WAIVER OF SIGNED CONSENT PROCESS

The applicable regulations indicate the following regarding the waiver of signed consent:

45 CFR 46.117

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

> *(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.*

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.