	SOP: Informed Consent Process for Research		
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1. PURPOSE


- 1.1. This SOP describes a process that in general is used to obtain informed consent from participants, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.
- 1.2. Other procedures may be suitable when approved by the IRB.
- 1.3. The process begins when an individual identifies a subject as a potential candidate for a research study.
- 1.4. The process ends when a subject or a subject's LAR provides legally effective informed consent or declines to do so.

2. REVISIONS FROM THE PREVIOUS VERSION


- 2.1. Revised from the 5/30/2017 version.
- 2.2.

3. SOP Statement

- 3.1. 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.
- 3.2. In this procedure "subject/representative" means:
 - 3.2.1. The subject when the subject is an adult capable of providing consent.
 - 3.2.2. LAR when the subject is an adult unable to give consent
 - 3.2.3. 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.
- 3.3. If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
- 3.4. If the subject is an adult unable to consent:
 - 3.4.1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
 - 3.4.2. Permission is obtained from a LAR
 - 3.4.3. A LAR must be in the class or persons approved by institutional policy or the IRB. See HRP-013-SOP – LARs, Children and Guardians.
- 3.5. If the subject is a child:
 - 3.5.1. The IRB must have specifically approved the protocol to allow the enrollment of children.
 - 3.5.2. Permission is obtained from both parents unless:
 - 3.5.2.1. One parent is deceased, unknown, incompetent, or not reasonably available;
 - 3.5.2.2. One parent has legal responsibility for the care and custody of the child; or
 - 3.5.2.3. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
 - 3.5.3. In the absence of a parent, permission may be obtained from an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care
- 3.6. If the subject/representative cannot speak English:
 - 3.6.1. The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak the language other than English that the subject understands.
 - 3.6.1.1. The IRB may require a certificate of translation for the non-English consent documents to verify the translations are accurate.
 - 3.6.1.2. Those who translate the consent document are to provide a brief description of their qualifications, skill or experience or serving in this role and sign the certificate of translation form or equivalent. See HRP-225 -FORM - Translation Certificate.

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- 3.6.1.3. The research investigator may wish to delay the initial translation of the consent documents until after the IRB has reviewed and approved the English versions.
- 3.7. Conduct all discussions in a setting that allows for privacy and confidentiality.
- 3.8. Any knowledgeable individual may:
 - 3.8.1. Review the study with the subject/representative to determine preliminary interest.
 - 3.8.2. If the subject/representative is interested, notify an investigator.
 - 3.8.3. If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.
- 4. RESPONSIBILITIES**
- 4.1. The principal investigator is responsible to ensure these procedures are carried out.
- 5. PROCEDURE**
- 5.1. If the consent process will be documented in writing with the long form of consent documentation:
 - 5.1.1. Obtain the current IRB-approved consent form or script.
 - 5.1.2. 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.
 - 5.1.3. Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance.
 - 5.1.4. If the subject/representative cannot read obtain an impartial witness to be present during the entire consent process and to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
 - 5.1.5. The witness may be a family member or friend. The impartial witness may not be a person involved in the design, conduct, or reporting of the research.
 - 5.1.6. 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.
 - 5.1.7. Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.
 - 5.1.7.1. When conducting federally supported research, 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.
- 5.2. If the requirement for written documentation of the consent process has been waived by the IRB:
 - 5.2.1. Obtain the current IRB-approved script.
 - 5.2.2. 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.
 - 5.2.3. When possible, provide a copy of the consent form to the subject/representative.
 - 5.2.4. 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.
 - 5.2.5. Read the consent document (or have an interpreter read the translated script) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.
 - 5.2.6. When conducting federally supported research, begin with a concise and focused presentation of key information that is most likely to assist the

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subject/representative to understand the reasons why one might or might not want to participate in the research.

- 5.3. Invite and answer the subject/representative's questions.
 - 5.4. Give the subject/representative time to discuss taking part in the research study with family members, friends, and other care providers or to take the written information home to consider as appropriate.
 - 5.5. 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:
 - 5.5.1. The subject/representative understands the information provided.
 - 5.5.2. The subject/representative does not feel pressured by time or other factors to make a decision.
 - 5.5.3. The subject /representative is capable of making and communicating an informed choice.
 - 5.6. If the subject/representative has questions about study interventions or compensation, provide factual information about available options.
 - 5.7. Once a subject/representative indicates that he or she does not want to take part in the research study, stop this process.
 - 5.8. If the subject/representative agrees to take part in the research study:
 - 5.8.1. If the subject is a child:
 - 5.8.1.1. Whenever possible explain the research to the extent compatible with the child's understanding.
 - 5.8.1.2. Request the assent (affirmative agreement) of the child unless:
 - 5.8.1.2.1. The capability of the child is so limited that the child cannot reasonably be consulted.
 - 5.8.1.2.2. The IRB has determined that assent was not a requirement.
 - 5.8.1.3. Once a child indicates that he or she does not want to take part in the research, stop this process.
 - 5.8.2. If the subject is an adult unable to consent:
 - 5.8.2.1. Whenever possible explain the research to the extent compatible with the adult's understanding.
 - 5.8.2.2. Request the assent (affirmative agreement) of the adult unless:
 - 5.8.2.2.1. The capability of the adult is so limited that the adult cannot reasonably be consulted.
 - 5.8.2.2.2. The IRB determined that assent was not a requirement.
 - 5.8.2.3. Once an adult unable to consent indicates that he or she does not want to take part in the research, stop this process.
 - 5.8.3. Obtain written documentation of the consent process according to HRP-091-SOP- Written Documentation of Consent.
- 6. MATERIALS**
- 6.1. Long form of consent documentation:
 - 6.1.1. Consent form HRP-013 - SOP - LARs, Children, and Guardians
 - 6.2. Requirement for written documentation of the consent process has been waived by the IRB:
 - 6.2.1. Consent script (same as consent form used for long form of consent documentation except that signature block is optional)
 - 6.3. HRP-013 - SOP - LARs, Children, and Guardians
 - 6.4. HRP-091 - SOP - Written Documentation of Consent
 - 6.5. FORM: Translation Certificate (HRP-225)
- 7. REFERENCES**
- 7.1. 21 CFR §50.20, §50.25
 - 7.2. 45 CFR §46.116
 - 7.3. AAHRPP element I-9