General Instructions for creating your consent form:

* Hover over text to get detailed instructions.
* Information that is highlighted and/or italicized is instructional text, and should not left on the form. Information in brackets must be edited, then brackets should be deleted.

IMPORTANT NOTES

Do not, under any circumstances, submit a consent form with instructional text still included. This will delay approval of your application.

The instructions in this form were created using hyperlinks. You must remove all hyperlinks before submitting your consent for review. To do this press CTRL + A to select the entire document and the press CTRL+ SHIFT+F9.



Informed Consent Form

**Study Title:** [Insert title here](#Title" \o "Insert a brief descriptive title here; should match title on IRB application)

**Consent Name:** [Insert consent name here](#ConsentName" \o "OPTIONAL.  Indicate consent identifier if there is more than one consent for your study (e.g., control consent) [DELETE IF NOT APPLICABLE])

|  |  |  |
| --- | --- | --- |
| Principal Investigator: | Investigator Name | [Telephone: (xxx) xxx-xxxx](#PIPhone" \o "This should be a LOCAL phone number and/or email) |
| [Emergency Contact:](#Emergency" \o "Delete for minimal risk study.) | [Name](#Emergency2" \o "Delete for minimal risk study; otherwise provide name(s) of project staff member that will be available at all times.) | [Telephone: (xxx) xxx-xxxx](#Emergency3" \o "Delete for minimal risk study; otherwise include local number will be answered 24 hours a day.) |

# [Key points you should kn](#KeyPoints" \o "Do not omit, move, or edit this section header. This section should provide the most important information about the study to help a potential participant decide whether to partcipate. Use simple language and do not include extraneous details here.)[ow](#KeyPoints" \o "Do not omit, move, or edit this section header. This section should provide the most important information about the study to help a potential participant decide whether to partcipate. Use simple language and do not include extraneous details here.)

* [We are inviting you to be in a research study we are conducting. Your participation is voluntary. This means it is up to you and only you to decide if you want to be in the study. Even if you decide to join the study, you are free to leave at any time if you change your mind.](#Invite" \o "Do not remove or edit.)

* [Take your time and ask to have any words or information that you do not understand explained to you.](#Understand" \o "Do not remove or edit.)

* [We are doing this study because we want to learn INSERT PURPOSE OF THE STUDY HERE.](#Purpose" \o "Provide a list or a few brief sentences here, explaining the purpose of the study)

* [Why are you being asked to be in this study?](#Inclusion" \o "Indicate the condition(s) or characteristic that resulted in your recruitment of this group of participants (e.g, you are a student struggling with depression/math skills). You may delete if not relevant. )
	+ [INSERT HERE](#Inclusion" \o "Indicate the condition(s) or characteristic that resulted in your recruitment of this group of participants (e.g, you are a student struggling with depression/math skills). You may delete if not relevant. )
* [What will you do if you agree to be in the study?](#Purpose" \o "Explain step-by step what the participant will do, make sure to include duration of their participation.)
	+ [INSERT STUDY PROCEDURES AND/OR USE TEMPLATE LANGUAGE BELOW](#Purpose" \o "Explain step-by step what the participant will do, make sure to include duration of their participation.)
	+ [Participation in this study requires [videotaping/audiotape] of [all procedures/list of procedures], by signing this consent form you are giving us permission to make and use these recordings.](#Recording" \o "Choose one if relevant or delete.)

*[OR](#Recording" \o "Choose one if relevant or delete.)*

* [We would like to](#Recording" \o "Choose one if relevant or delete.) *[[videotape/audiotape] [list of procedures], please indicate whether you will allow us to do so by initialing one of the following:](#Recording" \o "Choose one if relevant or delete.)*
	+ - * [\_\_\_\_\_(initials) Yes, I give permission for [videotaping/audiotaping]](#Recording" \o "Choose one if relevant or delete.)
			* [\_\_\_\_\_](#Recording" \o "Choose one if relevant or delete.)[(initials)](#Recording" \o "Choose one if relevant or delete.) *[No, I do not give permission for [videotaping/audiotaping]](#Recording" \o "Choose one if relevant or delete.)*

* [Can you be harmed by being in this study?](#Risks" \o "Provide a list of reasonable, foreseeable risks.  Use simple langauge.  You may use, edit, or delete the template language below. )
* [INSERT HERE OR USE TEMPLATE LANGUAGE BELOW](#Risks" \o "Provide a list of reasonable, foreseeable risks.  Use simple langauge.  You may use, edit, or delete the template language below. )
* [Being in this study involves no greater risk than what you ordinarily encounter in daily life.](#NoRisk)
* [Risks to your personal privacy and confidentiality: Your participation in this research will be held strictly confidential and only a code number will be used to identify your stored data. However, because there will be a link between the code and your identity, confidentiality cannot be guaranteed.](#PrivConf" \o "Example text for risk associated with coded data. Delete if not relevant to your study, or edit as needed.)

