

	<b>INVESTIGATOR GUIDANCE: Documenting Informed Consent</b>				
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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 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 Legally Authorized Representative (LAR).
  - 2.1.3. In the case of a child, when determined by the IRB:
    - 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 has determined permission from one parent is 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. If the consent process requires an Impartial Witness:
  - 2.2.1. 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.
  - 2.2.2. The Impartial Witness may not be a person involved in the research.

## 3 GUIDANCE

- 3.1. If the consent process will be documented:
  - 3.1.1. Verify that the document is in language understandable to the person providing consent.
  - 3.1.2. Verify the individual obtaining consent has been trained to do so and has been designed by the PI to serve in this capacity.
  - 3.1.3. If the IRB requires written documentation of assent, note one of the following:
    - 3.1.3.1. Assent of the child was obtained.
    - 3.1.3.2. Assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
  - 3.1.4. If required by the IRB, sponsor, or other body overseeing the research, have the following individuals personally sign and date the consent document:
    - 3.1.4.1. Person providing consent.
    - 3.1.4.2. Person obtaining consent, for studies determined greater than minimal risk.
    - 3.1.4.3. Impartial Witness if any.
- 3.2. If the consent process has been granted a waiver of subject documentation of consent and will occur in person:
  - 3.2.1. Verify that the document is in language understandable to the person providing consent.
  - 3.2.2. Verify the individual obtaining consent has been trained to do so and has been designed by the PI to serve in this capacity.



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- 3.3. Provide the person providing consent with a copy of the consent and/or assent document(s).
- 3.4. The person obtaining consent should write a dated progress note stating who obtained consent, the date of consent, if there were any issues during the consent process, and if the person providing consent was given a copy of the document(s).
- 3.5. File a copy of the consent document with the medical record when required by local policy.
- 3.6. Retain the signed and dated documents in the study records for the greater of:
  - 3.6.1. If all participants are adults: at least three years after completion of the research.
  - 3.6.2. If participants are children: until all participants are 18 years of age, or for three years after the completion of the research, whichever is longer.
  - 3.6.3. If the study involves Protected Health Information, a minimum of six years after the completion of the research.
  - 3.6.4. 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.
  - 3.6.5. 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.
  - 3.6.6. The retention period required by the sponsor.
  - 3.6.7. The retention period required by local, state, or international law.
  - 3.6.8. The retention period required by a site that is not part of FAU.

## 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