Informed Consent – Source Documentation and EMR

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Session Objectives

- Discuss procedures for best documentation practices of the informed consent
- List appropriate documentation requirements for informed consent
- Common audit findings

Informed Consent

- Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation
- Facilitating the potential subject's comprehension of the information
- Providing adequate opportunity for the potential subject to ask questions and to consider whether to participate
- Obtaining the potential subject's voluntary agreement to participate
- Continuing to provide information as the clinical investigation progresses or as the subject or situation requires.

FDA Guidance: “Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors”

Informed Consent Responsibilities

- The Principal Investigator (PI) does not have to personally conduct the consent process
- Can be delegated task to another individual knowledgeable about the research (qualified by training and knowledgeable regarding area of study)
- Delegation of the activity must be documented
- Individual conducting informed consent procedures must ensure effective implementation

ICH-GCP – Source Documentation

ICH-GCP defines source documentation as

"All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."

Good Documentation Practices

- ALCOA-C
  - Attributable
  - Legible
  - Contemporaneous
  - Original
  - Accurate
  - Complete

Consent Documentation

- Ensure that **all** signatures are complete on the current approved ICF
- Provide a copy of consent to participant or Legally Authorized Representative
- Retain original fully signed ICF
- After the informed consent process is complete, it is important to document your notes of the Informed Consent Process

Why is documentation important?

- To document softer processes of ICF – conversation, comprehension, voluntariness etc.
- Accurately remind ourselves and confirm the processes that led up to the patient signing consent (reconstruction)
- Procedures are clear to any external person such as auditor or FDA inspector
- Written confirmation – study related procedures were not done before signing consent
- **Ongoing** consent
- Safety and protection of human subjects
- ALCOA - C

What constitutes good informed consent process documentation?

- Study title, ICF version used
- Time signed
- Reasonable time given
- Comprehension
- No undue coercion
- Voluntary
- Opportunity given to ask questions (could also document the Q&A)
- Involvement of PI in the consent process if possible (even if delegated)
- No study related procedures were done before signing the ICF

Special considerations

- Witness and/or translator (if applicable) and who signed on which specific documents. For ex. Translated ICF, short form etc.
- LAR (legally authorized representative)
- Assessments or pictographs, if used
- Partner consent forms
- Assents

Common audit findings with IC process

- Missing signatures – participant/ LAR
- Missing HIPAA authorization
- No informed consent note
- Missing checkboxes for additional research components – additional sample collection, future use for research
- Missing elements of informed consent notes
- Discrepancies in documentation (ex. Conducted by PI per ICF but process documentation signed by CRC)

Informed Consent Sample Note

Name: John Smith

Short Title: DP1822 CHAC

The above named patient has volunteered to participate in the above named research study. This patient was counseled about their part in the participation of the research study and I have reviewed and discussed the informed consent form provided. This patient was given reasonable time to consider their decision to become a research subject in the absence of coercion or undue influence. The patient was given an opportunity to have their questions about the clinical trial and/or involved medical procedures answered. An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

No study related procedures were performed prior to the subject signing informed consent. Contact information was given to the patient.

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EMR Documentation of IC process

- EMR - research notes/ study coordinator notes/ physician notes
- Upload copy of the ICF into the EMR
- Beneficial for
  - Medicare billing compliance
  - Safety of participants in case of emergency
  - Could function as certified copies (if you have a policy in place) for remote monitoring and auditing

Exceptions to Documentation in the EMR

- Your institutional policy prevents it
- Studies deemed sensitive or stigmatizing (e.g., behavioral health, addiction studies)
- In such cases, use paper documentation in the research chart.

Scenario 1

Mr. John Doe has volunteered to participate in this trial. This patient was given a copy of the consent form for review. This patient was given reasonable time to consider their decision to become a research subject in the absence of coercion or undue influence. The patient was given an opportunity to have their questions about the clinical trial and/or involved medical procedures answered. An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

Contact information was given to the patient.

Ideal Scenario

STUDY IRB#: 7897

STUDY TITLE: Chase ICF version 2.0 (IRB approval dates 1/1/22 – 1/1/23)

Mr. John Doe has volunteered to participate **in the above mentioned trial**. This patient was given a copy of the consent form and we **reviewed and discussed the trial. They were counselled about their part in this research.** This patient was given reasonable time to consider their decision to become a research subject in the absence of coercion or undue influence. The patient was given an opportunity to have their questions about the clinical trial and/or involved medical procedures answered. An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

No study related procedures were performed prior to the subject signing informed consent.

Contact information was given to the patient.

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Scenario 2

Name: Mrs. Jane Smith

Short Title: DP1822 CHAC IRB no: 9098

The above named patient has volunteered to participate in the above named research study. This patient was counseled about their part in the participation of the research study and I have reviewed and discussed the informed consent form provided.

Patient asked questions about benefits and compensation, which was answered. An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

No study related procedures were performed prior to the subject signing informed consent. Contact information was given to the patient.

No documentation of whether reasonable time was given or opportunity to ask questions was given

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Ideal Scenario

Name: Mrs. Jane Smith
Short Title: DP1822 CHAC IRB no: 9098

The above named patient has volunteered to participate in the above named research study. This patient was counseled about their part in the participation of the research study and I have reviewed and discussed the informed consent form provided. **This patient was given reasonable time to consider their decision to become a research subject in the absence of coercion or undue influence. The patient was given an opportunity to have their questions about the clinical trial and/or involved medical procedures answered.**

Patient asked questions about benefits and compensation, which was answered**. We discussed the trial consequences at length and provided the patient with our contact information if they had any further questions.** An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

No study related procedures were performed prior to the subject signing informed consent. Contact information was given to the patient.

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Scenario 3

Name: Mrs. Jane Smith
Short Title: DP1822 CHAC

The above named patient has volunteered to participate in the above named research study. This patient was counseled about their part in the participation of the research study and I have reviewed and discussed the informed consent form provided. This patient was given reasonable time to consider their decision to become a research subject in the absence of coercion or undue influence. English was not this patient's primary language.

The patient was given an opportunity to have their questions about the clinical trial and/or involved medical procedures answered. An investigator was available during the informed consent process to discuss the trial's risks, benefits and other aspects with the potential subject.

In accordance with FDA informed consent Regulations (21 CFR 50.27), the patient has been provided with a copy of the Informed Consent Form. A copy will also be filed in the patient's medical record.

No study related procedures were performed prior to the subject signing informed consent. Contact information was given to the patient.

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Ideal scenario considerations

- If an interpreter or translator was utilized
- Witness
- Translated ICF or short forms
- Who signed what

Questions?

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