

OIA-317 WORKSHEET: Short Form of Consent Documentation

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The purpose of this worksheet is to provide support for IRB members or designated reviewers using the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when reviewing research involving the short form consent form documentation. This worksheet, or equivalent, is to be used. It does not need to be completed or retained.

1 Requirements for Written Short Form Consent Form Documentation (Check if “Yes.” All must be checked.)	
<input type="checkbox"/>	The written short form consent form states that the elements of consent have been presented orally to the subject or the subject’s legally authorized representative (LAR).
<input type="checkbox"/>	There is a written summary ¹ of what is to be said to the subject or the subject’s LAR that incorporates the required and appropriate additional consent elements in <i>OIA-314B WORKSHEET: Requirements for Informed Consent</i> , or equivalent.
<input type="checkbox"/>	The consent document and summary are accurate and complete.
2 Requirements for Short Form Consent Form Process	
<input type="checkbox"/>	An impartial witness will be present during the entire consent discussion.
<input type="checkbox"/>	For subjects who do not speak English, the witness is conversant in both English and the subject’s or the LAR’s language.
3 Requirements for Signature	
<input type="checkbox"/>	The subject or the subject’s LAR will sign and date the short form consent form.
<input type="checkbox"/>	The witness will sign and date the short form consent form and the summary.
<input type="checkbox"/>	The person obtaining consent will sign and date the summary.
<input type="checkbox"/>	If a subject or the subject’s LAR is unable to read: An impartial witness will be present during the entire consent discussion. The consent document witness signature line indicates that the witness was present for the entire consent discussion; the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject’s LAR; and that consent was freely given.
4 Requirements for Documentation to be Provided to Subjects	
<input type="checkbox"/>	A copy of the signed and dated summary will be given to the subject or the subject’s LAR.
<input type="checkbox"/>	A copy of the signed and dated short form consent form will be given to the subject or the subject’s LAR.
<input type="checkbox"/>	If there is a signature line for a subject’s LAR or parent, the IRB has approved inclusion of adults unable to consent, or <u>children</u> , respectively.

¹ The written summary may be a separately approved summary or the approved consent document in English.