**Texas Christian University**

**Fort Worth, Texas**

**CONSENT TO PARTICIPATE IN RESEARCH**

*[Remove all instructions in red, as well as italics and brackets prior to use with participants]*

**Title of Research:**

***[Funding Agency/Sponsor:]***

**Principal Investigator:** *[must be a TCU faculty or staff member]*

***[Co-investigators:]***

You are invited to participate in a research study. In order to participate, you must be *[eligibility criteria; e.g., age, gender, language, etc.]*. Taking part in this research project is voluntary.

*[NOTE: The Revised Common Rule requires a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. The key information must be presented first and should include the following:*

* 1. *Identification of the project as a research study and that participation is voluntary*
	2. *Purpose of the research, duration of participation, and a description of research procedures*
	3. *Foreseeable risks or discomforts, if any*
	4. *Expected benefits to subjects or others, if any*
	5. *Alternative procedures or treatments that might benefit the subject*

*(Note: applies primarily to clinical research)*

*Most social behavioral and education studies and many biomedical studies conducted at TCU have brief consent documents (2 or 3 pages) that meet this new requirement without the need for a separate key information section. This section is needed only if your project is complex or involves numerous (more than two) research procedures. If you are unsure whether the below summary is needed, please contact Research Compliance or the IRB Chairperson]*

*[A summary of things you should know:*

* *This is a research study involving human subjects that has been approved by TCU Institutional Review Board.*
* *The purpose of the study is to [briefly describe study purpose]. If you choose to participate, you will be asked to [do what, when, where, and how]. This will take approximately [period of time].*
* *Risks or discomforts from this research include [briefly describe].*
* *The study will [description of potential direct benefits to subjects – or no benefits].*
* *Taking part in this research project is voluntary. You don’t have to participate and you can stop at any time.*

*Please take time to read this entire form and ask questions before deciding whether to take part in this research project.]*

**What is the purpose of the research?** *[describe study purpose. If you included the summary above, provided specific details here]*

**How many people will participate in this study?**

If you decide to be in this study, you will be one of *[insert the total number of subjects]* participants in this research study.

**What is my involvement for participating in this study?**

If you agree to be in the study, we will ask you to do the following things**:**

*[provide a detailed description of what the subject will be asked to do in either in order of higher to lower frequency or in chronological order, whichever will help comprehension of the information for subjects. Include details to explain what, when, where, how.]*

We expect your participation to take about *[duration, number of interactions]. [Indicate if information collected will be linked to other data (e.g., research data, protected health information, or administrative data such as US Census data).]*

*[For projects involving the collection of sensitive information or the inclusion of questions that might be upsetting, include examples of the type of questions that will be asked or describe the sensitive topic areas that are involved.*

*If applicable, include a statement about whether research results (especially clinically relevant) will be shared with the subject and under what conditions. For example: “We may learn information about your health as part of the research. We will/will not share this information with you because research results are not reliable or proven as accurate].*

**How long am I expected to be in this study for and how much of my time is required?**

*[Please provide the number of hours, days, weeks, months, etc. for participation]*

**What are the risks to me for participating in this study and how will they be minimized?**

There are some risks you might experience from being in this study. They are *[describe specific risks, from most to least serious/frequent, and indicate what the study team will do to minimize those risks. Describe the risks in the order of the most serious to least serious if there are serious risks; or from the most frequent to the least frequent if the risks].* ***[OR]*** We don’t believe there are any risks from participating in this research that are different for risk that you encounter in everyday life.

*[Primary risks include physical, psychological, or informational risks. For informational risks (e.g., those involving breach of confidentiality), describe what you will do to protect the data during collection, while stored or during transmission of the data in the section below. Psychological risks (e.g., those associated with the completion of a particularly sensitive survey or interview) could be mitigated by providing subjects with contact information for counseling resources.]*

**What are the benefits for participating in this study?**

Although you will not directly benefit from being in this study, others might benefit because *[insert details].* ***[OR]*** You might benefit from being in this study because *[insert details].*

*[The benefits to the subject and/or society must be stated. If there are no benefits to the subject, state that fact.]*

**Will I be compensated for participating in this study?**

*[sample language: You will receive a payment* *of [include payment or reimbursement information here] for your participation. (If subjects receive class points or some other token, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdrawal from the study. If there is no compensation provided to the subject, state that fact here.) You will not be responsible for any costs to participate in this study. (If costs are associated, please state them here)]*

*[If compensation is more than $100 in a calendar year, include the following text:*

*Because this study pays more than $100, Texas Christian University will collect your name, address, social security number, and payment amount. This information will be safely stored and used for income tax reporting purposes only if your total payments from Texas Christian University are greater than $600 in a calendar year (January through December). If you receive more than $600 in payments from Texas Christian University in a calendar year, this information will be submitted to the Internal Revenue Service (IRS) for tax reporting purposes and an extra tax form (Form 1099) will be sent to your home. If you are a Texas Christian University employee, your research payments are tracked separately and are not included as part of your payroll].*

[*For research posing more than minimal risk to subjects include the following text*:

