IRB USE ONLY
Study Number:
Approval Date:
Expires:
Name of Funding Agency (if applicable):

Consent for Participation in Research

Title: *[insert title of study]*

Template Version: 3.15.2023

Key Information

This first part gives you key information to help you decide if you want to join the research study. We will explain things in more detail later in this form.

You are being asked to take part in a study about *[insert general description of the study]*. Be doing this study, we hope to learn *[briefly describe purpose of the study in simple language]*. You are being asked to take part because *[briefly describe the eligibility criteria]*. If you decide to join the study, **briefly describe most likely greater than minimal risk and potential direct benefits to the subject if applicable. Otherwise, delete.**

Taking part in this study is voluntary. This means you can say no now, or if you start the study, you can stop at any time. Please ask questions at any time if something is not clear in this consent form.

What will happen if I join the study?

If you join this study, you will be asked to *[explain tasks and procedures including details about completing surveys, interviews, tests and/or focus groups as applicable]*.

If given a survey, include this statement: We will give you a form with questions about *[describe the nature of the questions]*. You do not have to answer any questions you do not want to answer.

If participants will be audio or video recorded, include this statement: Your part in this study *[will or may]* be *[audio or video] r*ecorded.

Your part in the study will take *[insert length of time for participation, frequency of procedures or any other applicable information]* and will include about *[insert number of participants]* people.

What are the risks involved in this study?

There is a risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

If risks are greater than minimal, include this statement: Other possible risks related to this *[treatment, procedures, intervention or describe other]* are *[explain risk, including the likelihood of risk occurring]*. This *[treatment, procedure, intervention or describe other]* may also involve risks that are not expected at this time.

Will being in this study help me in any way?

Choose the most appropriate statement depending on if the study has direct benefits to the participant. Monetary compensation cannot be categorized as a benefit.

The possible benefits of being in this study are *[insert benefits that may be reasonably expected]*.

OR

We do not think that being in this study will help you personally; however, *[explain benefits to society e.g. contributions to knowledge about a condition]*.

Do I have to participate?

No. Your study is voluntary. This means you can say no now or, if you start the study, you may stop at any time. Saying no now or stopping at any time will not

affect your relationship with *[insert name of institution or organization]* in any way. You will not lose any services, benefits, or rights you would normally have it you decide not to join.

Delete if not applicable: If you decide to stop being in the study, *[describe what subjects should or must do e.g. inform the study team, return study device]*.

If the participants are prisoners, include the following statement: Being in this research will have no effect on your parole or probation.

What are the alternatives to participating in this study?

For studies that are not greater than minimal risk and are not HHS funded, this section may be omitted.

Choose from these options and modify as needed:
There are no alternatives to being in this study, other than to not be in the study, because it does not involve any treatment or other procedures that may help you.

OR

If you decide not to join this study, you have the following other options: *[using bullet points, describe alternative treatments, standard of care, or courses of action that are available to the subject]*.

Will it cost me anything to be in the study?

The study will not cost you anything. You or your insurance company will be responsible for the cost of your regular medical care, as usual. **Delete the language about regular medical care if the study does not involve medical care. If there are costs that may reasonably occur, change this statement to reflect those costs, e.g. parking costs, costs for medical supplies, etc.**

Will I be paid for being in the study?

Choose from these options and modify as needed.

No. You will not get any type of payment (for example, money) for being in this study.

OR

Yes. You will get *[insert payment, reimbursement, or participation credit]*. Payments will occur *[explain disbursement/conditions of payment]*. *[Include circumstances, if any, where partial payment or no payment may occur, such as if the participant does not complete a visit]*. You will be responsible for any taxes assessed on the compensation. **Delete the language about taxes if compensation is minimal (e.g. $10 or $25).**

What if I get sick or hurt because of the study?

If there are no potential risks for physical injury, do not include this section.

If emergency treatment for research-related injuries is arranged by, for example, having a medical doctor available for emergency treatment, it should be clearly stated. Sample language below.

If you get sick or hurt when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and any care you need.

If you are not here and get sick or hurt and you think it is because of the study, do these things:

- Call your doctor, or if an emergency, call 911.
- Give your doctor or ER staff the same of the this study *[insert name of study]*, the name of the head researcher *[insert name]* and a copy of this form if you have it.
- Call *[insert name and number of research team]*.

Then insert one of these options:

This treatment will be billed to you or your insurance company. No other form of payment is available.

OR

[Insert details of agreement negotiated with sponsor].

A statement for extended care should be put into the consent form.
Example: The institution has no program or plan for on-going medical care or hospitalization for research-related injuries or for payment for expenses.

If all of the participants are students at the Institution, it may or may not be appropriate to state: If injuries occur as a result of study activity, eligible institution students may be treated at the usual level of care with the usual cost for services as the *[insert name of Institution]*, but the Institution has no program or plan to provide payment in the event of a medical problem.

Who will see this information? How will you keep it private?

