Instructional text appears in **red**, **green** and **blue** **and should be removed prior to submission.**

**Red** text in **brackets [ ]** should be replaced by information for your study. If you don’t use a question, be sure to adjust the question numbers, so you don’t jump from question 13 to question 17

If you have any questions or need assistance completing this form, please call Dr. Jennifer Coronado (956) 326-3060, or e-mail irb@tamiu.edu

1. **Key Summary**

If the information sheet will be longer than 6 pages – principal investigator (PI) must provide a concise summary with enough detail that a reasonable person can clearly see what participant will be asked to do, risks and benefits and why subject may or may not want to participate. If this form is 6 pages or less, delete this heading and instructions.

1. **Introduction**

You are being asked to participate in 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. If you decide to participate in this study, you will also receive a copy of this form to keep for your reference. The Principal Investigator or his/her representative will provide you with any additional information that may be needed and answer any questions you may have. Your participation is entirely voluntary, and you can refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

1. **What is the purpose of the study?**

We are asking you to take part in a study of [state what you are studying.] We want to learn [state the purpose of the study in lay language]. You were selected to be a possible participant because [state why the subject is being selected to take part; e.g., you are a twin or because you have above average memory or because you are a college student and….]. [State the number] subjects are expected to take part in this study. This study is being sponsored/funded by [name sponsor/funding source]. *\*If research is not sponsored/funded, do not include this sentence.*

1. **What will I be asked to do?**

If you agree to participate in this study, you will be asked to [explain tasks and procedures (include details about completing surveys, interviews, tests, and/or focus groups as applicable)]. [Describe the research procedures, where the study will take place, and how long the subject’s participation is expected to take, etc. This information should be presented in a logical, generally chronological order, and should be presented in language the subject can understand.]. Your participation [will / may] be [audio / video] recorded. *\*If participants will not be audio/video recorded, do not include this sentence.*

1. **What are the possible discomforts and risks in this study?**

The risks associated with this study are [describe any known/expected risks in language understandable by the subject. List each risk, noting the likelihood of occurrence (likely, less likely, or rare) and the severity of the risk (serious or not-serious). *For example: Risks of procedure X include soreness and fatigue; these are likely and non-serious*. If applicable, state that there may be risks that are unknown at this time. Include not only physical risks, but social, psychological, financial, legal, etc. Where appropriate, include any steps that the subject should take to decrease risk. *For example: you should not participate if you have recently….*]. *\*If risks are minimal, you may state****:*** The risks associated in this study are minimal, and are not greater than risks ordinarily encountered in daily life.

Should you feel that you need counseling following your participation, you are referred to the TAMIU Community Counseling Center which offers free services, including to trauma victims and the general public: TAMIU Community Counseling Center, 5201 University Blvd. (Cowart Hall 213), Laredo, TX, 956-326-3120. In the event of an emergency, including potential harm to self, always call 911.

1. **Will I have to pay anything if I get hurt in this study?**

*This section is only necessary for studies involving greater than minimal risk. If the study is minimal risk then remove this section completely. Discussion of compensation for research-related injury should be included here.*

If you suffer any injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. You should report any injury to [insert PI name and phone number].

1. **What are the possible benefits to the participants for taking part in this study?**

[If there is a possible benefit, state the benefit as a possibility, not a guarantee, and add: We do not guarantee that you will benefit from participation. If there is no benefit to the subject, you may state: You will not benefit from taking part in this research study.] \*Please note that reimbursement for participation is not considered a benefit, nor are free services that may accompany participating. Benefit to the subject participating consists of a benefit associated with the design of the study.

1. **What are the possible benefits to society from this research?**

The knowledge gained from this study may contribute to our understanding of [insert text, do not list incidental benefits].

1. **Do I have to participate?**

No. Your participation is voluntary. You may decide not to participate or may discontinue participation in this project at any time, without loss of privilege or fear of retribution or evaluation by the experimenter, and without your current or future relations with Texas A&M International University [include any other cooperating institutions] being affected.

1. **Will I be compensated for my participation?**

You will receive [insert payment, reimbursement, or participation credit]. Disbursement will occur [explain conditions of payment]. *\*If there is no compensation state:* You will not receive any compensation for participating in this study.

*FOR GIFT CARDS – must use this language*

You [pick one: will receive/will be entered in a drawing for] a gift card in the amount of [insert payment amount]. Disbursement will occur [explain conditions of payment; if virtual payment, use this language: notification will be emailed to each winner/recipient, which you must acknowledge receipt, then a digital gift card will be emailed to each winner/recipient].

*\*If participants will receive class points or credit,* [Include information about points. Explain alternative task if participant does not want to participate but wants to obtain class points.]

1. **Are there any costs to participate?**

The following costs are necessary to participate [insert details about any costs]. *\*If there is no cost to participate state:* There are no costs for participating in this study.

1. **Who will know about my participation in this research study?**

This study is [anonymous OR confidential, *\*cannot be both*] and [describe how confidentiality or anonymity will be maintained*. Specifically state whether any identifiers will be removed For example: Your data will not contain anything to connect your identity with your information; The surveys will be anonymous; Data will be coded with numbers.*].

