**Consent to Participate in a Research Study at Texas A&M University-Corpus Christi**

**[study\_title]**

**Introduction**

The purpose of this form is to provide you information to help to make the decision on whether to participate in this research study. Please read the information below and ask questions before you make a choice.

Instructions: Please review and edit as needed. Fill in the fields in red. Once complete, please remove all blue instructional text. Upload in iRIS complete and finalized documents (no tracked changes). Word format is preferred to get complete use out of iRIS features like compare document feature.

**Who is doing this study?**

A study team led by [pi name] is doing this research study. Other research professionals may help them.

The following statement is required if there is a sponsor.  Funding for this study comes from the [study\_sponsor]. The study team will not receive any personal payment because of your decision.

**Why is this research being done?**

The goal of this research study is to [state the purpose of your study].

**Who can be in this study?**

We are asking you to be a part of this research study because state why they qualify for the study, i.e., you are a student attending X class.

To be eligible to be in this study, you must be: [inclusion criteria]

To be eligible to be in this study, you must not be: [exclusion criteria]

Up to [subject\_number] will be asked to be in this study.

**What will I be asked to do?**

If you agree to be in this study, the following things will happen: [describe the procedures involved]

If you agree to be in this study, you will be in this study for [duration; this MUST match duration in the IRB application].

**What are the risks involved in this study?**

If you indicated the risk level is less than minimal risk you can add this statement.

This research involves minimal risks (risks that you may experience in everyday life even if you do not participate in this study).

Review risks you entered in your application above and edit as needed. Review examples below if there are other risks to be considered and edit you risk list accordingly. Risks in the consent MUST match risks listed in the application.

Potential risk may include:

Confidentiality risk: Your participation will involve collecting information about you. There is a risk of loss of confidentiality.  Your confidentiality will be protected to the greatest extent possible. You do not have to give any information to the study that you do not want to give.

Survey Questions: Some questions may be embarrassing or uncomfortable to answer. Sample questions that you may be asked are: [add some sample questions that give subjects a flavor of what they will be asked]. You do not have to answers questions you do not want to.

Audio/Video Recording: If you choose to participate in this study, your interview will be audio/video recorded.  Any audio/video recordings will be stored securely in a password-protected file.  Any recordings will be kept until it has been transcribed and de-identified.  After transcription, the recording will be permanently deleted.

If you have any of these problems or changes in the way you feel about being in the study, you should tell the study team as soon as possible.

**What about protecting my information?**

Pick **one of the two** options to match your protocol answer regarding collecting identifiers.

This study is anonymous or confidential.

Include this paragraph if anonymous: The information collected from you will not include any identifiers (like names, addresses, phone numbers, and social security or individual taxpayer identification (ITIN) numbers). Your identity will not be known by the research team to protect your confidentiality. Please do not include any identifiers in the study documents.

Include this paragraph if confidential: When the information collected about you includes identifiers, the study can involve confidential information.

The following identifiers will be collected from you if you choose to participate in this research study:

[%identifiers%]

Your information will be protected by:

Add any other methods to protect the data to the list above from your IRB application. Here are some examples. Delete those that are not applicable to your study.

* Anonymous survey: The survey will not ask or collect any identifiers from you so researchers will not know who participated and who did not.
* The interview once transcribed will be anonymized (a process by which identifying information is removed) by using pseudonyms (a fictious name). The interview recording will be deleted after transcription.
* We will share your information only when we must, will only share the information that is needed, and will ask anyone who receives it from us to protect your privacy.
* No identifiers linking you to this study will be included in any report that might be published or presented.

If you selected confidential above, then you must add one of the two following sentences (45 CFR 46.116(b)(9)):

Once data analysis is complete, your identifiers will be removed from the research data, after such removal, the de-identified information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

OR

Once data analysis is complete,  your identifiers will be removed from the research data. Your information collected as part of this research, even after identifiers are removed, will not be used or distributed for future research studies.

**What are the alternatives to being in this study?**

Instead of being in this study, you may choose not to be in the research study.

**What are the possible benefits of this study?**

Choose one of the two following paragraphs to match the following answer in your application.

