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

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

STEP 1: Obtain most current approved consent document.

1. Obtain the current IRB approved version of the consent document (form # NIH-2514-1, Revision date 07-09) from the Clinical Center's website: https://ccrod.cancer.gov/confluence/display/CCRCRO/Templates.
2. Make sure all pages of consent document are present, legible and in order.
3. Check approval date and version to assure most current approved version. This is located on the last page of the informed consent document.
    - If not the current version, contact the IRB Administrative Office via email (nciirbadmin@mail.nih.gov) or phone (301.496.6375) to investigate the suspected discrepancy.

STEP 2: Determine who will be involved in the consent process.

1. The Principal Investigator or an Associate Investigator, listed in the protocol, will obtain informed consent.
    - IRB approval is required for anyone other than the Principal Investigator or an Associate Investigator to obtain consent.
    - The investigator is responsible for assessing that: the study participant is capable of making an informed decision; the study participant understands the information provided; and the study participant's consent is voluntary and free of any undue influence or coercion.
2. For research involving adults who are unable to provide consent or for study participants 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 participants with limited capacity to consent, Medical Administrative Series (MAS) policy M87-4 should be followed.
3. Ensure that a witness is available to observe signing of the consent document.

STEP 3: Initiate Informed Consent process. Medical Administrative Series (MAS) policy M77-2

1. Give study participant or study participant's LAR most current version of consent document.
2. Allow study participant or study participant's LAR time to read the consent document.
3. 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 participants rights as a participant, and alternatives to participation in the research study.
4. Ask study participant or study participant's LAR if he/she has any questions.
    - All questions about the trial should be answered to the satisfaction of the study participant or the study participant's LAR
5. When the study participant or study participant's 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.
6. If the study participant declines signing the consent, document in the medical record.

STEP 4: Obtain other signatures required on consent document.

1. After the study participant or study participant's LAR has signed and dated the consent document, the witness should sign and date the consent document..
2. The witness is attesting only that the study participant or study participant's LAR signed the document.
3. The investigator (Principal Investigator or Associate Investigator) who obtained consent should sign and date the consent document at the time of consent.

STEP 5: If appropriate, follow consent process for non-English speaking research subjects.

1. **Expected enrollment**of non-English speaking subjects will require an IRB-approved translated consent document.
    - A copy of the IRB-approved translated consent document is given to the subject.
2. **Unexpected enrollment** of non-English speaking subjects requires the use the short form consent.
   The following should be submitted to IRB using the short form application in iRIS:
    - A written summary, in English, (usually the existing IRB-approved informed consent document).
    - A Short Written Consent Form ("Short Form") in the subject's native language.
        - "Short form" consent documents for commonly spoken languages are available on the Clinical Center website: http://www.cc.nih.gov/protocolconsents/
          Note: Be sure that you choose the version of the short form consent that has the FDAAA language that is consistent with your written English consent document.
    - If the existing IRB-approved consent document contains the optional biopsy/specimen language, then 3 other forms are required:
        - English version "NCI Addendum to Short Form – Storage for Future Use.
        - "NCI Addendum to Short Form – Storage for Future Use" in the subject's native language.
        - The Certificate of Translation for a newly translated short form addendum. The IRB will already have the certificate of translation for previously translated languages.

Note: Be sure that you choose the version of the addendum that matches the specimen language that is consistent with your written English consent document.

- If you need to use the short form addendum for other language(s), please submit the English version for translation through the NIH Translation Office in the NIH Library using NIH Form 75 (http://nihlibrary.nih.gov/Services/Pages/Translations.aspx). Once translated, the above steps can then be followed.
  Note: Please check the IRB website first to see if the language needed is available first.
- When you receive back the IRB approval to use the short form consent process, save the approval in your regulatory file.

3. Discuss the research study (as described in #3 above) once you have received approval back from the IRB to use this process.
4. An interpreter, preferably independent from the study participant, must be present to facilitate discussion.
5. The study participant or the study participant's LAR signs and dates the "short form" or the translated consent document, whichever is used.
6. The interpreter will act as witness to consent and signs and dates both the written summary and either the "short form" or the translated consent document, whichever was used. The interpreter will note "Interpreter" under their signature line.
7. The investigator obtaining consent signs and dates the English written summary at the time of consent.

STEP 6: If appropriate, follow oral consent process (for illiterate or blind research subjects).

1. The oral consent process requires the use of 2 or 3 forms, reviewed and approved by the IRB: a written summary (ordinarily the existing IRB-approved consent document) and a short written consent document ("short form"). If the existing IRB-approved consent document contains the optional biopsy/specimen language, then a 3rd form is required: NCI Addendum to Short Form – Storage for Future Use.
   - The English "short form" (form # NIH-2514-1, Revision date 7-09) template is available on the Clinical Center website: http://clinicalstudies.info.nih.gov/protocol_consents/
   - The English NCI Addendum to Short Form – Storage for future use (form #NIH-2514-5, version date 2-11) template is available on the CCR IRB Administrative Office site: https://ccrod.cancer.gov/confluence/display/CCRCRO/NCI+Short+Form+Addendums+version+1
2. The study should be presented verbally to the subject (as above). The witness to the consent process must also witness the oral presentation.
3. The study participant or study participant's LAR and the witness sign and date the short form and if applicable, the NCI Addendum to Short Form – Storage for future use.
   - The witness is attesting only that the study participant or study participant's LAR signed the form.
4. The investigator obtaining consent and the witness sign the written summary (ordinarily the existing IRB-approved consent document).
   - In this case, the witness is attesting that the investigator presented the information in the written summary.
5. 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).

STEP 7: If appropriate, obtain assent from child participant. Medical Administrative Series (MAS) policy M92-5

1. Follow the IRB-approved procedures to obtain parental consent (e.g. whether one parent's signature is sufficient given the level of risk).
   - A study participant under the age of 18 is considered a minor child.
   - For the purpose of consent, a study participant under the age of 18 may be considered an adult if he/she is married, has a child, or is an emancipated minor or as determined by the state laws in which the participant resides.
2. If the IRB determines that the child's assent is needed, follow protocol-specified procedures for obtaining assent.
3. If a written assent is needed, the template document is found on the IRB's website: http://home.ccr.cancer.gov/intra/clin_ops/IRB/Forms_Templates/Assent_Template_10_2009.doc
4. The protocol should be explained to the child in an age appropriate way that the child could 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.

STEP 8: File the original, signed consent document in the study participant's medical record.

1. Make 2 copies of all pages of the signed and dated consent/assent document.
   - Place the original signed, dated consent/assent document in the study participant's medical record.
     - Medical Records Department will scan the document into CRIS.
   - Give the study participant or study participant's LAR a copy of the consent/assent document.
   - Place a copy of the consent/assent document in the study participant's research record.
   - When appropriate, a copy of both the original and translated signed and dated consent form should be filed together.

STEP 9: Document the consent process in the study participant's medical record.

1. Good clinical practice supports documenting the consent process in the study participant's medical record. The CRIS 'Informed Consent progress note' should be used. At a minimum the following should be included:
   - Date and Time consent was obtained.
   - Notation that the study was discussed and questions were answered.
   - Notation that a copy of the consent/assent document was provided to the study participant or study participant's LAR.
   - Notation of whether oral consent, consent of non-English speaking participant, or assent of pediatric study participant was performed. Include name of interpreter, if used.

STEP 10: Continue Informed Consent Process throughout duration of study participation.

1. Principal Investigator or designee should contact all study participants 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.
2. The study participant or study participant's 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 discussion of the new information may be initiated by having the study participant sign an IRB-approved revised consent document, by signing an IRB-approved information disclosure document, or by another mechanism; as determined and approved by the IRB.
   - The same consent procedures will be followed for re-consenting study participant or the study participant's LAR.

    - In the case of IRB-approved information disclosure document or another disclosure mechanism, 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 participants must immediately stop study treatment), contact the NCI IRB Chairperson for instructions.
    - If study participant declines to continue, follow withdrawal procedures.
3. Principal Investigator or designee should document the discussion with the study participant regarding the new findings and the study participant' s decision whether or not to continue on the study in a progress note in the medical record.

STEP 11: If appropriate, obtain a consent from study participants that will not be returning to the CCR.

1. Contact the study participant or study participant's LAR and explain the need for an additional consent per the situation.
    - Examples: if teams want to do additional testing on a research specimen that was already collected and the patient is not returning to the CCR.
    - Provide the study participant or the study participant's LAR with contact information in case they have further questions.
2. Mail approved copy of the consent to the study participant for review and signature.
    - Include a postage paid return envelope with the consent for the subject to use to mail the consent back.
3. Instruct study participant to have someone witness them sign and date the consent.
4. After the study participant or study participant's LAR has signed and dated the consent document, the witness should sign and date the consent document.
    - The witness is attesting only that the study participant or study participant's LAR signed the document.
5. The study participant should mail the consent back to a designated member of the clinical research team.