

IRB APPLICATION FOR HIPAA WAIVER OF AUTHORIZATION¹

IRB protocol #: _____

Title: _____

1. The use or disclosure of Protected Health Information (PHI)² involves no more than minimal risk to the privacy of individuals. **Explain** how the risks are reasonable in relation to the benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research. **Include** a detailed list of the PHI to be collected and a list of the source(s) of PHI.

Answer:

2. Describe the plan to protect identifiers and indicate whether PHI will be stored and who will have access (researchers must list all entities that might have access to the study's PHI such as ORI/IRB, University of Connecticut Health Center representatives, sponsors, FDA, data safety monitoring boards, and any others given authority by law).

Answer:

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is (explain below):

Answer:

Please describe the procedure used to destroy all the data collected during the study (electronically, paper, audio, video, photography, other) **OR**

Answer:

¹ HIPAA Regulations allow IRBs to waive the use of authorization form if all of the criteria requested are met.

² **PHI:** individually identifiable health information transmitted or maintained in any form (electronic means, on paper, or through oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.

Alternatively, the identifiers collected during the study will not be destroyed because (explain below):

Answer:

4. The research could not practicably be conducted without the waiver because:

Answer:

5. The research could not practicably be conducted without access to and use of the PHI because (explain below):

Answer:

6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Please note that researchers are also **accountable** for any PHI released under a waiver. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

Answer:

The information listed in the waiver application is accurate and all research staff³ will comply with the HIPAA regulations and the waiver criteria. All research staff will complete the UCHC HIPAA online training course.

I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any person or entity other than those listed on this form, except as required by law. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities I will seek IRB approval.

Principal Investigator Signature and Date: _____

Investigator's Name (Typed): _____

³ Research staff is defined as ALL study personnel (including PI) who are involved in the research.

**IRB Approval of HIPAA Waiver of Authorization
for Use of Protected Health Information (PHI)
Pursuant to 45 CFR 164.512 (i)(1)(i) and (i)(2)(i - v)**

IRB Protocol Number: _____

IRB Protocol Title: _____

The waiver satisfies the following elements as defined by 164.512(i)(2)(i and ii A-H):

- A. Use or disclosure of protected health information involves no more than minimal risk to the individuals;
- B. It is the opinion of the IRB that the waiver will not adversely affect the privacy rights and the welfare of the individuals;
- C. The research could not practicably be conducted without the waiver;
- D. The research could not practicably be conducted without access to and use of the phi;
- E. The privacy risks to the individuals whose phi is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;
- F. There is an adequate plan to protect the identifiers from improper use and disclosure;
- G. There is 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;
- H. There are 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 project, or for other research for which the use or disclosure of phi would be permitted.

The elements of phi to be collected as described in item 1 of the Application for Waiver have been determined to be the minimal necessary for the specified research.

This waiver has been reviewed and approved in accordance with the Common Rule under _____ Full Board Review _____ Expedited Review.

Signature of IRB Chair or Authorized Designee

Date