Consenting Non-English Speaking Participants

Version 3

PURPOSE
This document is intended to assist investigators with the enrollment of non-English speaking participants on research protocols.

DEFINITIONS

Verbal Translation Preparative Sheet (VTPS) – Serves as the short form written informed consent document (ICD) and is written in the language of the potential participant or legal representative. This form describes the elements of informed consent required to be presented to the participant during the translation of the English version of the ICD.

Legally Authorized Representative (LAR) - An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant’s involvement in the procedure(s) involved in the research.

Person Obtaining Consent - The person obtaining consent must be knowledgeable about the research study, in order to be able to answer questions about the study that may be asked by the participant or the participant’s LAR. The person obtaining consent must not be related to or a close associate of the participant or the participant’s LAR. This person may be the investigator, the participant’s physician, or a person indicated in the study as authorized to obtain informed consent.

Interpreter – A person fluent both in English and in the language of the participant or participant’s LAR. The interpreter serves as a facilitator of the consent process. The person obtaining consent may serve as the interpreter provided he/she is fluent in both English and the language of the participant or the participant’s LAR.

Investigators may use the M.D. Anderson Language Assistance department or another translation service.

Witness (to the oral presentation) – This person must be fluent in the language of the participant or the participant’s LAR in order to acknowledge that an understandable consent content was presented. The witness should speak English, as well as be fluent in the language of the participant or the participant's LAR, in order to acknowledge that an understandable consent content was presented.
The witness will be a family member or a close associate of the participant or the participant’s LAR. If needed, or if no one else is available, the witness may be an MDACC staff member not associated with the research trial. The witness must also be acceptable to the participant or the participant’s LAR. The witness may not be the person obtaining consent or a member of the research team.

The witness must serve as the witness to the entire verbal consenting process, as well as all signatures. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.

**PROCEDURE**

Procedures When Obtaining Consent Using a Translated Informed Consent Document

**Step 1: Obtaining Consent**
The person obtaining consent and who is fluent in the language understandable to the participant or the participant’s LAR, will explain the research to the participant or the participant’s LAR, as applicable. If the person obtaining consent is not fluent in the language understandable to the participant or the participant’s LAR, an interpreter will facilitate the consenting process. The interpreter may be the treating physician or the physician’s designee and not a family member.

The consent process should include a discussion of all the basic elements of informed consent and allow ample time for the participant’s questions to be answered.

**Step 2: Documenting Optional Procedures**
When a protocol contains optional procedures, the person obtaining consent through an interpreter*, when applicable, should explain the optional procedures to the participant and then initial the box next to optional procedures to indicate that:

- Optional procedures were discussed, and
- whether or not the participant agreed to participate in the optional procedures.

*If an interpreter is explaining the consent document, the interpreter is expected to initial the box next to optional procedures.

**Step 3: Obtaining Signatures**
The person obtaining consent, the participant or the participant’s LAR, and a witness will sign and date one original copy of the ICD.
Step 4: Distributing Copies
The original non-English ICD will be forwarded to Health Information Management Systems to be placed in the participant’s medical record, and one copy of the non-English ICD will be given to the participant or the participant’s LAR.

Step 5: Documenting in the Participant’s Medical Record
The person obtaining consent will document a progress note for the medical record that he/she has discussed the protocol (as per MDACC IRB policy) in a language that can be understood by the participant and answered all questions, in the presence of the interpreter, if applicable, and a witness. The documentation should include a statement that the ICD utilized was in the participant’s language, and whether or not the participant agreed to any optional procedures listed in the protocol.

Procedures When Obtaining Consent Using an English Informed Consent Document

Step 1: Obtaining Consent

Verbal Translation Preparative Sheet
Non-English speaking participants will be presented with the VTPS in the language of the participant or the participant’s LAR.

The participant or the participant’s LAR and a witness fluent in the participant’s language will sign and date one original copy of the VTPS.

If the VTPS is not available in the participant’s language, please contact the MD Anderson IRB Office.

