**Consent for Parent and Permission/Assent**

**to Participate in a Research Study**

**at Texas A&M University-Corpus Christi**

**[%study\_title%]**

##### WHO IS DOING THIS STUDY?

**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.

Below information merged from your application are shown in red. Please review and edit as needed. Once completed, please remove all blue instructional text.

**Who is doing this study?**

A study team led by [%pi\_name2%] is doing this research study. Other research professionals may help them.

The following statement is required if there is a sponsor. <Sponsor name> is working with <institution name> to do this research study. Funding for this study comes from the <sponsor name>. 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 [%purpose\_IRB%].

**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%]

To be eligible to be in this study, you must not be:

[%exclusion%]

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

**What will my child be asked to do?**

Being in this study involves:

[%proc\_involved%]

If your child agrees to be in this study, your child will be in this study for [%proc\_duration%].

If your child agrees to be in this study, the following things will happen:

[%desc\_procedure%]

## WHAT WILL HAPPEN TO MY CHILD IN THIS STUDY?

Add a brief summary of major study procedures and duration of study participation for the child:

Being in this study involves <<add a brief summary of study procedures>>. If you agree to be in this study, your child will be in this study for << add time in hours/days/weeks/months>>.

If you decide to be in this study, the following things will happen to your child:

* Participation will **involve collecting information about your child**. See Appendix: Study Procedures- Collecting Informationto learn more.
* Your child will be **asked to answer some questions** by <<a brief interview, filling out questionnaire, quality of life survey>>. These questionnaires will take about <<#>> minutes to complete. See Appendix: Study Procedures- Questionnaireto learn more.

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

There are certain risks in this study.

If you indicated the risk level is less than minimal risk you can add this statement: [%risk\_level%]

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

Potential risk may include:

[%potential\_risks%]

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.

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 child’s information?**

Pick one of the two options to match your protocol answer regarding collecting identifiers: [%identifiers\_syn%]

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:

[%conf\_protections%]

Add any other methods to protect the data to the list above from your IRB application. Here are some examples:

* 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: [%benefits%]

There may be **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 we receive if we agree to be in the study?**

Edit this section to match your application answer as to whether you are providing compensation:[%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*.*

Include if payment is $600 or greater:

**What are the tax consequences for receiving payment to participate in research?**

The total value of compensation to you from Texas A&M University-Corpus Christi (TAMU-CC) totals more than $600 in any calendar year, TAMU-CC must report this to the IRS on a Form 1099 with the recipient’s social security number (SSN) or individual tax identification number (ITIN).  You will receive a copy of this tax form.

Include if you require identifiers to make the payment that would not otherwise be collected for the research study:

TAMU-CC can only provide compensation if we have your <specify identifier required: SSN or ITIN Number>.  If you do not provide this number, you can still participate in the research study; however, you will not receive compensation. Your SSN or ITIN Number will be maintained in a secure manner.

**Do we 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 or your child are otherwise entitled.

**What if me or my child change our mind?**

You **may quit at any time**.  There will be no penalty or loss of benefits to which you or your child are otherwise entitled.

You may decide not to participate or quit at any time without your current or future relations with Texas A&M University-Corpus Christi or any cooperating institution being affected.

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 your child cannot be identified from the information there is no further risk to your child’s privacy. This information will continue to be used even after you or your child 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. Possible information may include conditions in which the participant may be withdrawn, costs to participate. Below are some examples:

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. [%ksp\_coi\_syn%]

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 for Investigator’s name.

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.

**PERMISSION OF PARENT OR LEGALLY AUTHORIZED REPRESENTATIVE**

The purposes, procedures, and risks of this research study have been explained to me. I have had a chance to read this form and ask questions about the study. Any questions I had have been answered to my satisfaction. A copy of this signed form will be given to me.

I give permission for\_\_\_\_\_\_\_\_\_\_\_\_ to participate in this research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent or Legally Authorized Representative Date

Delete second signature line if not obtaining signature from both parents.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent or Legally Authorized Representative Date

Delete section if using a separate assent form

**ASSENT OF MINOR**

I have been told what will happen to me if I am in this study. I know I do not have to be in this study. I may quit the study at any time and no one will be mad at me. I am able to ask questions. My questions have been answered. I agree to be in this research study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Minor Date

If children are not of an age to sign, you can replace signature line with another indication of assent like coloring.

Color this smiley face if you **do not** want to be in the study:

Color this smiley face if you **want** to be in the study:

**STUDY PERSONNEL**

(Personnel performing the consent process MUST be listed as study personnel. Double check your IRB application that you’ve included all personnel who may be obtaining consent in this study)

Any questions that have been raised have been answered to the individual’s satisfaction.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

Print Name of Person Obtaining Consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CONSENT WORKSHEET**

This worksheet is provided as instructional only as a tool to assist in conducting the consenting process. You can delete.

