Informed Consent: Process and Documentation

MARGARET HUBER, BSN, RN, CHRC
COMPLIANCE MANAGER
OFFICE OF COMPLIANCE
SHARA KARLEBACH, WHNP-BC, CIP
QA & EDUCATION CONSULTANT
EMORY IRB

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THE SPEAKERS HAVE NO CONFLICTS FOR THIS PRESENTATION

Objectives

- Describe the basic process of obtaining informed consent
- Explain documentation of the consent process
- Identify commonly observed mistakes in the consent process

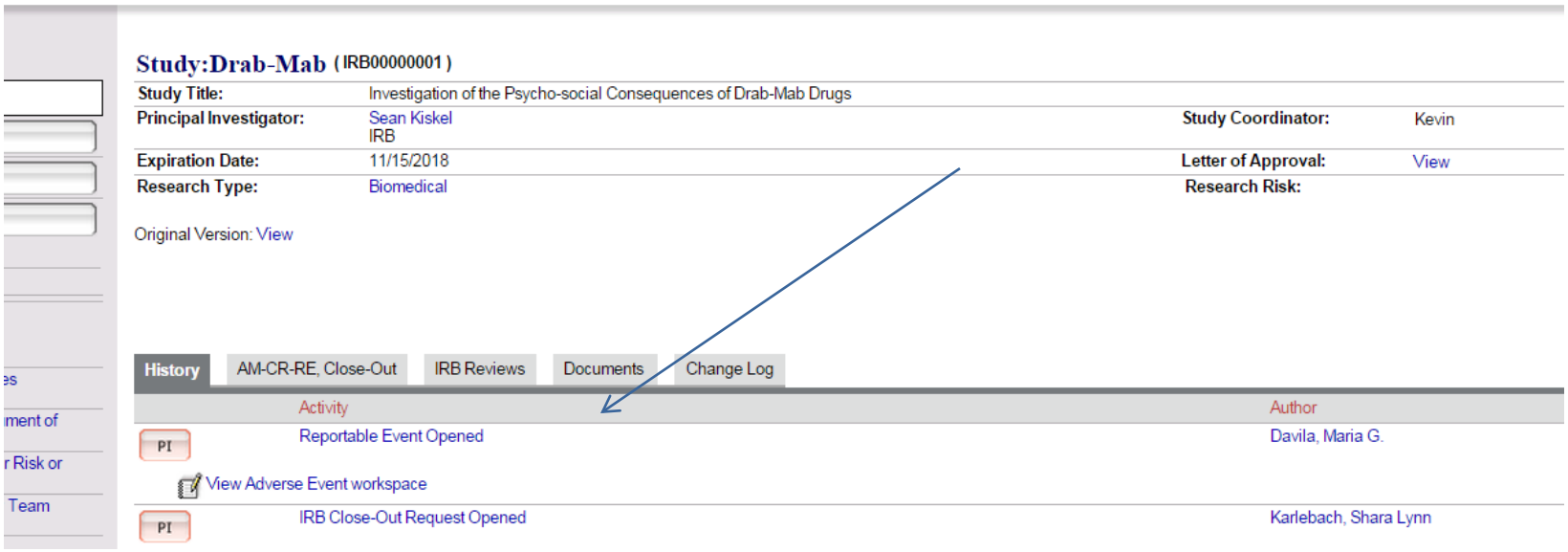
Informed Consent: Process + Documentation

- More than just a signature on a form
- Process of information exchange that may include:
  - Subject recruitment materials
  - Verbal instructions
  - Reading and signing the Informed Consent Form (ICF)
  - Q+A sessions and measures of subject understanding
- Documentation that the consent process has been completed correctly is crucial

Who Handles the Consent Process?

- Person should be **trained** regarding informed consent process and be **knowledgeable** about study
- FDA Requirements: IRB must know **who** will conduct consent process
  - FDA does not require the that the PI personally conduct the consent process, but the **PI is always responsible** for ensuring that the process is completed correctly
  - Study team should verify who can conduct the consent discussion with the sponsor and staff members who will obtain consent should be listed on the delegation of authority log, if applicable

Where to find the approved consent documents



Consent Discussion

- An approved study team member should review the form with the subject and have a **conversation** about the study
  - The conversation should allow for the subject to ask any questions he or she may have and for the researcher to assess the subject's level of understanding
  - The study team should take the time to ensure the subject understands all aspects of the study thoroughly, even if the subject claims to have read the document prior to the discussion

Documentation

- The subject should print his or her name, sign, date, and time the consent document.
- The person obtaining consent should then print, sign, date and time the consent document

Consent and Authorization

Please print your name and sign below if you agree to be in this study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed consent to keep.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

How to obtain written consent by phone

- First, make sure this method was approved by the IRB
- Send the ICF to the subject through the IRB-approved method
- Carry out the consent process by phone while the subject or representative reads along
- After the discussion, the subject or representative can sign the form and return it to investigators via mail, fax, secure email, or by posting it to a secure website
  - "Secure" means HIPAA-compliant if HIPAA applies to your study
- The subject may also bring the signed and dated consent form to the next study visit
- Be sure that the person obtaining consent signs and dates at the time the returned form is truly received
- Document any delays in the Consent Process Note. Do not provide a date or a time that is inaccurate.

