## Title of Research Study:

## Principal Investigator:

## Supported By: [if applicable – otherwise delete] This research is supported by \_\_\_\_\_\_\_\_\_\_\_\_\_.

## Collaborating Institutions: [if applicable – otherwise delete]

## Key Information about this research study:

## The following is a short summary of this study to help you decide whether to be a part of this study. More detail will follow below.

## The purpose of this study is \_\_\_\_\_.

* You will be asked to \_\_\_\_\_\_\_\_\_ [include a brief description of the study procedures. For example: You will be asked to complete a survey and a follow-up interview.]
* We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [total amount of time, and number of study visits].
* The primary potential risk of participation is \_\_\_\_\_\_\_.

## If your study will use incomplete disclosure as a research technique, you should include this language: “The information being provided in the consent is incomplete.”

## Why am I being asked to take part in this research study?

We are asking you to take part in this research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstances (i.e., patient, professional, consumer, etc.) or demographic / condition (i.e., age 18-45) that makes participants eligible for the research.]

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

We expect about \_\_\_\_\_ people will be in this research study.

## What should I know about participating in a research study?

* Someone will explain the research study to you. [Remove if not applicable.]
* Whether or not you take part is up to you.
* You can choose not to take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* You can ask all the questions you want before you decide.
* You do not have to answer any question you do not want to answer.

## What happens if I say, “Yes, I want to be in this research”?

Tell the participant what to expect using lay language and simple terms.

A description of the research activities and procedures, preferably in chronological order, and how often those activities and procedures will occur.

* The length and duration of study visits, activities, and procedures
* With whom the participant will interact
* When and where the research will be done
* What is being performed as part of standard or customary practice [i.e., If the study involves any type of clinical care, describe what is standard care and what is part of the research].
* When applicable, describe if audio or video recording or photography will take place as research activities. Explain whether audio-recording/video-recording/photography are required for participation or if those procedures are optional.
* [Include the following if participants are randomized to comparison groups:] The group of study participants you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being assigned to any given group.

## Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [describe the potential benefits of participation. to the participant, and any potential benefits to others/society. Financial compensation for participation is not a benefit]

## Is there any way being in this study could be bad for me?

List and describe reasonably foreseeable risks. If known, describe the probability and magnitude of the risk. Possible risks include:

* Physical
* Psychological / social
* Privacy
* Legal
* Economic
* Group or community risks

## [Include this paragraph in the consent for ALL studies that will collect data that are potentially identifiable:] A possible risk for any research is that confidentiality could be compromised – that is, that people outside the study might get hold of confidential study information. We will do everything we can to minimize this risk, as described in more detail later in this form.

## What happens if I do not want to be in this research, or I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate. If you do not want to be in this study or withdraw from the study at any point, your decision will not affect your relationship with [the program, other entity or person.] You can leave the research at any time and it will not be held against you.

If you decide to withdraw from this study, the researchers will ask you if the information already collected from you can be used.

**OR**

If you decide to withdraw from this study, any data already collected from you will be destroyed.

## How will the researchers protect my information?

Describe procedures that will be used to keep participant information secure and confidential. For example, use of encryption, storing identifiable information separately from the rest of the research data, keeping only de-identified transcripts of interviews/focus groups, etc.

If your study has **NIH funding or if you plan to apply for a Certificate of Confidentiality**, you must include language about the protections and limitations of the Certificate of Confidentiality here.

If your study will use **focus groups** for data collection, see additional about limitations on participant privacy/data confidentiality in the focus group setting.

## Who will have access to the information collected during this research 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.

[If applicable otherwise delete: Include one of the following statements in studies in which researchers are probing for or likely to elicit information about child abuse or neglect.]

If we learn about current or ongoing child abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

OR

We will not ask you about child abuse, but if you tell us about child abuse or neglect, we may be required or permitted by law or policy to report to authorities.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]

**How might the information collected in this study be shared in the future?** [if applicable – otherwise delete]

We will keep the information we collect about you during this research study for study recordkeeping [and for potential use in future research projects]. If the study data contain information that directly identifies participants: Your name and other information that can directly identify you will be stored securely and separately from the rest of the research information we collect from you.

For longitudinal research studies, include: The researchers [plan to/may] contact you again as part of this research study.

De-identified data from this study may be shared with the research community, with journals in which study results are published, and with databases and data repositories used for research. [If you will collect participant identifiers, include this sentence:] We will remove or code any personal information that could directly identify you before the study data are shared. Despite these measures, we cannot guarantee the anonymity of your personal data.

If you plan to maintain or share identifiable data for unspecified future research, a separate IRB application should be submitted with a protocol, consent and supporting documents (e.g., research registry). If the Principal Investigator (PI) of this study would like to provide an option for a participant to be contacted for a future study conducted by this PI, this option can be provided at the end and you should include this paragraph: The PI would like to retain your contact information to contact you for future research participation. This information will not be shared with other researchers, but will only be retained for potential interest in research with this PI. We will ask for your consent to do so at the end of this form. You can be in this current research study without agreeing to future research use of your identifiable information.

