



Los Angeles County Public Health, Ambulatory Care Network and
Health Services Administration Institutional Review Board (IRB)
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INSTRUCTIONS REQUESTING WAIVER OR ALTERATION OF HIPAA PRIVACY RULE AUTHORIZATION

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that provides safeguards to protect the health information of individuals. Since investigators may create, use or disclose individually identifiable health information or protected health information (PHI)¹ when conducting research, the IRB must assure compliance with HIPAA as it relates to research.

Under the HIPAA Privacy Rule, researchers are permitted to use and disclose PHI by obtaining a HIPAA-compliant authorization, or without individual authorization under limited circumstances. One way is by waiver of HIPAA authorization, which is roughly analogous to a waiver of informed consent. This provision might be used, for example, to conduct records research, when researchers are unable to use de-identified information, and the research could not practicably be conducted if the research participants' authorization were required, or to access existing databanks or repositories.

The IRB may alter or waive research participants' authorization for use or disclosure of PHI for research provided that the following criteria are met:

1. The use or disclosure of PHI involves no more than minimal risk to the individuals based on the presence of the following elements:
 - a. There is an adequate plan to protect the identifiers from improper use and disclosure.
 - b. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a

¹ PHI elements include: Names, all geographic subdivisions smaller than a state including street address, city, county, precinct, full zip code, all dates except year including date of birth (with the exception of individuals over the age of 89), admission date, date of diagnosis, discharge date, date of death, telephone numbers, fax numbers, electronic mail addresses, Social Security numbers, medical record numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate numbers, device identifiers and serial numbers, web universal resource locators (URLs), internet protocol (IP) address numbers, biometric identifiers, including finger and voice prints, full face photographic images and any comparable images, any other unique identifying number, characteristic or code.

health or research justification for retaining the identifiers or such retention is otherwise required by law.

- c. There are 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 HIPAA Privacy Rule permits.
2. The research could not practicably be conducted without the alteration or waiver.
3. The research could not practicably be conducted without the access to and use of the PHI. (45 C.F.R. § 164.512(i)(1)(i)).

To request a waiver of HIPAA authorization from the IRB, please complete the *HIPAA Waiver or Alteration of Authorization Request*