University of Vermont

Committees on Human Subjects
Serving the University of Vermont
and the UVM Health Network

RESEARCH PROTECTIONS OFFICE
213 Waterman Building
85 South Prospect St.
Burlington, Vermont 05405
Email – irb@uvm.edu
Human Subjects Research

External IRB/Privacy Board

Documentation of Waiver or Alteration of HIPAA Authorization or Review Preparatory to Research [45 CFR 164.512]

For research uses and disclosures of UVM Health Network Protected Health Information (PHI), the UVM IRB must document whether 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).

UVMHN policy allows members of the UVMHN workforce to access data through a preparatory to research exception to access patient information for recruitment; if PHI needs to be removed from the UVMHN environment or those accessing PHI are not UVMHN workforce, a Partial Waiver of HIPAA Authorization is required for recruitment.

This document should be completed by the External IRB/Privacy Board, or an equivalent document may be submitted if it contains the same information, when an External IRB has determined that a waiver or alteration is permissible under the regulations.

***Provide the following information about the* UVM Site:**

1. Name, email address, and department of UVM Principal Investigator:	
2. Name, email address, and department of person accessing PHI (if different from PI):	
3. Actual or approximate dates for the proposed research (start & stop dates):	
4. Brief description of the proposed research purpose/reason for the data use:	

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Documentation of HIPAA alteration or waiver approval:

1. List the IRB or Privacy Board name:	
2. List the type of alteration or waiver issued:	

3. List the date on which the alteration or waiver of HIPAA authorization or reviews preparatory to research were approved by the IRB or Privacy Board:

4. Provide a description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board. Include:
   - the covered entity from which the PHI will be obtained

   - source for access/collection of the PHI for review (i.e. EPIC, existing database or repository, shared drive, etc)

   - method of review of PHI (including any transfer of data outside of UVM Health Network)

   - specific PHI that will be accessed under the waiver (for example, specific tests, medical history, diagnoses, etc.)

   - start and stop dates for the data collection period(s) of interest

   - number of records needed

5. 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

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

☐ 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.

Documentation of approval of reviews preparatory to research:

45 CFR 164.512 allows reviews preparatory to research, defined as preliminary research activities necessary to assist in the development of a research hypothesis and/or aid in the recruitment of research participants. The IRB or Privacy Board obtained from the researcher confirmation 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 UVM Health Network systems 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.

IRB Chair or Designated IRB Member, name & title	
IRB Chair or Designated IRB Member, signature	
Date signed	