SOP: Informed Consent Process for Research				
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1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the Legally Authorized Representative (LAR) of adults unable to consent, or the parents or guardians of children.

1.2 The process begins when an individual identifies a subject as a prospective subject for a research study.

1.3 The process is ongoing and continues throughout the research activity until a subject or a subject's LAR declines participation, withdraws from the study, or the study is closed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Informed consent is an essential component of demonstrating respect for research participants and is required by both federal regulations and Virginia Tech, unless a waiver is requested and approved.

3.2 The exchange of information serves to ensure that prospective subjects/LARs clearly understand risks and benefits and receive other key information that is necessary in order to make an informed decision regarding voluntary participation in research.

3.3 The process does not merely provide lists of facts, but rather facilitates the prospective subject's/LAR's understanding of the reasons why one might or might not want to participate.

3.4 Unless otherwise instructed by the Virginia Tech IRB or HRPP, this process must occur prior to enrolling a prospective subject in research and must be properly documented.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible for ensuring that these procedures are carried out.

5 PROCEDURE

5.1 Conduct all discussions in a private quiet setting.

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

5.2.1 Obtain the current IRB approved consent form from Protocol Management or use the version you received with your most recent approval letter.

5.2.2 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.

5.2.3 Provide a copy of the consent form to the subject/LAR. Whenever possible, provide the consent form to the subject/LAR for review in advance of the consent discussion. Printing of names, signatures, and dating should be completed in the presence of an investigator. See "SOP: Written documentation of Consent (HRP-091)."

5.2.4 If the subject/LAR cannot read, obtain an impartial witness to be present during the entire consent discussion 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. The witness may be a family member or friend. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.2.5 If the subject/LAR cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/LAR. The interpreter must be able to communicate effectively, such that the information is presented in an accurate and clear manner.

5.2.6 Review the consent document (or have an interpreter read the translated consent document) with the subject/LAR. Begin with a concise and focused presentation of key information that is most likely to assist the subject/LAR to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.

5.3 If the requirement for written documentation of the consent process has been waived by the IRB:

5.3.1 Obtain the current IRB approved script.

5.3.2 Verify that you are using the most current IRB approved version of the study specific script and that the script language is understandable to the subject/LAR.

5.3.3 When possible, provide a copy of the script to the subject/LAR.

5.3.4 If the subject/LAR cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/LAR. The interpreter must be able to communicate effectively, such that the information is presented in an accurate and clear manner

5.3.5 Review the script (or have an interpreter translate the script) with the subject/LAR. Begin with a concise and focused presentation of the key information that is most likely to assist the subject/LAR to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.

5.4 Invite and answer the subject/LAR's questions.

5.5 Give the subject/LAR time to consider the information and discuss taking part in the research study with family members, friends and/or other care providers, providing a copy of the written information to take home, as appropriate.

5.6 Ask the subject/LAR questions to determine whether all of the following are true. If not, either continue the explanation or determine that the subject/LAR is incapable of providing consent:

5.6.1 The subject/LAR understands the information provided.

5.6.2 The subject/LAR does not feel pressured by time or other factors to make a decision.

5.6.3 The subject/LAR understands that there is a voluntary choice to make.

5.6.4 The subject/LAR is capable of making and communicating an informed choice.

5.7 Provide the institution approved information about treatments or compensation for injury, if applicable.

5.8 Once a subject/LAR indicates that they do not want to take part in the research study, this process stops. Thank the subject/LAR for their time and consideration.

5.9 If the subject/LAR cannot speak English the IRB must have specifically approved the protocol to allow the enrolment of subjects able to speak the language that the subject understands.

5.10 If the subject is an adult unable to consent, the IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.

5.10.1 Permission is obtained from an LAR.

5.10.2 An LAR must be in the class of persons approved by institutional policy or the IRB. See "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

5.11 If the subject is a child:

5.11.1 The IRB must have specifically approved the protocol to allow the enrollment of children.

5.11.2 Permission is obtained from both parents unless:

5.11.2.1 One parent is deceased, unknown, incompetent, not reasonably available

5.12 If the subject/LAR agrees to take part in the research study:

5.12.1 If the subject is a child:

5.12.1.1 Whenever possible, explain the research to the extent compatible with the child's understanding.

5.12.1.2 Request the assent (affirmative agreement) of the child unless:

5.12.1.2.1 The capability of the child is so limited that the child cannot reasonably be consulted.

5.12.1.2.2 The IRB determined that assent was not required.

5.12.1.3 Once a child indicates that they do not want to take part in the research study, this process stops. Thank the subject/LAR for their time and consideration

5.12.2 If the subject is an adult who is unable to consent:

5.12.2.1 Whenever possible explain the research to the extent compatible with the adult's understanding.

5.12.2.2 Request the assent (affirmative agreement) of the adult unless:

5.12.2.2.1 The capability of the adult is so limited that the adult cannot reasonably be consulted.

5.12.2.2.2 The IRB determined that assent was not a requirement.

5.12.2.3 When an adult unable to consent indicates that they do not want to take part in the research study, this process stops. Thank the subject/LAR for their time and consideration

5.12.3 Obtain written documentation of the consent process according to "SOP: Written Documentation of Consent (HRP-091)."

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 procedures "subject" means:

6.2.1 An adult capable of providing consent.

6.2.2 An 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 other than a parent authorized under applicable law to consent on behalf of the child for 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)

6.4 Unless the IRB affirmatively approved a protocol to include the following populations, the following categories of individuals may not be enrolled:

6.4.1 Adults unable to consent

6.4.2 Children

6.4.3 Pregnant women

6.4.4 Prisoners

6.4.5 Individuals unable to speak English

6.5 Read the consent document (or have an interpreter read the translated consent document) with the subject/LAR. Begin with a concise and focused presentation of key information that is most likely to assist the subject/LAR to understand the reasons why one might or might not want to participate in the research. Explain the details in such a way that the subject/LAR understands what it would be like to take part in the research study.

7 REQUIRED ELEMENTS OF INFORMED CONSENT

7.1 Unless the research is exempt or the IRB approves an alteration of some of the elements or waiver of documentation of informed consent, the informed consent document must include the following elements:

7.1.1 Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or an LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

7.1.2 A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

7.1.3 A description of any reasonably foreseeable risks or discomforts to the subject;

7.1.4 A description of any benefits to the subject or to others which may reasonably be expected from the research;

7.1.5 A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

7.1.6 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

7.1.7 For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7.1.8 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

7.1.9 A statement that participation is voluntary, refusal to participate will involves no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

7.1.10 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

7.1.10.1 A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

7.1.10.2 A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

8 MATERIALS

8.1 IRB approved consent form

8.2 IRB approved consent script

8.2.1 To be used with the requirement for written documentation of the consent process has been waived by the IRB

8.2.2 It is the same as consent form except that signature block is optional

8.3 SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).

8.4 SOP: Written Documentation of Consent (HRP-091)

9 REFERENCES

9.1 21 CFR §50.20, 50.25
9.2 45 CFR §46.116
9.3 HRP-502 Virginia Tech Informed Consent Template