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

Study Information Sheet

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 study. We will explain things more in detail later in this form.

- You are being asked to take part in a research study about *[insert general description of the study]*.
- By doing this study, we hope to learn *[briefly describe purpose of the study].*
- You are being asked to take part because *[briefly describe eligibility criteria]*.
- 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/video recorded include this statement:
Your part in the study *[will or may]* be *[audio/video]* recorded.

How long will I be in the study?

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

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 then minimal include the statement:

Possible risks related to this *[treatment, procedure, intervention or describe other]* are *[explain risk, including the likelihood of the risk occurring]*. This *[treatment, procedure, intervention or describe other]* may also involve risks that are currently not expected.

Will being in this study help me in any way?

Note: 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 maybe 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 participation 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 and/or organization]* in any way. You will not lose any services, benefits, or rights you would normally have if 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 anything]*.

If the participants are prisoners include the following statement:

Being in this research study will have no effect on your parole or probation.

What are the alternatives to participating in this study?

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

Choose from these options; 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; 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).**

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 to 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 participant anonymity will be accomplished and maintained].*

If the Institutional Review Board needs to look at study records, information that can be linked to you (e.g. 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 in this study, you *[will be/may choose to be] [audio and/or video]* recorded. Any *[audio and/or video]* recordings will be stored securely and only the research 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]** 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]*

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 send an email to *[email address]* for any questions or if you feel that you have been harmed.

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 by phone at (512) 206-5278 or email at IRB2@hhs.texas.gov. You do not need to give your name when you contact with IRB.