

## INVESTIGATOR GUIDANCE: Informed Consent

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### 1. PURPOSE

- 1.1. This guidance describes a process that in general is suitable to obtain informed consent.
- 1.2. Other procedures may be suitable when approved by the IRB.

### 2. BACKGROUND

#### 2.1. "Person providing consent" means:

- 2.1.1. In the case of a cognitive intact adult, the individual being asked to take part
- 2.1.2. In the case of an adult unable to consent, that individual's LAR
- 2.1.3. In the case of a child:
  - 2.1.3.1. One parent, if the other parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
  - 2.1.3.2. One parent if the IRB determined that permission from one parent was sufficient
  - 2.1.3.3. An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care
  - 2.1.3.4. Both parents

#### 2.2. "Consent information" means:

- 2.2.1. Long form consent document (when the IRB requires the long form of consent documentation)
- 2.2.2. Short form consent document and summary (when the IRB allows the short form of consent documentation)
- 2.2.3. Script or information sheet (when the IRB has approved a waiver of documentation of consent)

#### 2.3. Communicate in the preferred language of the person providing consent

#### 2.4. Unless the IRB affirmatively approved a protocol to include the following populations, such subjects may not be enrolled:

- 2.4.1. Adults unable to consent
- 2.4.2. Children
- 2.4.3. Neonates of uncertain viability
- 2.4.4. Nonviable neonates
- 2.4.5. Pregnant women
- 2.4.6. Prisoners
- 2.4.7. Individuals unable to speak English

#### 2.5. The short form of consent documentation may be use only if affirmatively approved by the IRB.

#### 2.6. For the short form of consent documentation:

- 2.6.1. The short form is a standard template translated into the subject's language.
- 2.6.2. The summary is the English version of the long form.

#### 2.7. For waiver of documentation of consent, the script is the long form without a signature block.

#### 2.8. Interpreters are to be conversant in both English and the language understood by the person providing consent. When allowed by institutional policy, the interpreter may be a member of the research team, or a family member or friend of the subject or person providing consent.

#### 2.9. If the consent process requires an <Impartial Witness>:

- 2.9.1. The <Impartial Witness> is to be present during the entire consent discussion and to attest that the information in the consent form and any other information

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provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.

2.9.2. The <Impartial Witness> may not be a person involved in the research.

### 3. GUIDANCE

- 3.1. Obtain the IRB-approved consent document, short form consent document, or script, as applicable.
  - 3.1.1. Verify that you are using the most current IRB-approved information.
  - 3.1.2. Verify that the consent document, if any, is in language understandable to the person providing consent.
- 3.2. If the person providing consent cannot read or the short form of consent documentation is used, obtain an <Impartial Witness>.
- 3.3. If the person providing consent cannot speak English, obtain the services of an interpreter.
- 3.4. Go over the information in the consent document using language understandable to the person providing consent.
  - 3.4.1. Do not provide any information to the person providing consent through which the person providing consent is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
  - 3.4.2. When providing information about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.
- 3.5. Invite and answer questions.
- 3.6. Evaluate whether the following is true for the person providing consent. If not, take steps to correct or determine that the person providing consent is incapable of providing consent:
  - 3.6.1. The person providing consent has been provided sufficient information.
  - 3.6.2. The person providing consent understands the information
    - 3.6.2.1. If the person providing consent has a disease or condition that may affect cognition, assess whether the person providing consent has sufficient cognitive capacity to legally provide informed consent.
    - 3.6.2.2. If the subject is pregnant, ensure the person providing consent is fully informed regarding the reasonably foreseeable effect of the research on the fetus or neonate.
  - 3.6.3. The person providing consent does not feel coerced or unduly influenced.
    - 3.6.3.1. Ensure there is no threat of harm or adverse consequences for a decision to not participate.
    - 3.6.3.2. Ensure that outside parties (family or caretakers) do not coerce or unduly influence the person providing consent, especially if that person is vulnerable to coercion or undue influence.
    - 3.6.3.3. Ensure that the amount of payment does not coerce or unduly influence economically disadvantaged individuals.
    - 3.6.3.4. For persons providing consent who are in a subordinate position to a member of the research team (e.g., employee or student), ensure that there is no threat of harm or adverse consequences to the subject's position for a decision to not participate.
  - 3.6.4. The person providing consent has sufficient time to make a decision.
    - 3.6.4.1. Provide the person providing consent with sufficient time to understand the information. Spend as much time as needed

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- 3.6.4.2. Provide the person providing consent with sufficient time to ask questions.
- 3.6.5. The individual providing consent understands the consequences of a decision.
- 3.6.6. The individual providing consent can communicate a choice.
- 3.7. Once a person providing consent indicates that he or she does not want to consent, stop.
- 3.8. If the subject is a child or adult unable to consent:
  - 3.8.1. Explain the research to the extent compatible with the subject's understanding.
    - 3.8.1.1. Ensure that parents or guardians do not coerce or unduly influence children.
    - 3.8.1.2. Ensure that outside parties (family or caretakers) do not coerce or unduly influence adults unable to consent.
  - 3.8.2. If the IRB determined that assent was a requirement and the subject is capable of being consulted, request the assent (affirmative agreement) of the subject.
    - 3.8.2.1. If the subject indicates that he or she does not want to take part, stop.

## 4. REFERENCES

- 4.1. 21 CFR §50.20, §50.25
- 4.2. 45 CFR §46.116