SOP: Written Documentation of Consent				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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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 consent process is ongoing and continues throughout the research activity until a subject declines to participate, withdraws from the study, or the study is closed. This SOP outlines the process for documenting consent in writing, including in an electronic format, to the extent required by this procedure.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Informed consent is an essential component of demonstrating respect for subjects and is mandated by both federal regulations and Virginia Tech, unless a waiver is requested and approved.
3.2 Unless otherwise instructed by the Virginia Tech IRB or HRPP, consent must be documented prior to beginning any research activities with the prospective subject.

4 RESPONSIBILITIES

4.1 The principal investigator (PI) 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 Obtain the current IRB approved consent form from Protocol Management or use the version you received with your most recent approval letter.
- 5.1.2 Verify that you are using the most current IRB approved and stamped version of the study specific consent form and that the consent form is in a language understandable to the subject/LAR.
- 5.1.3 All printing, signing, and dating should be completed in the presence of an investigator. Have the following individuals personally print, sign, and date the consent document:
  - 5.1.3.1 Subject/Legally Authorized Representative (LAR)
  - 5.1.3.2 Person obtaining consent (PI or authorized study personnel)
- 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 the child is so limited that the child cannot reasonably be consulted.
- 5.1.5 If an impartial witness was part of the consent process, have the impartial witness:
  - 5.1.5.1 Print, 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 understood by, the subject, and that consent was freely given.
- 5.1.6 Provide copies of the signed and dated consent document to the LAR. 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 requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/LAR had to be offered the opportunity to document his or her consent in writing, offer the subject/LAR 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 documents in the subject's study folder. The study folder should be kept secure at all times to protect the privacy of the participant.

6 DEFINITIONS AND BACKGROUND

6.1 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.

6.2 In this procedure "subject" means:

6.2.1 The subject when the subject is an adult capable of providing consent.

6.2.2 The LAR when the subject is an adult unable to give consent.

6.2.3 One or both parents or guardians 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.

6.3 "Consent information" means:

6.3.1 Long form consent document (when the IRB requires the long form of consent documentation).

6.3.2 Script or information sheet (when the IRB has approved a waiver of document of consent or for exempt research where consent is not required).

7 MATERIALS

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

7.1.1 IRB approved and stamped consent document

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

7.2.1 IRB approved summary (same content as the long form of consent documentation)

8 REFERENCES

8.1 21 CFR §50.27

8.2 45 CFR §46.117