

WORKSHEET: Waiver of Written Documentation of Consent

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The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following 4.202 (HRP-314) WORKSHEET: Criteria for Approval when research involves the waiver of written documentation of consent. This worksheet may 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 worksheet made on the previous review have changed, the Designated Reviewer may utilize this worksheet to make determinations required by the regulations, along with protocol-specific findings, justifying those determinations. It does not need to be completed or retained. The Designated Reviewer documents their review in the electronic “Submit Non-Committee Review” activity in eIRB+.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol-specific findings justifying those determinations. It does not need to be completed or retained.

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

1 Waiver of Written Documentation of Consent¹ (Check if “Yes”. All must be checked)

- 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 7: ELEMENTS OF CONSENT DISCLOSURE** in 4.202 (HRP-314) - WORKSHEET: Criteria for Approval.
- 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 (LAR).
- Written information describing the research **does not need to be provided** to the subject or the subject’s LAR.

2 Waiver of Written Documentation of Consent² (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 4.202 (HRP-314) - WORKSHEET: Criteria for Approval.
- 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 or LAR 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)(1)(ii)

² 45 CFR §46.117(c)(1)(i)



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3 Waiver of Written Documentation of Consent³ (Check if “Yes”. All must be checked)	
<input type="checkbox"/>	The research is not FDA-regulated.
<input type="checkbox"/>	The research is subject to the 2018 Rule.
<input type="checkbox"/>	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 4.202 (HRP-314) - WORKSHEET: Criteria for Approval.
<input type="checkbox"/>	The subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm.
<input type="checkbox"/>	The research presents no more than <u>Minimal Risk</u> of harm to subjects.
<input type="checkbox"/>	There is an appropriate alternative mechanism for documenting that informed consent was obtained.
Select one of the following: (One must be checked)	
<input type="checkbox"/>	Written information describing the research is to be provided to the subject or the subject’s LAR.
<input type="checkbox"/>	Written information describing the research does not need to be provided to the subject or the subject’s LAR.

³ 45 CFR §46.117(c)(1)(iii)