TITLE OF STUDY:

PROTOCOL NUMBER:

DEAR STUDY PARTICIPANT:

You are invited to participate in a research study of [Insert general statement about study].

You were selected as a possible participant because [Explain how subject meets the criteria to be in the study and/or was identified].

We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: [Name of PI, department (indicate University affiliation)]

Background Information

The purpose of this study is: [Explain research question and purpose in lay language]

Procedures:

If you agree to participate in this study, we will ask you to do the following things:

[Explain tasks and procedures: subjects should be told about video or audio taping, assignment to study groups, length of time for participation, frequency of procedures, etc.]

Risks and Benefits of participating in the Study

The study includes the following risks:
First, [Risk];

Second, [Risk]

(Risk must be explained, including the likelihood of the risk. State what measures will be used to lower these risks. If there are significant psychological risks to participation, the participant should be told under what conditions the researcher will terminate the study. If the risks are no greater than those encountered in everyday life, this should be stated.)

The benefits to participation are:
[Benefit(s)] *(If no benefits, state that here.)*

If changes to the potential or actual risks or benefits to you occur, you will receive a report of significant new findings and/or be asked to re-consent.

Compensation:

You will receive payment: [Include payment or reimbursement information here.]
(If subjects receive class points or some other token, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdrawal.)

Confidentiality:

The records of this study will be kept private. Reports resulting from this study will not include any information that will make it possible to identify you as a participant. Research records will be stored securely and only researchers will have access to the records.
(If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be erased.)

Voluntary Nature of the Study:

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with Texas A&M University-San Antonio [or with other cooperating institutions, insert names here]. If you decide to participate, you are free to not answer any question or to withdraw at any time without affecting those relationships.

Contacts and Questions:

You may ask any questions you have now. If you have questions later, **you are encouraged** to contact the Principal Investigator at [Location], [Phone number], [TAMUSA E-mail address].

(PI listed on the protocol is the only one to be listed as a contact.).

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher(s), **you are encouraged** to contact the IRB Chair at irb@tamusa.edu, or by phone (210) 784-2317.

You will be given a copy of this information to keep for your records.

Statement of Consent:

The signature below affirms that you are at least 18 years old, have received a copy of this consent form, have understood the above information, and agree to voluntarily participate in this research.

Signature:_____ Date: _____

Signature of parent or guardian:_____ Date: _____
(If minors are involved)

Signature of Investigator:_____ Date: _____

(PI should only include signature lines of participants that are signing the form to consent. You may not need all the lines and are not required to keep all of them unless you are collecting signatures for each line.)

DELETE THIS INFORMATION AFTER YOU'VE COMPLETED YOUR FINAL DRAFT OF THE INFORMED CONSENT

Comments:

A. This template can be tailored for different purposes if needed.
B. Remove *italicized* informational or [guidance sections] within the document.
C. Remove all highlighted areas for final copy.

D. When appropriate, the consent document should include the following additional information:
   1. Methodological procedures: Identification of any procedures in the research design.
   2. Alternative procedures or treatments: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
   3. Research-related injury: For research involving more than minimal risk, identification of the person to contact in the event of a research-related injury, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
   4. Unforeseeable risks: A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable.
   5. Termination of participation by the investigator: Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
   6. Additional costs: Any additional costs to the participant that may directly result from participation in this research.
   7. Consequences of discontinuing research participation: The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
   8. Exclusion requirements: Any pre-existing conditions (e.g., pregnancy) or other factors (e.g., age) that might exclude a potential participant from participation in the study.

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