

Waiver of Documentation of Informed Consent **45 CFR 46.117**

IRB may waive requirement to obtain a signed consent form for some or all of subjects if either of the following options are met:

Option 1

- a. the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality; each subject must be asked whether subject wants documentation; or
- b. The research presents no more than minimal risk and involves no procedures for which written consent is normally required.

Under these conditions, each subject (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the subject agrees to sign a consent document, only an IRB approved version should be used.

Option 2

- a. The research presents no more than minimal risk to the subject.
- b. The research involves no procedures for which written consent is normally required outside of the research context.

Option 3

- a. The subject (or legally authorized representative) are members of a distinct cultural group or community in which signing forms is not the norm.
- b. The research presents no more than minimal risk to the subject.
- c. There is an appropriate alternative mechanism for documenting that informed consent was obtained.