

Waiver/Alteration of HIPAA Authorization and the Privacy Board	Effective Date	08.10.2020
	Revision Date	

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to establish guidelines for:
- 1.1 Instances where the University and Medical Center Institutional Review Board (UMCIRB) will serve as the Privacy Board
 - 1.2 Membership requirements for Privacy Board members
 - 1.3 Scope of the Privacy Board
 - 1.4 Review criteria for granting Waivers and Alterations of HIPAA Authorizations
 - 1.5 Process for approving Waivers and Alterations of HIPAA Authorizations in research reviewed by the UMCIRB
 - 1.6 Process for approving Waivers and Alterations of HIPAA Authorizations in research reviewed by external IRBs
- 2.0 Research Protocols Affected:**
- 2.1 Human research activities in which the UMCIRB is serving as the Privacy Board.
- 3.0 SOP:** This SOP is to ensure that ECU has a duly constituted Privacy Board in compliance with the Privacy Rule, at 45 CFR parts 160 and 164. The Privacy Rule establishes a category of health information, defined as protected health information (PHI), that a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization. One way a covered entity can use or disclose PHI for research without an Authorization is by obtaining proper documentation of a Waiver or Alteration of the Authorization requirement by an Institutional Review Board (IRB) or a new type of review body, a Privacy Board.
- 4.0 Definitions:**
- 4.1 **Privacy Board:** a review body that may be established to act upon requests for a Waiver or an Alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. A Privacy Board may waive or alter all or part of the Authorization requirements for a specified research project or protocol. A covered entity may use and disclose PHI, without an Authorization, or with an altered Authorization, if it receives the proper documentation of approval of such Alteration or Waiver from a Privacy Board.
 - 4.2 **HIPAA Privacy Rule:** establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information and sets limits and conditions on the uses and disclosures that may be made of such information without patient Authorization. The Privacy Rule is located at 45 CFR Part 160 and Subparts A and E of Part 164.

- 4.3 Protected Health Information (PHI):** individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act (FERPA), as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
- 4.4 Covered Entity:** are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which the U.S. Department of Health and Human Services (HHS) has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.
- 4.5 Hybrid Entity:** A single legal entity that is a covered entity, performs business activities that include both covered and noncovered functions, and designates its health care components as provided in the Privacy Rule. If a covered entity is a hybrid entity, the Privacy Rule generally applies only to its designated health care components. However, non-health care components of a hybrid entity may be affected because the health care component is limited in how it can share PHI with the non-health care component. The covered entity also retains certain oversight, compliance, and enforcement responsibilities.
- 4.6 Institutional Review Board:** are appropriately constituted committees that have been formally designated to review and monitor human research.
- 4.7 Research:** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- 4.8 Authorization:** is an individual's (or their legal guardian's) permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual. An Authorization is composed of the following required elements:
- a. Specific description of what PHI will be used or disclosed
 - b. Who may use or disclose PHI
 - c. Who may receive the PHI
 - d. Purpose of the use or disclosure
 - e. Statement of how long the use or disclosure will continue.
 - f. Right to revoke Authorization.
 - g. Notice that the information may be disclosed to others not subject to the Privacy Rule.
 - h. Right to refuse to sign Authorization
 - i. The subject must sign the form and receive a signed copy for the Authorization to be valid.
- 4.9 Waiver of Authorization:** may be granted to remove the requirement of obtaining Authorization to use and/or disclose protected health information. Under 45 CFR 46.116, an IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent specified in this section, or may waive the requirements to obtain informed consent, provided the IRB finds and documents that the following criteria have been met:
- 4.9.1** The research involves no more than minimal risk to the subject.
 - 4.9.2** The Waiver or Alteration will not adversely affect the rights and welfare of the subjects.

- 4.9.3 If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
- 4.9.4 The research could not practicably be carried out without the Waiver or Alteration.
- 4.9.5 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4.10 Alteration of HIPAA Authorization: refers to a request for the removal of some, but not all of the required elements or statements of a valid HIPAA Authorization.

