



WORKSHEET: Short Form of Consent Documentation

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6.202 (HRP-317)	04.24.2024	1 of 1

The purpose of this worksheet is to provide support for IRB members or Designated Reviewers using the 4.202 (HRP-314) - WORKSHEET: Criteria for Approval 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.

NOTE: When Surrogate Consent is required (i.e., enrolling an adult represented by a surrogate to make decisions on their behalf), per NJ State Statute 26:14.1-14.5 Access to Medical Research Act, use of a short form consent process is not permitted. Instead, translation of the long form consent into the language understandable to the Surrogate must occur.

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.
<input type="checkbox"/>	There is a written summary of what is to be said to the subject that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in 4.202 (HRP-314) - WORKSHEET: Criteria for Approval.
<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.
<input type="checkbox"/>	The subject will sign and date the short form consent document.
<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 summary.
<input type="checkbox"/>	When a subject 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 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 parent or parents, the IRB has approved inclusion of children. If documentation of child assent is by having the child sign the Short Form Consent with the parent, a signature line for assent of the child also appears.