TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Consent Documentation	
	Section III: IRB Protocols	
	Number	Date
	IRB III-008	9/13/2025

1. PURPOSE

1.1. This SOP describes the general process used to obtain informed consent from participants, Legally Authorized Representatives (LAR) of adults unable to consent, or the parents or guardians of children, for studies where consent is required and the IRB has not waived the requirement to obtain consent.

1.2. Other procedures may be suitable when approved by the IRB.

1.3. The process begins when an individual identifies a potential participant for a research study.

1.4. The initial consent process concludes when a prospective participant (subject), LAR, or parent/guardian, as applicable, provides legally effective informed consent or declines to do so. Consent may be withdrawn at any time.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

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. This may include a co-investigator, student investigator, research assistant, or other research staff.

3.2. In this procedure “subject/representative” means:

3.2.1. An adult capable of providing consent.

3.2.2. LAR when the subject is an adult unable to give consent

3.2.3. One or both biological or adoptive parents when the subject is a child, or in the absence of a parent, an individual authorized under applicable law to provide consent on behalf of the child for general medical care.

3.3. If research requires consent from adults unable to do so, permission must be obtained from a LAR.

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

3.3.2. Permission is obtained from a LAR.

3.3.3. A LAR must belong to a category of individuals approved by institutional policy or the IRB.

3.3.4. When research is conducted in the State of Texas, the following individuals meet the LAR definition:

3.3.4.1. Legal guardian with the authority to make decisions regarding medical treatment.

3.3.4.2. Person designated as a surrogate decision-maker by the patient with a Medical Power of Attorney or Advance Directive.

3.3.4.3. In the absence of either of the above, an individual from the following list, in order of priority, who is available after a reasonably diligent inquiry, may consent on behalf of the subject:

- Spouse (including common law spouse);
- Adult child who has the waiver and consent of all other qualified adult children to act as the sole decision-maker;
- A majority of the reasonably available adult children;
- Parents;
- Individual clearly identified to act for the subject by the subject before the subject became incapacitated;
- Nearest living relative; and
- A member of the Clergy.

3.3.5. For research outside the State of Texas, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

3.4. If the subject is a child:

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

3.4.2. Permission is obtained from both parents unless:

3.4.2.1. One parent is deceased, unknown, incompetent, or not reasonably available;

3.4.2.2. One parent has sole legal responsibility for the care and custody of the child; or

3.4.2.3. The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

3.4.3. In the absence of a parent, permission may be obtained from an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

3.5. Unless the IRB has waived the requirement to obtain consent, when research involves children, consent may only be obtained from biological or adoptive parents or an individual legally authorized to provide consent on behalf of the child for general medical care[1]. Prior to obtaining consent from a non-parent, legal counsel must be consulted.

3.6. HHS and FDA's Subpart D applies to all research involving children. When research is conducted in the State of Texas, all individuals under the age of 18 years are children. Exceptions exist for:

3.6.1. Individuals under 18 years of age on active duty with the armed services of the United States of America.

3.6.2. Individuals 16 years of age or older, residing separate and apart from his/her parents, managing conservator, or guardian (with or without consent and regardless of duration) and managing his/her own financial affairs (regardless of the source of the income).

3.6.3. Individuals under 18 years of age seeking the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code.

3.6.4. Individuals under 18 years of age who are unmarried and pregnant when the research involves treatment related to pregnancy, other than abortion.

3.6.5. Individuals under 18 years of age seeking an examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use.

3.6.6. Individuals under 18 years of age serving a term of confinement in a facility of the Texas Department of Criminal Justice.

3.6.7. For research outside the State of Texas, a determination of who is a child is to be made with consultation from legal counsel.

3.7. When research is conducted in Texas, the following individuals are classified as guardians in accordance with state law:

3.7.1. An individual appointed by the court to protect a person who does not have the capacity to protect his or her own interests.

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

3.9. If the subject/representative cannot speak English:

3.9.1. The IRB must have specifically approved the protocol to permit the enrollment of subjects who speak a language other than English that the subject understands.

3.9.1.1. The IRB may require a certificate of translation for the non-English consent documents to verify the translations are accurate.

3.9.1.2. Translators of the consent document must provide a brief summary of their qualifications, skills, or experience and sign a certificate of translation or equivalent form.

3.10. Conduct all discussions in a setting that allows for privacy and confidentiality.

3.11. Any knowledgeable individual may:

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

3.11.2. If the subject/representative is interested, notify an investigator. This expression of interest does not constitute consent.