|  |
| --- |
| The purpose of this worksheet is to provide support for study team members performing and documenting the permission/assent process.ICF = Informed consent forms is used general abbreviation for permission/assent and consent forms. LAR = Legally authorized representative |
|  |
| Yes | N/A | Consent Prerequisites (Check if “Yes” or “N/A”. All must be checked) |
|[ ] [ ]  The study has been approved by IRB and all other requirements of sponsor or other entity have been fulfilled  |
|[ ] [ ]  ICF is approved by the IRB as demonstrated by stamp (with IRB # and approved dates). Unstamped ICFs should NEVER be used to consent subjects. |
|[ ] [ ]  The ICF is the most recent IRB-approved version. Outdated consent forms should NEVER be used. If unsure, login to iRIS to obtain most recently approved version.  |
|[ ] [ ]  The correct ICF is used when multiple types are approved.1. If enrolling a child, use the permission/assent.
2. If enrolling an adult, use adult consent.
3. If the study has multiple arms, use the document specific to the arm in which the subject is being enrolled
 |
|[ ] [ ]  No procedures have been performed prior to signing the consent form (including obtaining identifiable data, asking subjects questions, asking a subject to fast, withdrawal from current medication (washout), obtaining specimens for the study, conducting exams for research purposes when not routinely required). |
|[ ] [ ]  Staff conducting consenting process are listed on the IRB-approved protocol |
|[ ] [ ]  Study team member understands the requirements for the consent process for this particular study:1. Is assent of minors required by the IRB?
2. Are signatures of both parents required? (All risk category 3 studies require the signatures of both parents, or as otherwise deemed necessary by IRB).
3. Is a witness required? If utilizing phone consent, a fully translated consent, using Short Form consent, a witness is required. In all other circumstances, unless specifically required by the IRB, witnessing of consent is optional.
4. Is the study team member knowledgeable about study procedures to answer potential subject’s questions?
 |
|  |  |
| Yes | N/A | Appropriate individual approached  |
|[ ] [ ]  Confirm the subject meets approved inclusion/exclusion criteria. |
|[ ] [ ]  If enrolling children, confirm you are speaking with the parent or legal guardian. For legal guardian, verify court issued guardianship documents are in medical record. The following cannot grant permission for research unless they are also legal guardians: |
|  |  | * Stepparents
* Grandparents, aunts, uncles, etc.
 | * Individuals with Power of Attorney
* Foster parents for Wards
 |
|  |  |  |
| Elements of Consent Disclosure (The following issues will be discussed with the subject) |
| **Required Disclosures:** *(\*Starred elements can be omitted if there are none*.) [ ]  Who is sponsoring the study.\*[ ]  Conflicts of interest, if any.*\**[ ]  Purpose of the study and make sure the subject understands this is research.[ ]  Procedures to be followed in simple language.[ ]  Probability for random assignment to each treatment.\*[ ]  Procedures, which are experimental.*\**[ ]  Expected duration of the subject’s participation.[ ]  Any reasonably foreseeable risks or discomforts to the subject[ ]  Any potential benefits, making it clear if there is no direct benefit to the subject. | [ ]  Any appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*\**[ ]  Participation is voluntary and he/she may withdraw at any time.[ ]  Methods to ensure confidentiality of information are maintained.[ ]  The subject’s responsibilities.[ ]  Any additional costs to the subject that may result from participation in the research.[ ]  Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.[ ]  How to contact the research team for questions, concerns, or complaints about the research. |
| Yes | N/A | Consent Process (Check if “Yes” or “N/A”. All must be checked) |
|[ ] [ ]  Copy of ICF provided to subject and/or LAR before beginning discussion.  |
|[ ] [ ]  All questions by subject and/or LAR were answered to their satisfaction. |
|[ ] [ ]  Provide sufficient time for subject to review and consider whether to participate. |
|[ ] [ ]  To the degree possible, ensure the potential subject and/or LAR comprehend the information provided about the research. |
|[ ] [ ]  Capacity of minor to assent has been determined. If capable, assent is obtained.  |
| Yes | N/A | Signing Consent Form (Check if “Yes” or “N/A”. All must be checked) |
|[ ] [ ]  The parent will sign and date the permission document. |
|[ ] [ ]  Minor will sign and date the assent document. |
|[ ] [ ]  The person obtaining consent will sign and date the assent document. |
|[ ] [ ]  The witness will sign the document, when required. |
|[ ] [ ]  Review form for completion prior to ending visit. |
|  |  | * All blanks completed
* Check for all signatures.
 | * Dates are entered correctly.
* Future use options are answered.
 |
|[ ] [ ]  Corrections/notations are to be initialed and dated. Entries made by subject are corrected only by subject or LAR. Staff may add notes of clarification to the side if family is no longer present. Entries by staff should be clarified by staff who obtained consent. |
|[ ] [ ]  Distribute a copy of the signed and dated consent form to: Subject, LAR and original to research record |
| Yes | N/A | Document Consent Process in Research Record (Check if “Yes” or “N/A”. All must be checked) |
|[ ] [ ]  Required elements to document in research record:  |
|  |  | * Date and time of discussion
* Study identification (protocol # or abbreviated title)
* Individuals involved in discussion
* Individuals to whom study was explained
* Notation that concerns and/or questions were addressed
* Notation of who copies were given to
* Notation that consent obtained prior to performing procedures
 | * Notations of special circumstances (examples)
* Why child is not capable of assent if assent not obtained.
* Explanation of any corrections
* Notation if phone consent was used and description of process (can only be used if IRB approved)
* Notation of use of interpreter
 |