

Quick Reference Guide

Informed Consent for Research Subjects with Limited English Proficiency

This guide is a supplement to *INVESTIGATOR GUIDANCE HRP-802: Informed Consent* and *HRP-803: Documentation of Informed Consent*, as well as *Help Sheet: Consent – Waiver or Alteration*.

1. Ensure that:

- ✓ **Either a fully translated consent form or a short consent form in the subject's language has been approved by the IRB.** *The IRB will approve short forms that are posted on our website without a translation certificate. For all other translations, you must submit a translation certificate or other documentation of the translator's qualifications when you submit the translation for approval.*
- ✓ **A qualified interpreter is present.** *In-person translation is preferred, but the interpreter may be on the phone if this is not practicable. An interpreter present by phone may sign the consent form(s) via secure email or mail. The interpreter may be a member of the study team if appropriately qualified. The interpreter should not be the subject's friend or family member except in urgent circumstances. A subject who chooses to use his or her own interpreter must sign a waiver. Contact [OHSU Interpreter Services](#) to obtain this document.*
- ✓ **An impartial witness is present.** *The witness must not be part of the research team. The interpreter may be the witness if the interpreter is NOT a member of the study team. It is recommended that the witness be present in-person, but the witness may be present by phone or video if this is not practicable.*

2. Process and Documentation:

Option 1: Fully translated consent form

- ✓ Use an interpreter to facilitate the consent discussion and answer the subject's questions.
- ✓ Obtain signatures on the consent form from the subject, the person from the study team obtaining consent, and the impartial witness.
- ✓ Provide a copy of the consent form to the subject.
- ✓ Retain documentation in the study file as usual.

Option 2: Short consent form

- ✓ Have the interpreter verbally translate the full English consent form to the subject. Use the interpreter to facilitate discussion and answer the subject's questions.
- ✓ Allow the subject to read the short form. Answer any other questions the subject asks.
- ✓ Obtain signatures on the **short form** from the **subject** and the **impartial witness** (the witness may be the interpreter if not affiliated with the study team).
- ✓ Obtain signatures on the **full English consent form** from the **person obtaining consent** and the **impartial witness** (the witness may be the interpreter if not affiliated with the study team).
- ✓ Provide a copy of both the English consent form and the short consent form to the subject.
- ✓ Retain documentation in the study file as usual.