SOP#: PM-2c	**Obtaining and Documenting the Informed Consent Process – English-Speaking Children and Parents**
Version #: 1.0	**Next Review Date: 04/2026**
Approved Date: 04/2024	**Review Interval Period: Biennial**
NCI Clinical Director Signature/ Effective Date:	James Gulley, M.D., Ph.D. Digitally signed by James Gulley, M.D., Ph.D. Date: 2024.04.03 13:37:58 -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, remote consent and reconsenting.

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.

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.

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

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 child, including parental/guardian consent and child assent as applicable.

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

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)

PROCEDURES

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

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 version of the protocol's ICD and written assent document 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 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.

STEP 3: Send/give current IRB approved 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.

STEP 5: Initiate IC process

- 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 and 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 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 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 in iMed as applicable. 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 on a mobile signature device and the system will automatically date and time the signature.

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 IC/assent documents 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
  - Use of LAR and/or parents
  - Use of Assent

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.
- If reconsent is required by the IRB, please see SOP PM-2: *Obtaining and Documenting the Informed Consent Process (Adult and Pediatric) – General Information*.

STEP 11: 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 PM-2a: *Obtaining and Documenting the Informed Consent Process – Adult English-Speaking participants (Including Decisionally Impaired and Enrollment of NIH Staff).*

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

Review the 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.