

Privacy Rule

Under the guidelines of Privacy Rule (45 CFR 160 and 164) medical records may not be accessed for the purpose of research without satisfying certain conditions.

In general, an informed consent (authorization) should be signed by the subject (patient) permitting access. The authorization should be specific for the particular study, and should contain an ending date when the data will be destroyed and no longer accessed. For long-term studies, it is permissible to indicate "none" for an expiration date.

The informed consent for treatment, etc. may also include the authorization for medical records access.

Under certain conditions however, a "waiver" of the authorization requirement may be granted.

In granting a waiver from the authorization requirement, the IRB should consider the following criteria

- 1) the use or disclosure of potential health information involves no more than minimal risk to the privacy of individuals, based on at least the following elements
 - a) an adequate plan to protect the identifiers from improper use and disclosure; and
 - 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 required by law; and
 - c) adequate written assurances that the protected health information will not be reprocessed 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 this subpart; and
- 2) the research could not practicably be conducted without accessing the medical record, and
- 3) The medical records could not practically be accessed without a waiver of authorization