CHECKLIST: Waiver of Written Documentation of Consent Process		
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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 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). The Office of Human Research 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 primary IRB reviewer 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.
  2. The convened primary IRB reviewer completes this checklist to document determinations required by the regulations and the Office of Human Research retains this checklist in the protocol file.

The research must meet one of the following two sets of criteria

1	Waiver of Written Documentation of the Consent Process[1] (Check if "Yes." All must be checked)
☐	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 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314).
☐	The research presents no more than Minimal Risk of harm to subjects.
☐	The research involves no procedures for which written consent is normally required outside of the research context.

Select one of the following: (One must be checked)

☐ 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.

2	Waiver of Written Documentation of the Consent Process[2] (Check if "Yes." All must be checked)
☐	The research is not FDA-regulated.
☐	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 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314).
☐	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.
☐	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: (One must be checked)

☐ 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] 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(2)

[2] 45 CFR §46.117(c)(1)