Everything you have ever wanted to know but were afraid to ask
about the
Short Form

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Form of Informed Consent Document:

The informed consent form may be either:

(a) a written consent document that embodies the elements of informed consent that is read by or read to the subject or the subject’s Legally Authorized Representative; or

(b) a **Short Form** written consent document stating that elements of informed consent have been presented orally to the subject or the subject’s Legally Authorized Representative in accordance with the provision below entitled *Use of the Short Form*. 
What Do The Regs Say?

- OHRP “strongly encourages” a fully-translated written consent form.

- Regulations require that informed consent information be presented "in language understandable to the subject" ([http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html))

- They do allow for the “short form” though
How To Use The Short Form

1. The oral presentation and the short form written document should be in a language understandable to the subject;

2. The IRB-approved English language informed consent document may serve as the summary; and

3. The witness should be fluent in both English and the language of the subject. This is a common point of confusion among study teams.
Requirements for Ensuring Compliance with the Short Form Consent Process For Non-English Speakers

If your study targets a particular non-English speaking population, or if you expect to enroll more than 2 people of a specific non-English speaking population, you may be required to translate consent documents into that particular language. Please review the IRB Policies and Procedures for information regarding the translation policy.

Use of a short form is allowed when:
1. The Study Population page in eIRB includes “Subjects who are not able to clearly understand English”;
2. An Emory-provided short form is used or the IRB has approved a research team-provided short form;
3. Use is not expressly prohibited by the IRB; and
4. The study sponsor allows use of a short form.

If any of the above conditions are not met, an amendment requesting permission must be submitted and approved by the IRB prior to using a short form.

Procedure for Using a Short Form:

- No more than 2 short forms of the same language should be used for enrollment in a 12 month period. Any additional uses require consultation with the Emory IRB office.
- The person obtaining consent should ensure that contact information is noted on the short form in the blanks provided, with a name on the first line and phone number on the second line.
- A translator must read the English consent form and verbally translate the information to the subject or the subject’s legally authorized representative (LAR). If the subject is a child six years or older, the approved assent documents should also be verbally translated. The consent process must be witnessed by someone who is fluent in both English and the subject’s language. The translator may serve as the witness unless he or she is a member of the study team.
- A witness, who may also be the translator but cannot be affiliated with the study, must sign both the short form consent and the English consent (signing anywhere on the English consent signature page is acceptable).
  - Studies with optional consent items: The translator must write a comment on the last page of the short form to indicate that the subject made specific choices. The translator should indicate the subject’s choices on the English consent form and include the translator’s initials beside each choice.
- The study subject or LAR must sign the short form consent (not the English version). If an LAR provides consent, it should be recorded as a note in the subject’s research record. If enrolling a child, the assent form is verbally translated but the child does not sign any documents.
- The person obtaining consent must sign the English version of the IRB-approved consent form.
- The study subject, or LAR, must receive copies of the following:
  - The short form consent signed by the subject and the witness
  - The IRB-approved English consent signed by the witness and person obtaining consent

The original signed and dated IRB-approved English consent form should be filed with the original signed and dated short form consent in the subject’s research record.
You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact __________________ at __________________ any time you have questions about the research.

You may contact Emory University IRB at 404-712-0720 if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

____________________________  ____________________
Signature of Participant        Date

____________________________  ____________________
Signature of Witness           Date
Musical Signatures!

- Only the short form itself is to be signed by the subject or the representative.

- The witness shall sign both the short form and a copy of the summary. The witness can sign on the bottom of the summary form, even in cases where there is not a witness signature line.

- The person actually obtaining consent shall sign a copy of the summary.

- A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
Musical Signatures!

Additional requirements for studies involving FDA-regulated products and/or for AVAMC Research:

• The Human Subject or his/her Legally Authorized Representative shall sign and date only the short form (not the written summary). The witness and person obtaining consent both must sign and date the short form and a copy of the summary.

• The original short form and summary must be retained for the files. A copy of the summary and of the signed short form must be given to the subject or to his/her legally-authorized representative.
Optional Substudies etc?

Optional Consent Items for Short Form:

- If the English consent has optional consent items (e.g., extra blood for research, permission for central imaging review), the translator must write a comment on the last page of the short form to indicate the subject made specific choices on the English consent.

- The translator should indicate the subject’s choice (e.g., checks/circles Yes or No) and include the translator’s initials for each choice on the English consent.
What about HIPAA?

The Human Subject or his/her Legally Authorized Representative should sign and date the HIPAA authorization.
Note about Translators

• The IRB does not have a formal policy on who can translate but, best practice is to use translation services.

