

CHECKLIST: Waiver of Documentation of Consent

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Protocol #: _____ PI: _____ Reviewer: _____ Date: _____

This checklist is used to determine and document whether WRITTEN DOCUMENTATION OF THE CONSENT PROCESS can be waived for non-exempt <Human Research>. The research must meet one of the following two sets of criteria.

1 Waiver of Written Documentation of Consent for Confidentiality Risk (45 CFR 46.117(c)(1)) (All criteria must be met)

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| <input type="checkbox"/> | <ul style="list-style-type: none"> The research is not FDA-regulated. The only record linking the subject and the research would be the consent document. The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. <p>Comments: _____</p> |
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2 Waiver of Written Documentation of Consent for research involving <Minimal Risk> to subjects.(21 CFR 56.109(c) and 45 CFR 46.117(c)(2)) (All criteria must be met)

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| <input type="checkbox"/> | <ul style="list-style-type: none"> The research presents no more than <Minimal Risk> to subjects. The research involves no procedures for which written consent is normally required outside of the research context. A written statement regarding the research that embodies the elements of consent will be provided to the subject or the subject's legally authorized representative. <p>Comments: _____</p> |
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