



SOP: Informed Consent Process for Research

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	1/24/2013	M. Williams	M. Edwards	1 of 5

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 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 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 (LAR).
 - 3.4.3 A 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)."
 - 3.4.4 If there are any questions about whether a person is an LAR, contact the Office of the General Counsel.
 - 3.4.5 Ascertain from the LAR whether there are any individuals in a higher level of priority and, if so, obtain the consent of the individual in the higher level.
 - 3.4.6 Make reasonable attempts to contact those in the highest level of priority either by telephone or in person before obtaining consent from any individual in a lower level of priority.
 - 3.4.7 If there are no individuals in a higher level of priority, ascertain from the LAR whether there are other individuals within the same level of priority, and if so, whether the individual believes he or she may consent on behalf of all other individuals within that level of priority or whether he or she would first like to discuss the matter with such other individuals.
 - 3.4.8 Inform the LAR of the cognitive and health status of the research participant.
 - 3.4.9 Educate the LAR that:
 - 3.4.9.1 He or she should base his or her decision on the subject's expressed wishes or, if unknown, what the subject would have desired in light of his or her prognosis, values and beliefs. In the event of a disagreement among potential surrogates within the highest level of priority, the investigator may attempt to reach consensus through discussions with the potential surrogates. If consensus is not reached, the subject will not be enrolled in the study.



SOP: Informed Consent Process for Research

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	1/24/2013	M. Williams	M. Edwards	2 of 5

- 3.4.9.2 That he or she should make his or her decision based on substituted judgment, reflecting the subject's preferences and values, including religious and moral beliefs.
- 3.4.9.3 He or she should use best interest standards if the values of the individual are not known.
- 3.4.9.4 He or she should consider the potential subject's prior statements about and reactions to medical issues, when applicable to the study, and all facets of the potential subject's personality with which the surrogate is familiar -- with particular reference to his or her relevant philosophical, theological, and ethical values -- in order to extrapolate what decision the potential subject would make.
- 3.4.10 LARs may not receive any compensation or consideration of any kind for serving as an LAR or providing consent.
- 3.4.11 If at any time after the subject is enrolled in a study through the permission of an LAR and regains the capacity to provide consent, obtain the consent of the subject for continued participation in the research.
- 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 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.



SOP: Informed Consent Process for Research

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	1/24/2013	M. Williams	M. Edwards	3 of 5

- 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 member of the research team, 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 and summary (same as the English consent form used for long form of consent documentation).
 - 5.2.2 Verify that you are using the most current IRB-approved version of the study specific short consent form and summary that the short consent form is in language understandable to the subject/representative.
 - 5.2.3 Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.
 - 5.2.4 Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative. The interpreter may be a member of the research team, family member, or friend of the subject/representative.
 - 5.2.5 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.
 - 5.2.6 Have the interpreter translate the summary (not the short consent form) to the subject/representative.
 - 5.2.7 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.
 - 5.2.8 Have the subject/representative read the short consent 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.
 - 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.
 - 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 member of the research team, a family member, or friend of the subject/representative.



SOP: Informed Consent Process for Research

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	1/24/2013	M. Williams	M. Edwards	4 of 5

- 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's/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, a physician or physician extender must 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:



SOP: Informed Consent Process for Research

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-090	1/24/2013	M. Williams	M. Edwards	5 of 5

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 consent 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 (same information as 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