**PARENTAL CONSENT FOR RESEARCH**

**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.**

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

**PRINCIPAL INVESTIGATOR:** (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. 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 \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Purpose of the study**

Your child is being invited to participate in a study about Type of study because they are state why person is eligible for the study The purpose of the study is to examine (Purpose must be in layman terms)

Approximately (Number of study Participants in Complete Study) subjects will participate in the study with up to Number Recruited from site recruited from this site. Participation in the study will be a minimum of Length of Time Required to Participate.

##### Study Procedures and Duration

Describe all of the study procedures (including questionnaires, surveys, tapings, observations) and the duration for each study. Please make sure this language is directed towards the parents of the children.

###### In this section you must also explain how the children are to be randomized.

(i.e. At the beginning of the study, your child will be assigned by chance (similar to the flip of a coin) to one of two possible groups; (1) or (2). You will have a 50/50 chance of being assigned to one of the groups.

If there is more than one group describe the differences between procedures.

## Risks

Please describe the risks associated with the experimental method, procedure, survey or anything else involved with the study. If this is a survey, please explain about the risk of confidentiality if the study is not anonymous. Also explain that some questions or procedures may upset the individual and if this occurs they may stop at any time. **Please do not state that there are no risks in this study. There are risks in EVERY study.**

## Benefits

Please list all benefits related to the study. If there are no direct benefits to the children involved, use the example text below:

There will be no benefit to your child from participating in this study. We hope this study provides information, which contributes to the knowledge of (insert subject of the study).

### Costs

Please correct the following statement as needed:

“All study procedures required by the protocol will be provided free of charge during your child’s participation in this project. (If this is educational research, are the participants expectants to purchase any special software, books, supplies) You and your insurance company are responsible for the costs related to routine medical treatment and if in doubt about reimbursement, you should contact your third party payor. (The foregoing statement only applies if this is a medical research study and can be removed in education research protocols")

If there are no costs involved in the study, state:

There is no cost to you or your child for participating in this study.

**Impartial Third Party Contact**

If you wish to contact an impartial third party not associated with this study regarding any complaint you may have about the study or if you have questions about your child’s rights as a subject in this study, you may contact Steve Schmidt, Ph.D., Human Protections Administrator, Northeast Ohio Medical University, Rootstown, Ohio, 44272, phone (330) 325-6465 for information and assistance.

**Confidentiality**

If you agree for your child to become part of this study, his/her name will be held in confidence. Only the study staff, sponsor representatives involved in this study, independent ethics committees and those required by law will have direct access to the study records.

**Voluntary Participation / Early Withdrawal**Your child’s participation in this study is voluntary. Either you or your child may choose for your child to not to take part in the study, either of you can withdraw from the study at any time. Your child will not lose any benefits to which they are otherwise entitled. They will not be prevented from participating in future studies.

**Significant New Findings**

You will be told in a timely manner of any significant new information that may affect your willingness to have your child stay in this study.

**Conflict of Interest: PLEASE ADJUST THE FOLLOWING SECTION AS NEEDED**

## This research is funded (Either insert the Sponsor Name or state “not funded”) . The research team (is or is not) being compensated (Sponsor Name if applicable) for conducting the study. The researchers (do or do not) however, hold a direct financial interest in what is being studied.

Informed Consent Statement

I have read the contents of the consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent for my child to participate in this study. Signing this consent document does not waive my child’s rights or mine nor does it release the investigators, institution or sponsors from their responsibilities. I may call PI Name or one of her/his associates during routine office hours at Phone.

Include the following sections only if applicable to your study. If 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

I have been given a copy of this consent form and have had this form explained to me.

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Signature of Parent 1 Date

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Signature of Parent 2 (If possible) Date

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Person Obtaining Consent Date

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Signature of Investigator Date