**INFORMED CONSENT**

**Template Directions**

**This first page of the Informed Consent template provides directions for researchers. Delete this directions page from the Informed Consent form before submitting the consent form for your study to the Lamar University Human Subject Institutional Review Board (IRB).**

This template is a guide to be sure all aspects of consent are properly conveyed to the study participants according to federal guidelines. Some areas may not apply to all research projects. Researchers should modify and or remove any unnecessary information from this form.

If your research study will be registered with **ClinicalTrials.gov** you must include the following statement in the informed consent:

*A description of this study will be available at www.clinicaltrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this sit at any time.*

If the participants in the study are **prisoners**, you must include the following statement in the informed consent under the participation section:

*Your participation in this research study will have no effect on your parole or probation.*

***Instructions for Researcher:***

*On the following pages of the template, statements highlighted in yellow are instructions, which should be deleted from the final version of the Informed Consent.*

*Items in red on the following pages should be replaced with information specific to the research study.*

*Please remove this page of directions in the final version of the consent form.*



**INFORMED CONSENT**

**Study Title**

**Purpose of the Study**

You are being asked to participate in a research study about [insert general statement about study]. The purpose of this study is [explain the research questions and purpose in lay/simplified language]. If you agree to participate in this study, you will be asked to: [use bullet points to explain tasks and procedures including details about completing surveys, interviews, and/or focus groups where applicable].

The study will [insert length of time for participation, frequency of procedures, location of data collection, or any other applicable information].

**Risks**

This is a [minimal] risk research study. That means that the risks of participating are no more likely or serious than those you encounter in everyday activities. (If this study is greater than minimal risk indicate such, meaning that the risks are [slightly or significantly] higher than those you encounter in everyday activities). The foreseeable risks or discomforts include [list all foreseeable risks here, and ensure it is consistent with the study protocol; indicate likelihood of the risk occurring]. In order to minimize those risks and discomforts, the researchers will [list what the researcher is doing to minimize those risks, and ensure it is consistent with the study protocol]. You can withdraw from the study at any time, without any penalty.

**Benefits**

Participation in this study may directly benefit you by [list benefits, e.g. “making you more aware of your study habits” or “receiving a $2 gift card”] [or say, Participation may have no direct benefit to you.]. More broadly, this study may help researchers learn more about [Study Title] and may help future people with similar interests or issues.

**Confidentiality**

The researcher will make every effort to ensure that the information you provide as part of this study remains confidential. Your information will be collected through [Surveys/Questionnaires, Interviews, Video/Audio Interviews and/or Clinical Instruments/Test]. Describe how confidentiality is protected, for example assigning number to participants instead of using names. This information/data will be securely stored. [If the study will collect anonymous data describe how participants’ anonymity will be accomplished and maintained].

*If you are doing research in a group setting, please add the following statement.* We ask all group members to keep the information shared during the group session confidential, however we cannot guarantee that everyone will do so.

This informed consent form will be kept for three (3) years after the study as required by federal law and then it will be destroyed. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study.

**Participation**

Your participation in this research is completely voluntary. If you agree to participate now and change your mind later, you may withdraw at any time. If you choose to withdraw after we have already collected information about you, [state what you will do with that information].

*If photographs or audio/video recording will be used during the research study, you must include the following statement:*

Any photograph or audio/video recordings will be stored securely and only the research team will have access to the photographs or recordings. The photographs and recordings will be kept for three (3) years after the study as required by federal law and then it will be destroyed.

Participant must initial one:

*\_\_\_\_\_\_* I agree to be photographed or be audio/video recorded.

\_\_\_\_\_\_ I do not agree to be photographed or be audio/video recorded.

You [will or will not] receive any type of payment for participating in this study.

There is no cost to you for participating in the study.

**Contact**

Prior, during, and after your participation you may contact the researcher by email or phone [Insert researcher’s name, email address and phone number]. When asking questions about the research study please be sure to reference the researcher’s name and study title.

For concerns with any part of this study, please contact the Lamar University Institutional Review Board at rspa@lamar.edu.

**Signature**

You have been informed about the title of the study, the purpose of the study, the study procedures, the benefits of the study, and possible risks. You have been given a copy of this consent form. You have been given the opportunity to ask questions before signing this form.

By signing this form, you voluntarily agree to participate in this study, but you are not waiving any of your legal rights.

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

Participant’s Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_

Participant’s Signature Date

As part of the research team, I have explained the study title, study purpose, study procedures, benefits of the study, and possible risks involved with the research study.

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

Research Team Member Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_

Research Team Member Signature Date

**--------------------------------------------------------------------------------------------------------------------------------------------------------**

The following are participant signature options which require a different consent from the one in the template above.

**Delete those options not used.**

MINORS: In the event the protocol includes minors, the language below must be included.

**Minors** (individuals under the age of 18) are not legally able to consent to research. Consent must be provided by the participant’s parent or legal guardian. If a child is of an age and mental ability that s/he can understand the concept of research and research activity, the child’s assent must be sought and documented in addition to the parents.

**Minor Assent**

By signing below, you agree that the above information has been explained to you and all your current questions have been answered. You understand that you may ask questions about any aspect of this research study during the study and in the future. By signing this form, you agree that your child may participate in this research study.

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

Parent’s Printed Name

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

Parent’s Signature Date

PRINT THE CHILD’S NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Minor’s Assent: This research has been explained to me and I agree to participate.

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

Minor’s Signature Date

ADULTS LACKING THE CAPACITY TO CONSENT: In some cases, consent cannot be obtained from an adult participant because the research participant lacks the ability to read and comprehend the consent form (for example, the participant may have diminished cognitive abilities). In such cases, the researchers should seek the participant’s assent to participate in the study and the consent of the person legally responsible for the participant. If the participant does not wish to participate in the study, he/she cannot be enrolled in the study unless the person legally responsible for the participant determines that it is in the participant’s best interest.

In the event the protocol includes **adults lacking the capacity to consent**, the language below must be included.

**Adult Assent**

If you cannot give legal consent to take part in this study because you may have trouble reading or understanding this consent form, then the researcher will ask for your assent. Assent is your agreement to be in the study. The researcher will explain the study to you in words that you can understand. You should ask questions about anything you don’t understand. Then you should decide if you want to be in the research study. If you want to participate, you or someone who can sign a legal document for you must also give their permission and sign this form before you take part. By signing below, you agree to participate in this study:

PRINT the Adult’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Participant’s Signature Date

Consent of Guardian / Representative

If you have authority to consent on behalf of the above-named participant, please print your name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and indicate your relationship to the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

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

Participant’s Legal Guardian Signature Date

IRB 6/2019