



WORKSHEET: Short Form of Consent Documentation

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HRP-317	10.11.2013	1 of 1

The purpose of this checklist is to provide support for IRB members or Designated Reviewers using the WORKSHEET: Criteria for Approval (HRP-314) when reviewing research involving the short form of consent documentation. This worksheet is to be used. It does not need to be completed or retained.

1 Short Form of Consent Documentation (Check if “Yes”. All must be checked)

<input type="checkbox"/>	The written consent document states that the elements of consent have been presented orally to the subject or the subject’s legally authorized representative.
<input type="checkbox"/>	There is written summary of what is to be said to the subject or the legally authorized representative that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval (HRP-314).
<input type="checkbox"/>	The consent document and summary are accurate and complete.
<input type="checkbox"/>	An impartial witness is 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 language of the subject or the subject’s legally authorized representative.
<input type="checkbox"/>	The subject or the subject’s legally authorized representative will sign and date the short form consent document and the summary.
<input type="checkbox"/>	The witness will sign and date the short form consent document and the summary.
<input type="checkbox"/>	The person obtaining consent will sign and date the short form consent document and the summary.
<input type="checkbox"/>	When a subject or the subject’s legally authorized representative is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that 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 legally authorized representative, and that consent was freely given.
<input type="checkbox"/>	A copy of the signed and dated summary will be given to the person signing the document.
<input type="checkbox"/>	A copy of the signed and dated consent document will be given to the person signing the document.
<input type="checkbox"/>	If there is a signature line for a legally authorized representative or parent, the IRB has approved inclusion of adults unable to consent or children.