

Waiver of Authorization

Guidance

One way to use or disclose protected health information without authorization by the research participant is through a waiver of authorization. A waiver of research participants' authorization for use/disclosure of information must be approved by the IRB through full board or expedited review procedures.

This provision of the Privacy Rule might be used to:

- ❑ Conduct records research
- ❑ When researchers are unable to use de-identified information
- ❑ The research could not practicably be conducted if research participants' authorization were required.

The following criteria must be satisfied for an IRB to approve a waiver of authorization under the Privacy Rule:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the following elements:
 - ❑ An adequate plan to protect the identifiers from improper use and disclosure
 - ❑ 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,
 - ❑ 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 under this rule.
 - The research could not practicably be conducted without the waiver
 - The research could not practicably be conducted without access to and use of the protected health information

See Waiver of Authorization Form

The covered entity may then use or disclose protected health information for research purposes pursuant to a waiver of authorization by the IRB, provided it has obtained documentation (supplied by the IRB) of the following:

- ❑ Identification of the IRB and the date on which the waiver of authorization was approved
- ❑ A statement that the IRB has determined that the waiver of authorization satisfies the criteria of the rule
- ❑ A brief description of the protected health information for which use or access has been determined to be necessary by the IRB
- ❑ A statement that the waiver of authorization has been reviewed and approved under either normal or expedited review procedures
- ❑ The signature of the chair or other member, as designated by the chair, of the IRB.

See Approval of Request for Waiver of Authorization