

Waiver of HIPAA authorization

Woman's may use and/or disclose protected health information for research purposes without prospective written authorization provided that they provide a request for such waiver or partial waiver and the IRB agrees that the request satisfies the criteria at §164.512(i)(2)(ii) as listed below:

(a) The use or disclosure of the protected health information involves no more than minimal risk to the privacy of individuals based on:

(1) The provision of an adequate plan to protect the identifiers from improper use and disclosure; and

(2) The provision of an adequate plan to destroy the identifiers at the earliest possible opportunity consistent with the 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

(3) The provision of adequate written assurances that the protected health information 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 use or disclosure of protected health information would be permitted by law; and

(b) The research could not be practicably conducted without the waiver or alteration; and

(c) The research could not be practicably conducted without access to and use of the protected health information.

When Woman's IRB grants a waiver or partial waiver of written authorization as outlined above, it will provide documentation of its determinations as required by 45 CFR 164.512(ii):

1. Identification that the waiver was granted by the IRB, and the date on which the alteration or waiver was approved; and
2. A statement that the IRB determined that the alteration or waiver of written authorization, in whole or in part, satisfied the criteria,
3. A brief description of the protected health information for which use or access was determined to be necessary by the IRB; and
4. A statement that the alteration or waiver of HIPAA Authorization was reviewed and approved under expedited or full IRB review procedures.