

Waiver of Documentation of Consent

Waiver of documentation of consent: Also known as a verbal consent or waiving a signed consent. The investigator obtains consent, and the consent process still has all the requirements as written consent, but the subject does not sign a consent form.

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds any of the following to be true (45 CFR 46.117(c) or 21 CFR 50.109(c)):

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Options 1 and 2 are equivalent to FDA's #56.109(c)(1)

A sample of a consent that does not require signature can be found under the Templates: Exempt Information Sheet

Waiver or Alteration of Consent

Waiver of consent completely waives the requirement to obtain informed consent.

Alteration of consent allows the investigator to leave out or alter elements of the informed consent.

The IRB may approve a general alteration or waiver of informed consent under 45CFR46.116(f) under the following conditions:

1. The research is minimal risk.
2. The research could not practicably be carried out without the requested alteration.
3. If the research involves use of identifiable information or biospecimens, the research could not practicably be carried out without using the information/biospecimens in an identifiable format.
4. The alteration will not adversely affect the rights and welfare of the participants; and

5. Whenever appropriate, the participants or their legally authorized representatives will be provided with additional pertinent information after participation.

Note for FDA regulated studies: The FDA does not allow a waiver or alteration of the consent except in special circumstances.