GUIDELINE # 12: INFORMED CONSENT

I. PURPOSE

This guideline is to ensure that human subjects' research conducted complies with federal, state, and local laws, regulations, directives, and instructions. This guideline provides guidance that is used to obtain informed consent from participants.

II. STATEMENT

All human subjects research, irrespective of the source of funding, conducted by A&M- SA faculty, staff, and students must be submitted and reviewed in accordance with the Federal research regulations, Texas A&M System Guidelines, A&M-San Antonio (A&M-SA) Institutional Review Board (IRB) policies and local consideration.

Informed consent is a process, not merely a form. Informed consent is a fundamental mechanism to ensure respect for persons through provision of thorough information about the research in which the individual is invited to participate so that they can make an informed decision to participate voluntarily.

III. SCOPE

This guideline applies to all research conducted where the A&M-SA IRB serves as the Reviewing IRB.

IV. PROCEDURES

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 key study personnel.

In this procedure "human subject/representative" means:

- The human subject when the subject is an adult capable of providing consent.
- Legally Authorized Representative (LAR) when the human subject is an adult unable to give consent.
- One or both biologic or adoptive parents when the human 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.

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

If the human subject is an adult unable to consent:

- The IRB must specifically approve the protocol to allow the enrollment of adults unable to consent.
- Permission is obtained from a LAR.
- A LAR must be approved by the IRB.

If the human subject is a child:

- The IRB must specifically approve the protocol to allow the enrollment of children.

Permission is obtained from both parents unless:

- One parent is deceased, unknown, incompetent, or not reasonably available.
- One parent has legal responsibility for the care and custody of the child or
- The IRB has specifically approved the protocol to allow the permission of one parent regardless of the status of a second parent.

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.

If the human subject/representative cannot speak English:

The IRB must have specifically approved the protocol to allow the enrollment of Human subjects able to speak the language other than English that the human subject understands.

- The IRB may require a statement of translation for the non-English consent documents to verify the translations are accurate.
- Those who translate the consent document are to provide a brief description of their qualifications, skill or experience or serving in this role and sign the statement of translation.
- The investigator may wish to delay the initial translation of the consent documents until after the IRB has reviewed and approved the English versions.

Conduct all discussions in a setting that allows for privacy and confidentiality.
Key study personnel or trained staff members may:

- Review the study with the human subject/representative to determine preliminary interest.
- If the human subject/representative is interested, notify an investigator.
- If the human subject/representative is not interested, take no further steps regarding recruitment or enrollment.

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

- Obtain the current IRB-approved script.

- 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 human subject/representative.
- When possible, provide a copy of the consent form to the human subject/representative.
- If the human subject representative cannot speak English, obtain the services of an interpreter fluent in both English and the language understood by the human subject/representative. The interpreter may be a member of key study personnel, a family member, or a friend of the human subject/representative.
- Read the consent document (or have an interpreter read the translated script) with the human subject/representative. Explain the details in such a way that the human subject/representative understands what it would be like to take part in the research study.
- When conducting federally supported research, ensure that all elements of informed consent are presented to the human subject/representative to understand the reasons why one might or might not want to participate in the research.

Invite and answer the human subject/representative's questions. Give the human 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.

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

- The human subject/representative understands the information provided.
- The human subject/representative does not feel pressured by time or other factors to make a decision.
- The human subject/representative is capable of making and communicating an informed choice.

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

Once a human subject/representative indicates that they do not want to take part in the research study, stop this process. Consent to participate in the study may be withdrawn by the human subject/representative at any time without penalty.

If the human subject/representative agrees to take part in the research study:
If the human subject is a child:

- Whenever possible explain the research to an extent compatible with the child's understanding.
- Request the assent (affirmative agreement) of the child unless:
    - The capability of the child is so limited that the child cannot reasonably be consulted.

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

- Once a child indicates that they do not want to take part in the research, stop this process.

If the human subject is an adult unable to consent:

- Whenever possible explain the research to an extent compatible with the adult's understanding or follow the SOP for Legally Authorized Representative (LAR).
- Request the assent (affirmative agreement) of the adult unless:
  - The capability of the adult is so limited that the adult cannot reasonably be consulted.
  - The IRB determined that assent was not a requirement.

- Once an adult unable to consent indicates that they do not want to take part in the research, stop this process.

V. REVISIONS

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