**When to use this form:** Use this simplified Information Sheet **ONLY** when you are not getting handwritten signatures from subjects. This Information Sheet includes required elements for non-exempt studies.

**Instructions:**

* Please review and edit as needed.
* Fill in the fields in red. Delete sections that are not relevant to your study.
* Once complete, please remove all blue instructional text and return all text to black.
* Proofread your form.
* Upload in iRIS the final document (no tracked changes). Word format is preferred.

**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 with 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.

**Who is doing this study?**

A study team led by [pi name -This cannot be a student] 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 [provide a brief statement as to why they qualify for the study, i.e., you are a student attending X class, you are part of the Corpus Christi community.]

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, you will be [describe the procedures involved, i.e., complete an online survey, complete an online interview.]

This study will take approximately [state duration X minutes/hours]. This MUST match duration in the IRB application Section: Procedures Involved.

**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 IRB application and edit the informed consent as needed. Review risks you entered in your application. The risk in this section MUST match the risk in your IRB application.

Regulations require the subject is fully informed of all research risks. If the consent risk section does NOT match risks in the IRB application your IRB application being returned and delay approval.

Potential risk may include:

Survey Questions: 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.

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.

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?**

Your participation involves collecting information about you.

The following identifiers will be collected from you if you choose to participate in this research study: [list the identifiers]. This MUST match the list of identifiers you state in the Privacy and Data Confidentiality Section of the IRB application.

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.

Your information will be protected by:

Add 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.

* Add this statement if you will not know who completed the survey when results are returned: Anonymous survey: The survey will not ask or collect any identifiers from you. Your identity will not be known by the research team. Please do not include any identifiers in the study documents.
* Add this statement if your study involves recording: Audio/Video Recording: Audio/video recordings will be stored securely in a password-protected file.  The recordings will be kept until it has been transcribed.  The interview once transcribed will be anonymized (a process to remove identifying information like your name) by using pseudonyms (a fictitious name). The recording will be permanently deleted after transcription.
* No identifiers linking you to this study will be included in any report that might be published or presented.
* Sharing with others: We will share your information only when we must. We will only share the information that is needed. We will ask anyone who receives your information from us to protect your confidentiality.

**What happens to my data after the study is done?**

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. It is RARE that direct benefits are involved. Regulations require that benefits are not overstated. Your selection MUST match the answer in your IRB application. If the consent and application do not match your application WILL be returned and approval delayed.

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?**

Delete this section if you are not providing compensation to participants.

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); and
* Timing of disbursement.

You will receive the following:

[%compensation\_descrip%]

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.

No reimbursement (use this sentence only if you are not reimbursing subjects for these costs): There are no plans for the study to pay for these costs.

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.

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?**

You can call [%pi\_name2%] [This cannot be a student] 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, click here to schedule an interview session.

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.