This template is to be used when enrolling children and using educational records (FERPA applies).

Below information merged from your application are shown in red. The information in your application may require rewrite to make it friendly for potential subjects to read and understand.

Please review and edit. Failure to edit and proofread the consent form will result in your submission being returned and approval delayed.

Once complete, please remove all blue instructional text. Fill in incomplete sentences.

**INFORMATION IN BLUE IS INSTRUCTIONAL AND SHOULD BE REMOVED FROM THE FINAL DOCUMENT.**

**INFORMATION IN RED IS VARIABLE AND REQUIRES EDITING.**

**CHANGE THE TEXT BACK TO BLACK ONCE EDITING IS COMPLETE.**

**REVISIONS MAY NOT BE ACCEPTABLE TO REQUIRED LANGUAGE.**

**Use wording consistent with 5th to 8th grade reading level; simple words, short sentences, small paragraphs, etc.**

**Parental Permission and Child Assent 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.

**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. Funding for this study comes from [%study\_sponsor%]. The study team will not receive any personal payment because of your decision.

**Why is this research being done?**

[%purpose\_IRB%]

**Who can be in this study?**

We are asking your child to be a part of this research study because add reason why they are being asked.

To be eligible to be in this study, your child must be:

To be eligible to be in this study, your child must NOT be:

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

Detail the study procedures that will occur.

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

[%desc\_procedure%]

* Participation will **involve collecting information about your child, including information from your child’s educational record**.
* Your child will be **asked to answer some questions** by < 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?**

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).

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:

[%POTENTIAL\_RISKS%]

Review examples below and select disclosure statements match your risks in the IRB application.

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 concerns 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.

Did you indicate identifiers were being collected in the application? [%identifiers\_syn%]

If yes, then choose the confidential paragraph below. If no, then choose the anonymous paragraph below.

Include this paragraph if anonymous (Only use this option if NO identifiers are being collected from subjects during recruitment, consenting or during participation of the study): 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. 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.

Note: If you select this option and plan to use data for future research you will need to relate an IRB repository to manage the future use. In the Section "Other Committee Approvals", unselect None and select IRB. Then relate the repository submission. Repository templates can be added to your iRIS dashboard; just contact ORC to add. Otherwise, select the option below and you do not have to add a repository submission.

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.

Include this section if your study involves use of educational records and is subject to FERPA.

**Use of your child's educational records**

This study requires the use of your child’s educational records that are subject to Family Educational Rights and Privacy Act (FERPA).   Family Educational Rights and Privacy Act (FERPA) is a federal law that affords parents the right to access their children’s education records, the right to seek to have the records amended, and the right to have some control over the disclosure of personally identifiable information from the education records.

**What educational records are being used for this study?**

An education record is any record maintained by the institution that contains information directly related to a student. This includes, but is not limited to, grade information, disciplinary documentation, and billing and financial aid data. This study will require the study team to access and record the following information from your child’s educational record: .

Include this section if your study involves class recordings

**Use of your child's classroom recording**

This study will involve  recording of the class sessions your child attend. This recording performed in the classroom setting is subject to Family Educational Rights and Privacy Act (FERPA).   Family Educational Rights and Privacy Act (FERPA) is a federal law that affords parents the right to access their children’s education records, the right to seek to have the records amended, and the right to have some control over the disclosure of personally identifiable information from the education records.

The  recording will depict the class/instructor doing [describe what the video will depict].

Your child’s information will be protected by:

* The recording will be immediately downloaded from the portable recording device and saved in a password-protected secured location until transcription can occur.
* The recording once transcribed will be anonymized (a process by which identifying information is removed) by using pseudonyms (a fictious name). The recording will be deleted after transcription.
* Student faces will be blurred in the video.

**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.

Did you indicate direct benefits in the application? [%benefits%]

If no, select the first sentence, delete the second and the paragraph below. If yes, then delete the first statement and include the paragraph describing the 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 I receive if I am in the study?**

Edit this section to match your application answer as to whether you are providing compensation. Did you indicate compensation would be provided? [%compensation%]

If no, you can remove this entire section. If yes, then edit your answer provided in the application to include the following details about the compensation:

* 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%]

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.

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 you cannot be identified from the information there is no further risk to your privacy. This information will continue to be used 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. 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.

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.

Conflict of Interest: Did any of the study staff answer yes to having a conflict of interest? [%ksp\_coi\_syn]

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

Investigator’s name has a conflict of interest. [%ksp\_coi\_tml%].

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,< >  will not < >.   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\_cell\_phone%] or email at [%pi\_email%] with questions at any time during the study.

You may also call [%pc\_name2%] at [%pc\_cell\_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**](mailto: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**](mailto:irb@tamucc.edu) second signature line if not obtaining signature from both parents.

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

Signature of Parent or Legally Authorized Representative                Date

Include this section if your study requires release of educational records.

**PERMISSION OF PARENT TO RELEASE EDUCATIONAL RECORDS UNDER FERPA**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, consent \_\_\_\_ do not consent \_\_\_\_ to the release of my child’s education records to the research study team for the purpose of this research study.

I understand that education records include, but are not limited to, .

I understand my agreement is voluntary and is not a condition or requirement of my child’s participation in the class or attendance at .

I understand the information may be released orally or in the form of copies of written records, as preferred by the requester.

I understand that (1) I have the right not to consent to the release of my education records, (2) I have the right to inspect any records released pursuant to this consent, and (3) I have the right to revoke this consent at any time by delivering a written revocation to to no longer release information to any or all of the individuals listed below. I further understand that until this revocation is made, this consent shall remain in effect and my educational records will continue to be provided to the study team listed below.

Prior to signing this document, I have had an adequate opportunity to read and understand it, have had an opportunity to ask questions about it, and any questions I have had have been answered to my satisfaction.

 is authorized to release information to the following individuals:

Study Team Member

Study Team Member

Study Team Member

Include this section if your study requires classroom recordings. If your study also involves release of educational records you can combine with the section above. To combine add the first two paragraphs in this section to the section above.

**PERMISSION OF PARENT TO RELEASE CLASSROOM RECORDINGS UNDER FERPA**

I understand that classroom session may be audio and/or video recorded for purposes of this research study.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, consent \_\_\_\_ do not consent \_\_\_\_ to the release of my child’s education records that includes the recordings of my child’s voice, image, likeness or other personally identifiable information collected as my child participants in class to the research study team for the purpose of this research study.

I understand my agreement is voluntary and is not a condition or requirement of my child’s participation in the class or attendance at .

I understand the information may be released orally or in the form of copies of written records, as preferred by the requester.

I understand that (1) I have the right not to consent to the release of my education records, (2) I have the right to inspect any records released pursuant to this consent, and (3) I have the right to revoke this consent at any time by delivering a written revocation to to no longer release information to any or all of the individuals listed below. I further understand that until this revocation is made, this consent shall remain in effect and my educational records will continue to be provided to the study team listed below.

Prior to signing this document, I have had an adequate opportunity to read and understand it, have had an opportunity to ask questions about it, and any questions I have had have been answered to my satisfaction.

 is authorized to release information to the following individuals (please print clearly):

Study Team Member

Study Team Member

Study Team Member

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 want to be in the study:

Color this smiley face if you do not 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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_