Informed Consent – Non-English Speaking Individuals

What to do If You Need to Consent a Non-English Speaking Participant for Your Study Which Does Not Actively Recruit Non-English Speaking Participants

Contact the UH IRB Administration Office at 216-844-1529.

When non-English speaking individuals are not the targeted population for research, often informed consent and HIPAA Authorization documents are not yet translated into other languages as the needed language is not yet known

Consider if there sufficient time to obtain a fully translated version of the written consent form and HIPAA Authorization in the potential participant's native language.

What the Short Consent Form (Short Form) Informed Consent Process is and When it Should be Used

A "short form" consent form is a document that contains a brief paragraph stating that the elements of informed consent have been presented orally to the participant or the participant's legally authorized representative (LAR) in a language understandable to the participant.

May be appropriate for protocols that include the provision to include **individuals who do not speak English** as they are often a part of the general participant population but **they are NOT the target population.**

May be appropriate for participants who may be eligible to be enrolled in a research protocol where there may not be sufficient time to obtain a fully translated version of the written consent form and HIPAA Authorization in the **participant's native language**, a "short-form" informed consent may be approved for use by the IRB.

Using the **short form** in a specific language **can only be used once per language** per protocol. Should there be another non-English speaking participant who speaks the language in which the previously approved short form was written, that short form cannot be presented to them. The informed consent document (traditional long consent form) must be presented to the participant in a language that the participant understands.

When Informed Consent is Obtained From Non-English Speaking Participants Using a Translated Consent Form (Traditional Consent Form)

All of the following must be done;

1. The translated consent document must be approved by the IRB and be provided to participants in a language understandable to them.
2. A translator who is fluent in both English and the language of the participant must be present if the person obtaining consent does not speak the language of the participant.
3. The consent document must be signed and dated by the participant or the participant's legally authorized representative (LAR) (unless the IRB has waived written consent).
4. The consent document must be signed and dated by the person obtaining consent and, if the person obtaining consent does not speak the participant's language, by the translator (unless the IRB has waived written consent).
5. The informed consent process must be documented via a narrative or checklist to describe how it occurred, and who was involved.

When Informed Consent is Obtained From Non-English Speaking Participants Using a Translated Short Consent Form

All of the following must be done;

1. The translated short form consent document must be approved by the IRB and be provided to participant in a language understandable to them.
2. A translator who is fluent in both English and the language of the participant must be present if the person obtaining consent does not speak the language of the participant.
3. The English consent document must be used by the translator as the script.
4. The translated short consent document must be signed and dated by the participant or the participant's legally authorized representative (LAR) ***AND*** the translator. (unless the IRB has waived written consent).
5. The English consent document must be signed and dated by the person obtaining consent ***AND***, if the person obtaining consent does not speak the participant's language, by the translator.
6. The informed consent process must be documented via a narrative or checklist to describe how it occurred, and who was involved.
7. A fully translated consent document must be approved by the IRB and provided to the participant as an information sheet.

Documentation of the Process/Additional Considerations

The informed consent process must be documented via narrative or checklist to describe how the process occurred and who was involved.

Other study documents that will be filled out by the participant (e.g. log sheets, data collection forms, self-assessments, etc.) must also be translated to the participant's native language.

Ethical Considerations

The Belmont Report (1979) – Respect for Persons principle

References

UH IRB Policy – Other Vulnerable/Special Populations
21 CFR 50.27 – Protection of Human Subjects – Documentation of informed consent (Food & Drug Administration)
45 CFR 46.117 – Protection of Human Subjects – Documentation of informed consent (Department of Health and Human Services)