UNC School of Medicine Clinical Research Support Office

CRSO: IN THE KNOW

Documenting Informed Consent

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The requirements for obtaining and documenting informed consent for research studies are defined by the FDA, DHHS, ICH GCP, and local IRBs. The requirements vary depending on the exact study characteristics. Knowing what applies and how to operationalize the required procedures for various studies can seem overwhelming, but there are some general best practices to keep in mind!

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Under HHS regulations at 45 CFR 46.117 and FDA regulations at 21 CFR 50.27, when informed consent is required, it must be documented using an IRB-approved informed consent form (ICF) signed by the participant or the participant's legally authorized representative (LAR) unless the IRB specifically waives the requirement for documentation of informed consent.

Additionally, FDA regulations require that the ICF is dated by the participant or the participant's LAR at the time of consent. Good Clinical Practice guidelines at ICH E6(R2) 4.8 further requires that the ICF is signed and personally dated by person conducting the informed consent discussion. For studies conducted under an IND or IDE, FDA regulations specify that the case history for each participant shall document that informed consent was obtained prior to participation in the study.

Considering all these varying requirements, the UNC IRB has established the standard process for obtaining informed consent to include signature and date by the participant (or LAR) and the person obtaining the informed consent (see OHRE SOP 1101). In addition, the UNC IRB strongly recommends that investigators further document details of the informed consent **process** beyond signatures on the consent document, particularly for studies that are greater than minimal risk. Documenting the process verifies that informed consent did take place if the signed consent document is lost, that informed consent was obtained prior to an individual's participation in the study, that any questions or concerns raised by the participant were addressed during the informed consent process, and that consent is ongoing.

Documentation of the informed consent **process** can be achieved through utilization of a checklist or form and/or by writing a contextual note that is maintained with the study record. Documentation should ideally include:

- Study and participant identifier, date and time of discussion and name and/or signature of person completing the form/note
- List of individuals present during the consent discussion
- Confirmation that the participant was given enough time to read the consent form in their preferred language, verbalized understanding of the information, had an opportunity to ask questions, and agreed to participate prior to any study-related procedures
- Any questions from the participant and notation that the questions were answered
- Confirmation that the current IRB-approved consent form was used and that a copy of the consent form(s) was provided to the subject
- Notation of the use of an LAR, a verbal consent process, the short form method, or other unique circumstances

Templates and Additional Resources

You can find various templates for documenting the informed consent process on the CRSO Resource webpage. These templates may be modified to meet your individual study needs and workflows.

Additionally, the CRSO is currently developing an SOP to describe the general best practices and steps that should be followed when obtaining and documenting informed consent. As SOPs are developed, they will be shared with the SOM Research Community for review and feedback to ensure that the SOPs are appropriate and useful for every study team. Please stay tuned!

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