

**Western Carolina University  
Office of Research Administration  
Institutional Review Board Standard Operating Procedures**

<b>SOP# 217.1</b>	<b>TITLE: Privacy Board and Alteration/Waiver of HIPAA Authorization</b>	<b>Date Effective: 4/16/2024 Last Revision Date: Initial</b>
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## **I. Purpose**

This procedure sets forth guidelines for instances when the WCU Institutional Review Board will serve as the Privacy Board. It establishes the scope of the Privacy Board, the criteria used to review and grant waivers and alterations of HIPAA authorizations, and the process for conducting such reviews.

This procedure is to ensure WCU 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 Privacy Board.

## **II. Scope**

The WCU IRB will serve as the Privacy Board for any human subjects research protocols with a request to waive or alter the required HIPAA authorization.

## **III. Definitions**

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

Authorization - 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:

1. Specific description of what PHI will be used or disclosed
2. Who may use or disclose PHI
3. Who may receive the PHI
4. Purpose of the use or disclosure e. Statement of how long the use or disclosure will continue.
5. Right to revoke Authorization.
6. Notice that the information may be disclosed to others not subject to the Privacy Rule.
7. Right to refuse to sign Authorization

8. The subject must sign the form and receive a signed copy for the Authorization to be valid.

Covered Entity - 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.

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.

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. Principal Investigator: WCU full time Faculty or Staff Member responsible for the content of the IRB application and the conduct of the study.

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.

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.

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 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:

1. The research involves no more than minimal risk to the subject.
2. The Waiver or Alteration will not adversely affect the rights and welfare of the subjects.

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. The research could not practicably be carried out without the Waiver or Alteration.
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

#### **IV. Responsibilities**

1. Privacy Board Members:
  - a. Membership of the Privacy Board will meet the following federal requirements:
    - i. 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.
    - ii. 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.
    - iii. Does not have any member participating in a review of any project in which the member has a conflict of interest.
  - b. 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.
2. Principal Investigators:
  - a. 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.
  - b. Justification for a Waiver or Alteration of HIPAA Authorization must satisfy the following criteria:
    - i. 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:
      1. an adequate plan to protect the identifiers from improper use and disclosure.
      2. an adequate plan to destroy the identifiers at the earliest opportunity.
      3. 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.
    - ii. The research cannot practicably be carried out without a Waiver.
    - iii. The research cannot be done without this specific PHI.
  - c. Ensure that the requested PHI will be limited to the minimum necessary to conduct the research study.
3. Office of Research Compliance Staff:
  - a. Staff will review Waiver or Alteration of HIPAA Authorization requests for completeness prior to Privacy Board or Chair/designee review.

## **V. Procedures**

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.
2. When the IRB, 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.
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.
4. Communication of Privacy Board approval of Waivers or Alterations of HIPAA Authorizations will contain a statement identifying the date of the approval and a determination that the request satisfies the Waiver criteria.

## **VI. References**

45 CFR §§ 160, 164(a)(e)

20 U.S.C. 1232g