Campbell University Institutional Review Board
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Campbell University FWA00008608
CUIRB-IRB00009201

Request for HIPAA Alteration/Waiver of Individual Authorization

The Need for an Alteration/Waiver of Individual Authorization

The IPAA Privacy Rule established 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 IPAA 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 a 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 Privacy Board, established in accordance with 45 CFR 164.512 (I)(1)(i)(B)(1)-(3), prior to initiating the research.

Please note that research 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 research does not remove an 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 CUIRB

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 CUIRB to make these determinations, please submit your complete research proposal with this form. **Since the waiver must be a stand-alone document, please be sure to complete each item on the form, it is not acceptable to say "see attached".**

If this is a new research project, please include the Application for Research Review Form as required by the IRB.

☐ **Are you requesting an Alteration/Waiver of Authorization for Identifiable Health information for the complete research project? If yes complete section I – IV of the form.**

☐ **Are you requesting a Partial Waiver of Authorization for Identifiable Health Information for Subject Recruitment, do not complete Section III.2.**

I. Research Title:

II. Personnel

A. Principal Investigator

Name (Last, First)	Degree(s)	University Status/Title
Department	College	
Phone Number	E-mail address	

B. Additional Investigators (If Applicable)

Name (Last, First)	Degree(s)	University Status/Title
Department	College	
Phone Number	E-mail address	

Name (Last, First)	Degree(s)	University Status/Title
Department	College	
Phone Number	E-mail address	

Name (Last, First)	Degree(s)	University Status/Title
Department	College	
Phone Number	E-mail address	

C. Faculty Sponsor – required when PI is a student

Name (Last, First)	Degree(s)	University Status/Title
Department	College	
Phone Number	E-mail address	

III. Project Information

1. PROTOCOL/PLAN: State the objective of the research.

   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 it.

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 the 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 project's PHI such as CUIRB, sponsors, FDA, data monitoring boards, or other 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 or FDA requires keeping of PHI)*

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").*

IV. Investigator' Certification/Assurance

I certify that the information provided in this request for Alteration/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

To be completed by the IRB

V. Approval by the CUIRB

The CUIRB is established in accordance with 21 CFR 46.107 and 45 CFR 46.107

Based upon the information provided above, the CUIRB finds that this waiver/alteration of request meets all the legal requirements for a Waiver/Alteration 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)

☐ Full board review procedures (21 CFR 56.108(b) and 45 CFR 46.108(b)

IRB Reviewer: Date: