



Request for HIPAA Waiver under the HIPAA Privacy Rule

According to the HIPAA Privacy Rule, there are a limited number of conditions under which individuals' private health information (PHI) can be disclosed without their authorization for research purposes. Researchers who are using individuals' PHI must request a HIPAA waiver in order to document that they are properly handling this information, and risk is minimized. The IRB at Franciscan Missionaries of Our Lady University is authorized to grant this waiver. To obtain this waiver, please answer the questions below.

Name of the Project: _____

Principal Investigator: _____

Other Researchers: _____

1. Will the use or disclosure of protected health information (PHI) involve no more than minimal risk to individuals?
 Yes No

("Minimal risk" means that 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.)

- a. Is there an adequate plan to protect the health information identifiers from improper use and disclosure?
 Yes No

Describe plan:

- b. Is there an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is a research justification for retaining the identifiers, or such retention is otherwise required by law?
 Yes No

Describe plan:

- c. Do you, as the Principal Investigator or the PI's designee, attest that the PHI will not be used 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 the Privacy Rule?
 Yes No

2. Is it practical* to conduct the research without the waiver or alteration?

Yes No

If "No," explain why not:

3. Is it practical* to conduct the research without access to and use of PHI?

Yes No

If "No," explain why not:

*The test of practicability may be met, for example by:

- 1) The need for a large number of subjects.
- 2) A presumed or demonstrated inability to contact individuals for whom contact information may not be accurate.
- 3) The difficulty, in a retrospective study, of personally contacting each patient to approve the use of their information.
- 4) The likelihood that contacting patients could place the patients at a greater risk of loss of confidentiality or privacy.
- 5) The fact that many subjects may be deceased.
- 6) The fact that a lack of data from a few subjects may make the number of subjects available for the study too small for make the study reliable and valid.