

**ELEMENTS OF DOCUMENTATION REQUIRED FOR
WAIVER OF AUTHORIZATION
(Title 45 Code of Federal Regulations (CFR) 164.512(i)(2))**

1. The Health Insurance portability and Accountability Act (HIPAA) Privacy Rule requires that, if an IRB grants a waiver or alteration of the HIPAA Authorization, the Institutional Review Board (IRB) document the findings on which it based its decision. A request from an investigator to waive or alter the HIPAA authorization needs to be accompanied by information sufficient to make the required findings listed in the following.
2. The documentation must include all of the following:
 - a. Identification of the IRB
 - b. Date of IRB approval of waiver of authorization
 - c. Statement that alteration or waiver of authorization satisfies the following criteria:
 - (1) The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - (a) An adequate plan to protect the identifiers from improper use and disclosure
 - (b) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - (c) Adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
 - (2) The research could not practicably be conducted without the waiver or alteration; and
 - (3) The research could not practicably be conducted without access to and use of the requested information.
 - d. A brief description of the Protected Health Information (PHI) for which the IRB has determined use or disclosure to be necessary
 - e. Identification of the review procedure used to approve the waiver of authorization (either normal review procedures (38 CFR 16.108(b) or expedited review procedures (38 CFR 16.110)).
 - f. Signature of Chair of the IRB, or member designated by the Chair, to approve the waiver of authorization.