SOUTHWEST
TENNESSEE COMMUNITY COLLEGE

Waiver of Documentation of Informed Consent

45 CFR 46.117(c)

The Institutional Review Board (IRB) may consider waiving the requirement for obtaining documentation of informed consent if the following conditions are met. To request a waiver, justification for the waiver should be included in the IRB submission and should address each of the criteria listed below.

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)]

Institutional Review Board
Office of Institutional Effectiveness

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