

**SOP#: PM-2**

**Obtaining and Documenting the Informed Consent  
Process (Adult and Pediatric)**

**Version #: 4.2**

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**NCI Clinical Director Signature:**

**POLICY**

The informed consent process will be conducted in compliance with all regulations, guidelines and policies applicable to the protection of human subjects. A written informed consent document containing all the required elements must be used to document the subject's agreement to participate in the research study, unless the IRB had approved an alteration or waiver of such document. The IRB-approved informed consent document must not be altered in ANY way with handwritten notes or marking, except as described in Step 5 below.

The informed consent process must be documented in the medical record by the Principal Investigator or designee that was present for the process to establish that the subject was accurately and adequately informed, that no study-related procedures were initiated prior to obtaining informed consent, and that a copy of the informed consent document was given to the subject. The original signed informed consent document must be sent to the Health Information Management Department, where it will be scanned into the subject's medical record. Documentation of the informed consent process must be completed in the medical record within 1 day of the informed consent document being signed, if in person, or within 1 day of the telephone consent process.

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

- Use of short form consent for non-English speaking subjects
- Use of a telephone consent process
- Enrollment of minor subjects, including assent from the minor subjects
- Enrollment of adults unable to consent, including assent of subjects
- Enrollment of NIH employees

**BACKGROUND**

The conduct of clinical research studies, including clinical trials, is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. The ethical principle of respect for persons requires that subjects be given the opportunity to choose whether or not to participate in research.

Three elements are required for valid informed consent:

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

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

## **DEFINITIONS**

**Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical research protocol, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form. The informed consent process must be documented in the medical record.

**Subject:** An individual who is or becomes a participant in research, including a recipient of the test article or a control. A subject may be either a healthy volunteer or a patient.

**Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the clinical trial.

**Adult:** Anyone 18 years of age or older. For purposes of providing consent, a minor who is married, a parent, or an emancipated minor may also be considered an adult.

**Assent:** A child's affirmative agreement to participate in a clinical investigation. Assent may also be obtained from an adult deemed unable to provide informed consent for whom an LAR has provided written informed consent.

## **PURPOSE**

To describe activities involved with obtaining informed consent and documenting the informed consent process for the study subject in the Center for Cancer Research (CCR), National Cancer Institute (NCI).

## **RESOURCES**

### [DHHS Regulations](#)

- 45 CFR 46 Protection of Human Subjects
  - 46.102 Definitions
  - 46.116 General Requirements for Informed Consent
  - 46.117 Documentation of Informed Consent
  - 46.408 Requirements for Permission by Parents or Guardians and for Assent by Children

### [FDA Regulations](#)

- 21 CFR 50 Protection of Human Subjects
  - 50.3 Definitions
  - 50.20 General Requirements for Informed Consent
  - 50.25 Elements of Informed Consent
  - 50.27 Documentation of Informed Consent
  - 50.55 Requirements for Permission by Parents or Guardians and for Assent by Children.
- 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 Good Clinical Practice Consolidated Guidance
  - GCP 1. Glossary
  - GCP 4.8 Informed Consent of Trial Subjects

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](mailto:IRB@od.nih.gov) or 301-402-3713
- Short Form Consent Documents [website](#)

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

- SOP 12 -Requirements for Informed Consent
- SOP14A - Research Involving Vulnerable Subjects (General Considerations)
- SOP 14D- Research Involving Children
- SOP 14E - Research Involving Adults Who Are or May Be Unable to Consent
- SOP 14F - Research Involving NIH Staff as Subjects

NIH Medical Administrative Series (MAS) [Policies](#)

- MAS M77-2(rev.) Informed Consent
- MAS M92-5 (rev.) Research Involving Children and Children's Assent to Research
- MAS M87-4 (rev.) Consent Process in Research Involving Impaired Human Subjects

## PROCEDURES

### Step 1: Obtain most current approved informed consent document (ICD)

- Obtain the current IRB approved version of the protocol's ICD from NIH Clinical Research Studies Active Consent/Assent Documents [website](#).
- Make sure all pages of ICD are present, legible and in order.
- Check approval date and version to assure most current approved version. This is located on the first page of the ICD.
  - If not the current version, contact the IRBO for assistance.

### Step 2: Determine who will be involved in the consent process

- The Principal Investigator, an Associate Investigator or other designated individual identified in the protocol or Key Study Personnel form must obtain informed consent. The investigator obtaining consent is responsible for assessing that:
  - the study subject is capable of making an informed decision (i.e., having the capacity to consent for oneself at the time of the informed consent discussion);
  - the study subject understands the information provided; and
  - the study subject's consent is voluntary and free of any undue influence or coercion.
- For research involving adults who are unable to provide consent or for study subjects under 18 years of age, consent must be obtained from a legally authorized representative (LAR).
  - Individuals designated on NIH-200 Advance Directive or other valid advance directive, or court-appointed guardians are acceptable as LARs.
  - For study subjects with limited capacity to consent, HRPP SOP 14E and MAS policy M87-4 must be followed.
- If using the short-form process, ensure that a witness is available to observe the entire consent process. See below Step 5 for non-English speaking subjects and Step 7 for blind or illiterate subjects.

