	SOP: Written Documentation of Consent		
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1 PURPOSE

- 1.1 This SOP 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 process ends when the consent process is documented in writing, including in an electronic format, to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.
- 2.2 Revised from the 4/29/2021 version.

3 SOP Statement


- 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.
 - 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.

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 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, when required.
 - 5.1.3 Have the following individuals personally sign and date the consent document:
 - 5.1.3.1 Subject/Representative
 - 5.1.3.2 Person obtaining consent, when required.
 - 5.1.4 If the IRB required written documentation of assent, note on the signature block one of the following:
 - 5.1.4.1 Assent of the child was obtained.
 - 5.1.4.2 Assent of the child was not obtained because the capability of is so limited that the child cannot reasonably be consulted.
 - 5.1.5 Have the person obtaining consent personally sign and date the consent document, when required.
 - 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 Provide copies of the consent document to the subject/representative. A signed copy may be given by either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

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5.1.7.1 Investigators may ask the subject/representative to save an electronic version of the document to the electronic device.

5.2 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.

5.2.1 If the Subject/LAR declines, take no further action.

5.2.2 If the Subject/LAR accepts, follow the process to document consent in writing with the long form of consent documentation

5.3 Place the signed and dated consent documents in the subject's binder or equivalent.

6 MATERIALS

6.1 Consent document

7 REFERENCES

7.1 21 CFR §50.27

7.2 45 CFR §46.117

7.3 AAHRPP element I-9