

GUIDANCE FOR USING THE SHORT FORM CONSENT PROCESS FOR SUBJECTS WHO DO NOT SPEAK ENGLISH

A short form may be used when the majority of study subjects are English speakers and an occasional subject presents who does not understand the English consent form.

1. A short form is a written document providing the elements of informed consent.
2. A short form in the subject's language can be used with an oral presentation of the full English consent form. There must be a witness/translator to the presentation and the witness/translator must be fluent in English and the subject's language.

The IRB will receive all foreign language versions of the short form as a condition of approval.

Once a potential subject has been identified:

1. Complete Form 001 and include justification on Form 001 for the use of the short form.
2. Obtain foreign language short form*, English version of short form consent** and include contact and study information on both short forms. **No other changes can be made to the short forms.**
3. Submit to IRB for Expedited review and approval.

Note: An IRB submission must be made for each subject when the short form consent will be used.

Once foreign language short form is approved by the IRB:

4. The hospital translator services must be used, so in effect the translator will be the witness.
5. A short form must be signed by the study subject and witness/translator. Subject does **NOT** sign English version of the consent form.
6. The witness/translator and person obtaining consent signs the short form and the IRB approved English consent form.
7. The subject must be given copies of the signed IRB approved English version of the consent form and the translated version of the short form.

*The MLH IRB gratefully acknowledges permission of the Johns Hopkins IRB for the approved translations of the short forms available at: <http://irb.jhmi.edu/Forms/ShortFormTranslation.html>

**The English version of the short form consent is available on the ORA website at: <http://www.limr.org/oth/Page.asp?PageID=OTH003889>

Questions? - - Contact the Office of Research Affairs at 484-476-3414 or 484-476-2678