

SOP: Informed Consent Process for Research

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1. PURPOSE

- 1.1. This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR), otherwise known as a surrogate, of adults unable to consent, the parents or legal guardians of children or the State on behalf of a child who is a ward of the State.
- 1.2. The process begins when an individual identifies a subject as a potential candidate for a research study.
- 1.3. The process to obtain consent to enroll in the research ends when a subject or the subject’s representative provides legally effective informed consent or declines to do so. However, as the title suggests, consent is a process, not an event. It may be necessary for the investigator to confirm with the subject during the course of the study that s/he continues to agree to take part in the research. Such processes should be reflected in the protocol plan.

2. REVISIONS FROM PREVIOUS VERSION

- 2.1. None

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 “Legally Authorized Representative”, or LAR, means an individual who represents an adult lacking decisional capacity to consent. [NOTE: In NJ, a LAR is called a “surrogate”. Other states may use different terms.]
- 3.3. In this procedure “subject/representative” means:
 - 3.3.1. The subject when the subject is an adult capable of providing consent.
 - 3.3.2. LAR when the subject is an adult unable to give consent.
 - 3.3.3. 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.
 - 3.3.4. An advocate serving on behalf of a child who is a ward of the state.
- 3.4. If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.
- 3.5. If the subject is an adult lacking decisional capacity to consent (See HRP-390):
 - 3.5.1. The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
 - 3.5.2. Permission is obtained from a LAR. [Check State law to determine whether a witness to informed consent process is required. In NJ, a witness, who is not the subject, his/her guardian or authorized representative, or the researcher, and who can attest that the requirements for informed consent to the research have been satisfied, must sign and date the consent form.]
 - 3.5.3. A LAR must be in the class or persons approved by institutional policy or the IRB and consistent with laws of the State where the research will be conducted. (See HRP-391).
- 3.6. If the subject is a child:
 - 3.6.1. The IRB must have specifically approved the protocol to allow the enrollment of children. Check State laws as they vary on age and circumstances when a minor becomes an adult or is otherwise emancipated.
 - 3.6.2. Permission is obtained from both parents unless:
 - 3.6.2.1. One parent is deceased, unknown, incompetent, not reasonably available;
 - 3.6.2.2. Only one parent has legal responsibility for the care and custody of the child; or
 - 3.6.2.3. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

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- 3.6.2.4. In the absence of parental permission, consent may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.
- 3.6.2.5. **NOTE:** Unless the IRB determines otherwise, consent of both parents is only required for greater than minimal risk studies without the prospect of direct benefit [45 CFR 46.406/407 or 21 CFR 50.53/54]
- 3.6.2.6. **NOTE:** Additional protections apply when a child is a ward of the State. Check with the IRB. (See HRP-416.)

- 3.7. If the subject/representative cannot speak English:
 - 3.7.1. The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak language that the subject understands.
- 3.8. Conduct all discussions in a private and quiet setting.
- 3.9. Any knowledgeable individual may:
 - 3.9.1. Introduce the study to the subject/representative to determine preliminary interest.
 - 3.9.2. If the subject/representative is interested, notify an investigator or provide investigator contact information (as outlined in the IRB-approved protocol).
 - 3.9.3. 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:
 - 5.1.1. Obtain the current IRB-approved consent form.
 - 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 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 of the consent discussion.
 - 5.1.4. If the subject/representative cannot read due to illiteracy or low literacy, obtain an impartial witness to observe 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 or members of the community (i.e., tribal, tribunal, elders, etc.). The impartial witness may not be a person involved in the design, conduct, or reporting of the research study.
 - 5.1.4.1. The IRB may approve audio/visual recording to document verbal consent.
 - 5.1.5. If the subject/representative cannot read the consent form due to blindness visual-impairment, obtain an impartial witness to observe the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend or members of the community (i.e., tribal, tribunal, elders, etc.) The impartial witness may not be a person involved in the design, conduct, or reporting of the research study.
 - 5.1.5.1. For subjects who read Braille, the IRB may approve a consent document prepared in Braille. In order to assure itself that a Braille consent document is accurate, the IRB may require a transcription into print text or review of the document by an IRB member or other person who reads Braille. If possible, the subject will sign the Braille consent; otherwise, verbal consent will be witnessed as described at 5.1.5.
 - 5.1.5.2. The IRB may approve audio/visual recording to document verbal consent.

