

Full Waiver of HIPAA Authorization Requirements

The Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires an individual to provide signed permission prior to the use or transmission of the person's Protected Health Information (PHI) for research purposes. Such written permission is known as "Authorization" (see 45 CFR 164.508).

Federal regulations give authority to an IRB to approve a waiver of Authorization under the Privacy Rule. Waiver of Authorization is subject to the following requirements:

- The PHI use or disclosure in this project involves no more than minimal risk to the privacy of individuals whose PHI will be accessed, used, or disclosed.
- The principal investigator has presented to the IRB an adequate plan to protect PHI identifiers from improper use and disclosure;
- The principal investigator has presented to the IRB an adequate plan to destroy those PHI identifiers at the earliest opportunity;
- The principal investigator has assured the IRB in writing that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
- The principal investigator asserts that the research could not practicably be conducted (a) without the requested waiver, and (b) without access to and use of the PHI.

The information and assurances required in the points above should be described in detail in the appropriate sections of IRB Form B. Additional information may, if necessary, be provided in an addendum to Form B entitled, "Requirements for waiver of Authorization under HIPAA."

The IRB is authorized to approve a full waiver of Authorization under the HIPAA Privacy Rule for research proposals submitted for full-board or expedited review only.

To apply for a full waiver of Authorization, the principal investigator (PI) should complete the form, FULL WAIVER of Authorization Requirements for Protected Health Information under the HIPAA Privacy Rule, which can be found on the Forms page of this website. The PI completes the first section of the document, over his signature and the date of the request. This request form should be included as part of proposal packet submitted to the IRB for review.

When the proposal has been APPROVED by the IRB, under its usual procedures for full-board or expedited review, the chair of the IRB will sign and date the Approval section of the form. A digital copy of the form, with the approval signature of the IRB chair, will be returned to the PI. A copy of the signed form will also be retained as a part of the approved proposal document, in the Office of Research.