UNIVERSITY OF MIAMI	SOP: Written Documentation of Consent			
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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 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 None
2.2 Revised for clarification and to add information about electronic signatures.
2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

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 (See also HRP-093 – SOP - Electronic Signatures for Documentation of Consent):
- 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
  - 5.1.3.2 Person obtaining consent
- 5.1.4 If the IRB required written documentation of assent and approved a separate assent form:
  - 5.1.4.1 Have the child print his/her name, sign and date the assent form.
  - 5.1.4.2 Have the person obtaining assent print his/her name, sign and date the assent form.
- 5.1.5 If the IRB required the person obtaining assent to document that assent was obtained:
  - 5.1.5.1 Have the person obtaining assent sign below the statement confirming assent on the consent document.
- 5.1.6 If the IRB waived the requirement for assent from children because the capability of the child is so limited that the child cannot reasonably be consulted:

5.1.6.1 Document that the assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.1.7 The person obtaining consent will personally sign and date the consent document.

5.1.8 If an impartial witness was part of the consent and/or assent process:

5.1.8.1 Print the name of the impartial witness on the consent document.

5.1.8.2 Have the impartial witness personally sign and date the consent/assent document to attest that the information in the consent/assent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent/assent was freely given.

5.1.9 Provide copies of the signed and dated consent/assent 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.

5.2 If the consent process will be documented in writing with the short form of consent documentation:

5.2.1 Verify that the short consent form is in language understandable to the subject/representative.

5.2.2 Print the name of the following individuals on the short form consent document and the summary:

5.2.2.1 Subject/Representative

5.2.2.2 Person obtaining consent

5.2.2.3 Impartial witness

5.2.3 Have the following individuals personally sign and date the short form consent document and/or the summary:

5.2.3.1 Subject/Representative sign short form consent document

5.2.3.2 Person obtaining consent sign short form consent document

5.2.3.3 Impartial witness sign both short form consent document and summary

5.2.4 If the IRB required written documentation of assent on a separate assent form:

5.2.4.1 Have the child print his/her name, sign and date the assent form.

5.2.4.2 Have the person obtaining assent print his/her name, sign and date the assent form.

5.2.5 If the IRB required the person obtaining assent to document that assent was obtained:

5.2.5.1 Have the person obtaining assent sign below the statement confirming assent on the consent document.

5.2.6 If the IRB waived the requirement for assent from children because the capability of the child is so limited that the child cannot reasonably be consulted:

5.2.6.1 Document that the assent of the child was not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.2.7 Provide a copy of the signed and dated short consent document and a copy of the signed and dated summary to the subject/representative. This may be accomplished either by making photocopies or by having the above individuals sign and date two copies of the short consent document and summary.

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.

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

6 MATERIALS

6.1 If the consent process will be documented in writing with the long form of consent documentation:

6.1.1 Consent document

6.2 If the consent process will be documented in writing with the short form of consent documentation:

6.2.1 Short consent document

6.2.2 Summary (same content as the long form of consent documentation)

6.3 HRP-090 - SOP - Consent Process for Research

6.4 HRP-093 - SOP - Electronic Signatures for Documentation of Consent

6.5 HRP-317 - WORKSHEET - Short Form of Consent Document

6.6 HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

7 REFERENCES

7.1 21 CFR §50.27

7.2 45 CFR §46.117

7.3 AAHRPP element I-9