**Texas Christian University**

**Fort Worth, Texas**

**CONSENT TO PARTICIPATE IN RESEARCH**

*[Template Blood Drawing Study with HIPAA Authorization]*

*[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, you will be asked to provide a sample of blood *[insert amount of blood drawing in lay language: 1 tablespoon=15ml; 1 teaspoon=5ml].* The blood will be taken witha needle from your arm*.*

*[Insert one or both statements (or similar statements), if applicable, if health information will be collected from a subject.*

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.

*Insert any of the following statements that are applicable if the research will involve whole genome sequencing:*

Using DNA from your blood or tissue sample, we will study your entire genetic sequence, known as your genome. The genome sequence will be read and this information will be stored.

Your genomic data will be used to find differences and similarities among people related to disease or other health traits.

Your genomic data and health information will be studied along with information from other participants in this study, and it will be stored for future studies by this and other research teams.

*Insert one of the two below statements as applicable:*

*The information collected about you during this study and/or leftover blood samples 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 you. Researchers will not contact you for additional permission to use this information.*

**or**

*The information collected about you during this study and/or leftover blood samples will not be shared with other researchers for future research studies even if information or blood sample cannot directly identify you.]*

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

Your participation in this study will takeabout *X minutes*.

**Will results from the research be shared with me?**

*[Insert one of the following statements, as applicable:*

*No research results will be shared with you as the results will not reveal findings that may help you or your doctor diagnose you or have meaningful information to treat you.*

***or***

*The only research results that will be shared with you are: [insert results that are produced by standard practice procedures (e.g., blood pressure) or a CLIA-certified lab].*

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

The risks associated with this study are slight discomfort during the drawing of blood. You may feel pain or have bruising at the location of the blood draw. Some people may feel light-headed and a very few may faint. There is a rare risk of infection.

There is the possible loss of confidentiality if your data or information is disclosed outside of this study, but this is not likely.

**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].*

**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.]*

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

*There will be no costs to you for being in this study.*

or

 You will receive [insert amount] for your participation in this study.

*or*

We will reimburse your costs for transportation and parking [etc.].

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product

*[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?**

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.

**How will my confidentiality be protected? *[Sample language* –** Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy.

The specimens will be given a code number and separated from your name or any other *information that could identify you. The research file that links your name to the code number will be kept in a [Choose as appropriate: password protected database or locked file cabinet]. Only the Principal Investigator and the study staff will be able to see this file.*

*If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used.*

*Insert the following statements 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.*

*The following people and/or agencies will be able to look at, copy, use and share your research information:*

* *the investigators and researchers conducting the study;*
* *authorities from TCU, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.*
* *the Federal Office of Human Research Protections ('OHRP') and/or the [add FDA if applicable] United States Food and Drug Administration ('FDA');*
* *[If this study is sponsored (money or supplies are being provided)] the sponsor of this study, [name sponsor], including persons or organizations working with or owned by the sponsor may review your data for accuracy but may not copy information with your name on it.*
* *[List other entities that may receive and process PHI, i.e. Data Coordinating Center, Data Safety and Monitoring Board/Committee ...]*

*[Choose one of the following statements:]*

*Your authorization to use and share your health information does not have an expiration (ending) date.*

*[or]*

*Your authorization to use and share your health information will expire when the research is completed.*

*Once your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.*

*You may change your mind and revoke (take back) this consent and authorization at any time and for any reason.*

*However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the Researchers and the Sponsor (if applicable) may continue to use and disclose the information they have already collected.*

*[For blinded studies, please add:] To maintain the integrity of this research study, you generally will not have access to your protected health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to this information.]*

*[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.*

**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 without penalty or loss of benefits to which you are otherwise entitled. To revoke this consent and authorization and withdraw from the study, you must contact the Principal Investigator or staff member. [*Insert contact information*].

If you withdraw from the study, the Researchers and the Sponsor (if applicable) may continue to use your blood sample and the information they have already collected in the research.

**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 Dr. Floyd Wormley, Associate Provost of Research, research@tcu.edu

**Statement of Consent and HIPAA Authorization**

I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it. By signing this consent and HIPAA authorization form, I have not given up any of the legal rights.

*[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.]*

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Printed Subject Name

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

Signature Date

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

Printed Name of person obtaining consent

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

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