



## INVESTIGATOR GUIDANCE: Documentation of Informed Consent

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### 1. PURPOSE

- 1.1. This guidance describes a process that in general is suitable to document consent in writing.
- 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 cognitively 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. The short form of consent documentation may be use only if affirmatively approved by the IRB.
- 2.3. For the short form of consent documentation:
  - 2.3.1. The short form is a standard template translated into the subject's language.
  - 2.3.2. The summary is the English version of the long form.
- 2.4. If the consent process required an <Impartial Witness>:
  - 2.4.1. 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 provided was accurately explained to, and apparently understood by, the subject/LAR, and that consent was freely given.
  - 2.4.2. The <Impartial Witness> may not be a person involved in the research.

### 3. GUIDANCE

- 3.1. If the consent process will be documented with the long form:
  - 3.1.1. Verify that the document is in language understandable to the person providing consent.
  - 3.1.2. If the IRB required written documentation of assent, do one of the following:
    - 3.1.2.1. Note that assent of the subject was obtained.
    - 3.1.2.2. Note that assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
    - 3.1.2.3. Obtain the signature of the subject on the IRB approved assent form.
  - 3.1.3. Have the following individuals personally sign and date the consent document:
    - 3.1.3.1. Person giving consent
    - 3.1.3.2. Person obtaining consent
    - 3.1.3.3. <Impartial Witness>, if any
- 3.2. If the consent process will be documented with the short form:
  - 3.2.1. Verify that the document is in language understandable to the person providing consent.
  - 3.2.2. If the IRB required written documentation of assent, do one of the following:



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- 3.2.2.1. Obtain the signature of the subject on the IRB approved assent form.
- 3.2.2.2. Note in the study record that assent of the subject was obtained.
- 3.2.2.3. Note in the study record that assent of the subject was not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
- 3.2.3. Have the following individuals personally sign and date the consent document:
  - 3.2.3.1. Person giving consent
  - 3.2.3.2. <Impartial Witness>
- 3.2.4. Have the following individuals personally sign and date the summary:
  - 3.2.4.1. Person obtaining consent
  - 3.2.4.2. <Impartial Witness>
- 3.3. Provide the person providing consent with copies of the signed and dated documents.
  - 3.3.1. This may be accomplished either by making a photocopy or by having individuals sign and date two copies.
- 3.4. File a copy of the consent document with the medical record when required by local policy.
- 3.5. Retain the signed and dated documents in the study records for the greater of:
  - 3.5.1. Three years after completion of the research
  - 3.5.2. For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
  - 3.5.3. For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
  - 3.5.4. The retention period requested by the sponsor.
  - 3.5.5. The retention period required by local, state, or international law.
  - 3.5.6. The retention period required by a non-OHSU site.

## 4. REFERENCES

- 4.1. 21 CFR §50.27, 56.115(b), §312.62(c), §812.140(d)
- 4.2. 45 CFR §46.115(b), §46.117