

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

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TITLE: Informed Consent from Persons with Limited English Proficiency

SUMMARY:

The inclusion of Limited English Proficiency (LEP) populations in research is important to ensure that they receive an equal share of the benefits of research and they do not bear a disproportionate burden. The ethical principle of justice requires that individuals not be excluded from research that has the potential to directly or indirectly benefit them. The ethical principle of respect for persons requires that participants, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them. Because the participant's or legally authorized representative's ability to understand is a function of intelligence, rationality, maturity and *language*, Federal Regulations require that the information that is given to the subject or the legally authorized representative be in a language that is understandable to them [45 CRF 46.116].

In cases where potential research participants are Limited English Proficient (LEP), researchers presenting study information must make special provisions to ensure that the consent process and documentation are done in a language understandable to the participant and/or their legally authorized representative. This policy outlines the special provisions required.

POLICY/PROCEDURE:

This policy provides guidance for researchers regarding presenting study information and documenting informed consent and assent from participants and/or their legally authorized representatives with Limited English Proficiency (LEP).

021-1 Definitions

021-1.1 Limited English Proficiency (LEP): "The inability to speak, read, write or understand the English language at a level that permits an individual to

interact effectively with health care providers and social service agencies”
– Dept. of Health and Human Services.

021-1.2 Understandable Language: “...The information that is given to the subject or the [legally authorized] representative shall be in a language understandable to the subject or the representative”. 45CFR46.116 The IRB interprets this statement to mean that the information presented to the participant or legally authorized representative (either orally or in writing) should be in their preferred language (most often their native language or mother tongue) and using terms that are easily understood.

021-1.3 Interpreter: One who translates **orally** for parties conversing in different languages.

021-1.4 Translator: One who converts a **written** text from one language into a written text in a second language.

021-1.5 Certified/Screened Interpreter/Translator: One whose interpretation or translation competence has been tested and approved by a professional association or governmental body.

021-2 Inclusion and Exclusion of Participants

021-2.1 It is the responsibility of researchers to consider the potential that their research populations may include LEP participants and plan for their inclusion. Inclusion may be determined based on factors such as research design and requirements, patient demographics, and local area demographics. Researchers should make every effort to ensure adequate informed consent, parental permission and/or assent is obtained before LEP participants are enrolled.

021-2.2 Seattle Children’s IRB prohibits the exclusion of LEP populations from research unless there is sufficient justification for the exclusion. Justifications for the exclusion of LEP participants may include scientific and methodological limitations based on the lack of appropriate validated instruments, surveys, or assessments. In those cases, it is the researcher’s obligation to determine whether there are appropriate alternate instruments, surveys or assessments that could be used for LEP participants prior to excluding them. In some cases, use of small sample sizes may be sufficient justification when the inclusion of another language may confound the research results or not permit appropriate analysis of the data.

021-2.3 In most circumstances, the cost of translation and/or interpreter services will **not** be considered sufficient justification for the exclusion of LEP

participants in accordance with NIH guidelines. (*“Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources.” 59 FR 11146, March 28, 1994*)

021-3 Use of Interpreters in the Presentation of Research Information

021-3.1 When the participant or their legally authorized representative (referred to as representative) is LEP, a state certified/screened interpreter (referred to as interpreter) fluent in the language of the participant or representative **must** be involved in all informed consent discussions unless otherwise noted (see sections 021-3.2 and 021-3.4 for exceptions). The use of in-person interpreters is required in most cases.

021-3.2 In the case where a state certified/screened interpreter fluent in the language of the participant or their representative is not available because

- the language is one for which the state does not provide certification or screening **or**
- the state in which the research is being carried out does not provide certification for interpreters

a non-state certified professional interpreter may be used after an interpreter agency or similar entity with whom the interpreter is associated has provided a description of the qualification of the interpreter. Their qualifications must include fluency in both English and the language of the participant and/or representative.

021-3.3 The interpreter involved in an informed consent discussion may **not** be related to, or a close associate of, the participant or their representative even if they are certified/screened medical interpreters.

021-3.4 In certain cases, a bilingual research staff member fluent in the language of the participant or their representative may replace an interpreter in informed consent discussions (see section 021-7).

021-3.5 The IRB will determine the extent to which the requirements of this policy apply to international research studies.

021-4 Translation of Recruitment, Consent/Assent Forms, HIPAA Authorization Forms and other Research Documents

021-4.1 When the participant or their representative is LEP, the written recruitment materials, consent/assent form and HIPAA authorization form used to document consent must be in a language understandable to the

participant or legal representative. An IRB approved, certified translation of these written materials is required. (The IRB approved, certified translation of the consent/assent form is referred to as the translated consent/assent form). IRB-approved certified translated consent, assent and HIPAA Authorization forms in several languages are available on the IRB web site.

021-4.2 Sight translation (the verbal translation of written material into the spoken form) of research materials by an interpreter to the participant and/or representative is not permitted.

021-4.3 In order for the IRB to approve the use of translated written documents in a research study, the following should be submitted:

1. A stamped copy of the latest IRB-approved English version of the document (referred to as English version. For example, English consent/assent form.)
2. A copy of the translated document
3. An Affidavit or Certificate of Accuracy stating that:
 - the translated text is an accurate and complete translation of the English document
 - and**
 - the translation was done by a translator(s) who is/are certified/qualified/proficient in both English and the language of the participant or their representative (referred to as the target language)

Affidavits and Certificates of Accuracy from translation agencies are preferred and are required for commonly used languages (for examples see the IRB Website). Translation agencies confirm the qualifications of their translators and provide a higher level of translation quality by having more than one staff translator verify the accuracy and completeness of the translated document.

NOTE: Seattle Children's Translation Service does not provide translations for research studies. If you need assistance in locating an agency that provides certified translations, please contact the Human Subjects Protection Program (HSPP) at (206) 987-7804.

021-4.4 The IRB may require the translation of other research related documents (e.g. flyers, brochures, visual aids, tables, roadmaps, flowcharts, etc.) used in recruitment efforts, considered necessary in the presentation of research information or used to facilitate understanding of the research study by the LEP participant and/or representative.

021-4.5 All modifications to IRB-approved English versions of research documents must be submitted for IRB approval. Translated documents that no longer match the most recent IRB-approved English versions may **not** be used in the recruitment, presentation of research information or documentation of the consent/assent of LEP participants and/or representatives. Such translated documents need to be modified and submitted for IRB approval. Most modifications of translated research documents require re-certification (see section 021-4.3 above) prior to submission for IRB approval. Only minor changes (as defined herein) do not require re-certification. In general, a minor change is limited to the addition/deletion/modification of the names, telephone numbers, or email addresses of research team members unless those changes result in other changes to the consent or assent form (e.g. financial interest disclosures). Other minor changes may be submitted to the IRB for determination as to whether they qualify as minor. In cases where the IRB requires the re-consent of participants and/or representatives using modified consent/assent documents, for LEP participants and/or representatives, this must be done using IRB-approved translated versions of the IRB-approved modified documents.

021-5 Presentation of Research Information and Documentation of Informed Consent

021-5.1 In most cases, researchers will anticipate the enrollment of LEP participants and have an IRB-approved translated version of the consent form (referred to as the translated consent/assent form) **before** the participant or their representative is presented with the option of participating in the research. In these cases, the following is required:

021-5.1.1 An in-person interpreter shall be used for the oral explanation of the research. The researcher presenting the study information reviews all the elements of informed consent as detailed in the English consent form (which serves as a written summary of the oral presentation). After the participant or their representative agrees to participate in the research:

- 1) the researcher presenting the study information signs and dates the English consent form
and
- 2) records the name of the interpreter in the *Interpreter Information* section of the signature page on the same form. (Even though this section provides two places for interpreter names, only one will be used in this situation.)

021-5.1.2 The participant or their representative must sign the translated consent form in their language before being enrolled in the research.

021-5.1.3 The participant or their representative shall be given a signed and dated copy of:

- the English consent form
- and**
- the translated consent form

The researcher shall retain (for the research file) the original signed and dated English and translated consent forms.

021-5.2 The Short Form Consent

In situations where the need for a translated consent form was not anticipated, the IRB will allow the use of the Short Form Consent **only** in the scenario described below. The Short Form Consent outlines the type of information that is common to all research projects and that **must** be provided to the participant or their representative as part of obtaining informed consent (e.g., purpose of the research, risks, benefits, procedures involved, etc). The Short Form Consent does not provide specific details of a research study. Providing this information during the consent conference is the responsibility of the researcher.

The decision to participate in optional portions of research studies cannot be documented using the Short Form Consent. Therefore, optional portions of research studies should be presented to the participant and/or legal representative only after a full translation of the consent and/or assent form has been obtained and approved by the IRB (see sections 021-5.2.1.3 and 021-5.2.1.4 below)

Federal Regulations require a witness to the oral presentation of the research when using the Short Form Consent (45 CFR 46.117). The English and IRB-approved certified translated versions of the Short Form Consent in several languages are available to researchers on the IRB web site along with IRB-reviewed certified translated HIPAA forms. For language versions other than those available on the IRB web site, researchers need to obtain certified translations and submit them for IRB approval prior to their use (see section 021-4.3 above).

NOTE: If the IRB requires HIPAA authorization for the research study, the participant may be enrolled only if IRB-approved translations of both the Short Form and the HIPAA Authorization Form are available when presenting the study. (Please see policy IRB-031 for information on HIPAA authorization requirements.)

Researchers who use the Short Form Consent to document informed consent shall provide a cover page to the Short Form Consent that lists the title of the research study, the names and telephone numbers of the researchers, and an emergency number, if needed. An emergency number would be needed if there is a possibility for bodily injury or adverse event associated with taking part in the research study. In most cases, participants or their representatives who are LEP should be directed to call 911 for emergencies. Cover page templates are available to researchers on the IRB web site in the same languages as the Short Form Consent and HIPAA forms.

021-5.2.1 **Short Form Scenario.** The IRB allows the use of the Short Form Consent and cover page to document informed consent/assent and requires a subsequent certified translation of the approved English consent form specific to the research, if all the following criteria are met:

- a. The research offers the prospect of direct benefit to the participant
- b. There is urgent medical necessity such that enrollment of the participant cannot be delayed while the certified translation is being done or approved
- c. An IRB-approved translation of the Short Form Consent is available in a language understandable to the participant or legal representative on the IRB web site
or
a certified translation of the Short Form Consent is obtained by the researcher and approved by the IRB.

In the Short Form Scenario, the following is required:

- 021-5.2.1.1 An in-person interpreter shall be used for the oral explanation of the research. The researcher presenting the study information reviews all the elements of informed consent as detailed in the IRB-approved English version of the consent form (which serves as a written summary of the oral presentation). After the participant or their representative agree to participate in the research:
- 1) the researcher presenting the study information signs and dates the English consent and records the name of the interpreter in the *Interpreter Information* section of the signature page of both the English and the translated Short Form Consent
 - 2) the interpreter present signs as the witness on the Witness Information section of the signature page on both the English consent form and translated Short Form Consent (see section 021-5.3)
 - 3) the participant or their representative shall be given a copy of the signed and dated English consent form. The original signed and dated English consent form shall be retained in the researchers'

files.

NOTE: The LEP participant and representative must never be asked to sign the English version of the consent form.

- 021-5.2.1.2 The consent of the participant or their representative is documented in writing via the translated Short Form Consent, as follows:
- 1) the Short Form Consent is signed and dated by the participant and/or their representative
 - 2) the interpreter present signs as the witness on the Witness Information section of the signature page on both the English consent form and translated Short Form Consent.
 - 3) the original signed and dated Short Form Consent shall be retained in the researchers' files and the participant or representative shall be given a copy.
- 021-5.2.1.3 The researcher shall obtain an IRB approved certified translation of the most recent IRB-approved English consent form (specific to the research) in the participant's language (see section 021-4). The certified translation of the consent form shall be submitted to the IRB for approval prior to presenting it to the participant or representative. This translation and presentation needs to be done as quickly as possible after consent is documented via the Short Form Consent.
- 021-5.2.1.4 When an IRB-approved translated consent form has been obtained, the researcher shall deliver the translated consent form to the participant or representative in a timely manner and provide the opportunity to review the form and ask questions. After addressing any questions or comments from the participant or representative with the aid of an interpreter, the researcher will have the participant or their representative sign and date the translated consent form. The use of an in-person interpreter is preferred and in such case, the researcher shall record the name of the interpreter in the *Interpreter Information* section in the signature page of the English consent form (there are two spaces provided for interpreter names) and on the translated consent form. If the use of a telephone interpreter is necessary, the researcher shall make a note in the *Interpreter Information* section of the English consent form. The note must include mention that a telephone interpreter was used, name of the interpreter, the date the conversation occurred, and the reason why the use of a telephone interpreter was necessary.
- 021-5.2.1.5 The participant or representative shall be given a copy of the signed and dated translated consent form and a new copy of the

English consent form since a second interpreter name has been added to the *Interpreter Information* section of the signature page. The researcher shall retain the original signed and dated translated consent form in the same file as original signed and dated Short Form and English Consent form

- 021-5.3 As stated in section 021-3.1, an interpreter **must** be involved in all informed consent discussions involving LEP participants unless otherwise noted (see sections 021-3.2 and 021-3.4). When physically present and consent is documented using the Short Form Consent, the interpreter acts as a witness. By signing as witness, the interpreter certifies only that they were present during the oral presentation of the research information. As a witness, the interpreter is **not** certifying any of the following:
- the information presented by the researcher was an accurate and complete presentation of the study and contained the basic elements of consent as defined by regulation 45 CFR 46.116
 - the participant and/or legally authorized representative understood the information presented

It is the researcher's responsibility to ensure the study information presented was complete and accurate and to assess the understanding of the participant or representative before a decision about participation in the research is reached.

- 021-5.4 As a general rule, the researcher, participant and/or representative and witness should only sign forms that are in a language they understand. The researcher signs the English version of the consent form or, in the case of a certified bilingual researcher, the translated consent form (see section 021-7). The LEP participant and/or representative sign the translated consent, assent, Short Form Consent or Short Form Assent in their language. The interpreter fluent in the participant's and/or representative's language, as a witness, signs the English version of the consent form and translated version of the Short Form Consent or Short Form Assent.

021-6 Assent

021-6.1 In cases where assent is required, assent shall be obtained in accordance with policy IRB-020. If the need for a translated assent form is anticipated, the researcher shall obtain an IRB-approved translated assent form in accordance with section 021-4 above.

021-6.2 In cases where the potential participant is LEP, the study information shall be presented orally using a state certified/screened in-person interpreter fluent in the participant's language. If the participant agrees to take part in the research study,

- 1) The researcher presenting the study information must sign and date the English assent form and record the name of the interpreter present in the *Interpreter Information* section of the signature page.
- 2) If written documentation of assent is required via an IRB-approved translated assent form or Short Form Assent, the participant must sign and date the appropriate translated form in their language along with their representative.
- 3) If using a translated Short Form Assent, the interpreter present must sign as a witness in the Witness Information section of both the English assent form and the translated Short Form Assent.
- 4) If assent has been documented via an IRB-approved translated assent form or Short Form Assent, a signed and dated copy of both the English version of the assent form and the appropriate translated Short or translated assent form shall be given to the participant/representative.
- 5) The researcher shall retain the original signed and dated English assent form and translated assent or Short Form Assent in the same file as the translated consent or Short Form Consent used to document the representative's permission.

021-6.3 In cases where the participant is fluent in English, the participant shall be asked in which language (English or their native language) they would like to have the research information presented. If their preference is to have the research information presented in their native language, the assent should be obtained in accordance with section 021-6.2 above. If their preference is to have the research information presented in English, the researcher may present the study information to them in English, ensuring the interpreter present simultaneously interprets the information for the representative and encourages the representative's full participation in the discussion. If the participant agrees to participate and written assent is required, the participant must sign and date the English consent form or assent form as appropriate (along with the researcher) as required by the IRB. The participant/representative shall be given a copy of the signed and dated English form used to document assent. The researcher shall

retain the original signed and dated English consent or assent form in the same file as the original signed and dated translated consent form or Short Form Consent used to document the representative's permission.

