FLORIDA INTERNATIONAL UNIVERSITY

OFFICIAL UNIVERSITY POLICY

# HIPAA & Research: Obtaining Authorization or Waiver of Authorization # 2370.515

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

## POLICY STATEMENT

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.

## SCOPE

University Community (faculty, staff and students)

## REASON FOR POLICY

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.

## DEFINITIONS

| TERM | DEFINITIONS |
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| 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. |

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| Disclosure | 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 | 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 | 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 | Any information, whether oral or recorded in any form or medium, that<br>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<br>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 | 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:<br>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<br>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 |

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| | provision of health care to persons or the making of grants to fund the direct provision of health care to persons. |
| 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. |
| Individually Identifiable Health Information | Information that is a subset of health information, including demographic information collected from an individual, and<br>1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and<br>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<br>a. That identifies the individual; or<br>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:<br>• Transmitted by electronic media;<br>• Maintained in electronic media;<br>• Transmitted or maintained in any other form or medium.<br>• Protected health information specifically excludes:<br>1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g ("FERPA");<br>2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and |

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| | 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. |

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

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 160.103; 45 CFR 164.508; 45 CFR 164.512.

## CONTACTS

Office of Research Integrity
Florida International University
11200 S.W. Eighth Street – MARC 430
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Telephone: (305) 348-2494

## HISTORY

**Initial Effective Date:** December 31, 2017
**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: Obtaining Authorization or Waiver of Authorization # 2370.515a

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## 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.