



University Community (faculty, staff and students)

| SUBJECT (R*) | EFFECTIVE DATE (R*) | POLICY NUMBER (O*) |
|---|---------------------|--------------------|
| HIPAA & RESEARCH: CERTIFICATION OF REVIEW PREPARATORY TO RESEARCH | December 31, 2017 | 2370.510 |

POLICY STATEMENT (R*)

Protected health information (“PHI”) may be accessed by, or disclosed to, a researcher or research team if it is certified to be solely a review preparatory to research. All requests for such review must be authorized by the Covered Entity’s HIPAA Security Administrator in accordance with the Covered Entities’ internal procedures.

REASON FOR POLICY (O*)

To define the procedures necessary to access PHI for reviews preparatory to research.

RELATED INFORMATION (O*)

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

DEFINITIONS (R*)

“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 clearinghouse” means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches that either process or facilitate the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction, or receive a standard transaction from another entity and process or facilitate the processing of health information into a nonstandard format or nonstandard data content for the receiving entity.

“Health information” means 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.

“Health care provider” means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

“Health plan” means, for the purposes of Title II of HIPAA, an individual or group plan that provides or pays the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)) and including entities and government programs listed in the Rule. Health plan excludes:

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.

“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 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 or “ORI” is a unit within the Florida International University Division of Research.

“Principal Investigator” means 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” 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.

“Workforce” or “Workforce Member” 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. The HIPAA Privacy Rule permits the use and disclosure of PHI (*except* psychotherapy notes) to a Florida International University researcher to develop a research protocol or for similar purposes preparatory to research. This type of access is limited to a review of data to assist in formulating a hypothesis, determining the feasibility of conducting the study, determining cell size, or other similar uses that precede the development of an actual protocol. Researchers should be aware that this exception does *not* permit: (1) the continued use or disclosure of the PHI once the Principal Investigator has determined to go forward with the study; (2) any copying or removal of PHI from the facility/format in which the PHI is stored or maintained or (3) any contact of the persons whose PHI has been accessed.
2. In order to permit a use or disclosure of PHI under this exception, the researcher must assure:
 - a. the use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
 - b. no researcher will copy or remove any PHI from the health care component’s premises in the course of the review or make any notes that include PHI; and
 - c. the PHI for which use or access is sought is necessary for the research purposes.
3. Researchers seeking access to PHI for preparatory reviews must provide such assurances by completing the Florida International University (“FIU”) Certification of Review Preparatory to Research Form and providing it to by the Covered Entity’s HIPAA Security Administrator in accordance with the Covered Entities’ internal procedures.
4. In accordance with 2.b. above, the sharing of PHI pursuant to this certification is strictly prohibited.

RESPONSIBILITIES (O*)

All researchers are responsible for following the procedures stated in this policy. Prior to giving access to PHI belonging to, created or maintained by or on behalf of FIU, the FIU health care component, and workforce members must take reasonable steps to ensure that the procedures stated herein have been followed by the researcher.

HISTORY (R*)

December 31, 2017

RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT (R*)

Office of Research and Economic Development

RESPONSIBLE ADMINISTRATIVE OVERSIGHT (R*)

Office of Research and Economic Development
 MARC 430
 11200 S.W. Eighth Street
 Miami, Florida 33199
 Telephone Number: (305) 348-2494

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 information.

FORMS/ONLINE PROCESSES (O*)

Certification of Review Preparatory to Research Form

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**