5.0 Responsibilities:

5.1 Privacy Board Members:

- 5.1.1 Membership of the Privacy Board will meet the following federal requirements:
 - 5.1.1.1 Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;
 - 5.1.1.2 Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and
 - 5.1.1.3 Does not have any member participating in a review of any project in which the member has a conflict of interest.
- 5.1.2 Ensure requests for Waiver or Alteration of HIPAA Authorization have met the criteria set forth in the federal regulations, state laws and institutional policies and procedures before issuing final approval.

5.2 Principal Investigator/Study Staff/ Departments:

- 5.2.1 Provide the Privacy Board with the required information justifying the Waiver or Alteration of HIPAA Authorization. This requires the submission of a completed and signed “Waiver or Alteration of HIPAA Authorization” form.
- 5.2.2 Justification for a Waiver or Alteration of HIPAA Authorization must satisfy the following criteria:
 - 5.2.2.1 The use or disclosure of PHI involves no 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
 - 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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.
 - 5.2.2.2 The research cannot practicably be carried out without a Waiver; and
 - 5.2.2.3 The research cannot be done without this specific PHI.
- 5.2.3 Ensure that the requested PHI will be limited to the minimum necessary to conduct the research study.

5.3 UMCIRB Staff:

- 5.3.1 UMCIRB staff will review Waiver or Alteration of HIPAA Authorization requests for completeness prior to Privacy Board or Chair/designee review

6.0 Procedures:

6.1 The UMCIRB will serve as the Privacy Board and review Waiver or Alteration of HIPAA Authorization requests in the following:

- 6.1.1** Human subjects research protocols in which the UMCIRB has IRB oversight:
 - 6.1.1.1** Studies requiring review by the full convened IRB will have any Waiver or Alteration of HIPAA Authorization requests reviewed at the same meeting(s) as the protocol.
 - 6.1.1.2** When the UMCIRB, as the privacy board, reviews the Alteration or Waiver of Authorization, it must be approved by the majority of the privacy board members present at the meeting.
 - 6.1.1.3** The privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the Alteration or Waiver of Authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair.
 - 6.1.1.4** Communication of Privacy Board approval of Waivers or Alterations of HIPAA Authorizations will contain a statement identifying:
 - 6.1.1.4.1** The date of the approval
 - 6.1.1.4.2** A determination that the request satisfies the Waiver criteria as outlined in section 5.2.2 of this SOP
 - 6.1.1.4.3** Signature of the Chair or other member acting as their designee
 - 6.1.1.4.3.1** Per UMCIRB policy the electronic submission system (ePIRATE) documents electronic signatures within the system
- 6.1.2** Human subjects research in which the UMCIRB is not serving as the IRB of record, however the research is either conducted by:
 - 6.1.2.1** ECU students, staff or faculty
 - 6.1.2.2** Individuals conducting research on behalf of an institution that has requested the UMCIRB continue to serve as the Privacy Board for Waiver or Alteration of Authorization requests
 - 6.1.2.3** Expedited review procedures will be used for Waiver or Alteration requests in instances where the UMCIRB is only serving as the Privacy Board.
 - 6.1.2.3.1** Waiver or Alteration of HIPAA Authorization requests must be submitted to the Privacy Board via ePIRATE submission.
 - 6.1.2.3.2** Expedited review processes and communication of Privacy Board approval of Waivers or Alterations of HIPAA Authorizations will be conducted as described in sections 6.1.1.3 and 6.1.1.4 of this SOP.

Revision History:

Date	Change	Reference Section(s)

References:

Privacy Rule. Code of Federal Regulations:

<https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

UMCIRB Correspondence: Electronic Signatures

<https://rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/457/2019/08/Electronic-Signatures-and-UMCIRB-Correspondence-SOP.pdf>