**[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 information will tell you more about the study to help you decide whether you want to participate. Please read this information 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 and will not affect your relationship with [Insert appropriate entity (e.g., university, hospital)].

[Insert one of the following:]

As an alternative to participating in the study, you may choose not to take part.

***or***

As an alternative to participating in the study, [Insert description of alternative procedures that may be available to the subject].

**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.”]. [***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.

[***If the study is being conducted through Amazon MTurk***, insert the following:]

Your Mechanical Turk Worker ID will be used to distribute payment to you but will not be stored with the research data we collect from you. Please be aware that your MTurk Worker ID can potentially be linked to information about you on your Amazon public profile page, depending on the settings you have for your Amazon profile. We will not be accessing any personally identifying information about you that you may have put on your Amazon public profile page.

**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.]

***or***

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

**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. If the study has multiple parts and there is a separate payment for each part, describe the total amount of payment if the subject completes the entire study and also the payment for each part of the study.]

[***If the study is being conducted through Amazon MTurk***, insert the following:]

MTurk does not allow for prorated compensation. In the event of an incomplete HIT, [select one of the following:]

you will not receive any compensation.

***or***

you may receive partial compensation [describe plan to provide partial compensation.]

This study contains a number of checks to make sure that participants are finishing the tasks honestly and completely. As long as you read the instructions and complete the tasks, your HIT will be approved. If you fail these checks, your HIT will be rejected and you will not receive any compensation.

**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.

**PARTICIPANT’S CONSENT**

In consideration of all of the above, I give my consent to participate in this research study. By proceeding, I confirm that I am 18 years old, and agree to take part in this study.