**INFORMATION SHEET FOR USE OF DATA FROM CLASSROOM PROJECTS**

**[%study\_title%]**

**Introduction**

I am a student at Texas A&M University-Corpus Christi. As part of my classroom assignment, you participated in <describe what was done to them, i.e. a survey, an interview>.

The results of this classroom project were <interesting, showed the need for further exploration>. The classroom project has now been expanded to a research study.

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in a 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 the [%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 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 I be asked to do?**

Being in this study involves:

[%proc\_involved%]

Below are examples of prodcedure discussions. Edit to match your list above.

Be sure all risks in the protocol match the risk described in the consent form to avoid being sent back for changes requested.

Secondary review of the existing classroom data: 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.  Previously, you participated in a (describe what occurred in the classroom project, i.e., one-on-one interview or survey).

Being in this secondary analysis research study will allow us to relook at your data previously collected. This research study does not require additional participation.

If you allow your data to be included in this secondary analysis, the following things will happen: Your data will be qualitatively reviewed and analyzed for (describe what you are looking for in the re-review of their data).

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

If you agree to be in this study, the following things will happen:

[%desc\_procedure%]

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

If you indicated the risk level is less than minimal risk you can add this statement. Your answer = [%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. Below are examples of risk descriptions. Edit to match your list above.

Be sure all risks in the protocol match the risk described in the consent form to avoid being sent back for changes requested.

Secondary review of the existing classroom data: Your data has already been collected. There are no anticipated new risks related to data collection for this research study.

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/Interview 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 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. Your answer as to whether there are benefits: [%benefits%]

There are  **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. Your answer in your application as to whether compensation is provided:[%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.

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.

**What about protecting my information?**

Pick one of the two options to match your protocol answer regarding collecting identifiers. Your answer in the application as to whether identifiers are collected: [%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.

**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**

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.

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.