

Request for HIPAA Alteration to/Waiver of Individual Authorization from the University of Cincinnati Institutional Review Board ¹

The Need for an Alteration/Waiver of Individual Authorization

The HIPAA Privacy Rule establishes the conditions under which Protected Health Information (PHI) may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” (See 45 CFR 164.501). Under the HIPAA Privacy Rule, some research that was exempt from informed consent and/or Institutional Review Board (IRB) review will require authorization for the release of PHI or a Waiver of Individual Authorization issued by an IRB or Privacy Board.

In order to conduct research using medical records or other PHI from University Hospital, Inc. or another covered entity, the researcher must present an approved alteration to/waiver of the HIPAA individual authorization requirement to the covered entity which holds the PHI. The waiver must be approved by an IRB or a Privacy Board, established in accordance with 45 CFR 164.512 (i)(1)(i)(B)(1)-(3), prior to initiating the research.

Please note that researchers may access the covered entity’s PHI only for reviews preparatory to research without an individual authorization or alteration/waiver of individual authorization so long as the researcher does not remove any identifiable information from the covered entity. The information must be completely de-identified, or the waiver from the IRB will be required. A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule).

Submitting a Request for an Alteration/Waiver of Authorization to the University of Cincinnati IRB

An IRB or Privacy Board may approve an alteration or a waiver, in whole or in part, of the requirement for individual authorization if it determines that the research meets the criteria outlined in 45 CFR 164.512(i)(2)(i)-(v) as applicable.

In order for the University of Cincinnati IRB to make these determinations, please submit your protocol or plan in the following format. **(Submit original and one copy to the IRB Office, ML #0567, Room G08-Wherry Hall.)** Include all the elements listed.

¹ Please see <http://compliance.ucphysicians.com/HIPAA/default.asp> for further information

UNIVERSITY OF CINCINNATI
APPLICATION FORMAT FOR ALTERATION TO/WAIVER OF INDIVIDUAL
AUTHORIZATION

Name of Principal Investigator: _____ Phone # _____ Mail Location # _____
(Students conducting research to meet requirements of a University of Cincinnati academic program must also list a faculty advisor):

Name of Advisor: _____ Phone # _____ Mail Location # _____
Department: _____ Mail Location # _____

Other Researchers: _____

(All communications from the UC IRB will be directly with the Principal Investigator at the location noted above. If the PI is a Student, copies of correspondence will be sent to the faculty advisor.)

Name, Address, and Phone # of the Study Sponsor (if any): _____

Title of Research Study: _____

1. PROTOCOL/PLAN: State the objective of the research. (Include any background information that will help the IRB understand the objective if there is no protocol attached.)
- a) How, and/or from where, do you plan to gather the information?
 - b) List each element of the data set that will be used in the research and explain how the use of this data from the selected subject population satisfies the objective of the research. Include a copy of your data recording tool.
 - c) State the anticipated beginning and end dates of the research (or approximate length of data gathering activities).
 - d) Give an estimate of the number of records that will be involved in the project.
 - e) Is it practicable to conduct this research without using the PHI? ___ yes ___ no
If you answered no, explain why it is not practicable.
 - f) Is this a retrospective chart review: ___ yes ___ no
If you answered no, can you get authorization from the research subjects? ___ yes ___ no
If you answered no, explain why it is not practicable to get authorization for this research.
 - g) Is the risk to the individuals whose information you are using minimal? _____ (i.e., the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

OR

_____ more than minimal? If you answered “more than minimal” please explain what the risk is.

2. PROTECTION OF DATA: (HIPAA requires that there be an adequate plan to protect the identifiers from improper use and disclosure, that there be an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, and that there be adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, unless required by law or by oversight of the research by a regulatory agency.)

- a. What security measures will you take to protect the PHI from improper use or disclosure or reuse? (e.g., they are kept in a locked cabinet only available to the researchers, or they are maintained in a password-protected database and only the researchers have access to the password. List all of the entities that might have access to the study's PHI such as UC,, sponsors, FDA, data monitoring boards, any others given authority by law).
- b. When and how do you plan to destroy the PHI? If you do not plan to destroy the PHI, please give your rationale. (e.g., there is a plan to break any links to identifiable information, unless the links need to be maintained, in which case a reason should be given).
- c. What security measures will you take to assure that the PHI will not be reused? (e.g., "the information will not be used or disclosed for any purpose other than this specific research project").

Investigator's Certification/Assurance:

I certify that the information provided in this request for Alteration to/Waiver of Individual Authorization is complete and correct. I understand that I have the ultimate responsibility for protecting the confidential information of individuals and ensuring the privacy of their protected health information.

Signature of Principal Investigator

Date

Faculty Advisor (if PI is a student)

Date

IMPORTANT - TO EXPEDITE PROCESSING OF YOUR REQUEST PLEASE INCLUDE THE SECTION BELOW ON YOUR PROTOCOL OR PLAN.

Approval by the University of Cincinnati IRB:

The University of Cincinnati Institutional Review Board (IRB) is established in accordance with 21 CFR 56.107 AND 45 CFR 46.107

Based upon the information provided above, the University of Cincinnati Institutional Review Board finds that this waiver request meets all the legal requirements for a Waiver of Individual Authorization under HIPAA pursuant to 45 CFR 164.512 (i)(2)(i)-(v) and approves the request under

_____ Expedited review procedures (21 CFR 56.110 AND 45 CFR 46.110) OR by

_____ Full board review procedures (21 CFR 56.108(b) AND 45 CFR 46.108(b))

Chair, IRB ___ 1 ___ 2 ___ Soc. & Behav. Sciences

Date