Documenting Informed Consent

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Outline

- What is Documentation of Informed Consent?
- Which Method is Used When?
- What is a Short Form Informed Consent Document?
- Using the Long Form Informed Consent
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What is Documentation of Informed Consent?

- Refers to the regulatory requirements for documenting the consent process
- Does not include any institutional requirements
  - Uploading consents to the EMR
  - Writing a consent note in the EMR or study file
- Accomplished by one of two methods (unless waived)
  - Using the long form consent form
  - Using the short form consent form
- Documentation may be pen & paper or electronic
  - Must be Part 11 compliant if FDA regulated
  - Must be HIPAA compliant if PHI (e.g. diagnosis) is in ICF

Which Method is Used When?

- Long Form Method
  - Used when the study team has a long form consent in the language that the subject or LAR is comfortable communicating
  - If enrolling a non-English speaker, must have IRB approval
- Short Form Method
  - Used when the study team is approved to enroll non-English speaking subjects; AND
  - The study team does not have a long form consent in the language that the subject or LAR is comfortable communicating; AND
  - OIA has published a short form in the subject's/LAR's language.

What is a Short Form Informed Consent Document?

- States that the elements of informed consent will be/have been presented orally to the subject or LAR
- States that the key information (as required by the Common Rule) has been presented first
- States that the subject/LAR will be given a copy of the short form and written summary (i.e. long form consent form)
- Provides contact information for the study team and OIA
- Informs subject/LAR that study participation in voluntary

Using the Long Form Informed Consent

- The IRB reviews and approves a consent document as normal
- The researchers use the approved ICF and OIA-090 to conduct the consent process
- The researchers use the approved ICF and OIA-091 to document consent
- Any changes to the consent process or documentation must be approved by the IRB
  - Includes translations of the long form consent document
  - Includes enrolling non-English speakers

Using the Short Form Informed Consent

- The IRB reviews and approves a consent document as normal and approves the study to enroll non-English speakers
- Subject or LAR presents who does not speak a language for which there is an approved long form consent document
- Study team downloads the appropriate OIA published short form
- Study team provides translated short form to subject/LAR and reads the long form consent form to the subject/LAR with an interpreter and witness who understands both languages
  - Interpreter may also serve as the witness
- Consent is documented in accordance with OIA-091
- Studies greater than minimal risk or with multiple visits/interactions:
  - Long form is to be translated and the subject/LAR reconsented within 30 days.

References

- 21 CFR 50.27
- 45 CFR 46.117
- OIA-090
- OIA-091
- OIA Published Short Forms