There is **no** direct benefit to you from being in this research study.

There may be a direct benefit to you from being in this study.  Possible benefits may include:

[%benefits\_descrip%]

**What will I receive if I am in the study?**

Edit this section to match your application answer as to whether you are providing compensation.

If the answer above is no (you are not providing compensation, tangible property or reimbursement) you can remove this entire section.

Compensation provided: Edit the following information provided in your application. Be sure to include the following:

* The maximum compensation provided;
* Payment method (cash, gift card, check);
* Timing of disbursement; and
* If you require any identifiers to make the payment (Example: if you need SSN/ITIN or emails to deliver the payment that otherwise would not be collected for the research study)

You will receive the following:

[%compensation\_descrip%]

Reimbursement (use this sentence only if you are collecting receipts and giving subjects the exact amount they spent.) To reimburse you for study related expenses such as [taxi fare, hotel, meals] you will need to provide a receipt showing your expenses and that amount will be provided to you by the study team.  These payments are not considered to be taxable income.

Timing of disbursement. Add any details on how disbursement will be made over the time it takes to complete the study. If the study can be done in one setting, then you can delete this paragraph: If you do not complete the study, you will be compensated for the visits that were completed.  You will not be compensated for any unscheduled visits*.*

**Do I have to participate?**

No. **Being in a research study is voluntary.**  If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled.

**What if I change my mind?**

You **may quit at any time**.  There will be no penalty or loss of benefits to which you are otherwise entitled. Your decision not to participate or quit will not affect your current or future relations with Texas A&M University-Corpus Christi or any cooperating institution.

Inform the subjects what will occur with the data/samples collected about them up to the time of withdrawal.

If you withdraw from the study early for any reason, the information that already has been collected will be kept in the research study and included in the data analysis.  No further information will be collected for the study.

Add if applicable: The information that already has been collected will be de-identified (the information cannot be traced back to you individually). Because you cannot be identified from the information there is no further risk to your privacy. This information will continue to be used for research even after you withdraw.

**Is there anything else I should consider?**

If there is no additional information, then delete this section.

Use this section to disclose any other information that may affect a person’s decision to participate.

Potential costs to subjects.

Taking part in this study may lead to added costs to you, such as describe costs, i.e. parking costs, costs for child care, time off work.  There are no plans for the study to pay for these costs.

If you answered yes to the conflict of interest question, then the following statement is required. If no, then delete.

Investigator’s name has a conflict of interest. [%KSP\_COI\_descrip%].

The university and the IRB have reviewed this arrangement and determined that this relationship presents a potential conflict of interest.

The following statement is required if there is a conflict of interest and there is a remedy statement or management plan. In addition to informing you of this conflict of interest, Investigator’s name will not List items in the COI management plan: be involved in the recruitment of or enrolling study participants, will not participate in data and safety monitoring activities, will not be engaged in the recording of research data.

To learn more about this relationship, contact the Institutional Review Board below.

**Who can I contact with questions about the research?**

[%pi\_name2%] is in charge of this research study.  You may call [%pi\_name2%] at [%pi\_phone%] or email at [%pi\_email%] with questions at any time during the study.  You may also call [%pc\_name2%] at [%pc\_phone%] or email at [%pc\_email%] with any questions you may have.

**Who can I contact about my rights as a research participant?**

You may also call Texas A&M University-Corpus Christi Institutional Review Board (IRB) with questions or complaints about this study at **irb@tamucc.edu** or 361-825-2497. The IRB is a committee of faculty members, statisticians, researchers, community advocates, and others that ensures that a research study is ethical and that the rights of study participants are protected.

**CONSENT TO PARTICIPATE**

If you do not agree to participate in the research study, please state how they can exit the process, i.e., exit this form and do not fill out the survey, do not fill out the survey and turn in a blank survey without anything filled in.

To participate in this research study, state how to move forward with the study, i.e. click continue to begin fill out the survey.

By state the action by which they consent, i.e. clicking continue and filling out the survey, you are agreeing to participate in the study. By participating in this study, you are also certifying that you are 18 years of age or older.