

**SOP#: PM-2**

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

**Version #: 7.0**

**Next Review Date: 01/2026**

**Approved Date: 01/2024**

**Review Interval Period: Biennial**

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

**POLICY**

The informed consent 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 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 consent document. The IRB-approved informed consent document must not be altered in ANY way with handwritten notes or markings.

The informed consent process must be conducted by an investigator designated on the currently 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 informed consent 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 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 participant 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 participant. The original signed informed consent document must be sent to the Health Information Management Department, where it will be scanned into the participant's medical record. Documentation of the informed consent process must be completed in the medical record **within 1 business day** of the informed consent document being signed, if in person. If the informed consent 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 participants
  - Consent for minors when they reach the age of majority
- Enrollment of adults who are or become decisionally impaired
- Enrollment of NIH employees or family members of study team members

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

## **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 consent document.

Three elements are required for valid informed consent:

- 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 forms are signed and continues until the participant has completed participation. The informed consent 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 informed consent document (ICD) formalizes the participant's agreement to participate in the research study.

If an amendment/modification requires re-consenting per the IRB, the timing of the re-consent should be commensurate with the new information contained in the revised informed consent. For example, if the revised consent contains new risk information, participants must be re-consented as soon as possible and within 30 days of the approval of the revised informed consent. Otherwise, re-consent of all required participants must be completed within 90 days of the approval of the revised informed consent.

## **PURPOSE**

To describe activities involved with obtaining informed consent and documenting the informed consent process for the study participant who will sign an NIH consent document.

## **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
  - 46.408 Requirements for Permission by Parents or Guardians and for Assent by Children

### [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
  - 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 (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 Educational Resources](#)
  - iMedConsent™ User Guide
  - iMedConsent™ Frequently Asked Questions
- [iMedConsent™ Training Video](#)
- Training classes are also available via [iMedConsent™ HIMD Training](#)
- [Patient Mobile Signature Education Video](#) (2 minutes) – Send this link to participants to review prior to obtaining consent.

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

- Policy 301 - Informed Consent
- Policy 400 - Research Involving Pregnant Women, Fetuses, and Neonates Policy 401 - Research Involving Prisoners
- 402 - Research Involving Children
- 403 - Research with Participants Lacking Capacity to Consent
- Series 500 as applicable: FDA Requirements for Human Participants Research and Data and Safety Monitoring
- [NIH IRP HRPP Policy Glossary](#)
- IRBO Frequently Asked Questions (FAQ) [website](#)

## PROCEDURES

### **iMedConsent™ Process:**

iMedConsent™ is a web-based application for securing consent including the electronic capture of signatures, both research consents, clinical procedure consents and most admission consents. The signature on consent documents can be obtained using a signature pad, mouse or touchscreen. The iMed process can be used when the consent is obtained in person or if the consent process is conducted remotely.

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.

Your research protocol 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).

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/Al 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.

### **English-Speaking Adult Participant**

#### **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 or via iMed.

Note: If you don't see your consent in iMed, please contact [CCR OEC](#).

- 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 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 to allow time for review prior to the consent process**

#### **STEP 3: Determine who will be involved in the consent process**

- The Principal Investigator, an Associate Investigator or other designated individual identified in the protocol or PROTECT form must obtain informed consent.
- For research involving adults who lack the capacity to provide consent, 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.

#### **STEP 4: Initiate informed consent 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 or LAR if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the participant or LAR.
- When the study participant 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. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.
  - If the ICD contains any embedded questions, the participant must answer these as required.
- If the study participant 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.

**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. iMed will include these automatically.

**STEP 5: 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. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.

**Non-English-Speaking Adult Participant**

**Non-English-speaking participants cannot initial or sign any part of the English ICD.**

If the protocol has an approved fully translated long form:

**STEP 1: Obtain most current IRB approved informed consent document (ICD)**

- Obtain the current IRB approved translated long form of the protocol's ICDs from NIH Clinical Research Studies Active Consent/Assent Documents website or via iMed.
- Make sure all pages of each ICD are present, legible and in order.
- 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.

**IMPORTANT:** if the English version of the informed consent has been modified but the translated long form has not yet been approved, you must use the short form consent process below.

**STEP 2: Send/give current IRB approved version of ICD to participant to allow time for review prior to the consent process**

**STEP 3: Determine who will be involved in the consent process**

- Secure interpreter in the participant's language for the informed consent process. Provide the interpreter with the English consent as well as the fully translated long form.
- If one of the investigators is fluent in the participant's language, they may serve as an interpreter.

NOTE: Use of an adult family member for interpretation is not permitted unless a professional medical interpreter cannot be located.

**STEP 4: Initiate informed consent 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 study participant or LAR if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the participant or LAR.
- When the study participant 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 translated long form on the signature page where specified. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.

**STEP 5: Obtain other signatures required on fully translated long ICD**

- The investigator (Principal Investigator, Associate Investigator or designed individual) who obtained consent signs and dates the translated long form at the time of consent. When using iMed, the signatures are captured 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 informed consent process.

Note: A witness is not required if a translated long form is used during the informed consent process, unless the participant is illiterate or blind – see below Special Informed Consent Situations.

**Short Form Consent Process:** if the protocol does not have a fully translated long form:

**STEP 1: Obtain most current IRB approved informed consent document (ICD)**

- Obtain the current IRB approved English long form of the protocol's ICD from NIH Clinical Research Studies Active Consent/Assent Documents website or via iMed.
  - 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 participant's native language from the Short Form Consent Documents website or via iMed.

- Complete the header section on the short form with the institute name, PI name, protocol number and protocol title. Ensure that the protocol number is also entered on the footer section on each page of the short form. iMed will ask for this information and include in the short form.
- Complete the contact information on page 2 of the short form.
- Make sure all pages of each ICD are present, legible and in order.

**STEP 2: Send/give current version of ICD and short form to participant to allow time for review prior to the consent process**

**STEP 3: Determine who will be involved in the consent process**

- Secure interpreter in the participant's language for the informed consent process.
- If one of the investigators is fluent in the participant's language, they may serve as an interpreter.

NOTE: Use of an adult family member for interpretation is not permitted unless a professional medical translator cannot be located.

- When using the short-form process, ensure that a witness is available to observe the entire consent process. Per NIH 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 for more information if a bilingual witness is not available.

**STEP 4: Initiate informed consent 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 study participant or LAR if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the participant or LAR.
- When the study participant 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 short form on the signature page where specified. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.
- If the IRB approved long form consent document (i.e., English version) has embedded questions, then the investigator would respond on behalf of the participant.
  - The interpreter would ask the participant the embedded question(s) and convey their response to the investigator obtaining consent. Neither the interpreter nor the participant should record the response.
  - The investigator will indicate the response on the English IRB consent document by initialing the participant'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 participant does not want to provide a response, it is left blank.
- Include the discussion of embedded questions and participant's answers in the CRIS note.

**STEP 5: Obtain other signatures required on ICD**

- The investigator (Principal Investigator, Associate Investigator or designed individual) who obtained consent signs and dates the English ICD at the time of consent. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.
- The witness that observed the process must sign and date both the English long form and short form on the signature page where specified. When using iMed, the signatures are captured 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 informed consent process.

**English-Speaking Minor Participant**

**When the research involves a minor, no minor may be enrolled, screened, or have research procedures initiated, unless parental permission and minor assent is obtained, if applicable. Please review NIH policy 402 *Research Involving Children* before enrolling a minor.**

**STEP 1a: 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 minor given their age and what type of assent (verbal or written).

**STEP 1b: Obtain most current approved informed consent document (ICD)**

- Obtain the current IRB approved version of the protocol's ICD and written assent form if applicable, from NIH Clinical Research Studies Active Consent/Assent Documents website or via iMed.
- Make sure all pages of ICD and assent are present, legible and in order.
- 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.

**STEP 2: Send/give current version of ICD to participant to allow time for review prior to the consent process**

**STEP 3: Determine who will be involved in the consent process**

- The Principal Investigator, an Associate Investigator or other designated individual identified in the protocol or PROTECT form must obtain informed consent.
- Appropriate parent(s) to be involved in the informed consent process. Discuss with parent whether the minor should be involved in the process.



#### **STEP 4: Initiate informed consent 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 minor if he/she has any questions.
  - All questions about the trial should be answered to the satisfaction of the parent and minor.
- When the parent and minor have no questions and are ready and willing to consent to participate in the clinical trial, the parent documents such by signing and dating the informed consent document on the signature page where specified. When using iMed, the signatures are captured on a mobile signature device and 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 minor agree to participate verbally or by signing the written assent document as applicable. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.
- 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.

**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 5: 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. When using iMed, the signatures are captured on a mobile signature device and the system will automatically date and time the signature.

**Note:** If the parent and/or minor do not speak English, please also follow the process under section above "Non-English-speaking Adult Participant" and review the FAQ website under Resources.

#### **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 Informed Consent, and consult the Office of Education and Compliance for assistance.

#### **Remote IC Process**

**If appropriate, obtain initial consent or re-consent via remote consent procedure (i.e., telephone or video conference).**

**When conducting remote informed consent 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.

**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. Not needed with iMed.

**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 identified in the protocol or PROTECT form must obtain informed consent.
- If using the short form process, a witness is required at the site of the investigator. See above “Non-English-speaking participant” for more information about the short form witness.
- If the study participant 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 – see above “English speaking Minor Participant.”

**STEP 4: Initiate informed consent process**

- Review consent information via telephone or other 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. iMed will send a link to the participant to capture their signature and will automatically date and time the signature.
  - 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. When using iMed, the investigator obtaining consent will sign right after the participant using a mobile signature device and the system will automatically date and time the signature.
- If using the short form process, the investigator and witness sign the English long form using the date of telephone conversation during which the participant agreed. When using iMed, the investigator will sign the English long form and witness will sign the English long form and short using a mobile signature device. iMed will automatically date and time the signatures.

### **STEP 5: Obtain other signatures required on ICD**

NOTE: – when using iMed, all signatures are obtained in the iMed system at the time of the IC process. 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. See above **iMedConsent™ Process.**

- 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.
- If the short form process is used, the witness signs and dates the short form that had been signed by the participant using the date the informed consent was received.

**Note:** If the study participant 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 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.

### **The following Steps pertain to all types of consents:**

#### **STEP 6: File the original, signed informed consent document in the study participant’s medical record**

NOTE: When using iMed, the signed consent is automatically uploaded into CRIS when the document is marked complete. The signed consent is also available for the participant to view in the Patient Portal if that access has been activated.

- 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 or LAR 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 ICDs will be destroyed after 90 days per HIMD policy.

#### **STEP 7: 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 consent document being signed** and this note must be completed by someone who was present during the informed consent process.

- Please select all the Consent Types used during the informed consent process
  - Use of interpreters (including staff and other parties)
  - Use of assent
  - Short Form consent
  - Use of LAR and/or parents
  - Telephone consent
- 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 participant or LAR.
  - The consent was obtained prior to any research procedures being performed.
  - If applicable, oral consent or consent of non-English speaking participant was performed. In these cases, include name of interpreter, if used.
  - Assent process used for minor participant, as required.

#### **Documentation of remote consent**

When using iMed for remote consent, the consent is signed by all parties during the IC process and available in CRIS. Only one documentation of research consent note is needed since there is no waiting for the participant to send the signed document.

- **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 informed consent was obtained via telephone, that the participant agreed to participate, was instructed on signing the ICD and returning it, etc.

#### **STEP 8: Continue informed consent process throughout duration of study participation**

- The informed consent 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 re-consent is required by the IRB:
  - Follow the timing for re-consent in the IRB outcome letter (e.g., at time of next study visit).
  - If the IRB outcome letter does not specify when to obtain re-consent:
    - If new risk information is contained in the revised consent, participants must be re-consented as soon as possible and within 30 days of the approval of the revised informed consent.
    - In all other cases re-consent of all required participants must be completed within 90 days of the approval of the revised informed consent

Note: In order to facilitate the discussion of changes with the study participant, you may send them a pdf version of the tracked changes informed consent. 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 re-consented, 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.