**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.**

**CONSENT TO PARTICIPATE IN A**

**RESEARCH STUDY AT TEXAS A&M UNIVERSITY-CORPUS CHRISTI**

**<<Study Title>>**

We are asking you to be a part of this research study. Please read the information below and ask questions about anything that you do not understand before you make a choice.

**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. <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.

**Conflict of Interest**: Delete this section if not appliable. Add one of the following statements describing the conflict of interest is required if there is study personnel with a conflict of interest in the study. If multiple investigators have a conflict declared, they must have separate paragraphs for each.

<Investigator’s name> has a separate financial agreement with <sponsor name>, a sponsor of this study.

<Investigator name> personally receives income from the study sponsor for <<Financial disclosure: relationship, i.e. consultant, board member, equity owner>> work. The university and the IRB have reviewed

this arrangement and determined that this relationship presents a potential conflict of interest for << Investigator name>>. Therefore, << Investigator name>>’s relationship is being disclosed to you.

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>>.

If you have questions, contact Office of Research Compliance at research.compliance@tamucc.edu or 361825-2497.

**WHY IS THIS STUDY BEING DONE?**

The purpose of this research study is to <study objectives>.

**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/must not>:

• <state basic eligibility criteria, i.e. be over the age of 18>.

Up to << # of subjects>> will be in this study at about << # of sites>> different places. Up to << # of subjects>> will be asked to be in this study at <institution name>.

**WHAT WILL HAPPEN TO ME IN THIS STUDY?**

Tiered consent format: Give a brief description in the main body of the consent. Specific details of the individual procedures of the study can be added in the appendix. You do NOT have to follow this format and can place all procedural details in the body for simple studies so long as the informed consent information is concise and focused presentation on the key information that is most likely to assist a person in making the decision to participate.

Being in this study involves <add a brief summary of study procedures, answering questions in a survey, answering questions in an interview with the researchers, answering questions in a group with other participants>.

If you agree to be in this study, you will be in this study for <add total participation time in hours/days/weeks/months>.

Below are common study procedures that you can choose from or add your own. Not all may be applicable to your study. Delete those that do not apply.

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

* Your participation will **involve collecting information about you**. See Appendix: Study Procedures- Collecting Informationto learn more.
* You will be **asked to answer some questions** by <a brief interview with the research team, filling out questionnaire, quality of life survey, participating in a focus group with the research team and other participants>. These questionnaires will take about <#> minutes to complete. See Appendix: Study Procedures- Questionnaireto learn more.

**WHAT ARE THE RISKS** **OF THE STUDY?**

There are certain risks in this study. The main risk may include:

* <list important risks>.
* Embarrassing Questions: You will be asked about: <<general list topics>>. 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. You can exit the survey and stop at any time.
* Confidentiality risk: There is a risk of loss of confidentiality. Your confidentiality will be protected to the greatest extent possible. See Appendix: Confidentiality Risks to learn how your information is protected.
* 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 passwordprotected 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 BENEFITS OF BEING IN THIS STUDY?**

Choose one of the two following paragraphs:

There may be no direct benefit to you from being in this research study. By being in this study, you may help researchers << describe general society benefits; i.e., learn more about <x>>>.

There may be direct benefit to you from being in this study. Possible benefits may include <<Describe benefits>>. By being in this study, you may help researchers << describe general society benefits; i.e., learn more about <x>>>.

**PROTECTING MY INFORMATION**

This study is <anonymous or confidential>. Pick one or the other; can’t be both.

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 information collected about you includes identifiers (like <describe what identifiers are collected from the participant: name, date of birth, addresses, email, phone number and social security or individual taxpayer identification (ITIN) numbers>, the study can involve confidential information.

Explain to subjects how their data will be protect: Your information will be protected by:

* <add ways to protect their identity, i.e. restricting access to only authorized personnel, storing data in password-protected, secured location, etc. Some examples are provided below or add your own.>
* 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.
* Using de-identified information: All direct personal identifiers have been permanently removed from the data. No code or key exists to link the research information to your identifiable information.
* Using coded information: Your direct personal identifiers will be removed from the research record and replaced by a code. The key that links the code to your personal identifiers are stored separately from the research record under restricted access.
* All research records will be kept securely.
* Research records will be seen only by authorized research team members.
* 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 presentation.

For research involving the collection of identifiable private information or identifiable specimens, you must include one of the two statements (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 or biospecimens> 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 ABOUT EXTRA COSTS?**

Choose one of the two following paragraphs:

No costs to subjects. Participation in this study will not result in any extra costs to you. You will not have to pay anything extra if you are in this study aside from the personal time and travel costs it will take to come to all of the study visits.

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.

**WHAT WILL I RECEIVE FOR BEING IN THIS STUDY?**

Not providing payments, tangible property or reimbursement, you can remove this entire section or add You will not receive any payment for participating in this study.

Payments provided

You will receive <<List out payment and schedule be sure it is consistent with protocol>>. Maximum compensation for participating in the study is <<$>>. See Appendix: Payments to learn more about payments, payment schedule, and tax consequences for receiving payments.

Tangible Property provided

You will receive <<List out items you will provide in protocol>>.

Extra credit provided

Your teachers may elect to give extra credit for participating in research. This is not provided by the research team and is up to the teacher how much credit is given. <<Indicate how you will alert the teacher to know they participated, i.e. At the end of the survey, you will be provided with a completion certificate that you can give to your teacher to show proof of your participation in research.>>.

**WHAT ARE THE ALTERNATIVES TO BEING IN THIS STUDY?**

Instead of being in this study, you may choose not to participate.

If recruiting in a school, include information about the alternate procedures for those who will not participate.

<<If you choose not to participate, you will still be <<able to be a part of the curriculum offered or eligible for extra credit>>. While students who are participating will be <<list procedures, i.e. testing or interviewing with the research team>>, you will be <insert what alternative activity will occur>.**>>**

**WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?**

**Being in a research study is voluntary.** You do not have to be in this study. 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 withdraw from the study at any time** without penalty.

**WHO SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

<<PI name>> is in charge of this research study. **You may call <<PI name>> at << PI contact number>> with questions at any time during the study.**

You **may also call <<other study contact name>> at <<study contact number>> with any questions you may have.**

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**

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.

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

Signature of Participant Date

**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)

I have explained the purposes, procedures, and risks involved in this study in detail to:

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

Print name of Participant

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

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

Signature of Person Obtaining Consent Date Time

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

**TESTIGO/*WITNESS***

Required for phone consent process, when consenting non-English speaking persons with the short form method, or if the IRB has required a witness or patient advocate for the study. Delete this section if not applicable. If using for phone consent, you can delete the Spanish translation provided.

He presenciado el proceso del consentimiento y firma(s) para esta investigación científica. *I have witnessed the consent process and signature(s) for this research study:*

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

Firma del Testigo Fecha

*Signature of Witness Date*

Escriba el nombre del Testigo/*Print Name of Witness*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(También debe firmar el documento traducido/*Must also sign the translated document*)

**INTÉRPRETE/*INTERPRETER***

The following is required if you elected to recruit non-English speaking persons. Delete this section if you are not enrolling non-English speaking persons. You will secure an IRB approval for the English version first. Then add the translated version to the study as an amendment.

Yo estuve presente y presté servicios de interpretación durante la firma de este documento. *I was present and provided interpretation services during the signing of this document.*

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

Firma del Intérprete Fecha

*Signature of Interpreter Date*

Nombre del Intérprete en Letra de Molde/ *Printed Name of Interpreter*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(También debe firmar el documento traducido/*Must also sign the translated document*)

Relación del intérprete al Sujeto:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Relationship of Interpreter to Subject*

**Appendix: Study Procedures - Collecting Information**

Your participation will involve collecting information. The following information will be

* You do not have to give any information to the study that you do not want to give. By signing this form you are authorizing the collection and use of the information outlined in this form.
* Add this paragraph if reviewing existing data/records: If you choose to participate, the study team will collect information from your <<education or medical>> record. The information collected will include the following:

o <<Summary of information collected, i.e. test scores, demographic information, diagnosis, lab results, medications).

* Add if applicable: If you agree, the study team will access your records from time to time to update the information collected. This will happen because researchers may need to know how your <<test scores, health>> has changed over time.
* We will ask for your contact information, including your telephone number, so that we can call you to <<why calling, i.e., to get additional information that may be missing>>.
* Information above collected for this study will be shared with <<recipient investigator/sponsor>>.

**Appendix: Study Procedures- Questionnaire**

You will be asked about: <<general list topics>>. 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. You can exit the survey and stop at any time.

**Appendix: Confidentiality**

When information collected about you includes identifiers (like names, addresses, phone numbers and social security or individual taxpayer identification (ITIN) numbers), the study can involve confidential information.

A research record will be created and kept in the <internal location where research records are stored such as department name> research office. The research record may include documents that have your <name, assigned study ID number, home street address, telephone number, medical record number, account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, certificate/license numbers, vehicle

identifier/license numbers, web or internet address, finger or voice prints, full face photographs, or list other unique personal identifier>.

All research records will be maintained in a confidential manner. 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.

Add following paragraph if sharing research information with outside party:

Portions of the research record will be sent to <outside party such as sponsor>. This information sent to will include your <name, assigned study ID number, home street address, telephone number, medical record number, account number, insurance number, social security or individual taxpayer identification (ITIN) number, date of birth, dates of service, medical device number, fax number, email address, certificate/license numbers, vehicle identifier/license numbers, web or internet address, finger or voice prints, full face photographs, or list other unique personal identifier>. Once your information is shared outside of <institution name>, we cannot promise that it will remain private.

**Appendix: Payments**

Charts or tables to visually describe to subjects what will happen. This is also a handy reference for them to keep for future reference.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Reimburse for <X> expense | Payment | Notes |
| Study Visit 1 | X | $ <amount> |  |
| Study Visit 2 | X | $ <amount> |  |
| Study Visit 3 | X | $ <amount> |  |
| Study Visit 4 | X | $ <amount> |  |
| Study Visit 5 |  | $ <amount> |  |
| Study Visit 6 |  | $ <amount> |  |
| Study Visit 7 |  | $ <amount> |  |

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.

Payment: You will receive <payment amount, i.e. <X> dollars per visit>.

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*.*

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

If the total value of <<payments/property provided>> (pick one) to you from Texas A&M UniversityCorpus 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.

TAMU-CC can only <<make payments/provide property>> (pick one) if we have your SSN or ITIN

Number. If you do not provide this number, you can still participate in the research study; however, you will not receive <<payment/property>> (pick one). Your SSN or ITIN Number will be maintained in a secure manner.

**Appendix: Withdraw**

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.

of 10