1 PURPOSE

1.1 This procedure establishes the process to waive informed consent or to obtain informed consent from subjects, the legally authorized representatives of adults unable to consent, or the parents or guardians.

1.2 For waiver of consent, the process begins when the investigator requests a waiver of consent in the protocol. For informed consent, the process begins when an individual identifies a subject as a potential candidate for a research study.

1.3 For waiver of consent, the process ends when the IRB approves a waiver of consent. For informed consent, the process ends when a subject or the subject’s legally authorized representative provides legally effective informed consent.

2 REVISIONS FROM PREVIOUS VERSION

2.1 This SOP replaces the prior version dated 10/19/11.

3 POLICY

3.1 In this SOP, “investigator” means a principal investigator or an individual authorized by the principal investigator and approved by the IRB, such as a co-investigator, research assistant, or coordinator, to obtain consent for the protocol.

3.2 In this SOP, “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 other than a parent authorized to consent on behalf of the child to general medical care.

3.3 In this SOP, “child” means:

3.3.1 An individual under 18 years of age.

3.4 In this SOP, “summary” means:

3.4.1 The English version of the consent form.

3.5 In this SOP, “short form consent” means:

3.5.1 A consent form that contains the required elements of informed consent and that is translated into the subject’s native language. The Temple University IRB website contains a short form consent template.

3.6 If the subject is an adult unable to consent:

3.6.1 The IRB must have approved the protocol to allow the enrollment of adults unable to consent.

3.6.2 Permission is obtained from a legally authorized representative.

3.6.3 A legally authorized representative must be in the class of persons approved by institutional policy or the IRB.

3.7 If the subject is a child:

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

3.7.2 Consent is obtained from both parents unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child. The IRB may approve the protocol to allow the consent of one parent regardless of the status of a second parent. Minimal risk studies may require the consent of only one parent; however this must be approved in advance by the IRB.

3.7.3 In the absence of a parent, consent may be obtained from an individual authorized to consent on behalf of a child to general medical care.

3.8 If the subject/representative cannot speak or read English:
3.8.1 The investigator must submit the (a) short form consent and summary or (b) English consent form and translated full consent (see sections 5.3 and 5.4 of this policy) and accompanying certificate of translation for the short form consent/translated full consent to the IRB for approval before use. The certificate of translation attests that the translation is accurate. The certificate of translation can be from a person or from an organization or company that provides translation services.

3.9 Conduct all discussions in a private and quiet setting.

3.10 Any knowledgeable individual may:

3.10.1 Review the study with subject/representative to determine preliminary interest.

3.10.2 If the subject/representative is interested, notify an investigator.

3.10.3 If the subject/representative is not interested, take no further steps regarding recruitment or enrollment.

4 RESPONSIBILITIES

4.1 The principal investigator is responsible to ensure these procedures are carried out.

5 PROCEDURE

5.1 To request a waiver of consent, prior to beginning any study-related procedures, the principal investigator must justify a waiver of consent in the protocol. Please refer to Checklist #415 in the “references” section of the IRB website for the waiver of consent criteria.

5.2 If the subject/representative cannot read English (i.e. is illiterate), the individual obtaining consent must:

5.2.1 Verify that he/she is using the most current IRB-approved version of the consent form.

5.2.2 Whenever possible, provide the consent form to the subject/representative in advance of the consent discussion.

5.2.3 Obtain a witness to be present during the entire consent discussion to attest that the information in the consent form and any other information provided is accurately explained to, and apparently understood by, the subject/representative, and that consent is freely given. The individual obtaining consent must read the consent, in its entirety, orally to the subject. A copy of the consent document shall be given to the subject as well. 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.

5.2.3.1 If the subject is unable to consent and requires the consent of his/her legally authorized representative, and if the representative is literate, then follow the normal consent procedures.

5.2.3.2 If the subject is unable to consent and requires the consent of his/her legally authorized representative, and if the representative is illiterate, then follow the same procedures in 5.2.3 above for the illiterate representative as the person obtaining consent would do if the subject him/herself was illiterate.

5.3 If the subject cannot speak or read English (i.e. English is not the subject’s native language), and the subject’s language is rarely encountered by the investigator, given the location of the research and the potential study population:

5.3.1 Obtain IRB approval for the short form consent in the language the subject understands. Provide the short form consent and summary to the subject/representative.

5.3.2 Verify that you are using the most current IRB-approved version of the short form consent and summary.

5.3.3 Whenever possible, provide the short form consent and summary to the subject/representative in advance of the consent discussion.
5.4 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter must be an independent third party (i.e., not a member of the research team, family member, or friend of the subject/representative). Whenever possible, use the services of the Temple University Hospital interpreter service.

5.4.5 The interpreter’s oral presentation of the summary must be in a language understandable to the subject/representative.

