HRP-090 | 7/31/2024 | Author: C. Loeb | Approver: N. Johnson

SOP: Informed Consent Process for Research

1. PURPOSE
   1. This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.
   2. The process begins when an individual identifies a subject as a potential candidate for a research study.
   3. The process ends when a subject or the subject’s LAR provides legally effective informed consent or declines to do so.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. In this procedure “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the IRB to obtain consent for the specific protocol, such as a co-investigator, research assistant, or coordinator.
   2. In this procedure “subject/representative” means:
      1. The subject when the subject is an adult capable of providing consent.
      2. LAR when the subject is an adult unable to give consent.
      3. One or both biologic or adoptive parents when the subject is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent on behalf of the child to general medical care.
   3. If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
   4. If the subject is an adult unable to consent:
      1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
      2. Permission is obtained from a LAR.
      3. A LAR must be in the class or persons approved by institutional policy or the IRB. See HRP-013 - SOP - LARs, Children, and Guardians.
   5. If the subject is a child:
      1. The IRB must have specifically approved the protocol to allow the enrollment of children.
      2. Permission is obtained from both parents unless:
         1. One parent is deceased, unknown, incompetent, not reasonably available;
         2. Only one parent has legal responsibility for the care and custody of the child; or
         3. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
      3. In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.
   6. If the subject/representative cannot speak English:
      1. The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak the language that the subject understands.
   7. Conduct all discussions in a private and quiet setting.
   8. Any knowledgeable individual may:
      1. Review the study with subject/representative to determine preliminary interest.
      2. If the subject/representative is interested, notify an investigator or an individual authorized by the IRB to provide consent.
      3. If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.
4. RESPONSIBILITIES
   1. The principal investigator is responsible to ensure these procedures are carried out.
5. PROCEDURE
   1. If the consent process will be documented in writing with the long form of consent documentation:
      1. Obtain the current IRB approved consent form.
      2. Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in a language understandable to the subject/representative.
      3. Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.
      4. If the subject/representative cannot read, obtain an impartial witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.
      5. If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.
      6. Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.
      7. If the IRB has approved an electronic or virtual consent process, the following procedures should be followed:
         1. Email the consent document to the participant at least 24 hours prior to the consent session.
         2. Verify the identity of the subject/representative.
         3. Verify that the subject/representative can clearly see and hear you. Identify yourself and obtain a contact number in the event that the consent session gets disconnected or you experience technical difficulties.
            1. In the event that technical difficulties arise or there is a disconnection, re-contact the participant and offer to reschedule or try reconnecting.
         4. Verify that the subject/representative agrees to be recorded during the consent process.
         5. Verify that the consent form is in a language understandable to the subject/representative.
         6. Verify that the consent document has a statement such as, “The Auburn University Institutional Review Board has approved this document for use from \_\_\_\_ to \_\_\_\_, Protocol # \_\_\_\_\_.”
         7. Using a share screen, share the consent form with the subject/representative and carefully go over the consent form. Once the subject/representative has had an opportunity to ask questions, either 1) use Zoom to allow the participant to digitally sign the consent form, or 2) provide a Qualtrics link with the consent document for digital signature. Be sure that the electronic consent form has both a signature box as well as a text-entry box for the participant to type their name and date.
         8. Save the consent recording using the IRB-approved method in the protocol. Save the signed consent form or the digital image of the signature (i.e., the latter would be the case if using Qualtrics).
   2. If the requirement for written documentation of the consent process has been waived by the IRB:
      1. Obtain the current IRB approved script.
      2. Verify that you are using the most current IRB-approved version of the study specific script and that the script language is understandable to the subject/representative.
      3. When possible, provide a copy of the script to the subject/representative.
      4. If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.
      5. Read the script (or have an interpreter translated the script) with the subject/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.
   3. Invite and answer the subject/representative’s questions.
   4. Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.
   5. Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.
   6. Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:
      1. The subject/representative understands the information provided.
      2. The subject/representative does not feel pressured by time or other factors to make a decision.
      3. The subject/representative understands that there is a voluntary choice to make.
      4. The subject/representative is capable of making and communicating an informed choice.
   7. If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.
   8. Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.
   9. If the subject/representative agrees to take part in the research study:
      1. If the subject is a child:
         1. Whenever possible explain the research to the extent compatible with the child’s understanding.
         2. Request the assent (affirmative agreement) of the child unless:
            1. The capability of the child is so limited that the child cannot reasonably be consulted.
            2. The IRB determined that assent was not a requirement.
         3. Once a child indicates that he or she does not want to take part in the research study, this process stops.
      2. If the subject is an adult unable to consent:
         1. Whenever possible explain the research to the extent compatible with the adult’s understanding.
         2. Request the assent (affirmative agreement) of the adult unless:
            1. The capability of the adult is so limited that the adult cannot reasonably be consulted.
            2. The IRB determined that assent was not a requirement.
         3. Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
      3. Obtain written documentation of the consent process according to HRP-091 - SOP - Written Documentation of Consent.
6. MATERIALS
   1. Long form of consent documentation:
      1. Consent form
   2. Requirement for written documentation of the consent process has been waived by the IRB:
      1. Consent script or Information Letter (same as consent form used for long form of consent documentation except that the signature block is optional)
   3. HRP-013 - SOP - LARs, Children, and Guardians
   4. HRP-091 - SOP - Written Documentation of Consent
7. REFERENCES
   1. 21 CFR §50.20, 50.25
   2. 45 CFR §46.116
   3. AAHRPP element I-9