### Step 3: Initiate informed consent process

- Give study subject or LAR most current version of ICD.
- Allow study subject or LAR time to read the ICD.
- Discuss issues related to the essential elements of an informed consent:
  - Discuss the research study including procedures, treatment plan, potential risks, benefits of participation, study subject'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 subject or LAR if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the subject or LAR.
- When the study subject or LAR has no questions and is ready and willing to consent to participate in the clinical trial, he/she documents such by signing and dating the informed consent document on the signature page where specified. If the ICD contains any embedded questions, the subject must answer these as required.
- If the study subject declines to sign the consent, document reason in the medical record. DO NOT perform any research procedures on a subject that declines to sign the ICD.

**Note:** Per MAS policy, the ICD must include the subject's name and medical record number in the lower left corner of each page of the form.

### Step 4: Obtain other signatures required on ICD

- The investigator (Principal Investigator, Associate Investigator or designed individual) who obtained consent signs and dates the ICD at the time of consent.

### Step 5: If appropriate, follow consent process for non-English speaking research subjects

- **Expected enrollment** of non-English speaking subjects will require an IRB-approved translated consent document (long form consent).
  - A copy of the IRB-approved translated ICD is given to the subject.
  - Informed consent must be clearly communicated to the study subject in his/her language.
  - An interpreter might be needed to facilitate the discussion unless the investigator obtaining informed consent is not fluent in subject's preferred language.
  - A witness to the process is not required when using an IRB-approved translated long form consent document.
- **Unexpected enrollment** of non-English speaking subjects requires the use of the short form consent.
  - Ensure that the current protocol allows for enrollment of non-English speaking subjects and that the IRB has prospectively approved the use of the short form consent.
  - "Short form" consent documents for commonly spoken languages are available on the IRBO website

**Note:** Please read the instruction on the website to ensure you are using the correct version of the short form.

  - Give a copy of the short form in the subject's preferred language to the subject to review.
  - When using a short form process, a witness is required to be present for the entire oral consent discussion.
- Discuss the research study (as described in Step 3 above) utilizing an interpreter, preferably independent from the study subject, to facilitate discussion.
  - Prearrangements may be made via the Social Work Department to secure an interpreter.
  - The interpreter may act as witness to consent and sign documents as below. The interpreter must note "Interpreter" under his/her signature line(s) per HRPP SOP 12.

- Signatures required for translated long form:
  - The study subject or LAR signs and dates the translated consent document.
  - The investigator obtaining consent signs and dates the translated consent document.
- Signatures required for short form in subject's preferred language and English consent document:
  - The study subject or LAR signs and dates the short form.
  - A witness to the entire oral consent discussion signs and dates both the short form and the English consent document.
  - The investigator obtaining consent signs and dates the English consent document.
  - If the IRB approved long form consent document (i.e., English version) has embedded questions, then the investigator would respond on behalf of the subject.
    - The interpreter would ask the subject the embedded question(s) and convey their response to the investigator obtaining consent. Neither the interpreter nor the subject should record the response.
    - The investigator will indicate the response on the English IRB consent document by initialing the subject'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 subject's preference.
    - If the subject does not want to provide a response, it is left blank.
    - Include the discussion of embedded questions and subject's answers in the CRIS note.
- Also, complete the NIH Administrative Section on both the long form and the short form to indicate that an interpreter was used during the informed consent process.

**Step 6: If appropriate, obtain assent from child subject. Review HRPP SOP 14D and MAS policy M92-5**

- Follow the IRB-approved procedures specified in the protocol to obtain parental/LAR consent (e.g. whether one parent's signature is sufficient given the level of risk).
  - Per HRPP SOP 14 D "In cases where parents share joint legal custody for medical decision-making of a child (e.g., by a custody agreement or court order), both parents must give their permission regardless of the risk level of the research." (14D.6.1 Obtaining or Waiving Parental Permission)
  - The signature page of the ICD has a second signature line if needed for joint custody.
- If the IRB determines that the child's assent is needed, follow protocol-specified procedures for obtaining assent, either verbal or written.
- The protocol should be explained to the child in an age appropriate way that allows the child to provide a meaningful, informed assent. Explanation should include the following:
  - The reason for being at the research facility.
  - Expectations of what a child will experience in the hospital.
  - Description of procedures and immediate consequences of the procedures.
  - Explanation of reason for the study and the benefits to the child or other children.
- When minors reach the age of 18, they MUST be consented to the study using the standard informed consent document as parental/LAR consent is no longer valid after the subject becomes as adult. Even if a study is in data analysis only at the time the minor reaches 18, the investigators are still using identifiable specimens and data and the now-adult subject must be consented. Refer to the study protocol for more information about consenting minors when they reach the age of 18.

**Step 7: If appropriate, follow oral consent process (for illiterate or blind research subjects)**

- The oral consent process requires the use of 2 forms, reviewed and approved by the IRB: a written summary (ordinarily the existing IRB-approved informed consent document) and a short written consent document (“short form”).
  - English “short form” consent documents are available on IRBO website.

**Note:** Please read the instruction on the website to ensure you are using the correct version of the short form

- The study should be presented verbally to the subject (as described in Step 3 above). TA witness to the consent process must be available for the entire discussion. oral presentation.
- The study subject or LAR signs and dates the short form.
- A witness to the entire oral presentation signs and dates both the short form and the long form.
- The investigator obtaining consent signs and dates the long form.
- Whenever possible, information in the documents should be provided to the subject in a way that he/she can review and understand (e.g. tape recording, Braille document). This additional information must be approved by the IRB prior to use.

**Step 8: File the original, signed informed consent document in the study subject’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 subject’s medical record.
  - Give the study subject or LAR a copy of the signed consent/assent document. If the subject declines a copy, please document in the medical record.
  - Maintain a copy of the signed ICD in the subject’s research record until the scanned version is available in the subject’s medical record. Once the scanned version is available and verified, the copy may be destroyed.

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

**Step 9: Document the consent process in the study subject’s medical record**

- Good clinical practice supports documenting the consent process in the study subject’s medical record. The CRIS “Documentation of Research Consent” progress note should be used. The note must be completed within 1 day of the consent document being signed by someone who was present during the informed consent process.
- At a minimum, the following should be included:
  - Protocol number and/or short title
  - Date consent was obtained.
  - The study was discussed and questions were answered.
  - A copy of the consent/assent document was provided to the study subject or LAR.
  - The consent was obtained prior to any research procedures being performed.
  - If applicable, oral consent or consent of non-English speaking subject was performed. In these cases, include name of interpreter, if used.
  - Assent process used for minor subject, as required.

**Step 10: Continue informed consent process throughout duration of study participation**

- Principal Investigator or designee should contact all study subjects on study and inform them of any new findings, as appropriate, and determine their willingness to continue treatment/ participation on the study based upon the new information.

- The study subject or LAR must be informed of a change in protocol procedures that will affect the subject or a change in risk information, such as a newly documented adverse effect. The requirement to obtain the subject's or LAR's signature on an updated ICD (i.e., re-consent) is determined by the protocol sponsor and IRB.
  - The discussion of the new information may be initiated by having the study subject sign an IRB-approved revised ICD, by signing an IRB-approved information disclosure document, or by another mechanism; as determined and approved by the IRB.
  - The same consent procedures outlined above will be followed for re-consenting a study subject or LAR.
  - When an IRB-approved information disclosure document or another disclosure mechanism is used, the document used, and the notification process must be included in the medical record (see #9 above).
  - In the case of an emergency (i.e. study subjects must immediately stop study treatment), contact the IRBO for instructions.
  - If study subject declines to continue, follow withdrawal procedures.
- Principal Investigator or designee must document the discussion with the study subject regarding the new findings and the study subject's decision whether or not to continue the study in a progress note in the medical record.

**STEP 11: If appropriate and the protocol allows, obtain initial consent or re-consent via telephone.**

- Send currently approved copy of the ICD to the study subject for review and set up a time to review the consent with the subject.
  - Include a postage paid return envelope with the ICD for the subject to use to mail the signed ICD back, unless the subject will fax the signed document or send via secure email – see Note below.
  - Review consent information via telephone with subject.
  - If the study subject is a minor and the protocol requires assent of the minor, the minor must be present on the telephone during the informed consent and assent process.
  - If using the short form process, the witness to the oral presentation must sign both the short form and English long form. In this case, a member of the research team/other NIH staff that is present for the entire oral presentation may sign as the witness on both forms.
- If subject agrees to participate, ask the subject to sign the ICD and date the signature that day.
- If the subject “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 required signature has been obtained, the subject returns the entire signed document to the person obtaining consent, via fax, secure email or mail.
- 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 informed consent is received.

**Note:** If the study subject faxes the signed consent 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 subject to mail the original.
- Make two copies of the fully signed ICD and send one to the subject. Keep the other copy and send the original ICD to HIMD for scanning into the subject's CRIS record.

- Within 1 day of the telephone conversation during which the subject agrees to participate, document the conversation in the subject's CRIS record using Documentation of Research Consent note.
  - The date of the telephone conversation during which the subject 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 subject.
  - Include in Additional Comments the fact that informed consent was obtained via telephone, that the subject agreed to participate, was instructed on signing the ICD and returning it, etc.

**Note:** Email communication that may contain personally identifiable information (e.g., subject'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.