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XAVIER UNIVERSITY

Institutional Review Board

Request for HIPAA Alteration to/Waiver of Individual Authorization

Submit this form with your IRB Submission Form if you are using or disclosing Protected Health Information (PHI) from a covered entity and the patients whose PHI will be used/disclosed have not authorized the use/disclosure of the information for research purposes.

Title of Study: _____

Principal Investigator: _____

Address: _____

Phone: _____ E-mail: _____

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. In order to conduct research using medical records or other PHI from a covered entity, EITHER the patient must have provided, in advance, his or her written authorization for such use or disclosure OR the researcher, prior to initiating the research, must present to the covered entity which holds the PHI documentation that an IRB has approved an alteration to/waiver of the HIPAA individual authorization requirement.

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).

1. PROTOCOL/PLAN:
   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. Is it practicable to conduct this research without using the PHI? ☐ yes ☐ no
      If you answered no, explain why it is not practicable.

      _____

      _____

   d. 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.

_____

_____

e. 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).*

_____

_____

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*).

_____

_____

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