1 PURPOSE

1.1 This procedure establishes the process to obtain informed consent from subjects, the legally authorized representatives 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 potential candidate for a research study.

1.3 The process ends when a subject or the subject's legally authorized representative provides legally effective informed consent or declines to do so.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 In this procedure "investigator" means a principal investigator or an individual authorized by the principal investigator 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 other than a parent authorized under applicable law to consent on behalf of the child to general medical care.

3.3 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative

3.4 If the subject is an adult unable to consent:

- 3.4.1 The IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent.
- 3.4.2 Permission is obtained from a legally authorized representative.
- 3.4.3 A legally authorized representative must be in the class or persons approved by institutional policy or the IRB. See "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."
- 3.4.4 Subjects who are adults unable to consent will be withdrawn if they appear to be unduly distressed.

3.5 If the subject is a child:

- 3.5.1 The IRB must have specifically approved the protocol to allow the enrollment of children.
- 3.5.2 Permission is obtained from both parents unless:
  - 3.5.2.1 One parent is deceased, unknown, incompetent, not reasonably available;
  - 3.5.2.2 Only one parent has legal responsibility for the care and custody of the child; or
  - 3.5.2.3 The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.
- 3.5.3 In the absence of a parent, permission may be obtained from an individual authorized to consent under applicable law on behalf of a child to general medical care.

3.6 If the subject/representative cannot speak English:

- 3.6.1 The IRB must have specifically approved the protocol to allow the enrollment of subjects able to speak the language that the subject understands.

3.7 Conduct all discussions in a private and quiet setting.

3.8 Any knowledgeable individual may:

- 3.8.1 Review the study with subject/representative to determine preliminary interest.
- 3.8.2 If the subject/representative is interested, notify an investigator.
- 3.8.3 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 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.

5.1.2 Verify that you are using the most current IRB-approved version of the study specific consent form and that the consent form is in language understandable to the subject/representative.

5.1.3 Provide a copy of the consent form to the subject/representative. Whenever possible provide the consent form to the subject/representative in advance of the consent discussion.

5.1.4 If the subject/representative 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/representative, 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.

5.1.5 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a family member or friend of the subject/representative.

5.1.6 Read the consent document (or have an interpreter read the translated consent document) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

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

5.2.1 Obtain the current IRB approved short consent form, summary (the English consent form used for the long form of consent documentation), and a copy of the experimental bill of rights (medical experiments[1] only).

5.2.2 Provide copies to the subject/representative. Whenever possible provide the short consent form, summary, and the experimental bill of rights (medical experiments only) to the subject/representative in advance of the consent discussion.

5.2.3 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a family member or friend of the subject/representative.

5.2.4 Obtain the services of an impartial 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 short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given. The witness and the interpreter may be the same person. 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 Have the interpreter translate the summary (the English consent form used for the long form of consent documentation) to the subject/representative.

5.2.6 Through the interpreter, explain the details in such a way that the subject/representative understands what it would be like to take part in the research study. When necessary, provide a different or simpler explanation to make the information understandable.

5.2.7 Have the subject/representative read the short consent and the experimental bill of rights (medical experiments only) form or have the interpreter read the short consent form to the subject/representative.

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.

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[1] California Health and Safety Code Section 24170

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/representative.

5.3.3 When possible provide a copy of the script to the subject/representative in advance of the consent discussion.

5.3.4 If the subject/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a family member or friend of the subject/representative.

5.3.5 Read the script (or have an interpreter translate the script) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.

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

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

5.6 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.

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

5.7.1 The subject/representative understands the information provided.

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

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

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

5.8 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.

5.9 If the study is a clinical trial and the investigator above is not a physician or physician extender, the investigator should consider, and the IRB may require, that a physician or physician extender complete the following steps.

5.9.1 Invite and answer the subject/representative's questions.

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

5.9.2.1 The subject/representative understands the information provided.

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

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

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

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

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

5.11.1 If the subject is a child:

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

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

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

5.11.1.2.2 The IRB determined that assent was not a requirement.

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

5.11.2 If the subject is an adult unable to consent:

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

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

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

5.11.2.2.2 The IRB determined that assent was not a requirement.

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

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

6 MATERIALS

6.1 Long form of consent documentation:

6.1.1 Consent form

6.2 Short form of consent documentation:

6.2.1 Short consent form

6.2.2 Summary (the English consent form used for long form of consent documentation)

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

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

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

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

7 REFERENCES

7.1 21 CFR §50.20, 50.25

7.2 45 CFR §46.116