SOP#: PM-2b	**Obtaining and Documenting the Informed Consent Process Adult Non- English-Speaking Participants, Including Decisionally Impaired, and Reconsenting**
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NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.08.14 07:36:02 -04'00'

POLICY

The informed consent (IC) process will be conducted in compliance with all regulations, guidelines and policies applicable to the protection of human subjects. IRB approved written informed consent document (ICD) containing all the required elements must be used to document the participant's agreement to participate in the research study, unless the IRB had approved an alteration or waiver of such document. Please see SOP PM-2 *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric) – General Information (Including Reconsenting, iMedConsent and Remote Consenting)* for general information including use of iMed and remote consent.

When enrollment of non-English speaking participant is anticipated, consent must be obtained using an IRB approved translated long form consent. When enrollment of a non-English speaking person is not anticipated and there is no IRB approved translated long form consent in the language of the subject, the short form process may be used to document consent depending on the risk level of the study:

1. Greater than minimal risk studies (e.g., every drug/device study, observation studies that require a biopsy): A translated consent is required in the potential participant's preferred language with each/every consent/participant.
    a. If there is no translated ICD available in the potential participant's language, the enrollment of the individual should be delayed, UNLESS it is determined by the PI that it is justified to proceed with the short form consenting process because it is in the individual's best interest to enroll prior to the translation. The best interest of the individual means that it is necessary to ensure the rights, welfare, and safety of the individual. If the short form consent process is used, a translated consent should be requested ASAP.
2. Minimal risk studies (e.g., some questionnaire/ blood sample collection studies, natural history studies without CT/MRI scans): A short form consent may be used up to three (3) times in the same language on the study to consent participants during the lifetime of the study.
    a. After the use of 3 short form consents in a particular language, a translated consent form in that language is required to be used for future participants.

Whenever the short form is used, the IRB must be notified within 7 calendar days via a Reportable New Information (RNI) form in PROTECT. For more information, please see the NIH *Guidance for obtaining consent to participate in research from non-English speaking participants.* (v 06.27.2024)

Only the PSO staff are allowed to request a translation of the long form. When this is required, the study team must notify the PSO via the CCR translation Request Portal. See *Frequently Asked Questions Related to Enrolling Non-English-Speaking Participants in the CCR* posted under this SOP.

The use of iMedConsent™ (a web-based application) is the preferred method for the IC process, including electronic capture of signatures, unless the protocol sponsor does not allow it. The iMed process can be

used when the consent is obtained in person or if the consent process is conducted remotely. The research protocol or NIH addendum must specifically allow the use of iMed.

When a study may or will enroll an adult participant who lacks the capacity to provide consent, the protocol must state this and the conditions under which this participant will be enrolled and the use of a legally authorized representative (LAR). A legally authorized representative (LAR) is an individual or judicial or other body authorized under applicable law to make decisions on behalf of another individual. Individuals designated on NIH-200 Advance Directive or other valid advance directive, or court-appointed guardians are acceptable as LARs. See NIH Policy 403 - *Research with Participants Lacking Capacity to Consent* for more information. The protocol must also specify what will happen if a participant loses consent capacity during participation in the study.

Documentation of the IC process must be completed in the medical record **within 1 business day** of the ICD being signed.

PURPOSE

To describe activities involved with obtaining informed consent and documenting the informed consent process for the adult non-English speaking study participant who will sign an NIH consent document, including enrollment of non-English speaking adults who are or may become decisionally impaired. In addition, to describe the process when the IRB requires reconsent for the adult non-English speaking study participant after a modification to the informed consent document.

RESOURCES

NIH Clinical Research Studies Active Consent/Assent Documents website

The NIH Intramural Institutional Review Board Office (IRBO) website

- Contact the IRBO: IRB@od.nih.gov or 301-402-3713
- Short Form Consent Documents website

The NIH Intramural Human Research Protections Program (HRPP) Policies

- Policy 301 - *Informed Consent*
- Policy 403 - *Research with Participants Lacking Capacity to Consent*
- Series 500 as applicable: FDA Requirements for Human Participants Research and Data and Safety Monitoring
- NIH IRP HRPP Policy Glossary
- Informed Consent Information (including FAQs)

CCR Policies/Standard Operating Procedures (SOPs) website

PROCEDURES

Non-English-speaking participants cannot initial or sign any part of the English ICD, because they cannot read the document.

If the protocol has an IRB approved fully translated long form based on the current English ICD version:

STEP 1: Obtain current IRB approved ICD

- Obtain the current IRB approved translated long form of the protocol's ICDs from iMed. The documents are also available on the NIH Clinical Research Studies Active Consent/Assent Documents website.
- Check approval date and version to assure current IRB approved version. This is located in the footer of each page.
    - If not the current version, contact your PSO manager for assistance.

