**[Insert Protocol Title]**

**[Insert Principal Investigator Name]**

**ABOUT THIS RESEARCH**

You are 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 to participate. Please read this form and ask any questions you have before agreeing to be in the study.

**TAKING PART IN THIS STUDY IS VOLUNTARY**

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

**WHY IS THIS STUDY BEING DONE?**

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

You were 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 participate, you 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 be in the study, you 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 you 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 INFORMATION BE PROTECTED?**

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study. [Include the following, if applicable, “and databases in which results may be stored.” Also, 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 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.

This study is being done by researchers from the United States of America. General Data Protection Regulation is a European law which affords certain protections to individuals with respect to data that identifies them. As a research subject, we are asking for your consent to collect information about you for use in the research described in this form. If you have concerns about your information being used outside the EU, we recommend that you decline participation in this study.

**WILL MY 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 specimens [collected from you] 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 you 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.]

**WILL I BE PAID FOR PARTICIPATION?**

[Insert one of the following:]

You will not 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 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 subjects may be contacted in the future**, insert the following:] If you agree, we may contact you after your 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

**CAN I WITHDRAW FROM THE STUDY?**

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, [explain the procedure for withdraw from the study].

**PARTICIPANT’S CONSENT**

In consideration of all of the above, I give my consent 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 take part in this study.

**Participant’s Printed Name:**

**Participant’s Signature**: **Date**:

**Printed Name of Person Obtaining Consent:**

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

[**If the study involves children whose parents will provide consent for their child’s participation**, include the following:]

**Printed Name of Parent:**

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

[**If the study involves individuals who cannot consent for themselves**, include the following:]

**Participant’s Printed Name:**

**Printed Name of Legally Authorized Representative (LAR)**:

**Signature of LAR**: **Date:**