• Family members really should not be used to translate the consent documents for participants.
• ...“The IRB-approved English language informed consent document may serve as the summary”

• “The IRB must receive all foreign language versions of the short form document as a condition of approval under the provisions of §46.117(b)(2)”

• This is guidance, only

What Does IRB Need To Approve, Again?
The IRB Plan for Approval

• The IRB has multiple foreign-language versions of a standard English short form posted on our website

• These are considered already “IRB Approved”

• Studies can request the option of enrolling via short form at initial submission

• If not requested at initial submission, can request via amendment

• If the language you need is not already approved by the IRB – an AM would be required. Also, you would need to get the short form translated into the target language.
For Example

**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 short form 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
- Emory Short Form Consent - Russian
- Emory Short Form Consent - Spanish
- Emory Short Form Consent - Turkish
- Emory Short Form Consent - Vietnamese
Request at Initial Submission: “Study Population”

- Select “Subjects who are not able to clearly understand English”

<table>
<thead>
<tr>
<th>5.0 *</th>
<th>Indicate the study population types:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. You must select Adults and/or Minors.</td>
<td></td>
</tr>
<tr>
<td>2. You must select at least one additional population type.</td>
<td></td>
</tr>
</tbody>
</table>

- Adults (age 18 and over)
- Minors (under the age of 18)
- Normal volunteers
- Students - elementary school, middle school, high school
- Students - college
- Employees of Emory University or Emory Healthcare
- Patients
- Women of child-bearing potential, Pregnant women and/or fetuses, Lactating women
- Prisoners/Incarcerated
- Cognitively impaired
- Subjects who are not able to clearly understand English
Request at Initial Submission:
“Subjects who are not able to clearly understand English” (aka “the work-around”)

- We will revise our questions. For now, do your best...
- Need to make clear that use will be *rare*
- **Will be on a study-by-study basis**
What kind of study qualifies for the Short Form?

• The IRB will consider the study complexity and the amount and duration of participant involvement when determining if using the short form consent process is appropriate and can be approved.

• The IRB will also consider whether a significant number of people who speak the language in question would be expected to enroll, and may request a translation of the full consent (and HIPAA form, if separate) instead.
Multi-visit study may require written translation post-enrollment

- If a non-English speaking participant is initially consented for a study through an approved short form process, to the extent the study includes ongoing interventions or interactions with the participant, investigators and the IRB may assess the feasibility of translating the full English consent, *as well as other study-related documents*, into the participant’s language whenever possible.
The Literature: Using Family Members as Translators

• Using children is worrisome as they are not capable to deal with stress of parents/family disease (Levine et al, Case Study: A Fifteen-Year-Old Translator, The Hastings Center Report, 34, 2004)

• Issues with misunderstandings: medical terms (Corsellis 2008).

• Limited English proficiency (LEP): policy guidance from US-Corporation for National and Community Service about recipients of federal financial assistance need to provide meaningful assistance to people with LEP

• “The interviewees stated that family interpreters were not able to understand technical terms, had insufficient technical knowledge or would interfere in the communication by speaking for the patients themselves.” (Meyer 2010)
Common Questions:

• Does a translator have to be there for every follow up visit that involves study procedures?
  • Yes, the IRB would expect that a translator is available during follow up. Also, if you plan to re-consent, you should follow the short form process and plan to have a translator available.

• Who signs where?
  • Review the cover sheet for guidance on required signatures. Don’t try to remember!

• Can a family member serve as a witness?
  • Yes, assuming it is not a child. In any case, don’t use a member of the study team.
In summary

- **Who**: unexpected foreign-language speakers
- **What**: Generic short form in their language, oral translation of full English consent
- **When**: initial consent and re-consent
- **Where**: in-person, ideally. If this is not your plan, let us know with the initial submission or AM.
- **How**: Request up-front permission via “Study Population” section of eIRB smartform (otherwise amendment needed); use IRB-provided short form or submit your own for IRB approval; see Short Form cover sheet for who signs what
Short Form Questions?

- Emory IRB
  - irb@emory.edu
  - (404) 712-0720

- Rebecca Rousselle, CIP, Director
  - rrouss2@emory.edu
  - (404) 712-0785

- Shara Karlebach, RN, QA/Education
  - swilli7@emory.edu
  - (404) 712-0727

- Carol Corkran, MPH, CIP, Team Lead
  - ccorkra@emory.edu
  - (404) 712-8545
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For previous presentations and upcoming schedule, visit:

- https://apps.winship.emory.edu/intranet/clinicaltrials/mcr.php
A translator has to be available for follow-up visits that involve study procedures.

A True  B False
Post QUESTION 2
A non-English speaking subject /LAR signs the English version of the consent form.

A True  B False
Post QUESTION 3

The following people may serve as witness to the consent discussion

A. Co-Investigator
B. Subject’s spouse
C. Research coordinator
D. None of the above
Post QUESTION 4
A short form is not required for re-consent.

A True  B False
Post QUESTION 5
Use of a short form is allowed when:

A. The Study Population page in eIRB includes “Subjects who are not able to clearly understand English”
B. An Emory-provided short form is used or the IRB has approved a research team-provided short form
C. Use is not expressly prohibited by the IRB
D. The study sponsor allows use of a short form
E. All of the Above
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