**Informed Consent to Participate in Research** **and Authorization to Collect, Use, and Share your Health Information**

  ***[Remove all instructions in red, as well as italics and brackets prior to submitting to IRB]***

**Title of Research:**

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

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

*[The 2018 Common Rule requires consent documents to begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding why one might or might not want to participate in research. The first page of this template is designed to assist you with drafting that key information. Information in the Overview does not have to be reiterated in the sections following the Overview.]*

**Overview:** You are invited to participate in a research study. In order to participate, you must be *[eligibility criteria; e.g., age, gender, language, etc.]*.

Study Details: This study is being conducted at *[insert location at which research will be conducted if online or virtual please indicate here; via Qualtrics or Zoom for example.]* and is supported/sponsored by *[insert name of sponsor if applicable].* The purpose of this study is to [ insert a brief summary of the purpose]. *Briefly explain in a few sentences, in lay language (understandable at a 7th grade reading level), the purpose of the study and the* ***expected duration*** *of the prospective participants’ participation. Example: The purpose of this study is to find out.... Tell the person, in lay terms, how the research will be carried out and whether the research includes a one-hour interview, a two-hour focus group, a 20-minute questionnaire, a 90-minute lab session in which you will solve complex puzzles, etc.*

Participants: You are being asked to take part because *[explain in lay language the condition(s) or situation that makes the prospective participants eligible for the research. Example: We are asking you to take part in this study because you have anxiety. We want to see how this behavioral intervention helps people with anxiety.]* If you decide to be in this study, you will be one of *[insert the total number of participants]* participants in this research study at TCU*. [If the study includes multiple sites, add the following statement:* A total of *[number of Participants]* individuals will participate in the study at all sites.]

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. [*Explain whether there will be any loss of benefit or opportunities if participants decide to stop after they start*.]

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

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

**What are the risks 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 from 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 participants with contact information for counseling resources.] [If using DXA, please include the following in addition to the risk of radiation exposure; Participants should let the researchers know if they are in any other studies involving DXA scans to consider cumulative radiation exposure.]*

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

 *[provide a detailed description in lay terms of what the participant will be asked to do in either in chronological order, whichever will help comprehension of the information for participants. If there are multiple visits with different procedures occurring at each visit, it is suggested to list each in a separate paragraph and/or as bulleted items. Include details to explain what, when, where, how.]*

We expect your participation to take about *[number of interactions,* *and minutes per interaction, including total]. [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 audio- or videotaping will be used, the participant must be informed of taping and, if applicable, given the option to agree to the recording. Explain who will have access to these recordings, whether the information will be identifiable, how long the recordings will be maintained, (noting our policy is 3 years after the Final Report is submitted to the) and when the time comes, when and how they will be destroyed. If applicable, include a statement about whether research results (especially clinically relevant) will be shared with the participant 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].*

***[If your study involves storing blood/tissue for future research, include the following two paragraphs]***

In addition to the procedures outlined above, we are asking you to allow us to obtain and store samples of your *[blood/tissue]* for use in future research. These samples may be used for research on your disease or condition and others to assist in the development of new treatments. *[When storing samples for future use, specify where samples will be stored, by whom, for how long, when/how they will be destroyed, and if/how they can be withdrawn by the subject.]* We will take some of your *[blood/ tissue]* in addition to that which has already been obtained for research purposes. *[If extra blood or tissue is being taken, explain how much extra will be taken and how this will impact the procedures for obtaining the samples. Be sure to include any additional risks the collection of blood or tissue will have on the subject.]*

In addition to your sample being used for this study and future research, we would like to share it with other researchers. We will code your sample so that the researcher who uses it for other purposes does not know your identity. We will not release the code that links your sample to your personal identifying information for any reason.

**Are there any alternatives and can I withdraw?**

*[Use whichever statement is applicable:]*

You do not have to participate in this research study. *[This statement is sufficient if there are no alternatives for the participant.]*

*[Or]*

Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the participant could receive such as taking a different course of treatment, etc.]*You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. *[Explain the withdrawal process, this should be consistent with the information entered into your application] [If participants are students or employees, include as applicable: decision to participate or not to participate will not affect your student status (course grade) or job status.]*

**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 participant and/or society must be stated. If there are no benefits to the participant, state that fact.* ***Please note Compensation of ANY kind is not a benefit to participation.****]*

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

You will receive a payment of *[ Include payment or reimbursement information here]* for your participation. *(If participants 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 participant, 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, if not please delete:*

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 greater than minimal risk to participants 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 of 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.

