Grand Valley State University Institutional Review Board (IRB)	
Title: *Research Utilizing HIPAA-Protected Health Information*	
Section: 760	
Approved by IRBPPC: 04/16/2024	Approved by AIO/RIO: 05/16/2024
Effective Date: 05/16/2024	
Related documents: *210: Determination of Human Subjects Research* *G-2: HIPAA Compliance, Coded Private Information, and De-Identified Data*	

Policy

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law covering protected health information (PHI) from being accessed, used or disclosed without the patient's knowledge. PHI can be used for research purposes only with patient authorization, a waiver or alteration of patient authorization, or when the data is provided as a limited or de-identified data set. At GVSU, most research involving PHI is conducted in collaboration with an external healthcare organization.

This policy applies to the use of PHI for research purposes even if the research does not otherwise require IRB review, such as when the research involves a limited data set that is not readily identifiable and does not satisfy the definitions of human subjects found in IRB Policy 210: D*etermination of Human Subjects Research*. Except in certain limited situations, PHI may not be used for research purposes without prior review by the IRB.

The GVSU IRB serves as the HIPAA Privacy Board and has authority to approve waivers or alterations of HIPAA authorization when PHI will be accessed, used, or disclosed for research purposes. Requests for waiver and alteration of HIPAA authorization are required to be reviewed and approved by an IRB member.

Compliance with HIPAA is additional to the relevant privacy and confidentiality protections that are required by federal research regulations and University policies. In the event of conflict amongst these standards, adherence to the most restrictive standard is required.

Definitions

1. *Protected Health Information (PHI).* Any identifiable health information related to the care or treatment of a patient at a covered entity.

2. *Covered entity.* A medical clinic, hospital, health insurance company, or other institution that creates or process PHI.

3. *De-identified data*. Data that has been stripped of all identifying information and for which there is no means by which it could be linked back to the subjects from whom it was originally obtained.

4. *Limited data set*. A data set in which most of the PHI has been removed, except it can include dates (e.g., admission date, discharge date, date of service, date of birth, etc.), and city, state, and ZIP code. Limited data sets are considered PHI and are not considered de-identified data.

Procedures

1. Written HIPAA Authorization

a. If written HIPAA authorization will be obtained in the research, the authorization form must be submitted for IRB review. A valid authorization must be written in plain language, and the research participant must be provided with a copy of the signed HIPAA authorization. The HIPAA authorization can be combined with the research informed consent document, or it can be a separate document.

b. The authorization must contain the following core elements and required statements:
    i. Core elements:
        1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

        2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure (i.e., who will access the information).

        3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure (i.e., who will receive the information).

        4. A description of each purpose of the requested use or disclosure.

        5. An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure.

        6. Signature of the individual or their personal representative. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

    ii. Required statements:
        1. The individual's right to revoke the authorization in writing.

        2. The exceptions to the right to revoke and a description of how the individual may revoke the authorization.

        3. The consequences to the individual of a refusal to sign the authorization.

        4. The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by the HIPAA regulations.

2. Waiver or Alteration of HIPAA Authorization
    a. Any waiver or alteration to the HIPAA authorization must be voted on and documented separately from the vote for IRB approval. For protocols being reviewed under exempt or expedited review procedures, all reviewers, as well as the Chair reviewing the protocol, must approve the waiver or alteration. For protocols being reviewed under full board review, the IRB must approve the waiver or alteration by majority vote.

    b. The IRB will document the following:

i. The date the waiver or alteration was approved and the specific action taken.

ii. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or Privacy Board.

iii. A statement that all the following criteria have been satisfied to approve the waiver or alteration:

1. The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals.

2. An adequate plan exists to protect the identifiers from improper use and disclosure.

3. An adequate plan exists 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.

4. There is adequate written assurance 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, or for other research for which the use or disclosure of PHI would be permitted by HIPAA.

5. The research could not practicably be conducted without the waiver or alteration.

6. The research could not practicably be conducted without access to and use of the PHI.

c. The GVSU IRB may choose to accept the waiver by another IRB or Privacy Board. If the research has been reviewed by another IRB or Privacy Board and a waiver or alteration has already been approved, documentation of the waiver or alteration should be submitted with the initial protocol application.