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

4. RESPONSIBILITIES

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

5. PROCEDURE

5.1. If the consent process will be documented in writing using long form of consent documentation:

5.1.1. Obtain the current IRB-approved consent form or script.

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

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

5.1.4. If the subject/representative cannot read, an impartial witness must be present during the entire consent process and attest that the information in the consent form and any supplementary information provided was accurately explained and understood by the subject/LAR, and that consent was freely given.

5.1.4.1. The impartial witness may be a family member or friend but may not be a person involved in the design, conduct, or reporting of the research.

5.1.4.2. 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 a friend of the subject/representative.

5.1.5. 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.

5.1.5.1. When conducting federally supported research, begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

5.2. If the requirement for written documentation of the consent process has been waived by the IRB, but consent is still required:

5.2.1. Obtain the current IRB-approved script.

5.2.2. 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.

5.2.3. When possible, provide a copy of the consent form to the subject/representative.

5.2.4. 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.

5.2.5. Read the consent document (or have an interpreter read the translated 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.

5.2.6. When conducting federally supported research, begin with a concise and focused presentation of key information that is most likely to assist the subject/representative to understand the reasons why one might or might not want to participate in the research.

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

5.4. Give the subject/representative time to discuss taking part in the research study with family members, friends, and other care providers or to take the written information home to consider as appropriate.

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

5.5.1. The subject/representative understands the information provided.

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

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

5.6. If the subject/representative has questions about study interventions or compensation, provide factual information about available options.

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

5.7.1. If the subject is a child:

5.7.1.1. Whenever possible, explain the research to the extent compatible with the child's cognitive level of understanding.

5.7.1.2. Request the assent (affirmative agreement or written signature) of the child unless:

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

5.7.1.2.2. The IRB has determined that assent was not a requirement.

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

5.7.2. If the subject is an adult unable to consent:

5.7.2.1. Whenever possible, explain the research to the extent compatible with the adult's cognitive level of understanding.

5.7.2.2. Request the assent (affirmative agreement or written signature) of the adult unless:

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

5.7.2.2.2. The IRB determined that assent was not a requirement.

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

5.8. Once the subject/representative agrees to take part in the research study, follow the written document of consent process below:

5.8.1. If the consent process will be documented in writing using the long form of consent documentation:

5.8.1.1. Verify that the consent form is in a language understandable to the subject/representative.

5.8.1.2. Print the name of the following individuals on the consent document:

5.8.1.2.1. Subject/Representative

5.8.1.2.2. Person obtaining consent, when required.

5.8.2. Have the following individuals personally sign and date the consent document:

5.8.2.1. Subject/Representative

5.8.2.2. Person obtaining consent, when required.

5.8.3. If the IRB required written documentation of assent, note on the signature block one of the following:

5.8.3.1. Assent of the child was obtained.

5.8.3.2. Assent of the child was not obtained because the capability is so limited that the child cannot reasonably be consulted.

5.8.4. Have the person obtaining consent personally sign and date the consent document, when required.

5.8.5. If an impartial witness was part of the consent process

5.8.5.1. Print the name of the impartial witness on the consent document.

5.8.5.2. Have the impartial witness personally sign and date the consent document to attest that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject, and that consent was freely given.

5.8.6. Provide copies of the consent document to the subject/representative. A signed copy may be given either by making a photocopy or by having the above individuals sign and date two copies of the consent document.

5.8.6.1. Investigators may ask the subject/representative to save an electronic version of the document to an electronic device.

5.9. If the requirement for written documentation of the consent process has been waived by the IRB and the IRB determined that the subject/representative had to be offered the opportunity to

document his or her consent in writing, offer the subject/representative the option to document his or her consent in writing.

5.9.1. If the Subject/representative declines, take no further action.

5.9.2. If the Subject/representative accepts, follow the process to document consent in writing with the long form of consent documentation.

5.10. Place the signed and dated consent documents in the subject's binder or equivalent.

6. REFERENCES

6.1. 21 CFR §50.3, §50.20, §50.25, §50.27

6.2. 45 CFR §46.102, §46.116, §46.117, §46.402

[1] This is the DHHS and FDA definition of "guardian"

Approved by: Lori Kupczynski

Lori Kupczynski, EdD
Special Assistant to the Vice President,
Office of Research and Innovation

Date: 8 September 2025