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- 5.1.6. If the subject/representative cannot hear the consent discussion due to deafness or hearing-impairment, obtain an impartial witness to observe the entire consent discussion to attest that the information in the consent form and any other information provided was accurately explained, and apparently understood by, the subject/representative, and that consent was freely given. The witness may be a family member or friend or members of the community (i.e., tribal, tribunal, elders, etc.) The impartial witness may not be a person involved in the design, conduct, or reporting of the research study.
 - 5.1.6.1. If the subject/representative are otherwise fluent in American Sign Language, the IRB may approve a consent process using ASL and the IRB-approved written consent form. When this process is approved, the individual obtaining consent must use a certified interpreter fluent in ASL to conduct the consent process. If the certified interpreter is also a member of the research team, an impartial witness must also observe the entire consent discussion to attest that the information provided was explained, and apparently understood by, the subject/representative, and that consent was freely given. NOTE: The IRB or the research site where the consent process will take place may require that the interpreter be certified by a national organization or employed by the site or through a contracted interpreting agency.
 - 5.1.6.2. The IRB may approve audio/video recording to document consent using ASL.
- 5.1.7. If the subject/representative cannot speak English, obtain the services of a translator to translate the long form consent document into the language understood by the subject/representative. Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative to interpret the consent conversation between the subject/representative and the PI/person obtaining consent. The interpreter may be a member of the research team, a family member, or friend of the subject/representative.
 - 5.1.7.1. 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.
 - 5.1.8. Check State law to determine whether an impartial witness to the informed consent process is required. An interpreter may serve as an impartial witness—an individual who is not involved in the design, conduct, or reporting of the research study. [NOTE: When enrolling adults represented by a surrogate, New Jersey law requires an impartial witness who can attest that the requirements for informed consent to the research have been satisfied. The witness cannot be the subject, his/her guardian or authorized representative, the researcher or research staff.]
- 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-form consent and the IRB-approved English-version long form consent.
 - 5.2.2. Verify that you are using the most current IRB-approved version of the study specific short consent form in the language understandable to the subject/representative and the IRB-approved English-version long form consent.
 - 5.2.3. Provide copies to the subject/representative. Whenever possible provide the short form consent and English-version long form consent to the subject/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 subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.
- 5.2.5. Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short form consent and English-version long form consent, and any other information provided was accurately explained to, and apparently understood by, the subject/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, however, may not be a person involved in the design, conduct, or reporting of the research study.
- 5.2.6. Have the interpreter interpret the English-version long form consent for 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.
- 5.2.7. Through the interpreter explain the details in such a way that the subject/representative understand(s) 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 subject/representative read the short form consent or have the interpreter read the short form consent to the subject/representative.
- 5.2.9. **NOTE:** Consult State laws as they vary on use of short form consent when enrolling adults represented by a LAR. NJ State Law does not permit use of short form consent when enrolling adult subjects represented by a LAR (surrogate).
- 5.2.10. See Guidance Non-English-Speaking Subjects and HRP-507 Template: Short Form Consent for more information about the consent process documentation requirements, including use of witnesses, translators and interpreters.
- 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 verbal script or online consent or consent-information sheet.
 - 5.3.2. Verify that you are using the most current IRB-approved version of the study specific script or form and that the language is understandable to the subject/representative.
 - 5.3.3. When possible and applicable, provide a copy of the script to the subject/representative.
 - 5.3.4. 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.
 - 5.3.5. Where the consent process is a verbal/oral consent: 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.
- 5.4. Invite and answer the subject/representative’s questions. For online projects, the subjects/representative should be encouraged to contact the research team with any questions before clicking or affirming their participation in the online study. Give the subject/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.

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- 5.5. Invite and encourage the subject/representative to take the written information home, if applicable and appropriate, to consider the information and discuss the decision with family members and others before deciding.
- 5.6. 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 (See GUIDANCE: Surrogate Consent Process):
 - 5.6.1. The subject/representative understands the information provided.
 - 5.6.2. The subject/representative does not feel pressured by time or other factors to decide.
 - 5.6.3. The subject/representative understands that there is a voluntary choice to make.
 - 5.6.4. The subject/representative is capable of making and communicating an informed choice.
- 5.7. 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.
- 5.8. Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.
- 5.9. If the subject/representative agrees to take part in the research study:
 - 5.9.1. If the subject is a child:
 - 5.9.1.1. Whenever possible explain the research to the extent compatible with the child’s understanding.
 - 5.9.1.2. Request the assent (affirmative agreement) of the child unless:
 - 5.9.1.2.1. The capability of the subject child is so limited that the subject child cannot reasonably be consulted.
 - 5.9.1.2.2. The IRB determined that assent was not a requirement.
 - 5.9.1.3. Once a subject child indicates that he or she does not want to take part in the research study, this process stops.
 - 5.9.2. If the subject is an adult unable to consent:
 - 5.9.2.1. Whenever possible explain the research to the extent compatible with the adult’s understanding.
 - 5.9.2.2. Request the assent (affirmative agreement) of the adult unless:
 - 5.9.2.2.1. The capability of the adult is so limited that the adult cannot reasonably be consulted.
 - 5.9.2.2.2. The IRB determined that assent was not a requirement.
 - 5.9.2.3. Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.
 - 5.9.3. Obtain written documentation of the consent process according to “SOP: Written Documentation of Consent (HRP-091).”

6. MATERIALS

- 6.1. HRP – 013 SOP: Legally Authorized Representatives, Children, and Guardians
- 6.2. HRP – 091 SOP: Written Documentation of Consent
- 6.3. HRP – 317 WORKSHEET: Short Form of Consent Documentation
- 6.4. HRP - 390 WORKSHEET: Surrogate Consent – Determining Decisional Capacity
- 6.5. HRP - 391 WORKSHEET: Surrogate Consent – Selecting a Surrogate
- 6.6. HRP - 416 CHECKLIST Children
- 6.7. HRP - 417 CHECKLIST: Adults with Impaired Decision-Making Capacity
- 6.8. HRP – 502 a through 502f: TEMPLATES Consent
- 6.9. HRP – 503a and 503b: TEMPLATES Research Protocol
- 6.10. HRP – 507 TEMPLATE: Short Form Consent
- 6.11. GUIDANCE: Surrogate Consent Process



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6.12. Website Forms: Witness and Interpreter Consent Documentation Translator Qualifications and Assurances Form

7. REFERENCES

- 7.1. 21 CFR §50.20, 50.25
- 7.2. 45 CFR §46.116
- 7.3. NJ Access to Medical Research Act N.J.S.A. 26:14-1 through 26:14-5
- 7.4. NJ Age of Majority N.J.S.A. 9:17B-1 through 9:17B-4