

HIPAA

Guidance for Requesting and Completing the Waiver of Authorization

A waiver of authorization is a request to forgo the authorization requirements because the disclosure of protected health information (PHI) for research purposes is minimal risk to the subject and the research can not practically be done without access to/use of the PHI. The investigator must develop a written plan to protect the subject's protected health information.

Examples that would require a waiver of authorization:

1. **Researchers in the Covered Entity (CE) would require a waiver of authorization to remove PHI from the CE (i.e., sharing PHI with the sponsor) for the purpose of identifying subjects for a research study.** The waiver would only be granted if:
 - a. The investigator is submitting a screening log with PHI to a sponsor to identify potential subjects for a study; and
 - b. The investigator has not obtained informed consent/authorization from the subject; and/or
 - c. The screening log which contains PHI is disclosed to monitors or other agencies during the study.
2. **Retrospective medical record reviews** would require a waiver of authorization since it would be impractical to obtain authorization from the subjects.
3. **Researchers not in the Covered Entity (CE) would require a waiver of authorization to remove PHI from the CE.** The waiver would only be granted if:
 - a. The investigator is removing PHI from the Covered Entity; and
 - b. The investigator has not obtained informed consent/authorization from the subject.

Note: PHI is defined as any of the 18 identifiers listed below* in combination with health information transmitted or maintained in any form (electronic, paper, or oral) that relates to the past, present or future physical or mental health or conditions of an individual.

The following identifiers can be recorded and removed from the CE without requesting a waiver of authorization: initial three digits of the zip code if population is greater than 20K, age if less than 90, gender, and ethnicity.

*HIPAA recognized identifiers:

Names; All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes; All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, 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.