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1. PURPOSE

- 1.1. This procedure establishes the process to document the informed consent process in writing.
- 1.2. The process begins when a subject agrees to take part in a research study.
- 1.3. The documentation process ends when consent is documented in writing, including in an electronic format, to the extent required by this procedure.

2. REVISIONS FROM PREVIOUS VERSION

- 2.1. 1/1/21

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 “subject/representative” means:
 - 3.2.1. The subject when the subject is an adult capable of providing consent.
 - 3.2.2. The Legally Authorized Representative (LAR) when the subject is an adult unable to give consent. [LAR is a generic term used to refer to individuals who represent an adult lacking decisional capacity. The State of NJ uses the term ‘surrogate’; other states may use different terms.]
 - 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 authorized under applicable law to consent on behalf of the child to the child’s general medical care.
 - 3.2.4. An advocate serving on behalf of a child who is a ward of the State.

4. RESPONSIBILITIES

- 4.1. The principal investigator is responsible for ensuring 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. Verify that the consent form is in language understandable to the subject/representative.
 - 5.1.2. Print the name of the following individuals on the consent document:
 - 5.1.2.1. Subject/Representative
 - 5.1.2.2. Person obtaining consent
 - 5.1.3. Have the following individuals personally sign and date the consent document:
 - 5.1.3.1. Subject/Representative
 - 5.1.3.1.1. When subjects/representatives are unable to read a written consent form (due to low literacy/illiteracy or blindness/vision-impairment), or are deaf/hearing-impaired, subjects may provide oral consent. Subjects/representatives who cannot write, can indicate their consent by ‘making their mark’ on the consent form, when consistent with applicable State law. Under either circumstance, an audio/visual recording approved by the IRB may be used to document the consent process.
 - 5.1.3.1.2. For subjects/representatives who read Braille, and the consent document has been prepared in Braille, the subject/representative will sign the Braille consent document.
 - 5.1.3.1.3. For deaf subjects who are fluent in American Sign Language (ASL), and a certified interpreter fluent in ASL is provided, the subject/representative and the interpreter sign the consent form. Subjects may provide oral consent. Under such circumstances, an audio/visual recording approved by the IRB may be used to document the consent process.
 - 5.1.3.2. Person obtaining consent

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- 5.1.4. If the IRB required written documentation of assent of subject – child or an adult represented by a LAR—note on the signature block one of the following:
 - 5.1.4.1. Assent of the subject was obtained.
 - 5.1.4.2. Assent of the subject was not obtained because the capacity of the subject is so limited that the subject cannot reasonably be consulted.
- 5.1.5. Have the person obtaining consent personally sign and date the consent document.
 - 5.1.5.1. When a subject, who cannot read due to illiteracy or blindness, indicates their consent by ‘making a mark’ or provides oral consent, then the person obtaining consent provides the reason for lack of a signature or that an oral process was used and, if necessary that the subject gave verbal consent.
 - 5.1.5.2. The person obtaining consent will document the consent process in the research record and, if applicable, medical record in accord with the site’s policy.
- 5.1.6. If an impartial witness was part of the consent process:
 - 5.1.6.1. Print the name of the impartial witness on the consent document.
 - 5.1.6.2. 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.
- 5.1.7. 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.
- 5.1.8. Follow documentation conventions reflected in the signature blocks of 16.301 (HRP-502a) through 16.306 (HRP-502f) TEMPLATES Consent.
- 5.2. If the consent process will be documented in writing with the short form of consent documentation:
 - 5.2.1. Verify that the short form consent is in language understandable to the subject/representative.
 - 5.2.2. Print the name of the following individuals on the consent documents and have them personally sign and date the applicable document(s) as follows:
 - 5.2.2.1. Subject/Representative [short form consent]
 - 5.2.2.2. Impartial witness [short form consent & long form consent]
 - 5.2.2.3. Person obtaining consent [long form consent]
 - 5.2.2.4. Qualified Interpreter [long form consent]
 - 5.2.2.5. The qualified interpreter may also serve as the impartial witness if s/he is not a member of the research team. [Check performance site requirements for who may serve as a qualified interpreter or impartial witness, as their standards may be more stringent.]
 - 5.2.3. If the IRB required written documentation of assent of a child, document as follows:
 - 5.2.3.1. Assent of the child was obtained. [short form consent]
 - 5.2.3.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted. [long form consent]
 - 5.2.4. Provide a copy of the signed and dated short form consent document and a copy of the signed and dated English-version long form consent to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of each of the short form and long form consents, as applicable.
 - 5.2.5. NOTE: Check State law to determine whether short form consent is allowed when enrolling an adult subject represented by a LAR. NJ State law Access to Medical Research Act NJSA 26:14.1 – 14.5 prohibits use of short form consent when enrolling adults represented by a surrogate.
- 5.3. 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 in writing, offer the subject/representative the option to document his or her consent in writing.

5.3.1. If the subject/representative declines, take no further action.

5.3.2. If the subject/representative accepts, follow the process to document consent in writing with the long or short form of consent documentation. See NOTE at 5.2.6.

5.4. Place the signed and dated documents in the subject's research record.

6. MATERIALS

6.1. 6.002 (HRP – 090) SOP: Informed Consent Process for Research

6.2. 6.202 (HRP – 317) WORKSHEET: Short Form of Consent Documentation

6.3. 6.301 - GUIDANCE: Surrogate Consent Process

6.4. 7.001 (HRP – 013) SOP: Legally Authorized Representatives, Children, and Guardians

6.5. 16.301 -16.306 (HRP – 502a through 502q): TEMPLATES Consent

6.6. 16.360 (HRP – 507) TEMPLATE: Short Form of Consent

6.7. 16.351 - GUIDANCE: Non-English Consent

6.8. Website Forms: 16.354 - Witness and Interpreter Consent Documentation and 16.353 - Translator Qualifications and Assurances Form

7. REFERENCES

7.1. 21 CFR §50.27

7.2. 45 CFR §46.117