UNIVERSITY OF MIAMI

SOP: Written Documentation of Consent				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-091	7/9/2019	C.Gates	C.Gates	1 of 2

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 or 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.

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 Legally authorized representative 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 for ensuring 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 SOP: Electronic Signatures for Documentation of Consent HRP-093):

5.1.1 Verify that the consent form is in a language understandable to the subject/representative.

5.1.2 Have the following individuals print their names 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, a separate assent form is generally required.

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

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

5.1.6.1 Have the impartial witness personally print his/her name, sign and date the consent and assent documents to attest that the information in the consent/assent documents and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that informed consent/assent was given.

5.1.7 Provide copies of the signed and dated consent/assent documents to the subject/representative. This may be accomplished by making a photocopy of the consent/assent documents.

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 a language understandable to the subject/representative.

5.2.2 Have the following individuals personally print their names, sign and date the short form consent document:
- 5.2.2.1 Subject/Representative
- 5.2.2.2 Impartial witness

5.2.3 Have the following individuals personally print their names, sign and date the summary consent document:
- 5.2.3.1 Person obtaining consent
- 5.2.3.2 Impartial witness

5.2.4 If the IRB required written documentation of assent, a separate assent form is generally required.
- 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 Provide a copy of the signed and dated short consent document, assent form, and a copy of the signed and dated summary to the subject/representative. This may be accomplished by making photocopies of the short consent document, assent form, 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 (may be the long form of consent documentation approved by the IRB)

7 REFERENCES

7.1 SOP: Consent Process for Research (HRP-090):
7.2 SOP: Electronic Signatures for Documentation of Consent HRP-093):
7.3 WORKSHEET: Short Form of Consent Document (HRP-317)
7.4 CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)
7.5 21 CFR §50.27
7.6 45 CFR §46.117