

SOP#: PM-2

**Obtaining and Documenting the Informed Consent Process
(Adult and Pediatric) – General Information (Including
Reconsenting, iMedConsent and Remote Consenting)**

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**NCI Clinical Director Signature/
Effective Date:**

POLICY

Related CCR SOPs:

- PM-2a: *Obtaining and Documenting the Informed Consent Process – Adult English-Speaking participants (Including Decisionally Impaired and Enrollment of NIH Staff)*
- PM-2b: *Obtaining and Documenting the Informed Consent Process – Adult Non- English-Speaking participants (Including Decisionally Impaired)*
- PM-2c: *Obtaining and Documenting the Informed Consent Process – English-Speaking Children and Parents/Guardians*
- PM-2d: *Obtaining and Documenting the Informed Consent Process – Non-English-Speaking Children and Parents (including when only the child speaks English)*

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. This includes field cohort participants who consent with the NIH off site ICD. The IRB approved ICD must not be altered in ANY way with handwritten notes or markings.

The information given to the participant, which includes both information provided orally during the consent discussion and written information in the ICD, must be in language understandable to the participant. “Understandable” means the information presented to the potential participant is in a language and at a level the individual can comprehend (including an explanation of scientific and medical terms). Please see SOP PM-2b: *Obtaining and Documenting the Informed Consent Process – Adult Non-English-Speaking participants (Including Decisionally Impaired)* and SOP PM-2d: *Obtaining and Documenting the Informed Consent Process – Non-English-Speaking Children and Parents (including when only the child speaks English)* for more information about enrolling non-English speaking participants.

The Principal Investigator must ensure that investigators delegated to obtain IC are qualified to obtain IC and have completed appropriate training. These investigators must be delegated the task of obtaining IC and listed on the delegation log. In addition, the investigator must be designated on the currently IRB approved protocol or PROTECT Protocol Contact List to obtain consent. The investigator obtaining consent is responsible for assessing that:

- the study participant is capable of making an informed decision (i.e., having the capacity to consent for oneself at the time of the IC discussion);
- the study participant understands the information provided; and
- the study participant’s consent is voluntary and free of any undue influence or coercion.

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.

The IC process must be documented in the medical record by the Principal Investigator or designee that was present for the process to establish that the participant was accurately and adequately informed, that no study-related procedures were initiated prior to obtaining IC, and that a copy of the ICD was given to the participant. The original signed ICD must be sent to the Health Information Management Department, where it will be scanned into the participant's medical record. When using the iMedConsent process, the signed IC is automatically saved in the medical record. Documentation of the IC process must be completed in the medical record **within 1 business day** of the ICD being signed, if in person. If the IC process takes place remotely, documentation of this process must be initiated **within 1 business day** of participant agreeing verbally to participate.

The research protocol must specify the use of the following special consent circumstances, if applicable:

- Enrollment of minor participants, including assent from the minor participant
 - Consent for minors when they reach the age of majority

See SOP PM-2c: Obtaining and Documenting the Informed Consent Process – English-Speaking Children and Parents/Guardians and SOP PM-2d: Obtaining and Documenting the Informed Consent Process – Non-English-Speaking Children and Parents (including when only the child speaks English)
- Enrollment of adults who are or become decisionally impaired
- Enrollment of NIH employees or family members of study team members

Reconsenting

If a modification requires reconsenting per the IRB, please follow the timing for consent on the IRB outcome letter. If the letter does not specify a timeframe for consent, the timing of the consent should be commensurate with the new information contained in the revised IC. For example, if the revised consent contains new risk information, participants must be reconsented as soon as possible and within 30 days of IRB approval of the revised IC. Otherwise, consent of all required participants must be completed within 90 days of IRB approval of the revised IC.

BACKGROUND

The conduct of clinical research studies, including clinical trials, is based upon the voluntary consent of the participant who has been appropriately informed about a study's risks and benefits. The ethical principle of respect for persons requires that participants be given the opportunity to choose whether or not to participate in research. This includes field cohort participants who consent using the NIH off site ICD.

Three elements are required for valid IC:

- Disclosure of relevant information to prospective participants about the research
- Prospective participants' comprehension of the information
- Prospective participants' voluntary agreement, free of coercion and undue influence, to research participation.