English ICD
If the person obtaining consent is fluent in the language understandable to the participant or the participant’s LAR, he/she will verbally translate the information given in the English version of the ICD. If the person obtaining consent is not fluent in the language of the participant or participant’s LAR, an interpreter will verbally translate the information given in the English version of the ICD into a language understandable to the participant or the participant’s LAR. There should be ample time to allow for complete translation of the ICD and for the participant’s questions to be answered.

The person obtaining consent, a witness, and if applicable, an interpreter, will sign and date one original copy of the ICD.

NOTE: Participants should not be asked to sign a document that they cannot comprehend.
Step 2: Documenting Optional Procedures
When a protocol contains optional procedures, the person obtaining consent through an interpreter*, when applicable, should explain the optional procedures to the participant, and then initial the box next to optional procedures to indicate that:

- optional procedures were discussed with the participant, and
- whether or not the participant agreed to participate in the optional procedures.

*If an interpreter is explaining the consent document, the interpreter is expected to initial the box next to optional procedures.

Step 3: Distributing the VTPS and the English ICD
The original VTPS and English ICD will be forwarded to Health Information Management Systems to be placed in the participant’s medical record, and one copy of the VTPS and English ICD will be given to the participant or the participant’s LAR.

Step 4: Documenting in the Participant’s Medical Record
The person obtaining consent will document a progress note for the medical record that he/she has discussed the protocol (as per MDACC IRB policy) in language that can be understood by the participant and answered all questions with the assistance of an interpreter, if applicable, and a witness. The documentation should include a statement that a VTPS was utilized, and whether or not the participant agreed to any optional procedures listed in the protocol.

Step 5: Registering the Participant in CORe
The person registering the participant in CORe should indicate whether or not a VTPS was utilized, and if so, indicate which language.

Procedures When Utilizing a Legally Authorized Representative

When a legally authorized representative (LAR) must be utilized during the consent process (e.g., where the potential participant is a minor child or an incapacitated individual with impaired decision-making capacity), the interpreter facilitating the consent process must be fluent in English and in the language(s) spoken by the LAR, the minor and/or the incapacitated individual with impaired decision-making capacity. Pediatric assent must be obtained in compliance with the HRPP Manual Chapter 12.2.3. Children and Consenting Minors.
If the participant is a minor and the consent document has not been translated, the VTPS may be signed by the parent, the participant or both.

**Procedures When Utilizing a Telephone Interpreter**

When the translation process must involve the use of a telephone interpreter, the following procedures should be utilized:

- The telephone interpreter should be faxed a copy of the VTPS and the ICD.
- The patient should be given copies of both documents during the consenting process.
- The telephone interpreter should review the VTPS with the participant. If the VTPS is presented in the participant’s language, the interpreter will not need to translate the document verbatim. If the VTPS is not available in the participant’s language, the IRB should be consulted prior to the consent process.
- If the ICD is available in the participant’s language, then the VTPS does not need to be utilized. The telephone interpreter should review each section of the ICD with the participant.
- If the ICD has not been translated, the telephone interpreter should translate the ICD verbatim to the participant and ask the participant if they have questions related to the research. The person delegated to obtain informed consent or the investigator should be present to address the participant’s concerns.
- The consent document should then be faxed to the telephone interpreter for signature. The telephone interpreter should sign on the designated “translator/interpreter” line of the ICD. Once the interpreter’s signature has been obtained, the person obtaining consent and, if applicable, the participant should sign the ICD.

## APPROVALS

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<th>Date</th>
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<th>Initials</th>
<th>Description</th>
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<td>09/08/2009</td>
<td>New</td>
<td>WQ</td>
<td>Procedures When Obtaining Consent Using an English Informed Consent Document (removed &quot;the person obtaining consent&quot; as a required signature on the VTPS; 2nd bullet under English ICD, &quot;added interpreter&quot; as person that may sign the ICD.)</td>
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<tr>
<td>05/10/2010</td>
<td>Revision</td>
<td>WQ</td>
<td>Procedures When Obtaining Consent Using an English Informed Consent Document (added **If an interpreter is explaining the consent document, the interpreter is expected to initial the box Next to optional procedures.).</td>
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