

HRP-317 | 9/11/2023

WORKSHEET: Short Form of Consent Documentation

The purpose of this checklist is to provide support for IRB members or <u>Designated Reviewers</u> using HRP-314 - WORKSHEET - Criteria for Approval when reviewing research involving the short form of consent documentation. (<u>LAR</u> = "subject's <u>Legally Authorized Representative</u>")ⁱ

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

- □ The written consent document states that the elements of consent have been presented orally to the subject or the subject's LAR.
- □ There is written summary of what is to be said to the subject or <u>LAR</u> that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 WORKSHEET Criteria for Approval.
- □ The consent document and summary are accurate and complete.
- \Box An impartial witness is present during the entire consent discussion.
- □ For subjects/representatives who have a preferred language other than English, the witness is conversant in both English and the language of the subject or the subject's <u>LAR</u>.
- \Box The subject or the subject's <u>LAR</u> will sign and date the short form consent document.
- □ The witness will sign and date the short form consent document and the summary. If the witness is not physically present, as is the case for a remote interpreter, the ID number of the witness is written on the witness signature line of the short form consent and the summary.
- \Box The person obtaining consent will sign and date the summary.
- □ When a subject or the subject's <u>LAR</u> 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 <u>LAR</u>, and that consent was freely given.
- □ A copy of the signed and dated summary will be given to the subject or the subject's LAR.
- □ A copy of the signed and dated consent document will be given to the subject or the subject's LAR.
- □ If there is a signature line for a <u>LAR</u> or parent, the IRB has approved inclusion of adults unable to consent or children.

ⁱ This document satisfies AAHRPP elements II.3.F, III.1.F