THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

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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- 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.

Comments:

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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- 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.

Comments: