Procedure Title: Communication Barriers in Informed Consent

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	11/14/2024	**Executive Lead:**	Chief Research Officer
Effective:	11/14/2024	**Revision History:**	.00 – 11/14/2024
Approved by:	Institutional Review Board		
Procedure Number:	116.00		
Key Words:	Consent, Informed Consent, Limited English Proficiency, Deaf, Blind, Translator, Interpreter, Short Form		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU of the procedures to obtain informed consent from participants or LARs who have limited English proficiency, are deaf, have low literacy, or are blind.

Please see SOP 117 (Informed Consent and Assent Processes) for additional procedures to alter informed consent, waive informed consent, and obtain informed consent from participants, legally authorized representatives (LAR), or the parents or guardians of children.

Background:

The Belmont Report identifies "justice" and "respect for persons" as two fundamental ethical principles that must underlie the conduct of all human subjects research. The principle of justice requires that the burdens and benefits of research are equitably distributed. The principle of respect for persons requires that "adequate standards for informed consent are satisfied" so that participants are provided with sufficient meaningful information to decide whether they want to enroll in a research study.

45 CFR § 46.116 states "…the information that is given to the subject or the [legal] representative shall be in language understandable to the subject or representative…" For the purposes of this procedure, "understandable language" will be construed as any method of communication that will ensure effective communication when providing a potential subject with information during the consent process.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants,
- Impartiality when reviewing human subjects research,

- Remaining immune from pressure by the institution's administration, the investigators whose protocol are brought before it, or other professional and non-professional sources

The Office of Scholarly Activity (OSA) is responsible for:

- Supporting the investigator in the development of research protocols and the source documents required for the conduct of research,
- Overseeing and providing the necessary support to the IRB,
- Monitoring compliance with this SOP,
- Posting this SOP for the PNWU community.

The Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research,
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable FDA guidance,
- Seeking support from OSA and the IRB when questions arise.

Definitions:

Please reference the Glossary for complete definitions of additional terms not listed.

Certified Interpreter/Translator: A professional interpreter or translator who has successfully completed a certification program or exam providing them with certified credentials. A subset of these professionals includes those specifically certified to interpret or translate medical information, thus referred to herein as "certified medical interpreters/translators".

Clinical Procedure: For the purposes of this SOP, a clinical procedure in research refers to a course of action taken by a biomedical researcher with the intent to diagnose or treat disease or injury for which the presence of a certified medical interpreter would typically be required in a non-research context.

Impartial Witness: In cases where a participant is unable to read or sign the informed consent, an impartial witness attests that the participant has been completely informed of the nature of the study and has consented to participate. An impartial witness:

a. is independent of the research,
b. cannot be unfairly influenced by people involved with the research,
c. does not have a coercive relationship with the participant,
d. attends the informed consent process if the participant or the participant's legally authorized representative (LAR) cannot read or comprehend, and
e. reads any informed consent form and other written information supplied to the participant.

Interpreter: A person who interprets and relays information in real-time to facilitate oral or sign-language-based communication. Interpreters most often provide services for deaf individuals or those with limited English proficiency (LEP).

Qualified Interpreter/Translator: An individual who demonstrates a high level of proficiency in at least two languages and has the appropriate training, experience, or background to interpret or translate accurately.

Rather than limiting researchers by having very specific qualifications for translators and interpreters, the term "qualified" is left open for some categories of research so that researchers have flexibility. The IRB

can make a case-by-case determination as to whether the qualifications of the interpreter/translator/verifier are sufficient based on the project and the specific project documents. For minimal risk research involving clinical procedures or research deemed greater than minimal risk, professional certification will generally still be required.

For example, the IRB would not recommend researchers have a native Spanish speaker with no medical background to translate a complicated clinical trial consent form. Instead, a professional certification would be needed. On the other hand, if the project involves a simple survey where the risks are minimal and the research design is very simple, then a native speaker without a scientific/medical background would probably be qualified to translate the consent form or act as an interpreter.

Please see Appendix 1 for more information on qualification recommendations.

Short Form: A one-page form that identifies the PI, the title of the study, and summarizes the elements of informed consent, but does not describe any specific research study. It includes an attestation that the required elements of consent were presented orally to the participant by the PI (or designee). Short forms must be signed by the research participant and an impartial witness who observed the presentation of information. See 45 CFR § 46.117 (b)(2)

Signed: Any symbol or mark executed or adopted by a party with present intention to authenticate writing.

Translator: A person who converts written materials from one language to another. Typically, translators are used to translate study documents and consent forms.

Written Summary: 45 CFR § 46.116 requires that the "IRB shall approve a written summary of what is to be said to the participant or the representative" when using a short form consent. For the purposes of this SOP the written summary will be the same as the IRB approved informed consent.

Procedure:

Participants with Limited English Proficiency (LEP)

Consent Method #1: Long Form Written Consent

When the study population of any research project is expected to include a significant number of people who are not fluent in English but are fluent in any single language other than English, the PNWU IRB requires a full translation of the study's approved consent document from English into the appropriate language.

Please note: The PNWU IRB cannot pay for translation of documents or interpreter services and PIs should work with their departments, OSA, and funding agencies to pay for such work.

1. For initial review of a study, the Principal Investigator (PI) will submit only the English versions of the consent form and other study documents for review.

2. Following IRB approval of the study, the PI will have the consent document, and any other relevant materials, translated into the appropriate language by a qualified translator unaffiliated with the study team.
    a. In the case that a PI or study team member is qualified to translate the documents, written evidence that a third-party qualified translator has verified the accuracy of the translation is required.

b. For minimal risk research involving no clinical procedures, an IRB member with sufficient relevant language proficiency may verify the accuracy of translated documents. However, this option is available only on a case-by-case basis at the discretion of both the IRB Chair and the verifying IRB Member.
c. See Appendix 1 for more information on qualification recommendations.

3. Prior to being used, all translated versions of the approved documents, with a Certificate of Translation Form attached, must be submitted to the IRB as an amendment for approval.
    a. Such amendments may be approved the IRB Chair or designee through expedited procedure, except in cases where participants with LEP are at an inherently greater risk from participation compared to English proficient participants.

4. When consenting participants with LEP using the approved translated forms, the person obtaining consent must be fluent in both English and the language of the participant/LAR or assisted by a qualified interpreter.
    a. The interpreter:
        i. cannot be a minor,
        ii. cannot be a family member or friend of the participant or LAR,
        iii. must be fluent in English and the native language of the participant, and
        iv. must be present in person or by video conferencing for the oral presentation of the study-specific details.
    b. For research that involves clinical procedures or requires review by a convened board, a qualified interpreter unrelated to the study team is typically required.

5. All forms shall be signed by the person presenting the information, the participant and/or legal representative, and the interpreter, if one was present. The interpreter should note “Interpreter” under the signature line or similarly.
    a. These signature requirements do not apply when the IRB has granted a waiver of documentation of consent. Study teams should still make note when an interpreter is used and provide a total of such occurrences to the IRB if requested.

6. The participant and/or LAR will be given a copy of the signed informed consent document.

7. Because informed consent is an ongoing process, a qualified bilingual study team member or interpreter must be available for all research-related interactions involving participants or LARs with LEP.

<u>Consent Method #2: Short Form Consent</u>

In rare cases when a non-English speaking person is unexpectedly added to a study last-minute, and investigators do not have a written translation of the consent document, an oral translation process may be used. Investigators should carefully consider the ethical/legal ramifications of enrolling participants when a language barrier exists. If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective.

The short form consent process should not be used for more than three participants in any one language. If this limit is reached, the PI is expected to follow the procedure for Consent Method #1 going forward.

Please note: The PNWU IRB cannot pay for translation of documents (except for pre-translated short forms offered as a courtesy) or interpreter services and PIs should work with their departments, OSA, and funding agencies to pay for such work.

1. The IRB will maintain an approved selection of short forms in various languages that investigators may request for use in the short form consent process. These short forms must be translated by a certified translator.

2. Before consenting the participant with LEP, the PI will contact the IRB to initiate an Exception Request.

3. A short form in English and another in the language of the prospective participant will be provided to the PI if the Exception Request is approved.
    a. If no translation of a short form in the desired language is readily available, the PI must have the English short form translated into the desired language by a certified translator at their own expense. This newly translated short form must be presented to the IRB for approval along with a signed Certificate of Translation before use.

4. At the time of consent, the participant and/or LAR will first read the short form in their chosen language.

5. A qualified interpreter will orally translate the English version of the IRB-approved consent document and facilitate the question-and-answer phase between the potential participant and the investigator. When using the short form consent process the interpreter:
    a. cannot be a family member or friend of the participant,
    b. cannot be a member of the study team,
    c. must be fluent in English and the native language of the participant or LAR, and
    d. must be present in person or by video conferencing for the oral presentation of the study-specific details.

    Please see Appendix 1 for more information on qualification recommendations.

6. An impartial witness fluent in English and the language of the participant or LAR will be present during the oral presentation of the English version of the IRB-approved consent document.
    a. Generally, the witness should not be a family member or friend. The IRB may grant an exception if the participant refuses the presence of an unfamiliar witness, and the research is no more than minimal risk.

7. Required Signatures (Each person will need to sign the forms they can read.):
    a. The witness must sign both the short form and the IRB approved English consent document.
    b. The participant and/or LAR will sign the short form only.
    c. The person obtaining consent will sign the English informed consent document only.
    d. If a third-party interpreter is used, they will sign both the short form and the English version of the consent document. The interpreter should note “Interpreter” under the signature line or similarly.

8. The participant and/or LAR will receive copies of all forms.

9. Because informed consent is an ongoing process, a qualified interpreter must be available for all research-related interactions.

Low Literacy, Visually Impaired, or Blind Participants

During the course of the study, the PI may encounter an individual participant who is capable of providing legally effective informed consent but cannot read the informed consent and must rely solely on an oral presentation of the study.

1. When a PI wishes to consent an English-speaking participant who cannot read the consent document, the PI will contact the IRB and request an English short form.

2. The PI must provide an impartial witness to the oral presentation during the consent process.

3. All forms shall be signed by the person obtaining consent, the participant and/or LAR, and the witness.

4. The participant and/or LAR will receive copies of all forms.

5. During the course of the study, the PI should provide a witness to any oral presentation of written material if deemed appropriate.

Deaf Participants

During the course of the study, the PI may encounter an individual participant who has a limited or complete inability to hear the information presented during the consent process and the course of the study.

1. In the case of a deaf participant who prefers to communicate via sign language, the PI should provide an impartial sign language interpreter during the consent process. The interpreter should be available throughout the course of the study for all research-related interactions.
    a. Alternatively, the participant's preferred form of assistive technology may be used during the consent process if effective two-way communication can be achieved.

2. All forms shall be signed by the person obtaining consent, the participant and/or LAR, and the interpreter, if used.

3. The participant and/or LAR will receive copies of all forms.

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 /	J. Simmons	Original SOP

Appendices:

Appendix 1 – Translator, Interpreter, and Impartial Witness Recommendations

Appendix 1
Translator, Interpreter, and Impartial Witness Recommendations

Who can act as the translator?
This individual must be able to read, speak, and write in the required language and English.

	Exempt	Expedited - No Clinical Procedures	Full Board – No Clinical Procedures	Involves Clinical Procedures
Fluent Study Team Member	No	No	No	No
Non-Certified Translator Who is Not Part of the Study Team	Yes	Yes	No	No
Certified Translator Who is Not Part of the Study Team	Yes	Yes	Yes	Yes

Who can act as the interpreter when using Long Form Written Consent?
Must be able to read, speak, and write in the required language and English, and
Is available to interpret and answer a participant's questions at any stage of the study.

	Exempt	Expedited - No Clinical Procedures	Full Board – No Clinical Procedures	Involves Clinical Procedures
Friend or Family Member of Participant	No	No	No	No
Fluent Study Team Member	Yes	Yes	No	No
Bilingual Individual Who is Not Part of the Study Team	Yes	Yes	No	No
Certified Interpreter (non-medical) Who is Not Part of the Study Team	Yes	Yes	Yes	No
Certified Medical Interpreter Who is Not Part of the Study Team	Yes	Yes	Yes	Yes

Who can act as the interpreter when using Short Form Consent?
Must be able to read, speak, and write in the required language and English, and
Is available to interpret and answer a participant's questions at any stage of the study.

	Expedited - No Clinical Procedures	Full Board – No Clinical Procedures	Involves Clinical Procedures
Friend or Family Member of Participant	No	No	No
Fluent Study Team Member	No	No	No
Bilingual Individual Who is Not Part of the Study Team	Yes	No	No
Certified Interpreter (non-medical) Who is Not Part of the Study Team	Yes	Yes	No
Certified Medical Interpreter Who is Not Part of the Study Team	Yes	Yes	Yes

Who can act as an Impartial Witness?
Must be able to read, speak, and write in the required language and English.

	Minimal Risk	Greater Than Minimal Risk	Involves Clinical Procedures
Friend or Family Member of Participant	Maybe	No	Maybe, if Minimal Risk
Fluent Study Team Member	No	No	No
Bilingual Individual Who is Not Part of the Study Team	Yes	Yes	Yes