	CHECKLIST: Waiver of Documentation of the Consent Process			IRB # \$\$IRB Number\$\$
	NUMBER	DATE	PAGE	Review Type: \$\$review\$\$
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The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following “HRP 311 Worksheet: Criteria for Approval and Additional Considerations” when reviewing research involving a Waiver of 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 submits this completed checklist to the IRB office. 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 IRB Analyst for the convened IRB meeting completes the corresponding section of the meeting minutes 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 IRB reviewer(s) completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office retains this checklist in the meeting files.

Use a separate checklist for each waiver of written documentation determination for a study if more than one type of waiver/alteration applies.

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

1 Waiver of Documentation of the Consent Process – Confidentiality (45 CFR 46.117(c)(1)(i)) (All must be “Yes”)


<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not FDA-regulated.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The only record linking the subject and the research would be the consent document. (Note: In order to waive documentation under (c)(1)(i), all of the data collected must be anonymous which means recorded without any identifying information).
<input type="checkbox"/> Yes <input type="checkbox"/> No	The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. <i>Provide description of how documentation will occur if requested by subject (i.e., signed consent form, note on study record, documentation of verbal consent on the consent form, etc.):</i>

Select one of the following:

- Written information describing the research **is to be provided** to the subject or the subject’s legally authorized representative. The written information to be provided must include all required and appropriate additional elements of consent disclosure as described in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the **WORKSHEET: Criteria for Approval and Additional Considerations**.
- Written information describing the research **does not need to be provided** to the subject or the subject’s legally authorized representative.

2 Waiver of Documentation of the Consent Process – Consent not Normally Required Outside of the Research Context (21 CFR 56.109(c)(1) and 45 CFR 46.117(c)(1)(ii)) (All must be “Yes”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research presents no more than minimal risk ¹ of harm to subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research involves no procedures for which written consent is normally required outside of the research context. <i>Provide protocol specific findings justifying this determination:</i>

	CHECKLIST: Waiver of Documentation of the Consent Process			IRB # \$\$IRB Number\$\$
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Select one of the following:

- Written information describing the research **is to be provided** to the subject or the subject’s legally authorized representative. The written information to be provided includes all required and appropriate additional elements of consent disclosure as described in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in the **WORKSHEET: Criteria for Approval and Additional Considerations**.
- Written information describing the research **does not need to be provided** to the subject or the subject’s legally authorized representative.

3 Waiver of Documentation of the Consent Process – Distinct Cultural Groups (45 CFR 46.117(c)(1)(iii)) (All must be “Yes”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The research is not FDA-regulated.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The subjects or Legally Authorized Representatives are members of a distinct cultural group or community in which signing forms is not the norm. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	The research presents no more than Minimal Risk of harm to subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/> Yes <input type="checkbox"/> No	There is an appropriate alternative mechanism for documenting that informed consent was obtained. <i>Provide protocol specific findings justifying this determination:</i>

Select one of the following:

- Written information describing the research **is to be provided** to the subject or the subject’s legally authorized representative. The written information to be provided includes 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**
- Written information describing the research **does not need to be provided** to the subject or the subject’s legally authorized representative.