*Please tell the researchers if you have any injuries or other problems related to your participation in the study. You should contact your primary care physician for treatment. If your injury or sickness is an emergency, you should call 911 for an ambulance to take you to the emergency room. You or your insurance will be billed for whatever care you receive. Texas Christian University does not provide compensation or payment for any injury or physical harm that may occur as a result of being in this study. Also, Texas Christian University does not provide compensation for loss employment, income, or emotional duress that may result from your injury or harm.*

*By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.]*

*[Delete the below section regarding cost, if not applicable.]*

***[What are the costs to me to be a part of the study?***

*To participate in the research, you will need to pay for [Indicate what costs, if any, subjects will have to pay (such as parking).]*

*[Delete the below section regarding profit and conflict of interest, if not applicable.]*

***[Who can profit from study results?***

*Where a potential conflict of interest for a member of the study team (or for TCU) has been identified, subjects must be informed about the nature of the conflict. Examples include:*

* *Ownership, consulting, or other financial interest with the sponsor*
* *A company or other organization has an ownership or other financial interest in the product or technology under study, and might profit or otherwise benefit from the outcome of the study whose product is being studied, particularly if the company/organization is also the sponsor of the study or has a financial interest with the investigators*
* *TCU might/could be paid (e.g. licensing fees) in the future for the discoveries resulting from the study.*

***All actual and perceived conflicts must be disclosed. If a conflict is determined to exists, language must be included in this consent. Sample language includes:***

*“[Name of conflicted individual] is a named inventor on patents or patent applications or is the creator of copyrighted material that is licensed or optioned to company name] that will be used in this research. This means [conflicted individual] could gain financially.]*

**What is an alternative procedure(s) that I can choose instead of participating in this study?**

*[Insert information about any applicable alternative procedures or courses of treatment here. If not, you may use the following sample language to advise that there are no alternatives- There are no known alternatives available to you other than not taking part in this study. However, any significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you.]*

*[If this section or the above statements do not make sense for the study, you can ask the IRB to waive this element of consent.]*

**How will my confidentiality be protected? *[Sample language –*** *[I or We] plan to publish the results of this study. Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Your records may be reviewed by authorized University or other individuals who will be bound by the same provisions of confidentiality. (*Add to this list other parties that may have access to the participants records such as the US Department of Health and Human Services, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[You must include the following statements if the research is a clinical trial that is federally funded/conducted. Otherwise delete.] A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

*[If the researcher obtains informed consent for research covered by a Certificate of Confidentiality, NIH expects that the researcher will tell participants about the protections afforded by the Certificate and any exceptions to that protection. Sample consent language describing the protections, limitations and exceptions afforded by a Certificate is below. Researchers may adapt the language to the needs of the research participants and to the subject matter of the study. However, the language used* ***must cover the basic points noted below.*** *Otherwise, delete.]*

*This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.*

*[Language such as the following should be included if researcher intends to disclose  information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].*

*[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].*

*[General Data Protection Regulation (“GDPR”) Consent Form Language - If TCU is engaged in a study that is conducted in the EU/EEA, or otherwise involves individuals in the EU/EEA, include the following language]*

***Participants who are citizens of and/or reside in the European Economic Area (EEA)***

*As described elsewhere in this informed consent form, during the study, data pertaining to your participation in the study will be generated and recorded. We will collect from you your personal data and possibly sensitive personal data, including health-related data. We refer to all such data as “Your Data Records,” which will be specifically regulated in the EU/EEA under the General Data Protection Regulation (the “GDPR”). Your Data Records may be processed or used for the following purposes, which we refer to, collectively, as “Data Processing”:*

*[As applicable, add to the below list of data processing purposes to ensure that this informed consent includes all potential purposes for collecting and processing the data.]*

* *to carry out the study;*
* *to confirm the accuracy of the study;*
* *to monitor that the study complies with applicable laws as well as best practices developed by the research community;*
* *to make required reports to domestic and foreign regulatory agencies and government officials who have a duty to monitor and oversee studies like this one; and,*
* *to comply with legal and regulatory requirements, including requirements that data from this study, without information that could directly identify you, be made available to other researchers not affiliated with the study sponsor or with the study team.  It is possible, for example, that as part of efforts to make research data more widely available to researchers, regulatory authorities in some countries may require that Your Data Record, without information that could directly identify you, be made publicly available on the internet or in other ways.*

*The following entities and organizations may engage in Data Processing of Your Data Records:*

*[Revise the below list of recipients to identify the specific categories of natural persons and organizations that will receive study data.]*

* *the study team, including other people who, and organizations that, assist the study team:*
	+ *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*
	+ *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*
	+ *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_;*
* *the study sponsor: [insert name of study sponsor]*
* *device/drug manufacturer: [insert name of manufacturer]*
* *the TCU institutional review board; and*
* *domestic and foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one.*

*We may conduct the study in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. In addition, we may disclose Your Data Records for Data Processing to entities and individuals located in the United States or in other countries where the laws do not protect your privacy to the same extent as the laws in your country of residence. However, all reasonable steps will be taken to protect your privacy in accordance with the applicable data protection laws.*

