**[Insert Protocol Title]**

**[Insert Principal Investigator Name]**

**ABOUT THIS RESEARCH**

Your child is being asked to participate in a research study. Scientists do research to answer questions and learn new information. Some research might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide whether you want your child to participate. Please read this form and ask any questions you have before agreeing to allow your child be in the study.

**TAKING PART IN THIS STUDY IS VOLUNTARY**

You may choose not to allow your child to take part in the study or may choose for your child to leave the study at any time. Deciding not to allow your child participate, or later deciding to remove your child from the study, will not result in any penalty or loss of benefits to which you and/or your child are entitled and will not affect your or your child’s relationship with [Insert appropriate entity (e.g., university, hospital, school)].

[Insert one of the following:]

As an alternative to participating in the study, you may choose not to allow your child to take part. [If declining to participate affects a child’s care or participation in school or other activities, please explain here. For example, if the research involves classroom instruction, explain if other activities are available which would allow a child to remain in the classroom but not participate in the research.]

***or***

As an alternative to participating in the study, [Insert description of alternative procedures that may be available to the child, including standard therapy, education, or treatment without participating in the study].

**WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to [Insert explanation for why the research is being completed].

Your child was selected as a possible participant because [Insert explanation regarding how the subject was identified]*.*

The study is being conducted by [Insert investigator(s) name(s) and University/Departmental affiliation]. It is funded by [Insert Sponsor or funding agency name, if any].

**HOW MANY PEOPLE WILL TAKE PART?**

If you agree to allow your child to participate, your child will be one of [Insert number of subjects. It may also be appropriate to include the number of subjects in different cohorts or groups, if applicable] participants taking part in this study.

**WHAT WILL HAPPEN DURING THE STUDY?**

If you agree to allow your child to be in the study, your child will be asked to do the following things:

[Insert explanation of all activities/tests that are included in the study (e.g., assignment to study groups, study visits, surveys and questionnaires, focus groups, audio or video recordings, etc.). Include the following:

* Where the activities are performed and how frequently they are performed
* The expected amount of time each activity and/or visit will last
* The length or duration of subject participation
* Which activities are experimental and which would be done even if the subject does not participate in the research

**WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?**

While participating in the study, the potential risks include:

[Insert explanation of the risks, side effects, and/or discomforts of each of the activities completed in the study (e.g., physical, psychological, social, legal).

Examples of risk statements include:

* A risk of completing the survey is being uncomfortable answering the questions.
* There is a risk of possible loss of confidentiality.

[Insert an explanation of measures that will be employed to minimize the risks listed above. If applicable, include an explanation of any psychological, social, or medical services that may be required because of participation in the research (e.g., counseling, social support services, or medical services). If there are significant psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study.

Examples include:

* While completing the survey, you can tell the researcher that you feel uncomfortable or that you do not want to answer a particular question.

**WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?**

[Insert one of the following:]

We don’t expect your child to receive any benefit from taking part in this study, but we hope to learn things that will help scientists in the future.

***or***

The benefits to participation in the study that are reasonable to expect are [Insert a description of any direct benefit to the subject or benefit to others that may reasonably be expected from the research.]

NOTE: Payment to subjects is not considered a benefit of participating in the study and should not be listed in this section. If applicable, list it under the *Will I be Paid for Participation* section.

**HOW WILL MY CHILD’S INFORMATION BE PROTECTED?**

Efforts will be made to keep your child’s personal information confidential. We cannot guarantee absolute confidentiality. Your child’s personal information may be disclosed if required by law. No information which could identify your child will be shared in publications about this study [***Include the following, if applicable***, “and databases in which results may be stored.”]. [***If audio or video recordings will be made***, insert an explanation regarding who will have access to the recordings, if the recordings will be used for educational purposes, and when the recordings will be destroyed.]

Organizations that may inspect and/or copy your child’s research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the University of Notre Dame Institutional Review Board or its designees, [Insert Sponsor name, if applicable], and (as allowed by law) state or federal agencies, especially the Office for Human Research Protections (OHRP), who may need to access the research records.

[***If subjects will be recorded on photograph, video or audio and the subject can decline that recording***, insert the following:] We are recording [photograph/audio/video] of your child as a part of the study. Please let us know whether you agree to allow us to record your child:

\_\_\_\_\_\_ Yes, I agree to having my child’s photograph/audio/video used in the study.

\_\_\_\_\_\_ No, I do not agree to having my child’s photograph/audio/video used in the study.

[***If it is reasonably foreseeable that the study will have access to or collection of information that may legally require reporting to other officials,*** insert the following language***:***]

Laws require that we report information about known or reasonably suspected incidents of abuse or neglect of a child. If any investigator has or is given such information, he or she may be required to report it to the appropriate authorities.

[***If identifiable information from student education records will be disclosed to the study team***, insert the following language:]

The study will involve accessing information about your child which is protected by a law called FERPA. Your child’s student education records must be kept secure by their school, and can only be disclosed to researchers like us with your consent. The records we need to access for this study include the following: [Insert description of student education records to be disclosed to the study team]. The only people who will have access to these records for the research are [Insert description of those who have access to the identifiable information within the study team].

**WILL MY CHILD’S INFORMATION BE USED FOR RESEARCH IN THE FUTURE?**

[***If the research involves the collection or use of identifiable private information or biospecimens***, insert one of the following:]

Information or biospecimens [collected from your child] for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify your child will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent. [If re-identification is possible (i.e. more than a theoretical risk), insert a statement to that effect and describe any risks.]

***or***

Your child’s information or biospecimens will not be used or distributed for future research studies.

**WILL I BE PAID FOR PARTICIPATION?**

[Insert one of the following:]

Neither you nor your child will be paid for participating in this study.

***or***

[Insert a description of the details and any conditions of payment, including if partial payment is applicable]

**WHAT FINANCIAL INTEREST DOES THE RESEARCHER HAVE?**

[***If an investigator has a financial interest in this research***, insert the following:] One or more individuals involved in this study may benefit financially from this study. The Institutional Review Board (an ethics committee that helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.

**WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?**

For questions about the study, contact the researcher, [Insert name of investigator], at [Insert telephone number].

For questions about your or your child’s rights as a research participant, to discuss problems, complaints, or concerns about a research study, please contact Notre Dame Research Compliance at 574-631-1461 or at compliance@nd.edu.

**WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?**

[***If the subject’s parents may be re-contacted in the future***, insert the following:] If you agree, we may contact you after your child’s participation is over to request additional information. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I agree to be contacted for the purpose of collecting additional information.

\_\_\_\_\_\_ No, I do not agree to be contacted for the purpose of collecting additional information

**PARENTAL CONSENT**

In consideration of all of the above, I give my consent for my child to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to allow my child to take part in this study.

**Child’s Printed Name:**

**Printed Name of Parent:**

**Signature of Parent**: **Date**:

**Printed Name of Person Obtaining Consent:**

**Signature of Person Obtaining Consent**: **Date**:

[***If two (2) parents are required to provide consent for their child’s participation***, include the following:]

**Printed Name of Parent:**

**Signature of Parent**: **Date**: