|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study ID# |       | PI |       |  |

**Use this form for studies subject to the pre-2018 Common Rule.**

**[ ]  Criteria for 45 CFR 46.117(c)(1) *(Breach of Confidentiality) – this criteria does not apply to research subject to FDA regulations & policies.*** *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:*

[ ]  The only record linking the subject and the research would be the consent document

*Why does the research meet this criterion?*

[ ]  The principal risk would be potential harm resulting from a breach of confidentiality

*Why does the research meet this criterion?*

[ ]  Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern

*Why does the research meet this criterion?*

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

*Select one of the following:*

[ ]  Investigator is required to provide subjects with a written statement regarding the research

[ ]  Investigator is **NOT** required to provide subjects with a written statement regarding the research

*Comments?*

Waiver of documentation applies to:

 [ ]  Some subjects, please describe:

 [ ]  All subjects

**[ ]  Criteria for 45 CFR 46.117(c)(2) and/or 21 CFR 56.109(c)(1)) *(Minimal Risk).*** *An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds:*

[ ]  That the research presents no more than minimal risk of harm to subjects

*Why does the research meet this criterion?*

[ ]  Involves no procedures for which written consent is normally required outside of the research context

*Why does the research meet this criterion?*

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

*Select one of the following:*

[ ]  Investigator is required to provide subjects with a written statement regarding the research

[ ]  Investigator is **NOT** required to provide subjects with a written statement regarding the research

*Comments?*

Waiver of documentation applies to:

 [ ]  Some subjects, please describe:

 [ ]  All subjects

Comments:

|  |
| --- |
| IRB determination made by: |
| [ ]  Expedited reviewer | Name: |       | Date: |       |  |
|  |
| [ ]  Full board | Name of individual completing this form: |       | Meeting date |       |
|  |