**Will I be paid or given anything for taking part in this study?**

You will receive [type (e.g., cash, gift card, check) and total amount of compensation] for your participation in this study. Explain the following if relevant to your study:

* If payments will be prorated for any reason (including if a participant withdraws before completing all study procedures).
* If there will be any type of bonus payment, or any payment amount is contingent on decisions/performance of the participant or a group of participants.
* If you will use a raffle/lottery, explain the amount and total number of payments to be awarded; odds of winning (if known); approximate timing of the drawing; and how participants who are awarded will be notified.
* If participants will receive reimbursement for transportation, parking, or other expenses they incur due to participating in this study.

If there could be costs to participants for participating in the study (e.g., parking and transportation costs), describe those here.

If there will be no payment/reimbursement for study participation, state: There is no payment or reimbursement for participating in this study.

## Who can I talk to?

If you have questions, concerns, or complaints, you can contact the Principal Investigator [Name and contact phone or email] and [another investigator such as a student if appropriate.]. [For international studies, include the U.S. country calling code for the study team’s contact phone numbers, and contact information for the local collaborator (if any).]

This research has been reviewed and approved by an Institutional Review Board (“IRB”) – an IRB is a committee that protects the rights of people who participate in research studies. You may contact the IRB by phone at (XXX) or (email) if:

* Your questions, concerns, or complaints are not being answered by the research team.
* You cannot reach the research team.
* You want to talk to someone besides the research team.
* You have questions about your rights as a research participant.
* You want to get information or provide input about this research.

## Optional Elements:

[Include for any optional elements of the research. Otherwise delete.] The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Example Optional Elements

|  |  |  |
| --- | --- | --- |
| I agree | I disagree |  |
|  |  |  |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may use **[specify type of recording: audio, video, and/or photographs]** of me in scholarly presentations or publications when showing my face or hearing my voice might serve to help others understand the research. I may be identifiable as part of this activity. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_ | The researcher may keep my contact information in order to contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator. |
|  |  |  |

NOTE: Below you will find four signature blocks for various consent scenarios – the first signature block is to be used when the participant will sign the consent form – there are also signature blocks below if you will be obtaining consent online with or without documentation, and verbally. Choose the signature block that applies to your study and delete all the other signature blocks. If you will have variations of your study in which you will obtain consent using different methods (e.g., some participants will sign the consent form because they will interact with the research team in person, some will only participate online, etc., you need to submit a consent form that is appropriate for each method that you will be using to document consent).

When obtaining the participant’s written signature:

Signature for Adult 18 or Older Capable of Providing Consent

Your signature documents your permission to take part in this research.

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

Signature of participant Date

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

Printed name of participant

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

Signature of person obtaining consent Date

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

Printed name of person obtaining consent

If applicable: Signature for Witness of Consent Process

Add the following if a witness will observe the consent process, e.g., participant is illiterate, participant is visually impaired, or the participant is physically unable to sign. Otherwise delete.

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

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

Signature of Witness to Consent Process Date

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

Printed Name of Person Witnessing Consent Process

**Electronic Consent (**similar to written signed consent but obtained remotely on an electronic platform**)**

To obtain appropriate signed consent, a verified electronic-signature must be obtained. Include fields for the participant to type the participant’s name and the date in the electronic consent.

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Verbal consent:

There are a variety of reasons why it might not be feasible to obtain the participant’s signature on the consent form. For example, if consent and data collection will take place via telephone or Zoom obtaining the participant’s signature on the consent is cumbersome. In other studies (e.g., studies of illegal or socially stigmatized activities), the participant’s signature on the consent could create additional risk for the participant. If doing research in other countries, it may not be the norm for members of a distinct cultural group or community to sign a consent form. You must justify in your study protocol document why you do not plan to have participants sign the consent form.

If you will not be obtaining a signed consent or electronic signature, you must satisfy the requirements for a waiver of documentation of informed consent. The protocol must adequately justify the federal waiver criteria).

If the participant will not sign the consent form, delete the signature block above, and use this form as a study information sheet. When you contact the participant to begin data collection, review the main points of the consent information with the participant and verbally confirm that the participant agrees to be in the study before you start collecting data from the participant. You may audio-record the participant’s verbal consent to participate – if you plan to audio-record participants’ verbal consent, you must explain that in the protocol document.

Do you wish to participate? Record participant’s response: Yes No

Participant name or study ID number (if not recording participant’s name on the consent form to minimize risks to the participant, record study ID number instead):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Signature of Person Obtaining Consent Date

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

Printed Name of Person Obtaining Consent Date

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Online consent (consent obtained without signature - not electronic signature):

If you will not be obtaining a signed consent or electronic signature, you must satisfy the requirements for a waiver of documentation of informed consent. The protocol must adequately justify the federal waiver criteria. If this is the case, delete the signature block above and use the following consent language instead:

If you want a copy of this consent for your records, you can print it from the screen.

If you cannot print the consent and would like a copy for your records, contact the Principal Investigator with the contact information above.

If you wish to participate, please click the “I Agree” button and you will be taken to the survey.

If you do not wish to participate in this study, please select “I Disagree” or select X in the corner of your browser.