Guidance on Documenting Informed Consent

The purpose of this document is to provide Overall Principal Investigators and their research teams guidance on documenting the informed consent process. This documentation is required in addition to the signed informed consent form.

Note: Per CON-100, the person obtaining informed consent must document the consenting process in the medical record for all interventional research involving a drug, device, biologic, radiation, or surgery.

Method 1: Narrative Format
Describe how and when the consenting process occurred. Required elements include:

- A description of the consenting process
- The date(s) during which the process occurred
- A statement that the subject (or legally authorized representative) has received an explanation of the content of the informed consent document.
- If witnesses or others were present, this must be noted.
- When applicable, note that the subject (or legally authorized representative) had an opportunity to ask questions about the research.
- A statement that the subject (of legally authorized representative) received a signed and dated copy of the informed consent document.

Example Narrative Entry for Documenting Consent Process

[Current Date]: We discussed the rationale of the clinical trial, potential risks, the procedures that would be required as part of participation in the trial, the schedule of trial required visits, any financial issues that might be involved due to participation in the trial, that appropriate efforts would be made to maintain his/her confidentiality while a participant on the trial, and alternatives to clinical trial participation. These alternatives include [*list alternatives, along with other details as needed*]. We also acknowledged the experimental nature of the clinical trial and pointed out that no guarantees can be made regarding benefits to participating. We emphasized that clinical trial participation is voluntary, that his/her care would not be jeopardized if he/she declined participation, and that he/she is able to withdraw at any point. He/she realizes that the consent for participation is an ongoing process and that he/she can ask questions at any time. The subject (or legally authorized representative) read the informed consent document in detail, and his/her questions were answered to his/her satisfaction. He/she signed and dated the informed consent document, and a copy of the signed document was provided to him/her. The informed consent document was signed before any research procedures were performed.
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Method 2: Use the DF/HCC Template
Print a copy of the DF/HCC Informed Consent Documentation template from the DF/HCC website. The person obtaining informed consent should complete all elements and sign and date where indicated. Attach the documentation to the informed consent form, and send a copy for scanning into the medical record as required by CON-100 and institutional policy.