**What are my costs to participate in the study?**

*[Use only the following statements that apply to your research and delete what does not apply.]*

To participate in the research, you will/ will not need to pay for *[Indicate what costs, if any, participants will have to pay (such as parking)/ anything] [If the costs of the research are being paid by the study sponsor the following statement is required:]*

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

*[If there are costs associated with the study:]*

You or your insurance company will be expected to pay the costs for the following: *[list all procedures which will be the responsibility of the participant outside of routine care.]*

*[If commercial development is expected to arise from the study, include the following:]*

The findings from this research, which may include your biospecimens (even if identifiers are removed), may result in and be used for the future development of products that are of commercial value and/or profit. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

# Is there any conflict of interest?

*All actual and perceived conflicts must be disclosed. If a conflict is determined to exists, language must be included in this consent.* ***If there is no conflict please delete this section.***

*“[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.]*

**How will my confidentiality be protected?**

Every effort 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 personnel 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.]

*[****Please include ONE of the following statements if the research involves the collection of identifiable private information or biospecimens.****]*

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative *Or;*

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

*(If this study includes genetic testing, add the GINA statement below verbatim. If not, delete this section).*

**Will my genetic information be protected?**

A Federal law, called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

***Insert the following statement if health information will be collected from the medical record of subjects:***

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e., your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive.

[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 your research is NIH funded and you are conducting research involving sensitive, identifiable information, you have automatically received a certificate of confidentiality as a part of the terms and conditions of the award and are required to include this language. If your research is not NIH funded and you have applied for a certificate of confidentiality, insert this language as appropriate.]*

To help us protect your privacy, *[we will obtain/we have obtained]* a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances. The investigative team will voluntarily comply with Texas Statutes and federal regulations, which may mandate or permit certain disclosures *[list what will be reported, such as child abuse and neglect, or harm to self or others]* of protected information by the investigative team to appropriate individuals.

*[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]* ***If this does not apply to your study, please delete this section.***

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

Data collected for this research will be stored at the *[insert name of TCU study site, e.g. the Miller Speech & Hearing Clinic]*, located at the Texas Christian University in the United States.

***The following information may be used and disclosed to others:***

* Your research records
* All of your past, current or future medical and other health records held by your study site
* Your contact information, including your name, e-mail address and your mailing address
* *[Insert any other personal data that will be collected from EU participants, including, for example, information about participants’ ethnic or racial background, sexual history or sexual orientation, or political or religious beliefs.]*

Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: *[Insert appropriate business address.]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by TCU policies.

If you have concerns about the use or storage of your personal information, you have a right to lodge a complaint with the data supervisory authority in your country.

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>.  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?**

*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.*]*

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

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.

Dr. Brie Diamond, Chair, TCU Institutional Review Board, (817) 257-6152, b.diamond@tcu.edu; or Dr. Floyd Wormley, Associate Provost of Research, research@tcu.edu. For more information please visit our website <https://research.tcu.edu/research-compliance/irb/for-research-participants/>.

**HIPAA Authorization**

This research uses or discloses Protected Health Information as defined by the Health Insurance Portability and Accountability Act (HIPAA). By signing this form, you are permitting Texas Christian University to use your health information for research purposes. The names of the TCU researchers who will gather this information from you are listed at top of this document, including the lead researcher. We will collect the following health information from you:

***[list bulleted PHI that will be collected]***

 *[Include if applicable]* You are also allowing us to share your health information with individuals or organizations other than TCU who are also involved in the research and listed below.

 ***[list bulleted individual names, affiliation, institutions / organizations, or labs who will receive PHI]***

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.]*

***For online studies only****: [* *By selecting "Agree to participate" below, you are agreeing to be in this study. Make sure you understand what the study is about before you agree. You will be given a copy of this document for your records upon request. If you have any questions about the study after you agree to participate, you can contact the study team using the information provided above.]*

***(delete signature lines below if obtaining consent online)***

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

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Printed Participant 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 Participant Name

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

Printed Parent/Legally Authorized Representative Name and Relationship to Participant

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

Signature Date

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

Printed Parent Name and Relationship to Participant (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 recorded**

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

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

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

Signature Date

**Consent to Store & Use Data/Biospecimens for Future Research**

*I agree that my information may be stored and 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.*

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