

General Information:

The person consenting participants to the research may be the 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, or team member. Regardless of who is obtaining consent, the Principal Investigator is responsible to ensure the correct procedures are carried out.

The consent process and procedure for obtaining consent may occur with:

- an adult capable of providing consent;
- the legally authorized representative when the participant is an adult unable to give consent;
- one or both biologic or adoptive parents when the participant 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 participate in the research.

If the participant is an adult unable to consent, the IRB must have specifically approved the protocol to allow the enrollment of adults unable to consent. If permission is obtained from a legally authorized representative this person must be in the class or persons approved by institutional policy or the IRB. See “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).”

If the participant is a child, the IRB must have specifically approved the protocol to allow the enrollment of children. Permission is obtained from both parents unless: one parent is deceased, unknown, incompetent, not reasonably available; only one parent has legal responsibility for the care and custody of the child; or he IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent. See “Checklist HRP:

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

If the participant/representative cannot speak English the IRB must have specifically approved the protocol to allow the enrollment of participants able to speak in language that the participant understands.

All discussions for consent should be conducted in a private and quiet setting.

If at any point a participant/representative indicates that he or she does not want to take part in the research study, the process stops.

The Consent Process:

1. If the consent process will be documented in writing with the long form of consent documentation:
 - a. 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 participant/representative.
 - b. Provide a copy of the consent form to the participant/representative. Whenever appropriate provide the consent form to the participant/representative in advance of the consent discussion.
 - c. If the participant/representative cannot read, a verbal consent may be appropriate or you may need to have an impartial witness present during the consent discussion. If the study involves greater than minimal risk, there must be a witness to attest that the information in the consent form and any other information provided was accurately explained to, and apparently understood by, the participant/representative. The witness may be a family member or friend and may not be a person involved in the design, conduct, or reporting of the research study. The witness is there to verify that consent was freely given.
 - d. If the participant/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, a family member, or friend of the participant/representative.

- e. Read the consent document (or have an interpreter read the translated consent document) with the participant/representative. Explain the details in such a way that the participant/representative understands what it would be like to take part in the research study.
 - f. When obtaining consent is completed, you must offer a signed copy to the participant / representative. The participant /representative is not obligated to take the document but it must be offered.
2. If the consent process will be documented in writing with the short form of consent documentation:
- Note: The short form consent is typically used only when the potential participant does not speak English and there is not enough time to translate the approved written English consent form into a language understandable to him or her.
- a. 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 participant/representative.
 - b. Provide copies to the participant/representative. Whenever appropriate provide the short consent form and summary to the participant/representative in advance of the consent discussion.
 - c. Obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, family member, or friend of the participant/representative.
 - d. Obtain the services of an impartial witness who is fluent in both English and the language spoken by the participant/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 participant/representative. 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 as the witness is there to verify that consent was freely given.
 - e. Have the interpreter translate the summary (not the short consent form) to the participant/representative.
 - f. Through the interpreter explain the details in such a way that the participant/representative understand 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.
 - g. Have the participant/representative read the short consent form or have the interpreter read the short consent form to the participant/representative.
 - h. When obtaining consent is completed, you must offer a written copy to the participant / representative. The participant /representative is not obligated to take the document but it must be offered.
3. If the requirement for written documentation of the consent process has been waived by the IRB:
- a. It is your obligation to follow the same process of obtaining consent as described above. You will use a consent document following the consent template with the only difference is that the participant is not asked to sign the document.
 - b. It is your obligation to provide a copy of the script to the participant/representative.
 - c. If the participant/representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the participant/representative. The interpreter may be a member of the research team, a family member, or friend of the participant/representative.
 - d. Read the script (or have an interpreter translated the script) with the participant/representative.
 - e. Explain the details in such a way that the participant/representative understands what it would be like to take part in the research study.

- f. Invite and answer the participant/representative's questions and give the participant/representative time to discuss taking part in the research study with family members, friends and other care providers as appropriate.
 - g. Invite and encourage the participant/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.
 - h. Ask the participant/representative questions to determine if the participant/representative understands the information provided
4. If the participant/representative agrees to take part in the research study:
- a. If the participant is a child:
 - i. Whenever possible explain the research using language that is age appropriate and/or cognitively consistent with the child's ability to understanding.
 - ii. Request the assent (affirmative agreement) of the child unless the capability of the child is so limited that the child cannot reasonably be consulted or the IRB determined that assent was not a requirement. It is recommended that when appropriate, children under age 7 should be verbally assented and 7+ assented in writing.
 - iii. Once a child indicates that he or she does not want to take part in the research study, this process stops.
 - b. If the participant is an adult unable to consent:
 - i. Whenever possible explain the research to the extent compatible with the adult's understanding.
 - ii. Request the assent (affirmative agreement) of the adult unless the capability of the adult is so limited that the adult cannot reasonably be consulted or the IRB determined that assent was not a requirement.
 - iii. Once an adult unable to consent indicates that he or she does not want to take part in the research study, this process stops.