* + [If we learn something new and important while doing this study that would likely affect whether you would want to be in the study, we will contact you to let you know what we have learned.](#LearnNew" \o "Delete if not relevant to your study. )

* [What are the costs of being in the study?](#Costs" \o "Explain costs that will be incurred by participant OR delete if not relevant  OR state \"There  will be no additional costs to you by taking part in this study.\)
	+ [INSERT HERE](#Costs" \o "Explain costs that will be incurred by participant OR delete if not relevant  OR state \"There  will be no additional costs to you by taking part in this study.\)
* [Will you get anything for being in this study?](#Benefits1" \o "List any benefits to the participant or to others that can be reasonable expected. This could include monetary compensation, or extra credit. You can use sample text below or edit/delete as needed.)
	+ [INSERT HERE AND/OR USE TEMPLATE LANGUAGE BELOW](#Benefits1" \o "List any benefits to the participant or to others that can be reasonable expected. This could include monetary compensation, or extra credit. You can use sample text below or edit/delete as needed.)
	+ [For participation in research you may receive extra credit from your professor(s). Additional information will be collected for this purpose.](#ExtraCredit)

* + [You will not receive any payments for taking part in this study.](#NoPayment" \o "Include this statement if your study does not include payment for participation. Delete if this is not relevant.)
	+ You will receive XX for participating in the study.

* [What other choices do you have if you decide not to be in the study?](#Alternatives" \o "Delete if this is not relevant to your study or list appropriate alternatives here (e.g., other options for extra credit). )
	+ [INSERT HERE](#Alternatives" \o "Delete if this is not relevant to your study or list appropriate alternatives here (e.g., other options for extra credit). )
* [Could you be taken out of the study?](#Removal" \o "Delete if not relevant to your study or list circumstances that would result in withdrawal by the research team.)
	+ [You could be removed from the study if LIST CONDITIONS HERE](#Removal" \o "Delete if not relevant to your study or list circumstances that would result in withdrawal by the research team.)

# [Can the information we collect be used for other studies?](#ShareData" \o "Keep this section and  include one of template statements - editing as needed.)

[Information that could identify you will be removed and the information you gave us may be used for future research by us or other researchers; we will not contact you to sign another consent form if we decide to do this.](#ShareData" \o "Keep this section and  include one of template statements - editing as needed.)

[We will not use or distribute information you gave us for any other research by us or other researchers in the future.](#ShareData" \o "Keep this section and  include one of template statements - editing as needed.)

# [What happens if I say no or change my mind?](#Voluntary" \o "Do not delete this section.)

* [You can say you do not want to be in the study now or if you change your mind later, you can stop participating at any time.](#Penalty" \o "Edit as needed (e.g., if there are benefits that will be lost these should be listed here) but keep in mind that participants must be free to withdraw at any time.)
* [No one will treat your differently. You will not be penalized.](#Penalty)

# [How will my privacy be protected?](#Protection" \o "Below is sample text; add, delete or edit as needed.)

* [We will share your information with INSERT LIST HERE.](#SharingInfo" \o "Edit or delete.)
* [Your information will be stored with a code instead of identifiers (such as name, date of birth, email address, etc.).](#Coded" \o "Only include if your data will be coded.)

* [Even though we will make efforts to keep your information private, we cannot guarantee confidently because it is always possible that someone could figure out a way to find out what you do on a computer.](#Online" \o "Delete if not conducting an online study. May edit as appropriate.)

* [No published scientific reports will identify you directly.](#Publication" \o "Only include if applicable.)
* If it is possible that your participation in this study might reveal behavior that must be reported according to state law (e.g. abuse, intent to harm self or others); disclosure of such information will be reported to the extent required by law.
* This research is covered by a Certificate of Confidentiality from the U.S. Department of Health and Human Services. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

# [Who to contact for research related questions](#Researchquestions" \o "Do not delete. Make sure to edit to include contact information for a member of the study team.)

[For questions about this study or to report any problems you experience as a result of being in this study contact INSERT CONTACT NAME WITH LOCAL PHONE NUMBER AND UTRGV EMAIL ADDRESS.](#Researchquestions" \o "Do not delete. Make sure to edit to include contact information for a member of the study team.)

#

# Who to contact regarding your rights as a participant

This research has been reviewed and approved by the University of Texas Rio Grande Valley Institutional Review Board for Human Subjects Protections (IRB). If you have any questions about your rights as a participant, or if you feel that your rights as a participant were not adequately met by the researcher, please contact the IRB at (956) 665-3598 or irb@utrgv.edu.

# [Signatures](#Signatures" \o "If your study includes a request for waiver of documentation of consent, please remove. )

[By signing below, you indicate that you are voluntarily agreeing to participate in this study and that the procedures involved have been described to your satisfaction. The researcher will provide you with a copy of this form for your own reference. To participate, you must be at least 18 years of age. If you are under 18, please inform the researcher.](#Signatures" \o "If your study includes a request for waiver of documentation of consent, please remove. )

[\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_](#Signatures" \o "If your study includes a request for waiver of documentation of consent, please remove. )

[Participant’s Signature Date](#Signatures" \o "If your study includes a request for waiver of documentation of consent, please remove. )