

# Children's Hospital Institutional Review Board

## Information Sheet

### Consent Requirements for Language Minorities (Non-English Speaking)

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Institutions performing research, including Children's Hospital and Regional Medical Center have a responsibility to protect human subjects and to assure that equitable selection of research participants is fostered. Sometimes these goals create tension when research participants do not speak or understand English.

IRBs must encourage **justice** in subject selection, assuring that certain populations (minorities, women, children) are not excluded from research so that all groups share the benefits of research and that certain groups do not bear a disproportionate burden. **Justice** also requires that individuals, such as those who cannot read or understand English, not be excluded from research that has the potential to directly benefit them.

The cornerstone of protection for research participants is **informed consent**. The research participant or surrogate decision-maker, i.e., the parent or legal guardian for research involving children, must understand what the research involves, the potential risks and benefits of participating, and the alternatives available to them. **In cases where research participants do not understand or have a very limited understanding of English, the values of justice and informed consent must be balanced.**

In reviewing research projects, the IRB must determine by considering degree and likelihood of benefit, level of risk, environment, and other conditions, whether the inclusion of language minorities will be required. The IRB will balance the principles of justice and informed consent as described above. When preparing your IRB application for review, it is important that you consider whether your research is likely to involve individuals and families with limited or no English speaking skills and the steps you will take to accommodate these families.

This information sheet is to assist researchers in making appropriate arrangements for the inclusion of language minorities in their research projects. Researchers are responsible for budgeting funds to pay for the costs of accommodating language minorities in their research projects (costs of interpreters and translations).

**There are two aspects of the consent process to consider – the oral explanation of the research and the written documentation of informed consent.**

- **Informed consent must be obtained.** The **oral explanation** involves a discussion with participants and their parents (when applicable) before written consent is documented. The elements of informed consent (as detailed in the consent form) are discussed and families are encouraged to ask questions. Informed consent requires that the family comprehends the issues important in the research study. **When the participant or their parent (for minors) cannot understand English, an interpreter fluent in the family's language must be involved in all informed consent discussions.**

- **Informed consent must be documented.** With few exceptions, informed consent must be documented in writing (signed and dated consent forms).

## **Scenarios for Documenting Informed Consent for limited or non-English speaking families**

The IRB expects approved consent forms to be translated into the language of the research participant or parent when they do not understand or read English. A certified translator must do the translation. **Researchers need to anticipate the need for translations and interpreters when designing their research projects and budget funds accordingly. Researchers will be billed for these costs.**

The following explains the researchers' requirements for obtaining and documenting consent with language minority families under several scenarios.

### **Scenario A**

For most research studies, researchers will have time obtain a certified translation of the approved consent form **before** the participant is enrolled. In these situations, the following is required:

1. An interpreter is used for the oral explanation of the research. The researcher obtaining consent reviews all the elements of informed consent as detailed in the approved English version of the consent form. **The researcher obtaining consent and the interpreter who interprets this information sign and date the English version of the consent form.**
2. The participant or their parent (when participant is a minor) and the interpreter will sign a certified translation of the approved consent form in their language **before** enrolling in the research.
3. The participant is given a **signed and dated copy** of i) the English consent form and ii) the translated consent form. The researcher also retains for the research file a signed and dated copy of the English and the translated consent forms.

### **Scenario B**

There will be situations where researchers did not anticipate the need to have the consent form translated into a specific language. When the research offers the prospect of direct benefit to the participants and enrollment of the participants cannot be delayed while the certified translation is being done the IRB will allow enrollment of the participant using a **Short Form Consent**. **The Short Form Consent is available in the following languages – Spanish, Russian, Vietnamese, Chinese - Simplified, Chinese - Traditional, Korean, and Somali.**

When the Short Form Consent is used in Scenario B the following is required:

1. An interpreter is used for the oral explanation of the research. The researcher obtaining consent reviews all the elements of informed consent as detailed in the approved English

version of the consent form. **The researcher obtaining consent and the interpreter interpreting this information sign and date the English version of the consent form.** The family is given a copy of the signed and dated English version of the consent form.

2. Consent of the participant or parent is documented in writing on the “**Consent Form to Participate in Research – Short Form.**” The short form outlines the information the researcher must provide to the participant or parents in order to obtain informed consent. The information is general to all research and does not provide the specific details of the research project. **The short form is signed and dated by the participant or parent and by the interpreter present for the consent process (the witness).** The participant/parent and the researcher each retain a copy of the signed and dated short form.
3. The researchers must obtain a **certified** translation of the approved consent form (specific to the research) translated into the family’s own language. This translation needs to be done as quickly as possible. In most cases, Interpreter Services can have a certified translation done in 1-2 weeks. When the certified consent form has been translated into the family’s language, the researcher, with an interpreter present, reviews the information and has the **participant or their parent and the interpreter sign and date the translated form.** The family retains a copy of the signed translated form as well as the researcher. The researcher’s copy of the signed translated form would be attached to the original, signed Short Form.

### **Scenario C**

There may be limited situations when the researcher did not anticipate the need to translate the consent form into a specific language and the research poses no more than minimal risk to the participant. In these situations the IRB may allow the use of the Short Form Consent alone, i.e., without requiring a translation.

The IRB would have to determine the following apply:

- The research poses no more than minimal risk to the participant.
- The study procedures are simple and straightforward enough that informed consent can be obtained through the use of an interpreter and the short form alone. The study procedures must be of a very simple nature that allows the family to understand and remember without the use of a certified, written translation of the specific research consent form.
- This is a unique, unanticipated scenario and it is unlikely that future participants speaking this same language will be enrolled.

**Scenario C would not apply to research involving treatment or diagnosis or to research involving banking of specimens with identifiers for future research. Scenario C would not apply to research where it is likely the researcher will enroll additional participants who also require interpreters and short form in the same language.**

In Scenario C the following would be required:

1. An interpreter is used for the oral explanation of the research. The researcher obtaining consent reviews all the elements of informed consent as detailed in the approved English version of the consent form. **The researcher obtaining consent and the interpreter interpreting this information sign and date the English version of the consent form.** A signed copy of the English version is given to the participant or their parent.
2. The research participant or their parent and the interpreter present will sign and date the Consent to Participate in Research - Short Form in their language. The participant/parent receives a copy of the signed and dated short form. The researcher retains a signed and dated copy in their research files.

Researchers who use the short form as described in Scenario B or C, must prepare a first page to attach to the short form. The first page includes (in English) the title of the specific research study, the names and telephone numbers of the researchers, and an emergency number. A 24-hour emergency number is needed if there is a possibility for bodily injury or side effect from taking part in the research. Consider using 911 for families to call in an emergency.

## **HOW TO CONTACT INTERPRETER OR TRANSLATION SERVICES**

For assistance in obtaining an interpreter call Interpreter Services at Children's at 206-987-5010. For assistance in translations, call Translation Services at 206-987-2825.

## **CHECKLIST FOR INCLUDING LANGUAGE MINORITIES IN RESEARCH**

- Provisions have been made to have certified interpreters available for the entire consent process (initial and ongoing).
- Funds are available to pay for the costs of interpreters and translations.
- Translations of the consent forms for participants and/or their parents will be certified. (Short form or long form).
- The HIPAA authorization form must also be translated into the families' language. Children's HIPAA authorization form has been translated into the same languages as the short form and can be found on the IRB web site at <http://irb.seattlechildrens.org>

For questions about inclusion of language minorities in research or about documentation of informed consent for language minority families and children, contact the IRB office at [irb@seattlechildrens.org](mailto:irb@seattlechildrens.org) or 206 987-3930. One of the IRB staff will assist you.