

SOP#: PM-2a

Obtaining and Documenting the Informed Consent Process – Adult English-Speaking Participants (Including Decisionally Impaired and Enrollment of NIH Staff)

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Review Interval Period: Biennial

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

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.

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 HRPP 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.

NIH staff member and immediate family member are permitted to be enrolled in the research conducted at the NIH. The research protocol must specify possible enrollment of NIH staff or the immediate family member. For other requirements please refer to the NIH HRPP Policy 404 – *Research Involving NIH Staff*.

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 English speaking adult study participant who will sign an NIH informed consent document, including enrollment of adults who are or may become decisionally impaired, NIH staff member and immediate family member of study team.

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

The NIH Intramural Human Research Protections Program (HRPP) [Policies](#)

- Policy 301 - *Informed Consent*
- 403 - *Research with Participants Lacking Capacity to Consent*
- 404 - *Research Involving NIH Staff*
- 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

STEP 1: Obtain IRB current approved ICD

- Obtain the most current IRB approved version of the protocol's IC document from iMed. The consent is also available on the NIH Clinical Research Studies Active Consent Documents website.
- Check approval date and version to assure most current IRB approved version. This is in the footer of each page.
 - If not the current version, contact your PSO manager for assistance.

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

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

Note: If the participant is a NIH staff member, the investigator must request the participant review:

- [Leave Policy for NIH Employees Participating in NIH Medical Research Studies \(NIH Policy Manual 2300-630-3\)](#)
- [NIH Frequently Asked Questions \(FAQs\) for Staff Who are Considering Participation in NIH Research](#)

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).
- When the participant is an NIH staff member who is in a subordinate relationship with an investigator on the research team or is part of the work unit where the research is taking place, whenever possible, consent should be obtained by an individual in a non-supervisory relationship with the subject. Also, a consent monitor or other qualified investigator must be present to observe the consent.

STEP 4: 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 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 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 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 ICD

- The investigator who obtained consent signs on a mobile signature device and the system will automatically date and time the signature.

STEP 6: Provide signed copies of all ICDs 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.

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 Consent Platform
 - Telephone consent
 - Use of LAR and/or parents



OMITSCM NMN - Documentation of Research Consent

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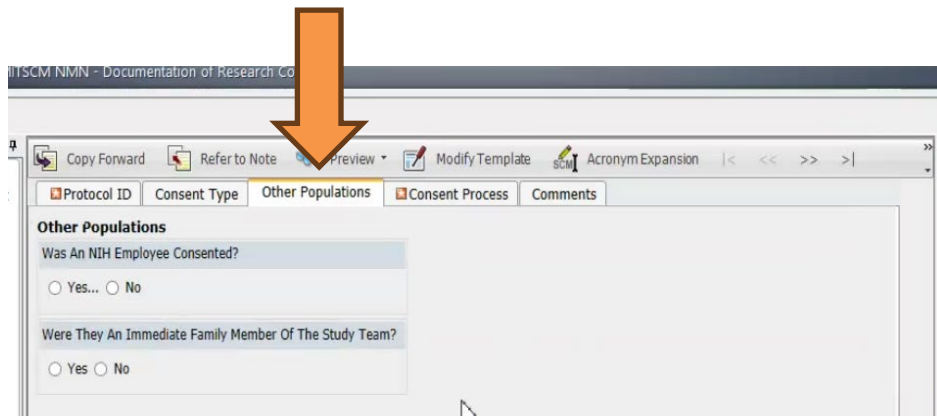
Protocol ID **Consent Type** Other Populations Consent Process Comments

Consent Type

How Was Consent Conducted?

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)... Telephone consent (paper consent only)...

- If the NIH employee or family member is enrolling, select the appropriate option under Other Populations tab.



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Protocol ID Consent Type **Other Populations** Consent Process Comments

Other Populations

Was An NIH Employee Consented?

Yes... No

Were They An Immediate Family Member Of The Study Team?

Yes No

STEP 9: 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*.

Special Informed Consent 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.