SOP#: PM-2d	**Obtaining and Documenting the Informed Consent Process – Non-English-Speaking Children and Parents (including when only the child speaks English) and Reconsenting**
Version #: 1.1	**Next Review Date: 04/2026**
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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 07:36:34 -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.

Federal regulations provide additional regulatory requirements for child participating in research. A child is a person who has not attained the legal age for consent to treatments or procedures involved in the research. Typically, a child is less than 18 years of age. A child may not be enrolled, screened, or have research procedures initiated, unless parental permission and child assent is obtained, as applicable.

Note: For the purposes of this SOP, a child's guardian (non-parent) can also consent on behalf of the child. Wherever the term "parent" is used in the SOP, the term "guardian" can be used when applicable.

The research protocol must specify the enrollment of children, including plan to:

- Obtain consent from one or both parents
- Obtain assent from the child, as applicable
- Obtain consent for minors when they reach the age of majority

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 consent document 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 as directed in the *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.

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 study participant who is a non-English speaking child, including parental/guardian consent and child assent as applicable. To also describe activities when only the child speaks English. In addition, to describe the process when the IRB requires reconsent for the study participant who is a non-English speaking child, after a modification to the informed consent document.

RESOURCES

DHHS Regulations

- 45 CFR 46 Protection of Human Participants
    - 46.408 Requirements for Permission by Parents or Guardians and for Assent by Children

FDA Regulations

- 21 CFR 50 Protection of Human Participants
    - 50.55 Requirements for Permission by Parents or Guardians and for Assent by Children.

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 402 - *Research Involving Children*

- 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 Child and Parent

Please review NIH Policy 402 *Research Involving Children* before enrolling a minor.

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

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

STEP 1: Review current protocol

- Determine if a single parental signature is required on the ICD
  - When parents share joint legal custody for medical decision-making of a child (e.g., by a custody agreement or court order), NIH policy requires both parents give their permission regardless of the risk level of the research.
- Determine if assent is required for the child given their age and type of assent (verbal or written).

STEP 2: Obtain current IRB approved ICD

- Obtain the current IRB approved version of the protocol's ICD and written assent form if applicable, 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 3: Send/give current IRB approved translated version of ICD to parent/child

- This will allow time for the parent/child to review prior to the consent process.

STEP 4: 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.
- Appropriate parent(s) to be involved in the IC process. Discuss with parent whether the minor should be involved in the process.
- Secure interpreter in the parent/child language for the IC process.
- If one of the protocol's investigators is fluent in the parent'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 5: 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 parent/child if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the parent and minor.
- Prior to obtaining the signatures, the document must be reviewed in its entirety to ensure the correct ICD and confirm all information entered on the Input tab is consistent with the participant's preferences.
- When the parent and child have no questions and are ready and willing to consent to participate in the clinical trial, the parent documents such by signing the ICD via iMed on a mobile signature device. The system will automatically date and time the signature.
  - If the ICD contains any embedded questions, the parent must answer these as required.
- Have the child agree to participate verbally or by signing the written assent document, if translated, in iMed as applicable. If not translated, obtain verbal assent.

  The assent process must be documented in the Documentation of Research Consent note in CRIS.

For remote consent: Parental and child signatures will be obtained through iMed MSC, Mobile Signature Capture via a link sent to the parent.

- If the parent or minor 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 6: 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 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.

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

For reconsent of existing non-English speaking child participants

- While waiting for IRB approval of the translated modified consent, DO NOT use the short form process.
  - Wait to reconsent the parent(s) of the child participant with the revised translated consent form.
- However, if the information in the modified consent needs to be provided to parent(s) emergently or it is in the best interest of the parent(s) 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 parent(s) of the child participant of the changes using a qualified medical interpreter and include the child depending on age and approved assent process.
  - Document in CRIS this discussion including the parent(s) and child'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 parent(s) signature (and child's if required) must be obtained on the revised translated consent document.

<u>For NEW enrollment of non-English speaking child participants</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 parent(s) of the child participant of the pending changes to the informed consent and include the child depending on age and approved assent process.
- Document this process and what information the parent(s) and participant were 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 parent(s) and participant and reconsent them at that time. The parent(s) signature (and child's if required) must be obtained on the revised translated consent document.
- Document this IC process in child participant's medical record.

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

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

STEP 1: Review current protocol

- Determine if a single parental signature is required on the ICD
  - When parents share joint legal custody for medical decision-making of a child (e.g., by a custody agreement or court order), NIH policy requires both parents give their permission regardless of the risk level of the research.
- Determine if assent is required for the child given their age and type of assent (verbal or written).

