|  |
| --- |
| **ASSENT FOR MINOR CHILDREN** |

**Instructions: \*The information in red is for guidance. Please remove and replace all red text (including these instructions) and insert study specific information in black ink prior to submitting this document with your IRB application for formal review. Please make sure the language and terms used is understandable to the age of the subjects you will be assenting.**

**TITLE:** “Insert the complete title of the study which needs to be in quotation marks”

**WHO IS DOING THE STUDY:** (Insert the PI’s complete name)

(Insert the title of PI)

(Insert the address of PI)

(Insert the e-mail of PI)

(Insert the phone number of the PI)

**KEY INFORMATION ABOUT THIS RESEARCH:**

The following is a short summary of this study to help you decide whether to be a part of this study or not. Information that is more detailed is listed later on in this form. [The following should be all one paragraph:]

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

You will be asked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [include a brief statement of the procedures that will be done. 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 \_\_\_\_\_\_\_\_\_\_\_\_\_. {hours/days/months/weeks/years, until a certain event] The primary risk of participation is \_\_\_\_\_\_\_\_\_\_\_\_\_\_. The main benefit is \_\_\_\_\_\_\_\_\_\_\_\_\_.

**WHAT AM I BEING ASKED TO DO?**

We are asking you and to take part in a project that (insert topic of the study) because you (insert why subject is eligible for the study). The purpose of the study is to (insert the purpose of the study in layman terms).

**WHAT HAPPENS IF I AGREE TO BE IN THE PROGRAM?**

(In this section describe, in detail, all procedures that children will be asked to complete as part of this study.)

###### In this section, if applicable, you must also explain:

###### how the subjects are to be randomized (e.g. During this phase, you will be assigned by chance (similar to the flip of a coin) to one of two possible treatment groups; (1) or (2). You will have a 50/50 chance of being assigned to one of the treatment groups. Neither study personnel, nor you, will know what treatment you are receiving. However, if necessary, this information is available.)

* If there is more than one group, explain the differences in procedures.
* Explain how this study may be blinded.
* If there is more than one group describe the differences between procedures if any.

**If you feel uncomfortable or upset, you may stop the project at any time**. If you agree to be in the study you will be not given any type of extra credit or special compensation. If you do not agree to be in the project, you will not be punished and no one will be mad at you.

**DURATION:**

In this section, describe how long it will take the children to complete each procedure explained above and how long it will take to complete the entire study.

## RISKS:

In this section, describe the potiential risks associated with the surveys, procedures or anything else involved with the study. Explain about the risk of confidentiality breach if the study is not anonymous. Also explain any potential risks if this is a survey. (e.g. that some questions may upset the individual, they may become tired or bored. **Please do not state here (or in the IRB Application Form) that there are no risks in this study. There are risks in EVERY study.)**

## BENEFITS:

In this section, list all potential benefits related to the study. If there is no direct benefit to the subject, the following text may be used in this section: “There will be no benefit to you from participating in this study. We hope this study provides information, which contributes to the knowledge of (insert subject of the study.”

Include the following sections only if applicable to your study. It not applicable, delete each section.

**Data Use**

Include 1 of the 2 statements below only if your study includes the use of identifiable private information or biospecimens.

“This study includes the use of your identifiable data or biospecimens. The identifiers might be removed from the identifiable private information/biospecimens and after such removal, the information or biospecimens could be used for future research studies. The unidentifiable date could also be distributed by another investigator for future research studies without additional consent from you.”

OR

“Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

**Commerical Profit:**

The specimens we collect from you may be used for commercial profit. You (will/will not) share in this commercial profit.

**Return of Research Results:**

Clinically relevant research results, including individual research results, will/will not be disclosed to you. (If they will be returned, describe under what conditions)

**ASSENT STATEMENT:**

I have listened to someone tell me what this project is and what I will be asked to do. I have been given the chance to ask questions, and my questions have been answered. I would like to participate in this project.

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

Child Signature Date

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

Person Obtaining Assent Date