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| --- | --- | --- | --- | --- |
| 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 | |  |
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