University of Colorado Colorado Springs

Request for Waiver of Elements of Authorization or an Altered Authorization

Date of Request:	Principal Investigator ("PI"):
Title of Research Project:	
Mailing Address:	
PI's email:	PI's Phone Number:

Instructions: In order for the Privacy Board to approve a waiver of HIPAA process or a partial waiver of any of the required elements of HIPAA, Federal Regulation 45CFR 164.512(i) requires the following:

Does your study involve the use or disclosure of protected health information (PHI)?
☐ Yes ☐ No
PHI = individually identifiable health information that is collected for treatment, diagnosis, or research purposes.

If yes, check off any of the following identifiable information you will be obtaining.

- ☐ Patient/Subject Name
- ☐ Medical device Identifiers
- ☐ Electronic Mail (Email Address)
- ☐ Address town or city*
- ☐ Internet protocols (IP) address
- ☐ Medical record numbers
- ☐ Address zip code*
- ☐ Full face photographic images
- ☐ Account numbers
- ☐ Fax number
- ☐ Address street location
- ☐ Web URL's
- ☐ Social security number
- ☐ Address state*
- ☐ Biometric identifiers (finger/voice prints)
- ☐ Health plan beneficiary numbers
- ☐ Telephone
- ☐ Certificate/license numbers
- ☐ Elements of dates (except yr.) related to person, i.e., date of admission or discharge dates, date of death*
- ☐ Any unique identifying number, characteristic or code
- ☐ Vehicle identification numbers and serial numbers including license plates
- ☐ Link to identifier (code)
- ☐ None of the above listed items will be recorded

Are you obtaining this information for recruitment purposes? ☐ Yes ☐ No
Are you obtaining this information for study purposes (i.e. data analysis, follow-up)? ☐ Yes ☐ No

Under Privacy rule provisions, research data that includes any of the 18 identifiers listed above cannot be considered de-identified. Authorization from the subject or a waiver of authorization granted by the UCCS Privacy Board is required. Items with an asterisk (*) may be included and considered a "limited data set." Use of data under the provision of a "limited data set" requires the signing of a data use agreement by the recipient (this includes researchers) and a request for a waiver of authorization.

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REQUEST FOR WAIVER OF HIPAA AUTHORIZATION

According to HIPAA Privacy Rule regulations, in order to use or disclose an individual's PHI in the conduct of research without the express authorization of the individual, all of the following criteria must be met.

A. The use of disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
- An adequate plan to protect the identifiers from improper use or disclosure.
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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**
- Adequate written assurances that the PHI 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 by regulation).

B. The research could not practicably be conducted without the alteration or waiver; **AND**

C. The research could not practicably be conducted without access to and use of the PHI.

Does your study meet all the above criteria for a waiver of HIPAA authorization? ☐ Yes ☐ No

Does your study qualify for a waiver of authorization using a limited data set (i.e. you checked only those boxes indicated with an asterisk (*)? ☐ Yes ☐ No
If yes, please attach a completed Data Use Agreement.

As PI of the research project indicated on this form, I make the following assurances to the UCCS Privacy Board:

☐ The PHI for which use or disclosure is sought is necessary for research purposes.

☐ I will provide the UCCS Privacy Board with written notification if any of the responses to the above questions change.

☐ I understand that the UCCS Privacy Board is NOT an Institutional Review Board and is not authorized to review and/or approve human subject's research regulated under the Common Rule.

☐ I understand that the above representations are binding upon and will inure to the benefit and obligation of the PI of the research project indicated on this form and his/her respective successors and/or assigns.

I will apply the above conditions to PHI maintained by the UCCS Covered Entity or Covered Component.

_____ ☐

Principal Investigator Signature Date