5.4.6 Obtain the services of a witness who is fluent in both English and the language understandable to the subject/representative to be present during the entire consent discussion to attest that the information in the short form consent, summary, and any other information provided is accurately explained to and understood by the subject/representative, and that consent is freely given. The witness and the interpreter may be the same person. A family member or friend may be the witness, but cannot be the interpreter. The witness may not be a person involved in the design, conduct, or reporting of the research study.

5.4.7 The interpreter must orally interpret the summary to the subject/representative.

5.4.8 The interpreter must explain the research study in such a way that the subject/representative understands what it would be like to take part in the study. The IRB strongly recommends that the interpreter be physically present with the subject when obtaining initial consent. A live interpreter or a language line interpreter may be used during follow up or other procedures.

5.4.9 Have the subject/representative read the short form consent.

5.4.10 Note that the use of the short form consent is discouraged by the IRB and the process in Section 5.4 should be used whenever possible. The short form consent should only be used if the subject’s language is rarely encountered by the investigator, given the location of the research and the potential study population.

5.4 If the subject cannot speak or read English (i.e., English is not the subject’s native language), and the subject’s language has a reasonable probability of being encountered by the investigator, given the location of the research and the potential study population, the entire English consent form must be translated into the subject’s native language. Examples of situations that require a translated consent form: if the Investigator is targeting a non-English speaking group; the research will be performed in a foreign country where English is not the primary language; or the demographic characteristics of clients of the site from which subjects will be recruited indicates that non-English speaking individuals are likely to be encountered.

5.4.1 Provide copies of the translated consent form and summary to the subject/representative.

5.4.1.1 Verify that you are using the most current IRB-approved version of the translated consent form and summary.

5.4.1.2 Whenever possible, provide the translated consent form and summary to the subject/representative in advance of the consent discussion.

5.4.1.3 The oral presentation must be in a language understandable to the subject/representative.

5.4.2 If the investigator is not a certified interpreter, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter must be an independent third party (i.e., not a member of the research team, family member, or friend of the subject/representative).

5.4.3 Obtain the services of a witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the consent form and summary and any other information provided is accurately explained to and understood by the subject/representative, and that consent is freely given. The witness and the
5.4.4 The interpreter must explain the research study in such a way that the subject/representative understands what it would be like to take part in the study. The IRB strongly recommends that the interpreter be physically present with the subject when obtaining initial consent. A live interpreter or a language line interpreter may be used during follow up or other procedures.

5.4.5 Have the subject/representative read the translated consent.

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

5.5.1 Obtain the current IRB-approved consent script and provide a copy to the subject/representative.

5.5.1.1 Verify that you are using the most current IRB-approved version of the study script.

5.5.1.2 Whenever possible, provide the script to the subject/representative in advance of the consent discussion.

5.5.2 Read the consent script with the subject/representative and explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

5.6 Invite and answer the subject/representative’s questions.

5.7 Give the subject/representative time to discuss taking part in the research study with family members, friends, and other care providers as appropriate.

5.8 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.

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

5.9.1 The subject/representative understands the information provided.

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

5.9.3 The subject/representative understands that there is a voluntary choice to make.

5.9.4 The subject/representative is capable of making and communicating an informed choice.

5.10 If the subject/representative has questions about treatments or compensation for injury, provide factual information and avoid statements that imply that compensation or treatment is never available.

5.11 If the study is a clinical trial and the investigator above is not a physician, a physician must complete the following steps.

5.11.1 Invite and answer the subject/representative’s questions.

5.11.2 Confirm that the following are true or repeat the above steps:

5.11.2.1 The subject/representative understands the information provided.

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

5.11.2.3 The subject/representative understands that there is a voluntary choice to make.
5.11.2.4 The subject/representative is capable of making and communicating an informed choice.

5.12 Once a subject/representative indicates that he or she does not want to take part in the research study, this process stops.

5.13 If the subject/representative agrees to take part in the research study:

5.13.1 If the subject is a child:

5.13.1.1 Whenever possible, explain the research to the extent compatible with the child’s understanding.

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

5.13.1.2.1 Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

5.13.1.2.2 The IRB determined that assent was not a requirement.

5.13.1.3 Once a child indicates that he or she does not want to take part in the research study, this process stops.

5.13.2 If the subject is an adult unable to consent:

5.13.2.1 Whenever possible, explain the research to the extent compatible with the adult’s understanding.

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

5.13.2.2.1 Not obtained because the capability of the adult is so limited that the adult cannot reasonably be consulted.

5.13.2.2.2 The IRB determined that assent was not a requirement.

5.13.2.3 Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.

5.13.3 Obtain written documentation of the consent process according to SOP: Written Documentation of Consent.

6 MATERIALS

6.1 Long form of consent documentation:

6.1.1 English consent form (also called “summary” for non-English speakers)

6.2 Short form of consent documentation:

6.2.1 Short consent form

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

6.3.1 Consent script (same as the consent form used for long form of consent documentation, except that the signature block is optional)

7 REFERENCES

7.1 21 CFR 50.20, 50.25

7.2 45 CFR 46.116