

## Supplemental Consent Language for Consent Document

The following additional information must be provided to prospective participants, when applicable. Instructions and optional language are in the red font – delete everything in red font and replace with applicable language pertinent to your study.

### 1. If funded by NIH

#### **This study has a Certificate of Confidentiality**

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this certificate, we cannot be forced by a court order or subpoena to disclose information that could identify you. However, there are times when your identity would not be kept secret, even with a Certificate of Confidentiality:

- If a government agency inspects the records, or to meet FDA requirements
- If you give someone written permission to receive this information, or if you tell someone the information yourself
- If you threaten to harm yourself or others
- In cases of child abuse
- If we are required to report cases of certain contagious diseases (such as HIV) to the state

### 2. If used for profits

#### **Profits from the research**

We may earn a profit from the data you provide for this research. We do not plan to share any of the profits with you.

### 3. If any researchers have a conflict of interest

#### **Conflict of Interest**

[Name] has a conflict of interest in this study. [Insert brief description of the nature of the conflict. Example: Dr. Jones owns the company that is providing the funding for this research]. We are managing this conflict by [describe].

### 4. If participants will incur any costs if they participate

#### **Costs to participate in the study**

A description of the costs to the participant that may result from participation in the research.

### 5. If a focus group is conducted

In the “Data Security, Storage, and Retention Period” section, add the following:

“Although we ask everyone in the group to respect the privacy and confidentiality of participants and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.”

### 6. If the study will enroll prisoners:

In the “Voluntary Participation” section, include the following:

Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

### 7. If the study will use incomplete disclosure and/or deception as research techniques

If you intend to withhold information about the real purpose of the study or purposely give participants false information about some aspect of the research (i.e., incomplete disclosure or deception), include one of the following statements in the “Participation Procedures and Duration” section of the consent.

For scientific reasons, this consent form does not include complete information about the research questions or topics being tested. You will be fully debriefed following your participation in the research.

OR

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation.

### 8. Mandatory reporting of potential child abuse or neglect

Some research may collect information or include a population which may lead to study teams becoming aware of potential child abuse or neglect. Study teams should be aware of mandatory reporting requirements and should include relevant information in the informed consent if the research collects data which could trigger mandatory reporting. If your study is that case, please add the following to the consent form.

By law, the study team must release certain information to the appropriate authorities if at any time during the study there is concern that child abuse or elder abuse has possibly occurred or you disclose a desire to harm yourself or others.

**-OR-**

We need to make you aware of one exception to confidentiality. If you disclose actual or suspected abuse, neglect, or exploitation of a child, it is our ethical and legal responsibility to report such situations to the appropriate authorities.