A researcher may request an alteration to, or waiver, in whole or in part, of the individual authorization (Authorization) required by 45 CFR 164.508 for use or disclosure of protected health information (PHI), as defined by the Health Insurance Portability and Accountability Act, as amended (HIPAA).

The Michigan State University (MSU) Institutional Review Boards (IRBs) will review requests for an alteration to, or waiver, in whole or in part, of the Authorization required by 45 CFR 164.508 for use or disclosure of PHI obtained from a clinic that is part of the MSU covered entity for human subject research projects that are subject to MSU HRPP Manual Section 4-1, Applicability. The MSU IRB may also review requests where PHI will be obtained from a non-MSU covered entity if the MSU IRB has entered into an arrangement with the non-MSU covered entity to review such requests.

The MSU IRB must follow either normal or expedited procedures as allowed by 45 CFR 164.512(i)(2)(iv)(B) and (C), and must document their approval of alterations to, or waivers of, authorizations as required by 45 CFR 164.512(i)(2)(i) through (iv).

Review and Documentation


Following HRPP Manual Section 7-6 HIPAA Compliance in Human Research, a Human Research Liaison is assigned to applications that may involve PHI. If an alteration to, or waiver, in whole or in part, of an Authorization is requested, the Human Research Liaison (HRL) will assign the project to a designated IRB member. The member conducts an expedited review or refers it to the IRB for convened review.

An IRB must follow the requirements of the Common Rule, include the normal (full board) review procedures or expedited review procedures, as applicable.
Review and approval follows the procedures as required by the level of review. See HRPP Manual 8-2 “Expedited Review Procedure” and/or 8-3 “Full Board Review Procedure” for policies and procedures on review and documentation.

Documentation of Waiver Approval
Documentation of waiver approval will be provided to the researcher and must include all requirements as stated in 45 CFR 164.512(i)(2):

For use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following:

(i) Identification and date of action
- Statement identifying the IRB and
- Date on which the alteration or waiver of authorization was approved

(ii) Waiver criteria
- Statement that the IRB has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria
  A. The use or disclosure of protected health information involves no more than 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 consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
     (3) Adequate written assurances that the protected health information 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 law
  B. The research could not be practicably be conducted without the waiver or alteration; and
  C. The research could not practicably be conducted without access to and use of the PHI

(iii) PHI needed
- A brief description of the specific PHI for which use or access has determined to be necessary by the IRB
(iv) **Review and approval procedures**
- A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited procedures.

(v) **Required signature**
- The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB.

The documentation will be copied to the MSU covered entity and/or non-MSU covered entity if the MSU IRB has entered into an arrangement with the non-MSU covered entity to review such requests.