**External IRB Documentation of Waiver or Alteration of HIPAA Authorization**

**45 CFR 164.512 (i)**

# For research uses and disclosures of UVMMC Protected Health Information (PHI), the UVM IRB must document whether or not a Health Insurance Portability and Accountability Act (HIPAA) waiver or an alteration of the Authorization requirement meets in whole or in part 45 CFR 164.512(i).

# This document should be completed by the Single IRB or an equivalent document may be submitted when a Single IRB has determined that a waiver or alteration is permissible under the regulations. (check the applicable boxes below):

***Documentation of alteration or waiver approval****.*

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| --- | --- |
| List the IRB or privacy board name:  |  |
| List the date on which the alteration or waiver of authorization was approved by the IRB or privacy board: |
|  |
| Provide 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: |
|  |

The IRB or privacy board has determined that the alteration or waiver, satisfies the following criteria (confirm by checking):

The use or disclosure of protected health information 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 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 this subpart;

The research could not practicably be conducted without the waiver or alteration; and

The research could not practicably be conducted without access to and use of the protected health information.

A statement that the alteration or waiver of authorization has been reviewed and approved under either full board or expedited review procedures, as follows:

(1) An IRB must follow the requirements of the Common Rule;

(2) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (1)(a)(ii)(2) above, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure;

(3) A 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; and

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 or the privacy board, as applicable.

***Reviews preparatory to research.***The IRB or Privacy Board obtained from the researcher representations that:

Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

The protected health information for which use or access is sought is necessary for the research purposes.