STEP 2: Obtain current IRB approved ICD

- Obtain the most current IRB approved English long 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 most current 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 parent/child 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 3: Send/give current IRB approved version of ICD and short form to parent/child

- This will allow time for the parent/child to review prior to the consent process.

STEP 4: Determine who will be involved in the IC process

- The Principal Investigator, an Associate Investigator or other designated individual must be identified in PROTECT to obtain consent.
- Appropriate parent(s) to be involved in the IC process. Discuss with parent whether the minor should be involved in the process.
- Secure interpreter in the participant's language for the IC process.
- If one of the investigators is fluent in the parent'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 5: 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 parent/child if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the parent/child.
- Prior to obtaining the signatures, the document must be reviewed in its entirety to ensure the correct ICD and confirm all information entered on the Input tab is consistent with the participant's preferences.
- When the parent and child have no questions and are ready and willing to consent to participate in the clinical trial, the parent documents such by signing only the short form via iMed on a mobile signature device. The system will automatically date and time the signature.
- If the IRB approved long form ICD (i.e., English version) has embedded questions, then the investigator would respond on behalf of the parent.
  - The interpreter would ask the parent the embedded question(s) and convey their response to the investigator obtaining consent. Neither the interpreter nor the parent should record the response.
  - The investigator will indicate the response on the English IRB consent document by initialing the parent'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 parent does not want to provide a response, it is left blank.
  - Include the discussion of embedded questions process in the CRIS note.

- Have the child agree to participate verbally or by signing the written assent document, if translated, in iMed as applicable. If not translated, obtain verbal assent. The assent process must be documented in the Documentation of Research Consent note in CRIS.

For remote consent: Parental and child signatures will be obtained through iMed MSC, Mobile Signature Capture via a link sent to the parent.

- If the parent or child 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 6: Obtain other signatures required on ICD

- The investigator who obtained consent signs the English ICD 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
- 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 Policy 301: *Informed Consent*, a translated long form must be provided to the non-English speaking participant. See Step 10 below.

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

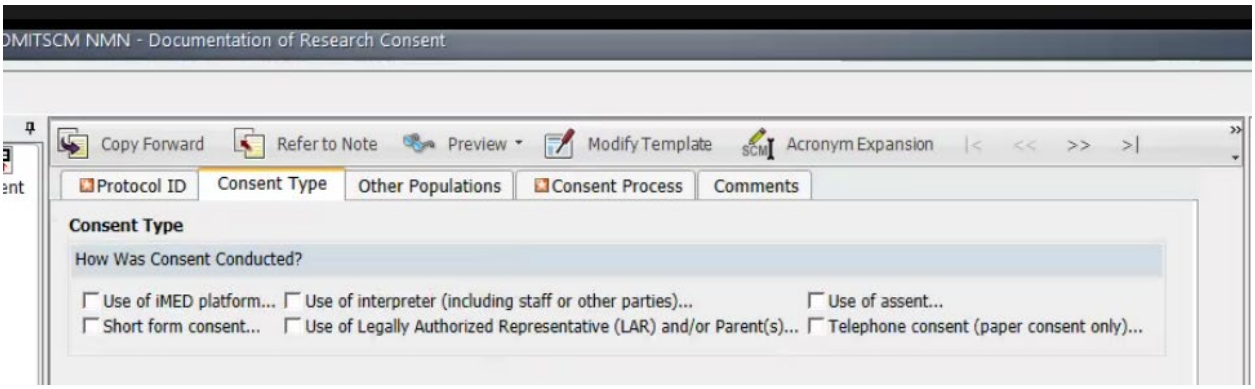
STEP 7: Provide signed copies of all consent/assent documents to the parent/child.

STEP 8 File the signed consent in medical record

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

STEP 9: 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
  - Use of assent



STEP 10: 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 11: 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.

STEP 12: When child reaches the age of 18, obtain informed consent

- When a child who was enrolled in research with parental consent permission reaches the legal age of consent to the procedures involved in ongoing research, parental consent is no longer valid. Consent must be obtained from the now adult participant: See SOP PM2b: *Obtaining and Documenting the Informed Consent Process – Adult Non-English-Speaking Participants, Including Decisionally Impaired, and Reconsenting.*

When child speaks English and parent do not:

- If the protocol requires written assent and child is of the appropriate age, the child may sign the English assent form if the parent agree.
- Otherwise obtain verbal assent with assistance of interpreter.

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

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

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