Project Title:

**You are invited to take part in a research study being conducted by Investigator Name, a researcher from Texas A&M University–Kingsville and** funded by [name sponsor/funding source, if applicable]. **The information in this form is provided to help you decide whether or not to take part. If you decide to take part in the study, you will be asked to read this consent form. If you decide you do not want to participate, there will be no penalty to you, and you will not lose any benefits you normally would have.**

**Why Is This Study Being Done?**

The purpose of this study is to PURPOSE.

**Why Am I Being Asked To Be In This Study?**

You are being asked to be in this study because INCLUSION/EXCLUSION CRITERIA.

**How Many People Will Be Asked To Be In This Study?**

NUMBER people (participants) will be invited to participate in this study locally. Overall, a total of NUMBER people will be invited at NUMBER/multiple study centers ***if research is being conducted at multiple sites***.

**Are there Alternatives to being in this study?**

***If this is not a treatment study:***

No, the alternative to being in the study is not to participate. Another activity will be given if you choose not to participate.

***For studies that give course credit:***

The alternative is to sign up for another study or to choose to complete another assignment as described in your syllabus.

***If this is a treatment study:***

The following therapies for treatment of CONDITION are available: TREATMENTS. You should talk to your personal doctor (or study doctor if appropriate) to discuss what would be right for you.

**What Will I Be Asked To Do In This Study?**

You will be asked to [describe task]. Your participation in this study will last up to LENGTH in hours/weeks/ months/years and includes NUMBER visits.

***Example template:***

Visit 1 (Week NUMBER)

This visit will last about LENGTH in minutes/hours. During this visit DESCRIBE PROCEDURES.

***Add, if applicable the following statement:***

You may be removed from the study by the investigator for these reasons:

* REASONS

***Add, if applicable the following statement:***

If you leave the study early, you may be asked to complete the following activities:

ACTIVITIES

**Will Photos, Video or Audio Recordings Be Made Of Me during the Study?**

***If video/audio recordings or photographs will be used or will not be used use the appropriate statements below to answer the question.***

The researcher will not take photo(s), video or audio recordings during this study.

***Language for Required recordings:***

The researchers will take photographs/make an audio and/or video recording during the study so that PURPOSE. If you do not give permission for the photograph/audio/video recording to be obtained, you cannot participate in this study.

***Language for Optional recordings:***

The researchers will take photographs/make an audio and/or video recording during the study so that PURPOSE only if you give your permission to do so. Indicate your decision below by initialing in the space provided.

\_\_\_\_\_\_\_\_ I give my permission for photographs/audio/video recordings to be made of me during my participation in this research study.

\_\_\_\_\_\_\_\_ I do not give my permission for photographs/audio/video recordings to be made of me during my participation in this research study.

**Are There Any Risks To Me?**

The things that you will be doing are no more/greater than risks than you would come across in everyday life. Describe risks, including physical, criminal, social, financial, economic, psychological risk as well as risks associated with breach of privacy or confidentiality.

***Suggested wording if applicable:***

Although the researchers have tried to avoid risks, you may feel that some questions/procedures that are asked of you will be stressful or upsetting. You do not have to answer anything you do not want to. ***(If applicable, add)***Information about individuals and/or organizations that may be able to help you with these problems will be given to you.

***(If applicable, add)***If you are or were to become pregnant, the particular treatment or study procedure might involve risks to the embryo or fetus, which are currently unknown.

**Are There Any Benefits To Me?** **(*\*If there are no direct benefits, this section may be omitted)***

The direct benefit to you by being in this study is [Describe Benefits].

**Will There Be Any Costs To Me?**

Aside from your time, there are some/no costs for taking part in the study.

**Will I Have To Pay Anything If I Get Hurt In This Study? *This section is only necessary for studies involving greater than minimal risk. If the study is minimal risk then remove this section completely.***

***Discussion of compensation for research-related injury should be included here. For industry-sponsored studies, this language must match the Clinical Trial Agreement. Please choose the statement that best applies.***

***1. When the study has no provision of treatment:***

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, all needed facilities, emergency treatment and professional services will be available to you, just as they are to the community in general. You should report any injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

***2. When the study is sponsor initiated, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols):***

If you suffer any injury as a result of taking part in this research study the sponsor of this study, <insert sponsor's name>, will pay for reasonable and necessary medical expenses if the injury is a direct result of taking the study medicine or undergoing study procedures, and not due to the natural course of any underlying disease or treatment process. You should report any such injury to <insert PI name and phone number>. You will not give up any of your legal rights by signing this consent form.

