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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314) when research involves a waiver of written documentation of consent. This checklist or equivalent must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[[1]](#footnote-1)   * For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist or equivalent to CHECKLIST: Non-Committee Review (HRP-402) or equivalent. The IRB Administration retains this checklist or equivalent in the protocol file. * For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist or equivalent made on the previous review have changed, one of the following two options may be used:  1. The convened IRB completes the corresponding section of the TEMPLATE MINUTES (HRP-501) to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist or equivalent does not need to be completed or retained. 2. The convened IRB completes this checklist or equivalent to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Administration retains this checklist or equivalent in the protocol file. | |
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| **IRB Number:** | |
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| **The following criteria must be met to qualify for waiver of written documentation of consent:** | |
| The research is Minimal Risk. | |
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| 1. **Regulatory criteria for waiver of written documentation of consent. The research must meet one of the following sets of criteria:** | |
|  | 45 CFR 46.117(c)(1)(i) All must be checked:  The research is not subject to FDA regulation.  The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from breach of confidentiality.  Each subject or legally authorized representative (LAR) will be asked whether the subject wants documentation linking the subject with the research, the subject’s wishes will govern. |
|  | 45 CFR 46.117(c)(1)(ii) or 21 CFR 56.109(c)(1)  The research involves no procedures for which written consent is normally required outside of the research context. |
|  | 45 CFR 46.117(c)(1)(iii) All must be checked:  The research is not subject to FDA regulation.  The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm.  There is an appropriate alternative mechanism for documenting that informed consent was obtained. |
| 1. **45 CFR 46.117(c)(2) and 21 56.109 (d)** **In cases in which the documentation requirement is waived, the IRB *may* require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.** | |

1. [↑](#footnote-ref-1)