

Waiver of authorization for research

Three criteria for approving requests for a waiver of authorization for research:

1. The use or disclosure of PHI must involve no more than minimal risk to the privacy, safety, and welfare of the individual.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to the PHI.

The IRB must also consider if the researcher has provided:

1. An adequate plan to protect the identifiers from improper use or disclosure.
2. An adequate plan to destroy the identifiers at the earliest opportunity, unless retention of identifiers is required by law or is justified by research or health issues.
3. Adequate written assurance that the PHI will not be used or disclosed to a third party except as required by law or permitted by an authorization signed by the research subject.