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The participant's signature on the consent form is only one part of the informed consent process. The participant's/legally authorized representatives signature on the consent form is considered "documentation of informed consent". The conversation that takes place before signing the consent document is considered the consent process. The consent process is ongoing throughout the lifecycle of the research and requires the researcher to document questions and concerns at the time of consent and throughout research participation.

The discussion that takes place before signing is equally critical and must be clearly documented. Thoughtful documentation helps demonstrate that participants were given adequate time, complete and understandable information, and a meaningful opportunity to ask questions before deciding whether to participate. When consent discussions are not documented, it can be difficult to show that informed consent was properly obtained. Missing documentation may raise concerns during audits or monitoring visits and can result in findings, corrective actions, or requests for additional clarification.

A brief consent documentation note in the medical record provides important context around the consent process. Alternatively, you can document consent by using the HRPP Consent Documentation Template to include in the research file. This note helps show that the participant understood what participation entails, that consent was obtained voluntarily, and that all required elements of informed consent were addressed. While the signed consent from remains essential, it does not replace the need to document the conversation itself.

The consent documentation note may include a summary of the topics discussed, participant questions and responses, confirmation that the most current IRB-approved consent was used, and any additional supports provided during the discussion (such as interpreter use). These notes should complement – not substitute for – the official consent form.

Proper documentation also supports ongoing study oversight. Clear records help research teams prepare for audits or monitoring visits, demonstrate regulatory compliance, and identify opportunities to improve consent practices across studies.

Why it matters:

- Federal regulations (45 CFR 46.116) and ICH GCP E6 (R3) require that participants be adequately informed, not merely asked to sign a document.
- Documentation provides evidence of voluntariness, comprehension, and ethical conduct of the consent process.
- Well-written notes support compliance reviews and can highlight areas for process improvement without duplicating the consent form itself.

Tip:

- Ask the HRPP for a Consent Documentation Template to help standardize your notes. Consent documentation should be stored in the participant's research file and, when applicable, in the medical record, in accordance with study and institutional requirements.

01.07.2026 – Vanessa Roxo