I. Policy
Under the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule, a covered entity may establish a Privacy Board to review requests for waivers or alterations of authorizations for uses and disclosures of protected health information (PHI) in research. This policy establishes the authority of a UW-Madison Institutional Review Board (IRB) to act as a Privacy Board for certain human subjects research as described more fully below.

II. Privacy Board Activities

A. This policy establishes the authority of a UW-Madison IRB to act as a Privacy Board, as needed, for exempt or non-exempt human subjects research (research) when the following apply:
   1. The University of Wisconsin-Madison has ceded IRB review to another organization,
   2. The Reviewing IRB will not serve as a Privacy Board,
   3. A waiver or alteration of authorization is required for the uses and/or disclosures of PHI for research purposes, and
   4. UW-Madison or UW Health personnel are engaged in human subjects research.

B. When acting as a Privacy Board for ceded research, an IRB will document it is functioning as a Privacy Board only and will have appropriate membership as required by the HIPAA Privacy Rule, as follows:
   1. The IRB will have at least two members with varying backgrounds and appropriate professional competency necessary to review the effect of the research on participants’ privacy rights under HIPAA.
   2. At least one member will be an independent member who is (1) not affiliated with the covered entity that will use or disclose the PHI in connection with the research, (2) not affiliated with the entity or entities conducting or sponsoring the research, and (3) not related to any person who is affiliated with the covered entity or the entities conducting or sponsoring the research.
   3. No Privacy Board Member may review a project of the member has a conflict of interest relevant to the research as defined in the UW-Madison IRB Members’ Conflicts of Interest Policy (https://kb.wisc.edu/gsadminkb/page.php?id=29466).

C. The Privacy Board does not exercise any of the functions to grant exemptions or approve human subjects research which instead fall under the purview of the IRB.
III. Institutional Review Board (IRB) Activities
   A. For research that is not ceded to an external IRB, each UW-Madison IRB has the authority to consider and approve waivers and alterations of authorization without acting as a Privacy Board.
   B. Review of authorizations for the use and disclosure of PHI are not a Privacy Board function. When a UW-Madison IRB oversees human subjects research, they confirm that any authorization language proposed by study teams, whether it is embedded within informed consent documents or a standalone authorization form, is accurate and complies with HIPAA Privacy Rule requirements.

IV. Definitions
   A. Institutional Review Board: A committee established under the Common Rule (45 CFR Part 46) and applicable FDA regulations (21 CFR Part 56) to provide ethical and regulatory oversight of research that involves human subjects.
   B. 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.
   C. Reviewing IRB: The IRB that serves as the IRB of record for institutions or personnel not affiliated with an organization with an IRB. Also referred to as IRB of record.

V. Procedures
   A. The UW-Madison IRBs are responsible for developing and maintaining processes relevant to when they act as a Privacy Board, including requirements for submission and review of studies that require review and approval of waivers and/or alterations of authorization to use and/or disclose PHI.
   B. When acting as Privacy Boards, the IRBs consult with the University of Wisconsin-Madison Privacy Officer as needed to complete their reviews or ensure compliance with the HIPAA Privacy Rule.
C. The Privacy Boards may review and approve requests for waivers or alterations of authorization under expedited procedures, as defined and permitted under the HIPAA Privacy Rule, or at a convened board meeting.
   1. An expedited review procedure can be used by the Privacy Board if the research involves no more than minimal risk to the privacy of individuals who are the subject of the PHI for which the use or disclosure is being sought.
   2. The review and approval may be carried out by the Privacy Board chair or by one or more Privacy Board members designated by the chair.
   3. A member with a conflict of interest may not participate in an expedited review.

D. Waivers or alterations may be granted for all components or some components of a research study in whole or in part.
   1. A waiver in whole occurs when a Privacy Board determines that no authorization will be required to use or disclose PHI for a particular research project.
   2. A partial waiver of authorization occurs when a Privacy Board determines that authorization may be waived for some participants or some component(s) of the study.
   3. An alteration of authorization occurs when a Privacy Board permits the removal of some, but not all, required elements of an authorization (e.g., signature).

E. To grant a waiver of authorization (in whole or partial) or altered authorization, a Privacy Board must find and document that the following criteria have been met:
   1. The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based on at least the presence of:
      a. An adequate plan to protect identifiers from improper use and disclosure;
      b. An adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if 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
         i. As required by law,
         ii. For authorized oversight of the research study, or
         iii. For other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
   2. The research could not practicably be conducted without the requested waiver or alteration.
   3. The research could not practicably be conducted without access to and use of the PHI.
V. Documentation Requirements

A Privacy Board will document when it grants waivers or authorizations of authorization and provide such documentation to the research team, which will describe the PHI for which use or access has been determined to be necessary for the research.

VI. Forms

None.

VII. References

- 45 CFR 164.512

VIII. Related Policies

- IRB Members’ Conflicts of Interest: https://kb.wisc.edu/gsadminkb/page.php?id=29466

VIII. For Further Information

For further information concerning this policy, please contact the UW-Madison HIPAA Privacy Officer or the UW-Madison IRB Office responsible for the oversight of the research study.

Reviewed By
UW-Madison Education/Social & Behavioral IRB
UW-Madison Health Sciences IRBs Office
UW-Madison HIPAA Privacy Officer
UW-Madison Office of Legal Affairs

Approved By
HIPAA Privacy and Security Operations Committee, June 14, 2018
HIPAA Privacy & Security Executive Board, August 6, 2018