*\*Possible text*: The records of this study will be kept private. Research records will be stored securely [Investigators should elaborate, i.e. locked file cabinet; computer files protected with a password]. People who have access to the records include [insert personnel who will access records]. Representatives of regulatory agenciessuch as the Office of Human Research Protections (OHRP) and university or university system officials may access your records to ensure compliance. Your records may also be viewed by the Institutional Review Board [you should list any sponsor or other agency that would have the right to view research data]. The data resulting from your participation may be used in publications and/or presentations but your identity will not be disclosed.

If you choose to participate in this study, you [will / may] be [audio / video] recorded. Any [audio / video] recordings will be stored securely [Investigators should elaborate, i.e. locked file cabinet; computer files protected with a password] and access to the recordings will be as referenced above . [insert one of these two sentences to explain disposal of recordings - Any recordings will be kept for [insert length of time] and then erased. or Any recordings and/or transcripts will be added to the Texas Data Repository collection for future research]. *\*If no audio/video recordings will be made, do not include this section.*

Information about you and related to this study will be kept confidential to the extent permitted or required by law.

1. **This project will collect** [insert particulars for collection of **identifiable private information** or **identifiable biospecimens]**. Provide statements as applicable to state:
* whether identifiers may be removed
* whether deidentified information or biospecimens may or may not be used or shared for future research.
* whether biospecimens will possibly be used for commercial profit and will participant share in that profit.
* whether any clinically relevant results, including individual research results, will be returned to the participant, and if so, under what conditions.
* whether project will or might include whole genome sequencing (i.e. human germline, somatic specimen to generate genome or exome sequence of that specimen)
1. **Is there anything else I should consider?**

[Use this section to disclose any other information that may affect the participant’s decision to participate in this research. Possible information may include: conditions in which the participant may be withdrawn from this study, costs of the treatment of research-related injuries, financial interests of PI, or any other disclosure. Also, this section may be used to disclose appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.] *\*If there is no additional information, remove this section.*

1. **Whom can I contact with questions about the research?**

If you have questions now, you may ask the [insert names of personnel performing consent]. If you have questions later, you may contact [list PI name, phone number, email address]. *If faculty member is the principal investigator, then also need to* [list name and contact information of the Chair of PI’s department phone number, email address. The higher the risk involved in a study, the more accessible a contact for questions and problems should be]

1. **Whom can I contact about my rights as a research participant?**

This research study has been reviewed by the Institutional Review Board (IRB) at Texas A&M International University. For questions regarding your rights as a research participant, or if you have complaints, concerns, or questions about the research, you can contact Dr. Jennifer Coronado (English), IRB Chair, 956-326-3060, irb@tamiu.edu, or Dr. Roberto Heredia (English/Spanish), 956-326-2637, rheredia@tamiu.edu.

**17**. Please be sure you have read the above information, asked questions and received answers to your satisfaction. Your participation in this research project is VOLUNTARY, and that you may withdraw from participation at any time WITHOUT COST to yourself. You have been given a copy of the information sheet.

**18.** For studies with GIFT CARDS, must use this language:

For studies with gift card incentives, participants must provide a phone number and email address for payment to be made.

Phone number

Email address

\_\_\_\_\_\_ I do not wish to provide my phone number and/or email address, but still would like to participate in this study. I understand that I am not eligible for gift card incentive if this information is not provided.

TEXAS A&M INTERNATIONAL UNIVERSITY

**WAIVER OF DOCUMENTATION OF INFORMED CONSENT**

Title of Project: Enter study title here

Principal Investigator: Enter name here

INSTRUCTIONS (delete everything in red font; DELETE COMPLETELY if not requesting a waiver): **This is not part of the informed consent document that is given to participants.** This is to inform the IRB that the principal investigator is wanting to request a Waiver of Documentation of Informed Consent (typically requested for on-line or telephone surveys) and the IRB may waive requirement for signed written consent form (45 CFR 46.116). The investigator must explain why this request is being made, how informed consent information will be provided to participant and the request must meet the following criteria:

Researcher still needs to provide the participant with informed consent information in either oral or written form (information sheet), but no signed consent form is collected.

If children are included, and investigator is requesting waiver of documentation of parental consent, must provide detailed explanation in the request to describe how these additional criteria will be met:

* Documentation of parental permission is not a reasonable requirement to protect the participants
* Appropriate mechanisms must be implemented to protect children as participants

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*REQUEST FOR WAIVER OF DOCUMENTATION OF INFORMED CONSENT\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

A waiver of documentation of informed consent is requested for this minimal risk study.

Insert a justification for why the waiver is being requested – example justifications are below in red font.

* The consent form would be the only document linking the participant to the research and a potential risk would be a breach in confidentiality. The waiver of documentation of informed consent will not adversely affect the rights and welfare of the participant.

**OR**

* Study has no more than minimal risk, and involves no procedures for which consent is normally required outside of the research environment The waiver of documentation of informed consent will not adversely affect the rights and welfare of the participant.