How to obtain written consent by phone with minor subjects

- Use the same procedure to obtain consent from the parent or legal guardian and assent from the minor subject
  - Be sure to document assent based on age-based guidelines, or IRB requirements
- If the only contact to obtain consent is completed remotely, please contact the IRB to decide how to appropriately verify the identity of the parent or guardian providing consent for the minor subject's participation

Suggestion for documenting consent by phone

- Add a line for the study team to document the date that the informed consent process was completed by phone
- Another line should document the date when the person obtaining consent received the signed informed consent form

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Date Time - informed consent process completed by phone

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date Time -after subject's signed copy is received**

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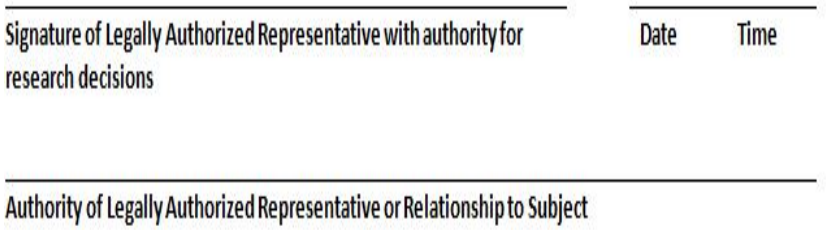
Using a Legally Authorized Representative (LAR)

- In some instances, a subject may not be able to provide informed consent for his or herself:
  - Acute illness, loss of consciousness, or situations where the subject's decision-making power is otherwise compromised
- In these instances, the subject's next-of-kin may be able to provide consent for the subject (see IRB P&Ps which reflect GA State Law on who can be LAR)
  - * For **non-therapeutic** studies, the LAR must have durable Power of Attorney for research; they cannot just be next of kin



Illiterate or blind subjects

- Read the entire consent or assent document aloud and document that the subject cannot read
- An impartial individual should witness the process and document that the process took place, that the subject verbalized understanding, and the subject consented to participate

Subjects Who Do Not Speak English- translators in the consent process

- For Consent documents that are translated into subject's language:
  - A certified translator should be present to assist the person obtaining consent as needed
  - If a non-certified translator is used during the consent process, a statement from the translator attesting to the translator's proficiency in English and the other language (e.g., he/she is a native born speaker of the other language and has completed 4 or 5 years of education in English or other evidence that he/she speaks and reads both languages fluently) should be documented in the consent process note

Subjects Who Do Not Speak English- documenting the consent process

- It is appropriate for the person obtaining consent to sign the document printed in the translated language
- An impartial witness must sign, after the subject and the person obtaining consent have signed the ICF
  - There should be a separate line for a witness signature on the translated ICF
  - The impartial witness can be the same person as the translator

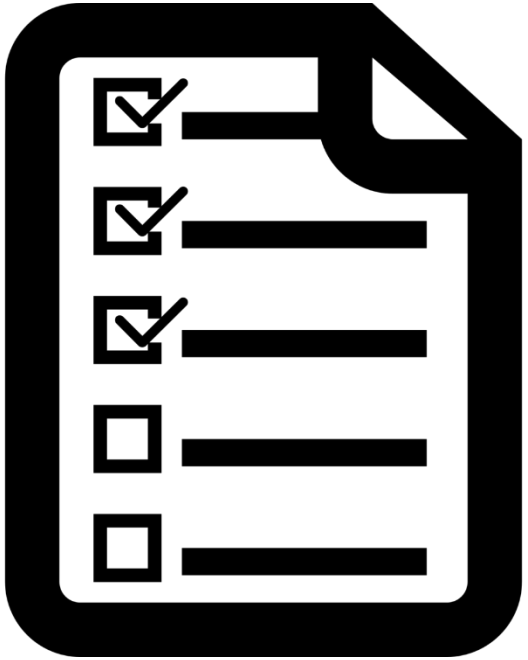
When to use a "Short Form"

- A short form is a consent document that informs the subject, *in their own language*, what they should expect to be told about the study
- The study must be IRB-approved for use of a short form. The form itself does not need IRB approval as long as the IRB-supplied forms are used (see next slide)
  - If study team wishes to create their own short form in a language not offered by Emory IRB or CHOA, the form must be submitted to the IRB and approved first
- Subject signature on the form confirms that the required information has been covered during the consent discussion (which requires certified interpreter, with rare exceptions)
- This form is not appropriate if a study is expecting to recruit more than one or two subjects who speak the language and who are not proficient in English

