

## Mccaslin,Gailine P

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**From:** Mahoney,Michael P  
**Sent:** Tuesday, January 23, 2018 8:22 AM  
**To:** irbmail-l@lists.ufl.edu  
**Cc:** Mccaslin,Gailine P  
**Subject:** Important info: Enrolling research subjects who do not speak or read English

Attention researchers:

If you wish to obtain informed consent from a research subject who does not speak or read English, you must do one of the following. NOTE: simply using an interpreter is **NOT** sufficient.

1. If you are primarily seeking consent from subjects who do speak and read English, but unexpectedly want to enroll someone who does not speak or read English, you must:
  - a. **Extra “short form”:** Use an IRB approved “short form” that is translated into the subject’s native language. The “short form” is a generic consent form that states general requirements required under the regulations such as the subject is being asked to participate in research, they can refuse to participate without penalty, contact information for the IRB, etc. Based on an analysis of the population in Gainesville, the IRB has already approved short forms in Spanish and Hindi (available on our website, see links below).
  - b. **Interpreter:** Have a competent interpreter fluent in English and the subject’s native language.
  - c. **Summary:** the competent interpreter should present an IRB approved written summary of the protocol. The IRB approved Informed Consent form written in English can serve as the written summary.
  - d. **Researcher:** A member of the research team who is approved by the IRB to obtain informed consent should participate in the process, answer questions, and seek informed consent.
  - e. **Witness:** A witness who is fluent in English and the subject’s native language must witness the informed consent discussion. The competent interpreter may serve as the witness.
  - f. If the subject gives consent to participate, the following must occur:
    - i. The subject (or LAR) should sign and date the “short form”.
    - ii. The witness should sign and date (a) the “short form” and (b) the IRB approved Informed Consent written in English
    - iii. The person obtaining consent should sign and date the IRB approved Informed Consent written in English
    - iv. Give the subject copies of the “short form” and the IRB approved Informed Consent written in English.

We advise that you make a research note to file to document that the above process occurred.

2. If you know that you will be seeking consent from subjects who don’t speak or read English, you must:
  - a. have your Informed Consent form translated into the native language by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.
  - b. have the translated consent approved by the IRB.

### Helpful links:

- Investigator Guideline “*Consenting Subjects Who Cannot Speak or Read English*”: <http://irb.ufl.edu/wp-content/uploads/Consenting-Subjects-Who-Cannot-Speak-or-Read-English.pdf>
- Spanish version of the “short form”: <http://irb.ufl.edu/wp-content/uploads/ICF-spanishshort.pdf>.
- Hindi version of the “short form”: <http://irb.ufl.edu/wp-content/uploads/ICF-Hindi.pdf>

**What if you need a “short form” for a subject who speaks a language other than Spanish or Hindi?**

- You will need to have the “short form” translated by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.
  - The English version of the short form that you can translate may be downloaded at: <http://irb.ufl.edu/wp-content/uploads/frm-icf-short.docx>
- Obtain IRB approval: the IRB must review and approve this translated document. Submit a minor revision to your study. If this is the only change you make the IRB should be able to quickly review and approve the revision.

**Questions?** Please contact the IRB:

- IRB-01: (352) 443-9444 [ufirb-l@lists.ufl.edu](mailto:ufirb-l@lists.ufl.edu)
- IRB-02: (352) 392-0433 [irb2@ufl.edu](mailto:irb2@ufl.edu)
- IRB-03: (904) 244-9427 [IRBSubmission@jax.ufl.edu](mailto:IRBSubmission@jax.ufl.edu)