information. To the extent that such federal and state laws provide stricter privacy protections, those laws continue to apply and must be abided by in connection with research conducted by FIU researchers or at FIU research facilities.

3. The IRB must review and approve all research involving human subjects and will determine if the proposed research meets the requirements specified in 1.a. and 1.b above. If the research is to be performed pursuant to section 1.b, the IRB will approve the form of the HIPAA authorization form to be used in the research study.

4. The HIPAA Privacy Rule allows a researcher to have limited access to PHI (without copying or removal) where the researcher is determining the feasibility of a study as a review preparatory to research. In order to access PHI as preparatory to research, the researcher must comply with the policy entitled "HIPAA & Research: Certification of Review Preparatory to Research."

5. All research involving deceased individuals must follow the requirements and approval process outlined in the policy entitled "HIPAA & Research: Certification for Research Using Decedent Protected Health Information."

RESPONSIBILITIES (O*)

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

HISTORY (R*)

RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT (R*) Office of Research and Economic Development **RESPONSIBLE ADMINISTRATIVE OVERSIGHT (R*)** Office of Research and Economic Development MARC 430	The University Policies and Procedures Library is updated regularly. In order to ensure a printed copy of this document is current, please access it online at http://policies.fiu.edu/ . For any questions or comments, the "Document Details" view for this policy online provides complete contact

11200 SW 8th Street Miami, Florida 33199 (305) 348 - 2494	information.

FORMS/ONLINE PROCESSES (O*)

Links to the above referenced Form(s) available in the "Document Details" Section of the online version of this policy document.

***R = Required *O = Optional**