Research consent is an ongoing process. It starts well before any ICDs are signed and continues until the participant has completed participation. The IC process involves meeting with the potential participant, outlining the nature of the study, the risks and benefits of participating, alternatives to participation, and all other information necessary for the participant to make an informed decision whether or not to participate. The ICD formalizes the participant's agreement to participate in the research study.

PURPOSE

To describe general requirements when obtaining informed consent and documenting the informed consent process for all types of research participants. Specific requirements for different types of research participants (adult English-speaking, adult non-English speaking, English speaking children participates and non-English speaking children) are located in subsequent SOPs.

RESOURCES

[DHHS Regulations](#)

- 45 CFR 46 Protection of Human Participants
 - 46.102 Definitions
 - 46.116 General Requirements for Informed Consent
 - 46.117 Documentation of Informed Consent

[FDA Regulations](#)

- 21 CFR 50 Protection of Human Participants
 - 50.3 Definitions
 - 50.20 General Requirements for Informed Consent
 - 50.25 Elements of Informed Consent
 - 50.27 Documentation of Informed Consent
- 21 CFR 312 Investigational New Drug Application
 - 312.62 Investigator Record Keeping and Record Retention

[International Council on Harmonisation-Good Clinical Practice \(ICH-GCP\)](#)

- E6 (R2) Good Clinical Practice Consolidated Guidance
 - GCP 1. Glossary
 - GCP 4.8 Informed Consent of Trial Participants

NIH Clinical Research Studies Active Consent/Assent Documents [website](#)

iMedConsent™ Process Resources:

- Via [CRIS Education Resources](#) > Communication with Other Staff and Patients > iMed Consent
 - iMedConsent™ User Guide
 - iMedConsent™ FAQs \
 - iMedConsent™ Training Video
 - iMedConsent™ Patient Instructions Video (2 minutes) – Send this link to participant to review prior to obtaining consent
- Training classes are also available via [iMedConsent™ HIMD Training](#)

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*
- 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

iMedConsent™ Process:

iMed consent is accessed via CRIS, which allows the completed consent with signatures to be viewable in CRIS within a few minutes of completing the consent and signature process.

The research protocol or NIH addendum must specifically allow for the use of iMed consent. If the protocol allows for iMed consent, this is the preferred method (versus using a paper consent). Please note that some sponsors do not allow the use of iMed.

The signature of the investigator obtaining consent must be done after the participant, parent and/or LAR signature/initials are captured in the iMed system. Please ensure that signatures and initials (participant, parent, LAR) are appropriately captured on the iMed consent prior to the investigator signing consent. To check if signatures have been captured on the iMed consent, click on the Signature tab. A date and time will be noted next to the signatures that have been captured, with the Signature of PI/AI marked as Incomplete. If a witness signature is required, that must also be done after the participant, parent and/or LAR signature/initials are captured.

When conducting remote IC using synchronous audio/video, only NIH-approved platforms may be used – see Policy 301 *Informed Consent*

When conducting remote consent using the iMedConsent process, discuss with the participant how this process will happen and send them the Patient Mobile Signature Education video to review. During the consenting process, the iMed system will send the participant a link to capture their signature remotely via a phone/tablet.

Remote IC Process Using a [Paper Document](#)

When conducting remote IC using synchronous audio/video, only NIH-approved platforms may be used – see Policy 301 *Informed Consent*

STEP 1: Send/give current version of ICD to participant to allow time for review prior to the consent process

- Send a postage paid return envelope with the ICD for the participant to use to mail the signed ICD back, unless the participant will fax the signed document or send via secure email.

Note: Please include the participant's name and medical record number on the lower left corner of each page of the ICD prior to participant signing the document.

STEP 2: Set up a time to review the consent with the participant.

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.

STEP 4: Initiate IC process

- Review consent information via telephone or other NIH- approved remote method with participant.

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

- If participant agrees to participate, ask the participant to sign the ICD and date the signature that day.
 - If the participant “needs to think about it,” you must set up a time to speak with them again, so you hear them verbally agree to participate.
- Once the ICD has been signed, the participant returns the entire signed document to the person obtaining consent, via fax, secure email or mail.

STEP 5: Obtain other signatures required on ICD

- When the original consent (or faxed version) arrives at the Clinical Center, the investigator obtaining consent signs the document and dates the signature with the date the IC is received.

Note: If the study participant faxes the signed document to the person obtaining consent, the fax becomes the “original” once the person obtaining consent signs the document. There is no need for the participant to mail the original.