We will do our best to make sure no one outside the study knows you are part of the study. To protect your privacy and the confidentiality of information about you we will do the following: *[Describe how participant privacy and confidentiality of participant data will be accomplished and maintained. Sample language below.]*

- We *[will/will not]* take your name off information and study samples that we collect from you during the study. We will give your information and study samples a code so that no one can identify you.
- When we share the results of the study *[insert details here, e.g. in medical journals]*, we will not include your name or anything else that could identify you.
- *[If the study will collect anonymous data, describe how participants anonymity will be accomplished and maintained.]*

If the Institutional Review Board needs to look at study records, information that can be linked to you (for example, your name) will be kept private as much as the law allows.

If audio/video recordings will be made, include the following statements:

If you choose to take part in this study, you *[will be/may chose to be] [audio and/or video]* recorded. Any *[audio and/or video]* recordings will be stored securely and only the study team will have access to the recordings. Recordings will be kept for *[insert length of time]* and then erased.

If the research involves collection of identifiable private information or identifiable biospecimens, you must include one of the following:

We *[or someone else; please specify]* may use the samples we collect from you for future research. **If this is expected,** *[insert how you expect to use it]*. **If it is not immediately expected, but you want to preserve the option, insert the following:** However, we currently have no specific plans to do so. We *[or someone; clarify]* may eventually profit from the research done with your samples. You *[will/will not]* share in this profit. **Delete the language about profit if no commercial use/gain is expected.**

OR

We will not use the samples we collect from you for commercial profit or another research project. They will only be used to help us learn *[insert main purpose of specimen collection]*.

For studies registered on ClinicalTrials.gov you must include the statement: A description of this study will be posted on http://www.ClinicalTrials.gov *[Enter Identifier Number]* as required by US Law. This web site will not include information that can identify you (for example, your name). At most, the website will include a summary of the results. You can search this web site at any time.

What should I know about the collection of genetic information?

If the research is not collecting genetic information, do not include this section.

Adapt the following text to the current study. If the genetic information created as part of this study may be shared outside the study team and/or uploaded to a publicly available database, make sure risk associated with that sharing are addressed.

Genetic testing involves certain risks. Genetic testing can sometimes reveal information about you or, in some cases, your family members since genetic conditions may be shared among relatives. If someone else learns about this information, there is a risk of being discriminated against, feeling stigmatized, or having trouble getting a job or insurance. Your genetic information is unique to you.

So even if it does not include your name or other identifying information, there is also a risk someone could trace your information back to you. While the researchers think the chance of someone being able to identify you through your genetic information alone is small, this risk may change in the future as people find new ways of tracing information.

If the current study involves genetic testing and/or whole genome sequencing, please include the following, edit as appropriate. Otherwise, delete.

We will use your samples for genetic testing. This testing will look at the genes that may be responsible for *[explain in clear, understandable terms]*.

Delete if not applicable: We will do a genetic test called whole genome sequencing using your samples. This process allows us to see your entire genetic code. This code is what determines things specific to each person, such as hair and eye color and risks for diseases.

If the research collects genetic information the following must be included:

If results will be returned to the individual, include this; otherwise delete. If you receive the results of the genetic testing, you might be upset about what you might learn about risks to your health or your family members' health. For example, you might feel concern about a possible genetic disorder that has not shown up yet.

If neither the results of planned testing nor incidental findings will be returned to the individual, include this; otherwise delete. The genetic testing will be done for research purposes only, and we do not plan to return any results to you or your doctor.

If genetic data/samples will be shared with the sponsor or other investigators, add the following; otherwise delete. We may share the genetic information we learn from this study with *[e.g., the sponsor—name the sponsor; other researchers; etc.]*. This information will not include anything that identifies you, such as your name or any other personal information about you.

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 ask for genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions about your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding 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 and all employers with 15 or more employees must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it prohibit discrimination based on a genetic disease or disorder that you already know about.

If I stop being in the study, what will happen to my information and samples collected in the study?

We *[will/will not]* be able to take your information and samples out of the study after it has started.

Delete "and samples collected" if not samples involved.

What if I have questions?

Prior, during or after you are in this study you can contact the researcher *[insert name]* at *[phone number]* or sent an email to *[email address]* for any questions or if you feel that you have been harmed.

Only include this statement if the study is Expedited or Full Board:

This study has been reviewed and approved by the Institutional Review Board 2 and the study number is *[study number]*.

What if I have questions about my rights as a research participant?

For questions about your rights or complaints about this study, you can contact the Institutional Review Board (IRB) by phone at (512) 206-5278 or email at IRB2@hhs.texas.gov. You do not need to give your name when you contact the IRB.

Signature

By signing this form you agree you have been informed about this study's purpose, procedures, possible benefits and risks. You have been given a chance to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to be in this study. By signing this form, you are not waiving any of your legal rights.

You will be given a copy of this form.

_____
Printed Name

_____ _____
Signature Date

_____
Printed Name of Guardian/
or Legal Acceptable Representative

_____ _____
Signature Date

As a representative of this study, I have explained the purpose, procedures, benefits, and the risks involved in this research study.

_____

Print Name of Person obtaining consent

_____ _____

Signature of Person obtaining consent Date