

Waiver of Documentation of Informed Consent **45 CFR 46.117(c)**

1. IRB may waive requirement to obtain a signed consent form for some or all of subjects if:
 - 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.

2. In cases where documentation is waived, the IRB may require investigator to provide subjects with written statement regarding the research.

[Note that 1a above is not included in FDA. 1b is included in FDA and HHS regulations 21 CFR 56.109(c)]