Where to find IRB approved Short Forms

Documenting Use of Short Form (Non-FDA)

- Obtaining Consent
  - Witness signs Short Form and ICF
  - Translator signs nothing, unless serving as witness
  - Person obtaining consent signs ICF
- Giving Consent
  - Participant, Parent of a Minor, or Legally Authorized Representative signs the Short Form



Documenting Use of Short Form (FDA)

- For studies involving FDA-regulated products:
  - The witness and person obtaining consent must sign both the short form and the ICF
  - A copy of the signed short form and ICF must be given to the subject

Documentation of Consent for Optional items when Using Short Form

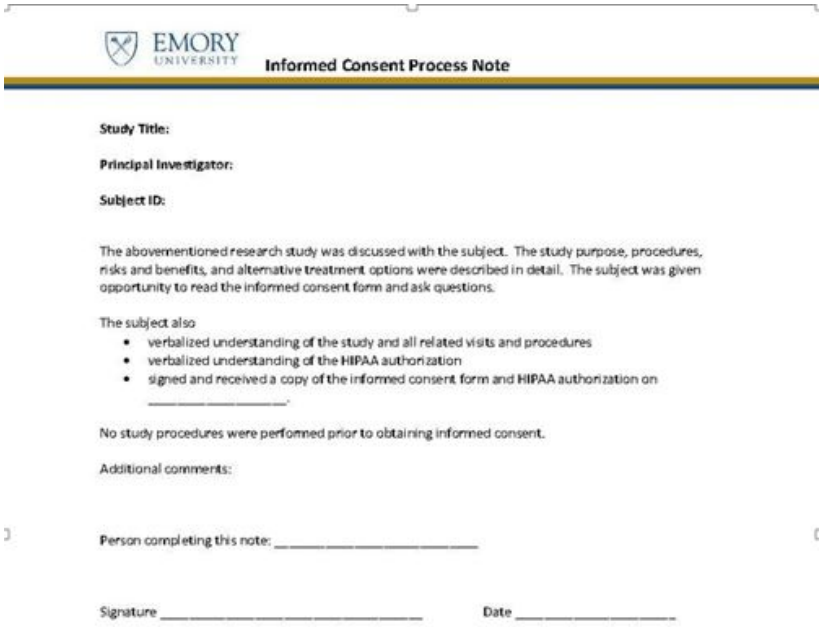
- The translator must indicate the subject's choice regarding options in the English ICF and initial each choice
- The subject's choices should also be listed in a comment written by the translator on the short form

You're not done yet:

- Provide the subject a copy of the form to keep for reference
  - The form has contact information in it in case the subject has any questions later
- If the study is following ICH-GCP, make sure the subject receives a copy of the **signed** ICF

You're not done yet:

- Verify that the consent form is complete
- Add an Informed Consent Process Note to the subject's file
  - You can develop your own format if desired
  - Use the template found under Clinical Trial Tools on these websites: CTAC, IRB, OC & OCR; this template can be modified to include specific documentation of standard processes.



EMORY UNIVERSITY

Informed Consent Process Note

Study Title:

Principal Investigator:

Subject ID:

The abovementioned research study was discussed with the subject. The study purpose, procedures, risks and benefits, and alternative treatment options were described in detail. The subject was given opportunity to read the informed consent form and ask questions.

The subject also

- verbalized understanding of the study and all related visits and procedures
- verbalized understanding of the HIPAA authorization
- signed and received a copy of the informed consent form and HIPAA authorization on _____.

No study procedures were performed prior to obtaining informed consent.

Additional comments:

Person completing this note: _____

Signature _____ Date _____

Commonly Observed Errors in Consent Documentation

- Faxed/Emailed forms: wrong date or time is used
- Person obtaining consent signs before subject
- Person obtaining consent dates and times subject's signature
- Corrections made inappropriately
- Consents faxed/emailed when the study wasn't approved for that process

Commonly Observed Errors in Consent Documentation

- Fields left blank in the ICF
- The original document cannot be located, only a copy exists
- Unapproved study staff performing informed consent discussion
- No documentation of consent process note or note to file regarding irregularities

References

- 21 CFR § **50.27** Documentation of informed consent
- 21 CFR § **312.62** Investigator recordkeeping and record retention
- 21 CFR § **812.140** Records
- FDA Guidance E6 Good Clinical Practice § 4.8
- FDA IRB Information Sheets – "A Guide to Informed Consent"

Contacts

- Margaret Huber, BSN, RN, CHRC
  mhuber@emory.edu
  404-727-2233

- Shara Karlebach, WHNP-BC, CIP
  swilli7@emory.edu
  404-712-0727