



## SOP: Informed Consent Process for Research

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### 1 PURPOSE

- 1.1 This procedure establishes the process to obtain informed consent from participants, the legally authorized representatives of adults unable to consent, and/or the parents or guardians of children.
- 1.2 The process begins when an individual identifies a participant as a potential candidate for a research study.
- 1.3 The process ends when a participant or the participant's legally authorized representative provides legally effective informed consent or declines to do so.
- 1.4 This procedure applies to non-exempt research.

### 2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/22/2018

### 3 POLICY

- 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 "participant/representative" means:
  - 3.2.1 The participant when the participant is an adult capable of providing consent.
  - 3.2.2 Legally authorized representative when the participant is an adult unable to give consent.
  - 3.2.3 One or both biologic or adoptive parents when the participant is a child or in the absence of a parent a person other than a parent authorized under applicable law to consent.
- 3.3 If the participant is an adult unable to consent:
  - 3.3.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
  - 3.3.2 Permission is obtained from a legally authorized representative.
  - 3.3.3 A legally authorized representative must be in the class or persons approved by institutional policy or the IRB. See "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."
- 3.4 If the participant is a child:
  - 3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
  - 3.4.2 Permission is obtained from both parents unless:
    - 3.4.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
    - 3.4.2.2 Only one parent has legal responsibility for the care and custody of the child; or
    - 3.4.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
  - 3.4.3 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, education, or other care.
- 3.5 If the participant/representative cannot speak English:
  - 3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of participants able to speak language that the participant understands.
  - 3.5.2 The IRB must have approved a Short Form consent document or fully translated consent document for use.
- 3.6 Conduct all discussions in a private and quiet setting.



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- 3.7 Any knowledgeable individual may:
  - 3.7.1 Review the study with participant/representative to determine preliminary interest.
  - 3.7.2 If the participant/representative is interested, notify the principal investigator.
  - 3.7.3 If the participant/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 that contains the approval information within the document's header.
  - 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 language understandable to the participant/representative.
  - 5.1.3 Provide a copy of the consent form to the participant/representative. Whenever possible provide the consent form to the participant/representative in advance of the consent discussion.
  - 5.1.4 If the participant/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 participant/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.
  - 5.1.5 If the participant/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, a family member, or friend of the participant/representative.
  - 5.1.6 Read the consent document (or have an interpreter read the translated consent document) with the participant/representative. Begin with a concise and focused presentation of key information that is most likely to assist the participant/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 participant/representative understands what it would be like to take part in the research study.
  - 5.1.7 If the participant agrees to participate in the research activities, follow the consent documentation process outlined in the Written Documentation of Consent SOP (HRP-091).
- 5.2 If the consent process will be documented in writing with the short form of consent documentation:
  - 5.2.1 Obtain the current IRB approved short consent form and summary (same as the English consent form used for long form of consent documentation).
  - 5.2.2 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary that the short consent form is in language understandable to the participant/representative.
  - 5.2.3 Provide copies to the participant/representative. Whenever possible provide the short consent form and summary to the participant/representative in advance of the consent discussion.



