Purpose

To provide guidance for the process of conducting informed consent when using the short-form consent with non-English speaking subjects.

Note: If an external IRB is being used, please refer to their policies and guidance documents.

What is a short-form consent document?

The short-form consent template is a document that includes the DHHS-required elements of an informed consent process to enroll a non-English speaking subject on a research study. The short-form describes and documents part of the consent process for a non-English speaking subject.

When can it be used?

If during the screening period of an IRB approved study, an unanticipated non-English speaking subject is encountered and there is insufficient time to translate the IRB approved informed consent form (ICF) to the subject's language, then the short-form consent can be used.

Reminders:

- Check with the sponsor to see if translated consent forms are available. This is the preferred method.
- Review the approved protocol with your regulatory team member to ensure the study allows enrollment of non-English speaking subjects using the short-form consent process.
- Sponsors may need to be contacted first to seek permission to enroll non-English speaking subjects.

How many times can it be used?

Once the short-form consent has been used to enroll a non-English speaking subject three (3) times in the same language, the full English version of the consent form must be translated into the subject's language and submitted for IRB approval. There may be circumstances in which the IRB might require the ICF be translated into the subject's language prior to using it 3 times. This is dependent on the complexity of the study and at the discretion of the IRB at the time of initial review.

What other documents need to be translated after the use of the short-form?

If the study requires the use of written materials to be provide to subjects, those documents may be required to be translated into the subject's language and submitted for IRB approval prior to use. AdventHealth Interpreter Services may be able to provide document translations at **FH.Interpreter.Services.Dept@adventhealth.com**.

Step by Step Guide - how to use the short-form consent and document the process:

Step 1 - Obtain the Short-Form Consent

Once it is determined a study may enroll non-English speaking participants, if an IRB approved ICF is not available in the subject's primary language, proceed to your Florence eRegulatory binder for a specific study.

NOTE: In circumstances where studies do not have a binder in Florence and/or dedicated ORI Regulatory Team Member, follow the steps below to obtain a short form consent found in IRBNet when appropriate.

- Select the "Forms and Templates" tab.
- Select "AdventHealth IRB – Documents for Researchers".
- Select the **HRP-503 - TEMPLATE Consent Short Form** in the appropriate language.

Note: *The short-form consent is translated into 6 common languages: Spanish, Creole, Portuguese, Arabic, Vietnamese, Hindi, and Polish. If the short-form consent is needed in another language, contact IRB.*

- Be sure to print the English short-form for your reference and appropriate language short-form consent for use.

Step 2 - Select Mode of Communication

Types of interpreter services available:

- In person: to schedule, call 407-303-5600 ext. 1106707 between 6am to 4pm or after hours 24/7 support center at 407-303-3025
- By Phone: Stratus Video: In House dial extension 8510, or 110-8510, or 1 (855)-485-2638
- By Video: Use iPad

NOTE: *Personnel from Interpreter Services may not serve as the <Impartial Witness> during the consent process.*

Interpreter Services website:

https://ahsonline.sharepoint.com/Central-Florida/interpreterservices

Term	Definition
Bilingual Staff	Members of AH Staff who speak other language(s) and converse with subjects in the same language. They may communicate with the subject; however, they may not interpret for other staff unless they are a Qualified Bilingual Staff (QBS).
Impartial Witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the entire consent process and reads the consent document and any other written information supplied to the subject as part of the

	consent process. This specifically excludes Research Personnel on the study.
Qualified Bilingual Staff (QBS)	Interpret for another staff member or physician but cannot sight translate* a document.
Qualified Medical Interpreters (includes Sign Language interpreter)	Interpret in all modes of communication (oral, conversational, and sight translation*).
Sight Translation*	When a form/document that is not in the subject's language is interpreted to the subject in their language, this cannot be done by a Qualified Bilingual Staff. Must be performed by a Qualified Medical Interpreter.

Step 3 - Consent Process

Once Interpreter Services and an <Impartial Witness> are present, the consent process can begin.

NOTE: *An <Impartial Witness> must be present to attest that the researcher has informed the subject of all aspects of the study as outlined in the IRB approved English ICF (Long Form/Written Summary).*

If upon completion of study explanation, the subject voluntarily agrees to participate, complete the following:

- The subject, <Impartial Witness> present, and qualified medical interpreter or qualified bilingual staff, sign and date the short-form consent in the subject's language. If using the video or phone interpreter services, record the name and ID number of the interpreter.
  Note: *Research staff member should always have the English version of the short-form consent document for reference, to ensure all elements listed on the short-form consent are covered.*
- The research staff member and <Impartial Witness> will sign the IRB approved English ICF (Long Form/Written Summary) and print the name of the study subject (no subject signature). By including the subject's name on the ICF, it links the subject to the specific study.
- A copy of both executed short-form consent and the IRB approved English ICF (Long Form/Written Summary) must be provided to the subject.
- Place a copy of the signed documents in the subject's medical record (when applicable).

NOTE: *The non-English speaking subject should not initial pages of the IRB approved English ICF (Long Form/Written Summary) since they have not read the document. If the study has optional procedures included on the IRB approved English ICF that require subject initials, this must be documented on a progress note since the subject should not initial the document.*

Step 4 - Documentation of the Process

Documentation must be included in the research records of who was present during the informed consent process. Remember, if it's not documented, it did not happen. Providing this documentation will demonstrate the informed consent process was performed in accordance with regulatory and institutional requirements. It is recommended that an informed consent process checklist be used for all research studies that require consent.

The following information should be captured during the informed consent process and documented in a progress note or checklist:

- Name of person obtaining informed consent.
- Date and time (time suggested for acute studies only) informed consent was obtained. If time was not captured on the informed consent form, then a note should be written that documents the informed consent was obtained prior to any study procedures. This is especially important when the consent process and study procedures are performed the same day.
- Name of subject (or study ID#) and/or name of <Legally Authorized Representative>.
- Name of witness and relation to subject (if any).
- Name of interpreter, their relation to the subject, and language interpreted.
- Any questions or concerns the subject and/or LAR had and whether they were addressed appropriately.
- A note stating that a signed copy was provided to the subject and included in their medical records, when applicable.

Once the informed consent process is documented, file all documents in the research record including the original signed short-form consent, the IRB approved English ICF (Long Form/Written Summary), progress note and/or informed consent process checklist.

For questions or concerns regarding this process, please contact the IRB office at 407-200-2677or email ORL.IRB.General@adventhealth.com.

References

AHO SOP 010.024- Language and Communication Assistance
CW AHC 107 POLICY Definitions in Human Research
CW AHC 110 POLICY Legally Authorized Representatives Children and Guardians in Research
CW AHC 216 SOP Informed Consent Process and Written Documentation of Informed Consent
HRP-840 Interpreter Services Guide for Researchers
QUICK GUIDANCE: Short-Form Consent Use in Research
QUICK GUIDANCE: Informed Consent Process for Non-English-Speaking Subjects in Research
HRP-509 TEMPLATE: Informed Consent Process Checklist