Note: Email communication that may contain personally identifiable information (e.g., participant’s name, medical record number and signatures on the signature page) **MUST** be sent via secure email.

Important: “Verbal” consent is not allowed unless the protocol specifies that verbal consent will be used and the IRB approves the process. Obtaining written consent via telephone is NOT “verbal” consent. Consent is not considered legally effective until the signed document is received by the person obtaining consent. No research procedures may be performed until the signed document is received.

STEP 6: Give participant a copy and file the original, signed ICD in the study participant’s medical record

- Make 2 copies of all pages of the signed and dated ICD and assent document if used.
 - Send the original signed, dated consent/assent document(s) to Health Information Management Department (HIMD) for scanning into the study participant’s medical record.
 - **Give the study participant a copy of the signed consent/assent document.** If the participant declines a copy, please document in the medical record. If the consent process took place remotely, mail or send via secure email the fully signed consent.
 - Maintain a copy of the signed ICD in the participant’s research record until the scanned version is available in the participant’s medical record. Once the scanned version is available and verified, the copy may be destroyed.

Note: Original paper ICDs will be destroyed after 90 days per HIMD policy.

After the ICD is Signed:**STEP 1: 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 selected 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 Consent Platform
 - Telephone consent (for paper consent only)

The screenshot shows a software interface for documenting research consent. The title bar reads 'DMITSCM NMN - Documentation of Research Consent'. Below the title bar is a toolbar with icons for 'Copy Forward', 'Refer to Note', 'Preview', 'Modify Template', and 'Acronym Expansion'. A tabbed interface is visible with tabs for 'Protocol ID', 'Consent Type', 'Other Populations', 'Consent Process', and 'Comments'. The 'Consent Type' tab is active, showing a form titled 'Consent Type' with a section 'How Was Consent Conducted?'. This section contains several checkboxes for different consent methods: 'Use of iMED platform...', 'Use of interpreter (including staff or other parties)...', 'Use of assent...', 'Short form consent...', 'Use of Legally Authorized Representative (LAR) and/or Parent(s)...', and 'Telephone consent (paper consent only)...'.

Documentation of remote consent using paper consent

- **Within 1 day of the telephone conversation during which the participant agrees to participate**, document the conversation in the participant's CRIS record using Documentation of Research Consent note.
 - The date of the telephone conversation during which the participant agrees to participate in the study is the date of consent.
 - If the signed ICD is received prior to writing the note, only one note will need to be written.
 - If the signed ICD is not received before the note is written, include only the relevant information in the Documentation of Research Consent process note. Another note will be written with updated information once you receive the signed ICD. This second note should be completed within 1 day of receiving the signed ICD.
 - Make sure to document that the fully signed copy of the ICD was sent to the participant.
 - Include in Additional Comments the fact that IC was obtained via telephone, that the participant agreed to participate, was instructed on signing the ICD and returning it, etc.

STEP 2: 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.
- The study participant or LAR must be informed of a change in protocol procedures that will affect the participant or a change in risk information, such as a newly documented adverse effect. If there is new information to give the study participant or any other change to the protocol, the IRB must be notified, usually via protocol modification. The modification request includes how subjects will be notified of these changes with a description of who will be

notified and how they will be notified. See the *Guidelines for Reconsenting* for guidance on how to determine the elements of the notification plan.

- The IRB modification outcome letter will specify how to notify study participants of any change to the protocol/consent.
 - If reconsent is required by the IRB:
 - Follow the timing for reconsent in the IRB outcome letter (e.g., at time of next study visit).
 - If the IRB outcome letter does not specify when to obtain reconsent:
 - If new risk information is contained in the revised consent, participants must be reconsented as soon as possible and within 30 days of IRB approval of the revised IC.
 - In all other cases reconsent of all required participants must be completed within 90 days of IRB approval of the revised IC
- Note:** In order to facilitate the discussion of changes with the study participant, you may send them a pdf version of the tracked changes IC. Do not send a word version as this will show who worked on the document.
- If a study participant declines to continue or declines to be reconsented, follow withdrawal of consent procedures.
 - In the case of an emergency (i.e., study participants must immediately stop study treatment), contact the IRBO for instructions.
 - Principal Investigator or designee must document the discussion with the study participant regarding the new findings and the study participant's decision whether or not to continue the study in a progress note in the medical record.

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

Review the NIH HRPP 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 IC discussion in these special situations. The witness must sign the ICD in the appropriate space.