## Title of Research Study:

## Principal Investigator:

## Purpose of the Study and Reason for Your Involvement:

*If you are providing consent for someone else (e.g., your child, a next-of-kin, or someone for whom you are the legal guardian or are designated as a surrogate decision maker on a medical power of attorney), please note that in the sections that follow the word “you” refers to the person for whom you are providing consent.*

Specify the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.

We invite you to take part in a research study because…. (*Indicate* the circumstances or conditions that make participants eligible to participate in the research study.)

## Participation in the Study:

1. Whether or not you take part is up to you.
2. Participation is totally voluntary.
3. You can agree to take part in the study and later change your mind.
4. Your decision not to participate will not be held against you.
5. You may ask all the questions you want about the study before you decide.

## Contact information:

If you have questions, concerns, complaints, or think the research has harmed you, you may talk to the research team at: *(*Provide contact information on the research team.)

This research is being overseen by an Institutional Review Board (“IRB”). You may also talk to them at (210) 458-6473 or IRB@utsa.edu if you have questions regarding your rights as a research participant or other questions, concerns, or complaints.

## Participant Role in the Research Study:

Using simple language and terms, tell the participant what to expect if he or she volunteers to participate in your study. Be sure to indicate any activities that will take place regardless of participation such as course exams, assignments, etc.

 Be sure to include the following items:

* A time-line description of the procedures that will be followed, including the duration and frequency of the procedures.
* Identification of all procedures to be used in the study to collect data.
* Description of any private, identifiable information about the participant that may be collected for use in the research (e.g., grades, employment records, etc.).
* Nature of participant interaction with PIs.
* Location where and date that the research will be conducted.
* Duration of participants’ participation.
* If applicable, indicate that the participant will be contacted for future research.
* If applicable, indicate that you are asking to retain the data for use in future research.

Other Options for Participation in the Research Study:

If there are alternatives to participation in the study that may be advantageous to the participant, please include a description of those alternatives; otherwise, delete this section.

## Additional information:

1. If the study is grant-related or industry sponsored research, please indicate the funding source; otherwise, delete.*(For example: This research is being funded by ….)*

 2. If the study will pay participants, please indicate how much will be paid; otherwise delete.*(For example: If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ for your time and effort.)*Be sure to **i**ndicate if the amount is pro-rated by research visit or research procedure.

3. If the study will incur costs to the participants due to participation, please indicate what those costs will be; otherwise, delete.

Risks and Discomforts:

 Indicate if there are any related risks or discomforts to participation in the research study. If known, describe the probability (likelihood) and magnitude (seriousness) of the risk. Include physical, psychological, legal, social, economic, and privacy risks. Do not include “loss of confidentiality.” (State “None” if there are no reasonably expected research -related risks.)

Benefits for Participation:

Describe any possible individual benefits from participation in the study; otherwise, delete. Suggested language: “We cannot promise any benefits to you or others for participating.”

Participant Privacy and Research Record Confidentiality:

Specify any protections you will have in place.

Suggested language: Your data will not contain anything to connect your identity with your information. or The surveys will be anonymous. Your research records will not be released without your consent unless required by law or a court order. Your records may be viewed by the Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law. The data resulting from your participation may be used in publications and/or presentations but your identity will not be disclosed.

You may be advised by the IRB to include additional information in the consent form if your study includes prisoners as participants, the study is greater than minimal risk, the study is subject to FDA oversight, or there is additional information that participants should be made aware of.

**Signature Block**

|  |
| --- |
| Your signature documents your permission for the named participant to take part in this research. |
|
|  |  |
| Name of participant (Age if minor) |  |
|  |  |  |
| Signature of Participant (or participant’s legally authorized representative) |  | Date |
|  |  |  |
| Signature of person obtaining consent |  | Date |

***Add the following block if you will document assent of the participant.***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the participant is so limited that the subject cannot reasonably be consulted.
 |

***Add the following block if a witness will observe the consent process.***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant. |
|  |  |  |
| Signature of witness to consent process |  | Date |