MAIN LINE HOSPITALS INC. IRB
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. The IRB approved English consent form is used to lead the consent discussion in a summary format.

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 an impartial witness and translator. The presentation and the witness/translator must be fluent in English and the subject's language, the translator may act in the role of impartial witness.

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. The PI/research team will follow IRB Policy XII: Informed Consent Documentation, prior to submission of the iMedRIS amendment request for use of Short Form consent.
2. Obtain foreign language short form*, English version of short form consent** and revise the form to include protocol title, Principal Investigator's name, contact and study information on both short forms. **No other changes can be made to the short forms.**
3. Submit to IRB an amendment to protocol request via the iMedRIS system for Expedited IRB review and approval.

   Note: An IRB iMedRIS 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, and the translator must be impartial to the research. The PI may consider use of the translator to act in the role of the impartial witness as applicable.

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: JHM- Revised Common Rule (hopkinsmedicine.org)

**The English version of the short form consent is available on the ORP website at:
Policies, Forms & Guides | Office of Research Protections | Research | Main Line Health

Questions? - -
Contact the Office of Research Protections at
610-225-6221 or 610-225-6222
OR by email at MLH_IRB@mlhs.org

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