*[Please include the following paragraph if transferring personal data to the United States.]*

*We have entered into a data transfer agreement with [recipient], which is based on standard contractual clauses approved by the European Commission and ensures an adequate protection for Your Data Records. You may obtain a copy of the standard EU contractual terms by contacting the Principal Investigator.*

*[Please always include the following language if you include any other language regarding the GDPR]*

*The GDPR gives you certain rights with regard to Your Data Record. You have the right to request access to, or rectification or erasure of, Your Data Record. You also have the right to object to or restrict our Data Processing of Your Data Record. Finally, you have a right to request that we move, copy or transfer Your Data Record to another organization.*

*You can gain access to your records by contacting the Principal Investigator.  For a complete description of Texas Christian University’s privacy of information policy, you may access it at* [*http://www.tcu.edu/privacy.asp*](http://www.tcu.edu/privacy.asp)*.  For any questions or concerns regarding your data privacy, please contact Mr. Aaron Munoz, Data Protection Officer at Texas Christian University at* *a.v.munoz@tcu.edu**.*

*Unless otherwise described elsewhere in this consent form, there is no limit on the length of time we will keep Your Data Record for this research because it may be analyzed for many years. We will also retain Your Data Record to comply with our legal and regulatory requirements. We will keep it as long as it isuseful, unless you decide you no longer want to take part. You are allowing access to this information indefinitely as long as you do not withdraw your consent.*

*You may withdraw your consent at any time.  If you withdraw your consent, this will not affect the lawfulness or our collecting, use and sharing of Your Data Record up to the point in time that you withdraw your consent. Even if you withdraw your consent, we may still use Your Data Record that has been anonymized so that the data no longer identifies you. In addition, we may use and share Your Data Record that has been pseudonymized (by removal of your name and certain other identifiers so that the data does not directly identify you) as permitted by applicable law for purposes of: (a) public health (e.g., ensuring high standards quality and safety of health care and/or of medicinal products or medical devices), (b) scientific or historical research or statistical analysis as permitted by applicable European Union or European Union Member State laws and (c) archiving in the public interest. Further, we will maintain Your Data Record in fully identifiable form if required by law.*

**What will happen to the information collected about me after the study is over?**

*[Sample language - I/We will/will not keep your research data to use for [future research or other purpose. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project.* ***[OR]*** *Your name and other information that can directly identify you will be deleted from the research data collected as part of the project. ]*

*I/We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.]* ***[OR]*** *[We will not share your research data with other investigators.]*

**Is my participation voluntary?**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed*, [provide details how a participant can withdraw and about disposition of data]*. *[Describe anticipated circumstances, if any, under which the subject’s participation may be terminated by the PI without the consent of the subject].*

**Who should I contact if I have questions regarding the study?**

You can contact [insert name of Investigator or designated research staff member] at [insert email and phone number] with any questions that you have about the study.

**Who should I contact if I have concerns regarding my rights as a study participant?**

Dr. Dru Riddle, Chair, TCU Institutional Review Board, (817) 257-6811, d.riddle@tcu.edu; or Ms. Lorrie Branson, JD, TCU Research Integrity Officer, (817) 257-4266, l.branson@tcu.edu.

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. You will be given a copy of this document for your records. A copy also will be kept with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*[GDPR applicable: Include the following text if GDPR language was added to this form.]*

*[You consent to the collection, use and transfer of Your Data Record, which includes health and other sensitive personal data, for the purpose of carrying out the research study and know that you can withdraw your consent at any time, and we will stop processing your personal data, except as described above.]*

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

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

Printed Subject Name

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

Signature Date

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

Printed Name of person obtaining consent

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

Signature Date

*[Delete the below section regarding parent or legally authorized representative, if not applicable.]*

**Parent or Legally Authorized Representative Permission**

By signing this document, you are agreeing to [your child’s **OR** the person’s named below] participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

*I understand what the study is about and my questions so far have been answered. I agree for [my child* ***OR*** *the person named below] to take part in this study.*

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

Printed Subject Name

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

Printed Parent/Legally Authorized Representative Name and Relationship to Subject

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

Signature Date

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

Printed Parent Name and Relationship to Subject (when 2 signatures are required)

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

Signature Date

*You also may need dated consent for specific activities, when those activities are optional. Whether an activity is required or optional must be clearly described in the main body of the consent above. Examples of optional research activities are provided below:*

**Consent to be audio/video recorder**

I agree to be audio/video recorded. Yes \_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_\_

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

Signature Date

**Consent to Use Data for Future Research**

*I agree that my information may be shared with other researchers for future research studies that may be similar to this study or may be completely different. The information shared with other researchers will not include any information that can directly identify me. Researchers will not contact me for additional permission to use this information.* (Note: This separate consent is not necessary if you will only store and share deidentified data.) Yes \_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_\_

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

Signature Date

**Consent to be Contacted for Participation in Future Research**

*I give the researchers permission to keep my contact information and to contact me for future projects.* Yes \_\_\_\_\_\_\_\_ No \_\_\_\_\_\_\_\_\_\_

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

Signature Date