

# Short Form Consent Refresher



# IRB Review

- The IRB determines if the use of the short form consent process is appropriate when enrolling research participants who do not speak English.



# Short Form Consent

- The federal regulations (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2)) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.
- A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary.



# Short Form Consent

- Summary Form – the English version of the consent form that includes all of the elements of consent.
- Short Form – an informed consent, *in the participant's language*, stating all of the elements of consent have been presented orally.
- Witness – should be fluent in both English and the language of the research participant



# Signatures

- Short Form signed by:
  - Participant or Legally Authorized Representative
  - Witness\*
- Summary Form:
  - Person Obtaining Consent (POC)
  - Witness\*

\*Witness may be the interpreter, study staff, or a family member



# Summary Slide

- Investigators are encouraged to **recruit a diverse subject population including those who do not speak English**. The full consent form should be translated into the participant's language whenever possible. However, with **prior IRB approval, OHRP permits the use of a short form consent process when a non-English speaking subject is unexpectedly encountered**. Researchers request this in their eProtocol application and the **IRB must approve before its use**. Researchers need to have an **interpreter read the full English consent document**, and the person obtaining consent and a witness must sign and date the English consent. The participant and the witness must sign and date the short form template in the participant's language. **Researchers can use the vetted short form template in various languages on the IRB [website](#)**.



# Questions?

