1. PURPOSE
   1. This procedure establishes the process to document the informed consent process in writing.
   2. The process begins when a subject agrees to take part in a research study.
   3. The process ends when the consent process is documented in writing to the extent required by this procedure.
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. Legally authorized representative 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 authorized under applicable law to consent on behalf of the child to the child’s general medical care.
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. Print the name of the subject on the consent document.
      2. Print the name of the person obtaining consent on the consent document.
      3. Have the subject/representative personally sign and date the consent document.
      4. If the IRB required written documentation of assent, note on the signature block one of the following:
         1. Assent of the child was obtained.
         2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
      5. Have the person obtaining consent personally sign and date the consent document.
      6. If an impartial witness was part of the consent process:
         1. Print the name of the impartial witness on the consent document.
         2. Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.
      7. Provided copies of the signed and dated consent document to the subject/representative. This may be accomplished either by making a photocopy or by having the above individuals sign and date two copies of the consent document.
   2. If the consent process will be documented in writing with the short form of consent documentation:
      1. Print the name of the subject on the short consent document.
      2. Print the name of the person obtaining consent on the summary.
      3. Print the name of the impartial witness on the short consent document and the summary.
      4. Have the subject/representative personally sign and date the short consent document.
      5. Have the person obtaining consent personally sign and date the summary.
      6. Have the impartial witness personally sign and date the summary and the short consent document.
      7. If the IRB required written documentation of assent, note on the signature block on the short consent document one of the following:
         1. Assent of the child was obtained.
         2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
      8. Provide a copy of the signed and dated short consent document and a copy of the summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.
   3. If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to document his or her consent is writing, offer the subject/representative the option to document his or her consent is writing.
      1. If the subject/representative declines, take no further action.
      2. If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation.
   4. Electronic consent
      1. Electronic consent document includes all elements in HRP 311 Criteria for Approval and Additional Considerations **Section 8-Elements of Consent Disclosure**
      2. The date of the electronic signature will be captured **(N/A if waiver of documentation of consent is requested and justified).**
      3. Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.
      4. See HRP 311 Criteria for Approval and Additional Considerations for further informed consent process requirements for electronic consent.
   5. Place the signed and dated documents in the subject’s binder.
6. MATERIALS
   1. If the consent process will be documented in writing with the long form of consent documentation:
      1. Consent document
   2. If the consent process will be documented in writing with the short form of consent documentation:
      1. Short consent document
      2. Summary (same content as the long form of consent documentation)
7. REFERENCES
   1. 21 CFR 50.27
   2. 45 CFR 46.117
   3. HRP 311 WORKSHEET Criteria for Approval and Additional Considerations