FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

University Community (faculty, staff and students)

SUBJECT (R*)	EFFECTIVE DATE (R*)	POLICY NUMBER (O*)
HIPAA & RESEARCH: OBTAINING AUTHORIZATION OR WAIVER OF AUTHORIZATION TO CONDUCT RESEARCH	December 31, 2017	2370.515

POLICY STATEMENT (R*)

All research which will involve the access to, creation of, or disclosure of protected health information ("PHI") must be submitted for prior Institutional Review Board (IRB) approval to the Office of Research Integrity ("ORI") within the Office of Research and Economic Development.

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.

REASON FOR POLICY (O*)

In order to ensure that researchers obtain research subjects' HIPAA authorization or waiver of HIPAA authorization prior to the use or disclosure of PHI that is not otherwise permitted or required by the HIPAA Privacy Rule. Also provides direction on when a valid HIPAA authorization for release of information is required from a research subject and what a valid HIPAA authorization must contain.

RELATED INFORMATION (O*)

45 CFR 160.103; 45 CFR 164.508; 45 CFR 164.512.

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" 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 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 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 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 HIPAA Privacy 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 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.

"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.

"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.

PROCEDURES (O*)

A. HIPAA Authorization
   1. The HIPAA authorization form approved by the IRB must be completed by the Principal Investigator for the research subject's review and signature. It is the responsibility of the Principal Investigator to ensure that the HIPAA authorization form covers the uses and disclosures necessary for the research study. If the Principal Investigator has any questions or concerns when preparing the HIPAA authorization form, the Principal Investigator should consult with the Office of Research Integrity.
   2. The HIPAA authorization form must be signed by the research participant prior to his/her enrollment in the research study. In presenting the HIPAA authorization form to prospective subjects, researchers may not suggest that failure to sign the form will limit access to any treatment that may be available **outside the study**. Any questions about the availability of such treatment outside the study should be referred to the prospective subject's treating healthcare provider. Any other questions about the HIPAA authorization form should be directed to the Office of Research Integrity.
   3. The HIPAA authorization form must include the following elements:
      a. A description of the PHI to be used or disclosed that identifies the PHI in a specific and meaningful fashion.
      b. The name or other specific identification of the person(s) or class of persons authorized to make the requested use or disclosure.
      c. The name or other specific identification of the person(s) or class of persons to whom FIU may make the requested use or disclosure.
      d. A description of each purpose of the requested use or disclosure.
      e. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of research" or "none" is sufficient if the authorization includes use or disclosure of PHI for the creation of a research repository or database.
      f. Signature of the participant and date. If the authorization is signed by a personal representative of the participant, a description of the representative's authority to act for the participant.
      g. The following statements must be included in the authorization.

i. The participant's right to revoke the authorization in writing, and the exceptions to the right to revoke.
ii. A description of how the individual may revoke the authorization.
iii. The consequences to the participant if he/she refuses to sign the authorization.
iv. When the researcher can condition enrollment on failure to obtain authorization.
v. The potential for PHI disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer protected by the federal regulations.

4. Improper Procedures:
   a. In the event that a Principal Investigator fails to obtain proper HIPAA authorization from the research participant before beginning the research study, the principal investigator must notify the Office of Research Integrity as soon as practicable, but in any event within ten (10) days from discovery.

B. Waiver of Authorization

A covered entity may use or disclose PHI for research purposes pursuant to a waiver of authorization granted by the IRB, provided it has obtained documentation of all of the following:

1. Identification of the IRB and the date on which the alteration or waiver of authorization was approved;
2. A statement that the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the criteria in the HIPAA Privacy Rule set forth below;
3. A brief description of the PHI for which use or access has been determined to be necessary by the IRB;
4. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as such procedures are applicable to the review of the underlying PHI; and
5. The signature of the chair or other individual, as designated by the chair, of the IRB.
6. To qualify for a waiver of authorization, the Principal Investigator must be able to demonstrate that:
   (1) The research use of the PHI does not represent more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
      a. An adequate plan to protect the identifiers from improper use and disclosure;
      b. An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
      c. Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted under the HIPAA Privacy Rule;
   (2) The research could not practicably be conducted without the waiver of authorization; and
   (3) The research could not practicably be conducted without access to and use of the PHI.
7. If the Principal Investigator determines that the preceding factors have been met, he or she should request a Waiver/Alteration of HIPAA Authorization within the FIU IRB Approval Form.

RESPONSIBILITIES (O*)

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

HISTORY (R*)

December 31, 2017

RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT (R*)	
Office of Research and Economic Development	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/ .
RESPONSIBLE ADMINISTRATIVE OVERSIGHT (R*)	
Office of Research & Economic Development MARC 430 11200 S.W. Eighth Street Miami, Florida 33199 Telephone Number: (305) 348-2494	For any questions or comments, the "Document Details" view for this policy online provides complete contact 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**