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- 5.2.4 Obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, family member, or friend of the participant/representative.
- 5.2.5 Obtain the services of an impartial witness who is fluent in both English and the language spoken by the participant/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the participant/representative, and that consent was freely given. The witness and the interpreter may be the same person. 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.
- 5.2.6 Have the interpreter translate the summary (not the short consent form) to the participant/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the participant/representative to understand the reasons why one might or might not want to participate in the research.
- 5.2.7 Through the interpreter explain the details in such a way that the participant/representative understand what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.
- 5.2.8 Have the participant/representative read the short consent form or have the interpreter read the short consent form to the participant/representative.
- 5.3 If the requirement for written documentation of the consent process has been waived by the IRB:
  - 5.3.1 Obtain the current IRB approved consent.
    - 5.3.1.1 Examples include online consent, verbal consent script, or informational document (exempt research).
  - 5.3.2 Verify that you are using the most current IRB-approved version of the consent text and that the language is understandable to the participant/representative.
  - 5.3.3 When possible provide a copy of the consent text to the participant/representative.
  - 5.3.4 If the participant/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, a family member, or friend of the participant/representative.
  - 5.3.5 Read the consent (or have an interpreter translate the consent) with the participant/representative. Begin with a concise and focused presentation of the key information that is most likely to assist the participant/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 participant/representative understands what it would be like to take part in the research study.
- 5.4 If incomplete disclosure or deception is used in non-exempt human research the IRB must first grant a waiver or alteration of the informed consent requirements.
  - 5.4.1 Follow the applicable components of the consent process outlined in section 5.1.
  - 5.4.2 After study participation, the participant may be provided with a **debriefing session, debriefing statement, or post-debrief consent form** after their involvement is complete in a way that is consistent with the IRB-approved protocol.
    - 5.4.2.1 If appropriate, the debriefing process may fully inform participants about any elements that were obscured or falsely represented in the consent.
    - 5.4.2.2 The debriefing process must include:
      - 5.4.2.2.1 Complete disclosure of the deceptive/incomplete disclosure aspect(s) of the study



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- 5.4.2.2.2 An explanation of the reasons for the deception/incomplete disclosure.
- 5.4.2.2.3 An opportunity for the participant to ask questions
- 5.4.2.2.4 If appropriate, an opportunity for the participant to withdraw the provided data.
- 5.4.3 Participants who withdraw their consent prior to the study's completion, may be debriefed.
- 5.5 Invite and answer the participant/representative's questions.
- 5.6 Give the participant/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 participant/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 participant/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the participant/representative is incapable of consent:
  - 7.1 The participant/representative understands the information provided.
  - 7.2 The participant/representative does not feel pressured by time or other factors to make a decision.
  - 7.3 The participant/representative understands that there is a voluntary choice to make.
  - 7.4 The participant/representative is capable of making and communicating an informed choice.
  - 7.5 If the participant/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.
  - 7.6 Once a participant/representative indicates that he or she does not want to take part in the research study, this process stops.
  - 7.7 If the participant/representative agrees to take part in the research study:
    - 7.7.1 If the participant is a child:
      - 7.7.1.1 Whenever possible explain the research to the extent compatible with the child's understanding.
      - 7.7.1.2 Request the assent (affirmative agreement) of the child unless:
        - 7.7.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.
        - 7.7.1.2.2 The IRB determined that assent was not a requirement.
      - 7.7.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.
    - 7.7.2 If the participant is an adult unable to consent:
      - 7.7.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.
      - 7.7.2.2 Request the assent (affirmative agreement) of the adult unless:
        - 7.7.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.
        - 7.7.2.2.2 The IRB determined that assent was not a requirement.
      - 7.7.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
    - 7.7.3 Obtain written documentation of the consent process according to "SOP: Written Documentation of Consent (HRP-091)."
- 8 MATERIALS**
  - 8.1 **TEMPLATE:** Long Form Consent Form Documents:



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- 8.1.1 Social Behavioral Consent (HRP-582)
- 8.1.2 Biomedical Consent (HRP-592)
- 8.1.3 Written Assent (for minors) (HRP-1707)
- 8.1.4 Verbal Assent Script (HRP-1708)
- 8.1.5 Parent Consent and Permission with Child Assent (HRP-1711)
- 8.1.6 Parent Permission with Child Assent (HRP-1712)
- 8.2 CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)
- 8.3 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
- 8.4 CHECKLIST: Children (HRP-416)
- 8.5 SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)
- 8.6 SOP: Written Documentation of Consent (HRP-091)
- 8.7 WORKSHEET: Short Form of Consent Documentation (HRP-317)
- 8.8 Guidelines for Research Involving Deception or Incomplete Disclosure

## 9 REFERENCES

- 9.1 21 CFR §50.20, 50.25
- 9.2 45 CFR §46.116