Side effects (injury) can happen in any research study. These effects may not be your fault or the fault of the researcher involved. Known side effects have been described in the “Are there any risks to me?” section of this consent form. However, side effects that are not currently known may happen and require care. You do not give up any of your legal rights by signing this form.

**Will I Be Paid To Be In This Study?**

You will not be paid for being in this study **OR** You will receive Payment/Reimbursement/Participation Credit. Disbursement will occur [explain conditions of payment]. [Include circumstances, if any, where partial payment or no payment may occur]

**Will Information From This Study Be Kept Private?**

***(if applicable***) The records of this study will be kept private. No identifiers linking you to this study will be included in any sort of report that might be published. Research records will be stored securely and only [insert individuals or groups who will have access to this data] will have access to the records.

***(for FDA regulated studies)*** A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about you will be stored in locked file cabinet; computer files protected with a password. This consent form will be filed securely in an official area.

People who have access to your information include the Principal Investigator and research study personnel. Representatives of regulatory agenciessuch as the Office of Human Research Protections (OHRP) or *(if FDA regulated)* the Food and Drug Administration (FDA) and entities such as the Texas A&M University Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly.

***(if applicable)***The agency that funds this study (INSERT SPONSOR NAME) and the institution(s) where study procedures are being performed (INSERT SCHOOL, HOSPITAL, CLINIC, INSTITUTION) may also see your information. However, any information that is sent to them will be coded with a number so that they cannot tell who you are. Representatives from these entities can see information that has your name on it if they come to the study site to view records. If there are any reports about this study, your name will not be in them.

Information about you and related to this study will be kept confidential to the extent permitted or required by law.

**Who may I Contact for More Information?**

You may contact the Principal Investigator, name of Principal Investigator plus his/her degree, to tell him/her about a concern or complaint about this research at XXX-XXX-XXXX or email address. ***For student/resident research, add:*** You may also contact the Protocol Director, name of PD at XXX-XXX-XXXX or email address. ***For alternate contact (Co-PI, faculty sponsor, etc.), add:*** You may also contact the research role, name of Alternate Contact at XXX-XXX-XXXX or email address.

For questions about your rights as a research participant, to provide input regarding research, or if you have questions, complaints, or concerns about the research, you may call the Texas A&M University-Kingsville Institutional Review Board at the Office of Research and Graduate Studies by phone at 361-593-2677 (please leave a message if there is no answer), or by email at ResearchCompliance@tamuk.edu.

**What if I Change My Mind About Participating?**

This research is voluntary and you have the choice whether or not to be in this research study. You may decide to not begin or to stop participating at any time. If you choose not to be in this study or stop being in the study, there will be no effect on your student status, medical care, employment, evaluation, relationship with Texas A&M University, etc. ***(If applicable, add)***Any new information discovered about the research will be provided to you. This information could affect your willingness to continue your participation.

**STATEMENT OF CONSENT**

**I agree to be in this study and know that I am not giving up any legal rights by participating. The procedures, risks, and benefits have been explained to me, and my questions have been answered. I know that new information about this research study will be provided to me as it becomes available and that the researcher will tell me if I must be removed from the study. I can ask more questions if I want, (if applicable) and I can still receive services if I stop participating in this study. A copy of this entire consent form will be given to me. I confirm that I am 18 years of age or older.**

**INVESTIGATOR'S AFFIDAVIT**:

Either I have or my agent has carefully explained to the participant the nature of the above project. I hereby certify that to the best of my knowledge the person who read this consent form was informed of the nature, demands, benefits, and risks involved in his/her participation.

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| **THIS RESEARCH PROJECT HAS BEEN REVIEWED & APPROVED BY THE TEXAS A&M** **UNIVERSITY—KINGSVILLE INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS. FOR QUESTIONS, COMPLAINTS, OR CONCERNS ABOUT THE RESEARCH, YOU MAY CONTACT THE OFFICE OF RESEARCH AND GRADUATE STUDIES BY PHONE AT 361-593-2677, OR BY EMAIL AT**ResearchCompliance@tamuk.edu |
| **Protocol #: 0000-000 / 00000** |