**CHECKLIST: Waiver of Documentation of Consent**

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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)*

   - 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)*

   - 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: