# 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.

# REVISIONS FROM PREVIOUS VERSION

* 1. Toolkit 5.1 release and other administrative updates.

# 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.
  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:

3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent. **See HRP-013 - SOP - Legally Authorized Representatives, Children, and Guardians.**

* 1. If the subject is a child:
     1. The IRB must have specifically approved the protocol to allow the enrollment of children**. See HRP-416 - CHECKLIST - Children.**
  2. If the subject is pregnant:
     1. The IRB must have specifically approved the protocol to allow the enrollment of pregnant women. **See HRP-412 - CHECKLIST - Pregnant Women**.
  3. If the subject/representative cannot speak English:
     1. The IRB must have specifically approved the protocol to allow the enrollment of non-English speaking subjects.
  4. If the subject/representative speaks and understand English but does not read or write:
     1. The subject may “make their mark” on the consent document in lieu of signing. A witness is required for research enrolling individuals who are unable to read (e.g. a subject is illiterate) or whose LAR is unable to read. The witness must be present for the discussion to attest to the validity of the subject’s signature.
  5. All discussions must be conducted in a private and quiet setting.
  6. 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.
     3. If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

# RESPONSIBILITIES

* 1. The Investigator is responsible for ensuring these procedures are carried out.

# PROCEDURE

* 1. If the consent process will be documented in writing:
     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, or is physically unable to talk or write, 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. If possible, it is recommended that the witness should not be related to the subject i. 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.
  2. If the requirement for written documentation of the consent process has been waived by the IRB for verbal consent:
     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. If the requirement for written documentation of the consent process has been waived by the IRB for online consent:
     1. Obtain the current IRB-approved online consent.
     2. Verify that you are uploading the most current IRB-approved version of the study specific online consent.
  4. Invite and answer the subject/representative’s questions.
  5. Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.
  6. 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.
  7. 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.
  8. 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.
  9. Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.
  10. 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 is 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 is 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.

5.11 If re-consent of subjects is required, please refer to section 5.1 or 5.2 herein and follow all procedures.

# MATERIALS

* 1. HRP-013 - Legally Authorized Representatives, Children, and Guardians
  2. HRP-091 - SOP - Written Documentation of Consent
  3. HRP-416 - CHECKLIST - Children
  4. HRP-412 - CHECKLIST - Pregnant Women

# REFERENCES

* 1. 21 CFR §50.20, 50.25
  2. 45 CFR §46.116
  3. AAHRPP element I-9

i FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023) <https://www.fda.gov/media/88915/download>