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| The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the **CHECKLIST: Criteria for Approval and Additional Considerations** when research involves the waiver of written documentation of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)* 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 to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to CHECKLIST: Non-Committee Review (HRP-402) and the IRB Office retains this checklist in the protocol file.
* For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist 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, in which case this checklist does not need to be completed or retained. For Veterans Administration (VA) research, minutes must also document protocol specific findings justifying these determinations.
2. The convened IRB completes this checklist to document determinations required by the regulations and the IRB Office retains this checklist in the protocol file. For Veterans Administration (VA) research, records must also document protocol specific findings justifying these determinations.
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| The research must meet one of the following three sets of criteria.  |
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| 1. Waiver of Written Documentation of the Consent Process *(21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(2))* (All must be “Yes” – Records or minutes must document protocol-specific findings justifying each of the following determinations.)
 |
| [ ]  Yes [ ]  No | The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in **Section 8: ELEMENTS OF CONSENT DISCLOSURE** in the **CHECKLIST: Criteria for Approval and Additional Considerations.** |
| [ ]  Yes [ ]  No | The research presents no more than Minimal Risk of harm to subjects. |
| [ ]  Yes [ ]  No | The research involves no procedures for which written consent is normally required outside of the research context. |
| [ ]  Yes [ ]  No | The research does **NOT** involve newborn dried blood spots. |
| Select one of the following:[ ]  Written information describing the research **is to be provided** to the subject or the subject’s legally authorized representative.[ ]  Written information describing the research **does not need to be provided** to the subject or the subject’s legally authorized representative. |
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| 1. Waiver of Written Documentation of the Consent Process *(45 CFR §46.117(c)(1))* (All must be “Yes” – Records or minutes must document protocol-specific findings justifying each of the following determinations.)
 |
| [ ]  Yes [ ]  No | The research is not FDA-regulated. |
| [ ]  Yes [ ]  No | 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 disclosure in **Section 8: ELEMENTS OF CONSENT DISCLOSURE** in the **CHECKLIST: Criteria for Approval and Additional Considerations.** |
| [ ]  Yes [ ]  No | The only record linking the subject and the research would be the consent document. |
| [ ]  Yes [ ]  No | The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. |
| [ ]  Yes [ ]  No | Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. |
| Select one of the following:[ ]  Written information describing the research **is to be provided** to the subject or the subject’s legally authorized representative.[ ]  Written information describing the research **does not need to be provided** to the subject or the subject’s legally authorized representative. |
| 1. **Waiver of Written Documentation of the Consent Process** - Distinct Cultural Groups- requirements to or alter the consent process:

[ ]  Yes [ ]  No[ ]  N/A The subjects or legally authorized representatives are members of a distinct cultural group or community in  which signing consent documents is not the norm. [ ]  Yes [ ]  No[ ]  N/A There is an appropriate alternative mechanism for documenting that informed consent was obtained. |
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