021-7 Certified Bilingual Staff

021-7.1 When the researcher is bilingual in English and the language of the participant or their representative and they have been either state certified/screened as interpreters or have passed an IRB approved language fluency assessment, they may review all the elements of informed consent as detailed in the translated consent form in the participant's or their representative's language without an interpreter present. This is only permitted if an IRB-approved translated consent form is available before the participant or their representative is approached for consent purposes. Please contact HSPP for information on IRB approved language fluency assessments.

In this case, documentation of consent is obtained as follows:

021-7.1.1 After the participant or their representative agrees to participate in the research, the researcher obtaining consent and the participant or their representative sign and date the translated consent form. The researcher signs as the researcher obtaining consent and records their name as the interpreter in the *Interpreter Information* section of the signature page.

021-7.1.2 The participant or their representative shall be given a signed and dated copy of the translated consent form. The researcher shall retain (for the research file) the original signed and dated translated consent form and attach an unsigned copy of the English version of the consent form.

021-7.2 In cases where the need for a translated consent form was not anticipated and use of the Short Form Consent is allowed as indicated in section 021-5.2.1, an in-person interpreter (in addition to the researcher) shall be present for the oral presentation of the research. The bilingual certified researcher may review all the elements of informed consent as detailed in the English consent form (which serves as a written summary of the oral presentation) in the participant's or their representative's language without the aid of the interpreter present. In this case, documentation of consent is obtained as follows:

021-7.2.1 After the participant or their representative agrees to participate in the research study, the researcher obtaining consent signs and dates the English consent form and records their name as the interpreter in the

Interpreter Information section of the signature page. The participant or their representative must sign and date the translated Short Form Consent along with the interpreter present who signs as a witness in the Witness section of the signature page. In this case, the witness must be the interpreter as they understand the language being spoken. The interpreter, as a witness, must also sign the English consent form in the Witness Information section of the signature page.

021-7.2.2 The participant or their representative shall be given a signed and dated copy of the English consent form and the translated Short Form Consent. The researcher shall retain (for the research file) the original signed and dated English consent form and translated Short Form Consent.

021-7.2.3 If a subsequent IRB-approved translated consent form is required, it shall be obtained as quickly as possible. Once it is obtained, it shall be delivered to the participant or their representative in a timely manner. The participant or their representative shall be given the opportunity to review the form and ask questions. After addressing any questions or comments from the participant or their representative, the bilingual certified researcher will have the participant or their representative sign and date the translated consent form. The researcher signs the translated consent form as the researcher obtaining consent and records their name as the interpreter in the *Interpreter Information* section of the signature page.

021-7.3 When assent is required and the participant is LEP, the bilingual certified researcher may present the research information to the participant in their language without an interpreter present. This is only permitted if an IRB-approved translated assent form is available before the participant is approached for assent purposes. In this case, documentation of assent shall be obtained as described in 021-7.1.1 and 021-7.1.2 above. If the need for a translated assent form was not anticipated, assent shall be obtained in accordance with section 021-7.2 above.

021-8 Translation Costs

021-8.1 As stated in section 021-2.1, it is the responsibility of the researcher to consider the potential that their research populations may include LEP participants and plan for their inclusion. It is also the responsibility of the researcher to anticipate the need for translation of recruitment materials, consent/assent forms and other research related information in order to ensure adequate informed consent, parental permission and assent is obtained from LEP participants and their representatives.

021-8.2 Researchers shall be responsible for budgeting funds to provide for the costs of obtaining interpreters and translations of recruitment materials, consent/assent forms and other research related documents (i.e. flyers, brochures, visual aids, tables, roadmaps, flowcharts, etc.) provided and/or used in the presentation of research information to potential LEP participants or their representatives as required by the IRB. Researchers may apply for additional funding for translation costs (see policy OIA- 001: Institutional Support for Translation Costs).

Submitting Office: Institutional Review Board (IRB)

Approved by:

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