

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 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

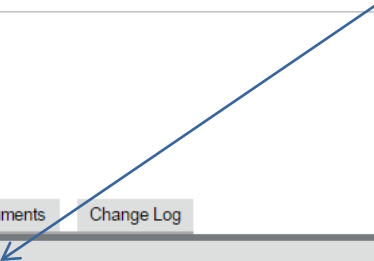
Study: Drab-Mab (IRB00000001)

Study Title:	Investigation of the Psycho-social Consequences of Drab-Mab Drugs		
Principal Investigator:	Sean Kiskel IRB	Study Coordinator:	Kevin
Expiration Date:	11/15/2018	Letter of Approval:	View
Research Type:	Biomedical	Research Risk:	

Original Version: [View](#)

History | AM-CR-RE, Close-Out | IRB Reviews | **Documents** | Change Log

	Activity	Author
	Reportable Event Opened	Davila, Maria G.
 View Adverse Event workspace		
	IRB Close-Out Request Opened	Karlebach, Shara Lynn



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

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

Signature of Legally Authorized Representative with authority for research decisions

Date Time

Authority of Legally Authorized Representative or Relationship to Subject

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

The screenshot shows a website interface with a navigation bar at the top containing links for HOME, ABOUT, POLICIES, FORMS & GUIDANCE, EDUCATION, EIRB, MEMBERS, and PARTICIPANTS. The 'FORMS & GUIDANCE' link is highlighted. On the left side, there is a vertical menu with categories: New Submission Guidance, Consent Toolkit (with sub-links for Instructions & Guidance, Short Forms, and Waivers/Alterations), Does My Project Need IRB Review?, Stamping Template & Guidance, Frequently Asked Questions, Clinical Studies, Sociobehavioral & Public Health, Reportable Events, and External IRBs. The main content area displays a breadcrumb trail: Home » New Submission Guidance » Consent Toolkit » Short Forms. Below this is the title 'Short Forms' in a large, bold font. A paragraph explains that a short form consent is used for non-English speaking subjects when a translated version is not available. It states that the procedure is detailed in the IRB Policies and Procedures - Section 44, and that a step-by-step guide is provided as a coversheet. A list of available languages follows, starting with 'Emory Short Form Consent - English (For Reference Only)' and including Arabic, Armenian, Chinese, French, Gujarati, Japanese, and Korean.

HOME ABOUT POLICIES FORMS & GUIDANCE EDUCATION EIRB MEMBERS PARTICIPANTS

New Submission Guidance

Consent Toolkit

- Instructions & Guidance
- Short Forms
- Waivers/Alterations

Does My Project Need IRB Review?

Stamping Template & Guidance

Frequently Asked Questions

Clinical Studies

Sociobehavioral & Public Health

Reportable Events

External IRBs

Home » New Submission Guidance » Consent Toolkit » Short Forms

Short Forms

A short form consent is used to enroll non-English speaking subjects when a version of the consent form translated into the subject's language is not available. A short form is intended to allow the enrollment of a non-English speaker when it was unexpected that such a language would be necessary. The procedure for using a shortform is described in the IRB Policies and Procedures - Section 44. A step-by-step guide to using a short form is provided as a coversheet on each document.

- **Emory Short Form Consent - English** *(For Reference Only)*
- Emory Short Form Consent - Arabic
- Emory Short Form Consent - Armenian
- Emory Short Form Consent - Chinese
- Emory Short Form Consent - French
- Emory Short Form Consent - Gujarati
- Emory Short Form Consent - Japanese
- Emory Short Form Consent - Korean

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.

The image shows a screenshot of a form titled "EMORY UNIVERSITY Informed Consent Process Note". The form includes fields for "Study Title:", "Principal Investigator:", and "Subject ID:". Below these fields is a paragraph of text: "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." This is followed by a section "The subject also" with a bulleted list: "• verbalized understanding of the study and all related visits and procedures", "• verbalized understanding of the HIPAA authorization", and "• signed and received a copy of the informed consent form and HIPAA authorization on _____". Below this is the text "No study procedures were performed prior to obtaining informed consent." and a section "Additional comments:". At the bottom, there are lines for "Person completing this note: _____", "Signature _____", and "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