IMPORTANT: if the English version of the ICD has been modified but the translated long form has not yet been approved, you must use the previous version of the translated long form – see below.

STEP 2: Send/give IRB approved version of ICD to participant/LAR

- This will allow time for the participant/LAR to review prior to the consent process

STEP 3: Determine who will be involved in the consent process

- The Principal Investigator, an Associate Investigator or other designated individual must be identified in PROTECT to obtain consent.
- For research involving adults who lack the capacity to provide consent, consent must be obtained from a legally authorized representative (LAR).
- Secure interpreter in the participant's/LAR's language for the IC process.
- If one of the protocol's investigators is fluent in the participant's language, they may serve as an interpreter. Use of an investigator as an interpreter MUST be documented in CRIS.

Note: Use of an adult family member for interpretation is not permitted. If a professional medical interpreter cannot be located, please see Policy 301: *Informed Consent.*

STEP 4: Initiate IC process with the assistance of the interpreter

- Discuss the essential elements of an informed consent:
    - Discuss the research study including procedures, treatment plan, potential risks, benefits of participation, study participant's rights as a participant, and alternatives to participation in the research study.

Note: Discussions about protocol treatment and alternatives to participation must be carried out by an appropriately licensed provider (i.e., MD, DO, NP, PA).

- Ask study participant/LAR if he/she has any questions.
- All questions about the trial should be answered to the satisfaction of the participant/LAR.
- Prior to obtaining the signatures, the document must be reviewed in its entirety in iMed to ensure the correct ICD and confirm all information entered on the Input tab is consistent with the participant's preferences.
- When the study participant/LAR has no questions and is ready and willing to consent to participate in the clinical trial, he/she documents such by signing the translated long form via iMed on a mobile signature device. The system will automatically date and time the signature.
    - If the ICD contains any embedded questions, the participant/LAR must answer these as required.

For remote consent: Participant/LAR signature will be obtained through iMed MSC, Mobile Signature Capture via a link sent to the participant/LAR.

- If the study participant/LAR declines to sign the consent, document reason in the medical record. DO NOT perform any research procedures on a participant that declines to sign the ICD.

STEP 5: Obtain other signatures required on fully translated long ICD

- The investigator who obtained consent signs on a mobile signature device and the system will automatically date and time the signature.
- The investigator must also complete the NIH Administrative Section on the translated long form to indicate that an interpreter was used during the IC process. Select the second option:

  An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is:_____.

  Note: A witness is not required if a translated long form is used during the IC process, unless the participant is illiterate or blind.

<u>If the protocol has an IRB approved fully translated long form based on **previous** English ICD version:</u>

<u>For reconsent of existing non-English speaking participants:</u>

- While waiting for IRB approval of the translated modified consent, DO NOT use the short form process.
  - Wait to reconsent participants with the revised translated consent form.
- However, if the information in the modified consent needs to be provided to participants emergently or it is in the best interest of the participant to be informed of the changes before the translated version is available and approved by the IRB (such as information about new risk(s) and/or urgent or new research procedure that cannot wait for the translated version):
  - The research team should verbally inform the participant of the changes using a qualified medical interpreter.
  - Document in CRIS this discussion including the participant's willingness to continue study participation.
- Reconsent once the translated consent is available, even if the participant was notified of changes and agrees to continue to participate. The participant's signature must be obtained on the revised translated consent document.

<u>For NEW enrollment of non-English speaking participant:</u>

- While waiting for IRB approval of the translated modified consent, DO NOT use the short form process.
- For the informed consent process, use the existing version of the translated consent document. Follow procedure above for specific steps in the initial consenting process.
- In addition, verbally inform the participant of the pending changes to the informed consent.
- Document this process and what information the participant was verbally told in the consent note in the participant's medical record.
- When the modified version of the translated consent document is available, provide it to the participant and reconsent them at that time, obtaining the participant's signature on the updated version of the translated consent document.
- Document this IC process in participant's medical record.

Short Form Consent Process: if the protocol does not yet have ANY fully translated long form:

STEP 1: Obtain current IRB approved ICD

- Obtain the most current IRB approved English long form from iMed. The document is also available on the NIH Clinical Research Studies Active Consent/Assent Documents website.
  - Check approval date and version to assure most current IRB approved version. This is located in the footer of each page.
    - If not the current version, contact your PSO manager for assistance.
- Obtain the appropriate version of the short form version in the participant's/LAR's preferred language from iMed. The documents are also available on the Short Form Consent Documents website.
  - Enter institute name, PI name, protocol number and protocol title in iMed to have it included in the short form.
  - Complete the contact information on page 2 of the short form.

Note: If using a paper form the above information should be entered manually into the short form.

