HRP-317 | 1/1/2024

WORKSHEET: Short Form of Consent Documentation

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

☐ An impartial witness[ii] is present during the entire consent discussion.

☐ For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject's LAR.

☐ The subject or the subject's LAR will sign and date the short form consent document.

☐ The witness will sign and date the short form consent document and the summary.

☐ The person obtaining consent will sign and date the summary.

☐ When a subject or the subject's LAR 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 LAR, and that consent was freely given.

☐ A copy of the signed and dated summary will be given to the person signing the document.

☐ A copy of the signed and dated consent document will be given to the person signing the document.

☐ If there is a signature line for a LAR or parent, the IRB has approved inclusion of adults unable to consent or children.

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

[ii] The FDA recommends "…that an impartial third party not otherwise connected with the clinical investigation (for example, clinical staff not involved in the research, a patient advocate or an independent interpreter) serve as the witness. The witness must be present physically or by some other means, for example, by phone or video conference, during the oral presentation, not just the signing of the consent form (21 CFR 50.27(b)(2))." *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.