

Federal regulations and Castle IRB allow a "short form consent" process to be used with participants who do not read/understand English as an alternative to the standard informed consent process when translated versions of the consent form were not anticipated and are not available. In such cases, a "short form consent" is given to the participant in their native language to explain what information will be presented to them orally via interpreter.

To use a short form consent process:

- Please contact Castle IRB at <u>irbteam@castleirb.com</u> in advance if the protocol is not approved to enroll non-English speaking participants.
- Use a translated version of the short form consent, available below. The English version can be used to translate to the desired language, if not readily available. Castle IRB can facilitate translations by emailing irbteam@castleirb.com.
- The short form consent process requires an interpreter and witness to be present.
 - The interpreter can also serve as witness if physically present and not a member of the research team. The interpreter can be a member of the research team if not also serving as witness. A telephone interpreter cannot serve as witness.
 - The witness must be conversant in both languages and should not be a member of the research team.
- The interpreter should present the IRB approved informed consent orally to the participant.
- The following persons must sign the Short Form and IRB-approved Informed Consents:
 - Short Form: participant, witness, study team member obtaining consent
 - o Informed Consent Form: witness, study team member obtaining consent
- Verify institutional requirements for HIPAA Authorization when using a short form consent.
- An IRB-approved, translated version of the full informed consent document should be provided to the enrolled participant following use of the short form for greater than minimal risk studies, and those taking place over multiple visits. Promptly submit an amendment to Castle IRB to facilitate and/or to seek approval of translated versions of the consent and other participant-facing documents, typically within 30 days of use of the short form consent. If translated versions are being submitted, also provide the Certificate of Translation.