STEP 2: Send/give IRB approved version of ICD to participant/LAR

- This will allow time for the participant/LAR to review prior to the consent process

STEP 3: Determine who will be involved in the consent process

- The Principal Investigator, an Associate Investigator or other designated individual must be identified in PROTECT to obtain consent.
- For research involving adults who lack the capacity to provide consent, consent must be obtained from a legally authorized representative (LAR).
- Secure interpreter in the participant's language for the IC process.
- If one of the investigators is fluent in the participant's language, they may serve as an interpreter. Use of an investigator as an interpreter MUST be documented in CRIS.

Note: Use of an adult family member for interpretation is not permitted. If a professional medical interpreter cannot be located, please see Policy 301: *Informed Consent*.

- When using the short-form process, ensure that a witness is available to observe the entire consent process. Per Policy 301: *Informed Consent*, the witness should be fluent in both the participant's language and English. If using the CC Language Interpreter Program, the interpreter must serve as a witness when facilitating the short form consent process. Please review Policy 301: *Informed Consent* for more information if a bilingual witness is not available.

STEP 4: Initiate IC process with the assistance of the interpreter

- Discuss the essential elements of an informed consent:
  - Discuss the research study including procedures, treatment plan, potential risks, benefits of participation, study participant's rights as a participant, and alternatives to participation in the research study.

Note: Discussions about protocol treatment and alternatives to participation must be carried out by an appropriately licensed provider (i.e., MD, DO, NP, PA).

- Ask study participant/LAR if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the participant/LAR.
- Prior to obtaining the signatures, the document must be reviewed in its entirety in iMed to ensure the correct ICD and confirm all information entered on the Input tab is consistent with the participant's preferences.

- When the study participant/LAR has no questions and is ready and willing to consent to participate in the clinical trial, he/she documents such by signing the short form via iMed on a mobile signature device.
- If the IRB approved long form ICD (i.e., English version) has embedded questions, then the investigator would respond on behalf of the participant.
    - The interpreter would ask the participant the embedded question(s) and convey their response to the investigator obtaining consent. Neither the interpreter nor the participant should record the response.
    - The investigator will indicate the response on the English ICD by initialing the participant's response using the investigator's initials. If initials are not required (i.e., there is a yes/no response only), the investigator would answer per the participant's preference.
    - If the participant does not want to provide a response, it is left blank.
    - Include the discussion of embedded questions process in the CRIS note.

For remote consent: Participant/LAR signature will be obtained through iMed MSC, Mobile Signature Capture via a link sent to the participant/LAR.

- If the study participant/LAR declines to sign the consent, document reason in the medical record. DO NOT perform any research procedures on a participant that declines to sign the ICD.

STEP 5: Obtain other signatures required on ICD

- The investigator who obtained consent signs on a mobile signature device and the system will automatically date and time the signature.
- The witness that observed the process must sign both the English long form and short form on a mobile signature device and the system will automatically date and time the signature
    - If the witness is remote, their signatures on the short form and long form will be obtained through iMed MSC, Mobile Signature Capture via a links sent to the witness.
- The investigator must also complete the NIH Administrative Section on both the long form and the short form to indicate that an interpreter was used during the IC process and whether or not the interpreter served as a witness.

IMPORTANT: Per NIH HRPP Policy 301: *Informed Consent*, a translated long form must be provided to the non-English speaking participant. See Step 9 below.

The following Steps pertain to both types of consent (translated long form or short form consent):

STEP 6: Provide signed copies of all consent documents to the participant/LAR

STEP 7: File the signed consent in the medical record

- The original, signed ICD will be uploaded automatically into CRIS when the document is marked complete in iMed.

STEP 8: Document the consent process in the study participant's medical record

- Good clinical practice supports documenting the consent process in the study participant's medical record. The CRIS "Documentation of Research Consent" progress note should be used. The note must be completed **within 1 day of the ICD being signed** and this note must be completed by someone who was present during the IC process.
- In CRIS select the Structured Note Titled: *Documentation of Research Consent*
    - Complete all applicable information specific to the IC process

- Please select all the Consent Types used during the IC process
  - Use of iMed Platform
  - Short Form consent
  - Use of interpreters (including staff and other parties)
  - Use of LAR and/or parents

STEP 9: Provide translated long form to participant

- If using the short form process for a greater than minimal risk study, the long form must be translated as soon as possible and provided to the participant.
- Please see the CCR *Frequently Asked Questions Related to Enrolling Non-English-Speaking Participants in the CCR* posted under this SOP.

STEP 10: Continue IC process throughout duration of study participation

- The IC process should continue throughout the study, with the participant's willingness to continue participation documented in the medical record.

<u>Special Informed Consent Situations</u> (e.g., illiterate or blind research participants and/or participants unable to sign their name)

Review Policy 301: *Informed Consent*, review the IRBO FAQs on Informed Consent, and consult the Office of Education and Compliance for assistance.

IMPORTANT: A witness is required to be present during the entire IC discussion in these special situations. The witness must sign the ICD in the appropriate space.