

**Children's Hospital and Health System, Inc.
Administrative Policy and Procedure
Children's Research Institute**

**SUBJECT: Human Research Review Board - HRRB –
Non-English Speaking Subjects and-or Legally
Authorized Representatives**

POLICY

I. Purpose:

- A. To define the standards and parameters at Children's Hospital of Wisconsin (CHW) for the involvement of non-English speaking subjects in research.
- B. Specifically, to outline the requirements for obtaining informed consent and other required study documentation of non-English speaking subjects. Note: Although this policy refers to informed consent forms, it is equally applicable to assent forms when the HRRB has determined assent is required.

II. Policy:

- A. Definitions
 - 1. Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in a research study. Under Wisconsin law, a Legally Authorized Representative may be the parent, guardian or legal custodian of a minor, the person vested with supervision of a child under state law, the Guardian of a person adjudged incompetent, as defined under state law, the personal representative or spouse of a deceased subject, or any person authorized in writing by the subject or a health care agent designated by the subject as a principal under state law if the subject has been found to be incapacitated under state law except as limited by the power of attorney for health care instrument.
 - 2. Non-English Speaking Subjects: An individual unable to verbally comprehend the spoken English language or read and comprehend documents written in English.

B. Non-English speaking subjects will not be excluded from research that may have potential benefits. Investigators will plan for populations that are likely to be recruited into the study and translations will be incorporated into the study design to allow for appropriate recruitment and enrollment.

C. Informed Consent

1. All research must be categorized into one of the following categories:
 - a. Expected Enrollment of Non-English Speaking Subjects: In most circumstances, investigators are required to obtain a translated written consent document in a language understandable to the subject or the subject's legally authorized representative (LAR) if it is expected that non-English speaking subjects will be participating in the study.
 - i. The Human Research Review Board (HRRB) must receive the translated version of the informed consent as a condition of approval.
 - ii. To avoid duplicate translations, the investigator may obtain the translated document(s) after the HRRB has conditionally approved the English version(s).
 - iii. Expedited review of the translated version(s) may be acceptable if the protocol, English version of the consent, and all other pertinent materials have been conditionally approved by the convened HRRB.
 - b. Unexpected Enrollment of Non-English Speaking Subjects: If the investigator unexpectedly encounters a non-English speaking subject or subject's LAR and there is no prospective HRRB-approved consent in the subject's language, the investigator may rely on oral translation. A "short form" written consent document, in a language the subject understands, must be used to document that the elements of informed consent required by the HRRB were presented orally. Thereafter, if the investigator expects additional enrollment of subjects speaking the same language, the investigator will be responsible for obtaining translation of the informed consent in accordance with (a) above. When this method is used:
 - i. The HRRB or HRRB Chair, under expedited review, shall have approved a written summary of what is to be said to the subject or the LAR. For purposes of this section, the English version of the consent may be used as the written summary if the HRRB or HRRB Chair approves of its use.
 - ii. There shall be a witness to the oral presentation.

- iii. The witness shall sign both the short form and a copy of the summary.
 - iv. The subject or the LAR needs to sign the short form consent only.
 - v. The person actually obtaining consent shall sign a copy of the summary.
 - vi. Both a copy of the summary and the short form shall be given to the subject or subject's LAR.
2. The HRRB can rely on one certified translation. Two-way translations (i.e., back to English) are not required.
 3. Unless the investigator or his/her designee is fluent in the prospective subject's language, an interpreter will be necessary to facilitate the conversation. The interpreter should not be a member of the subject's immediate family or a close friend. Whenever possible, interpreters should be provided copies of the relevant consent documents well before the consent conversation with the subject or subject's LAR. The interpreter may sign the consent document as the witness and, if so, should note "interpreter" under the signature line.
- D. Any recruitment materials (including advertisements and websites) that have been translated must also be provided to the HRRB. In addition, investigators should translate all study materials that will be distributed to non-English speaking subjects, such as surveys or questionnaires, and submit these to the HRRB when the translated consent is submitted.
- E. All translated documents must be approved by the HRRB before non-English speaking subjects can be enrolled into the study.

PROCEDURE

- A. The investigator must specify whether enrollment of non-English speaking subjects is expected on the initial study application.
1. In order to avoid duplicate translations, the investigator must obtain a translated consent form and any recruitment and/or study materials after the HRRB has conditionally approved the English version of these documents.
 2. The translated documents must be accompanied by a certification from the translator.

3. If the fully convened HRRB has approved all other aspects of the study with the exception of the translated versions of the consent and recruitment or study materials (as applicable), the HRRB Chair, relying on the certification of a qualified translator may expedite review of the translated document(s).
- B. Investigators or their designees unexpectedly encountering non-English speaking subjects should prepare a written summary of what is to be said to the subject or the subject's LAR and present it to the HRRB Chair for prior approval. If the investigator proposes to use the English version of the informed consent form as the written summary, a copy must be provided to the HRRB Chair by the investigator or his/her designee at the time of the request.
1. If the investigator or the person primarily responsible for obtaining consent is not fluent in the prospective subject's language a CHW-approved interpreter should be contacted.
 2. A member of the subject's immediate family or close friend of the subject may not be used as an interpreter.

Approved by the Medical Executive Committee 10/02/2006

Jon E. Vice, President CHHS, Inc.

References:

- A. 45 CFR 46.116, 46.117
- B. 21 CFR 50.20, 50.27

Documentation (Documents & Forms):

- A. HRRB Registration Form