**[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 OTHER OPTIONS?**

[Insert one of the following statements:]

There may be other options for your clinical care, including [Insert details regarding other possible options such as standard therapy care, drug treatment, management of symptoms, etc.].

***or***

You have the option to choose not to participate in this study.

**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.

**WILL I RECEIVE MY RESULTS?**

[***If relevant results will be returned***, insert one of the following:]

We may learn things about you from the study activities which could be important to your health or wellbeing. [If applicable, insert a description under what circumstances subjects will be provided research results and how subjects will be notified.] You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

**or**

We may learn things about you from the study activities which could be important to your health or wellbeing. If this happens, you can decide whether you want this information to be provided to you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.] If you decide that you want this information, you may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions. Please initial one of the following options:

\_\_\_\_\_\_ Yes, I want to be provided with this information.

\_\_\_\_\_\_ No, I do not want to be provided with this information.

**or**

[***If relevant results will not be returned***, insert the following:] We may learn things about you from the study activities which could be important to your health or wellbeing; however, we will not share any of these research results with you.

**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.

**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]

**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.

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***The sections that follow should be inserted when applicable to the study. Please review them, revise and include any which apply, and remove all that do not apply to your study.***

**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]. [***If withdrawal from the study prior to completion could pose risk to the subject***, insert a description of what those risks might be and how orderly termination will occur.]

[***If appropriate***, insert the following:] Your participation may be terminated by the investigator without regard to your consent in the following circumstances: [Insert a description of when and why study participation may be terminated and how orderly termination will occur].

[***If appropriate***, insert the following:] You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be terminated by [Insert Sponsor/investigator, as appropriate] if [Insert a reason for possible premature termination].

[***If the study is a clinical trial***, insert the following:] A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[***If the study is NIH funded***, you automatically receive a Certificate of Confidentiality, and must include this section. If the study is not NIH funded but the study has obtained or intends to obtain one, insert the following, as appropriate:] For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

1. if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
2. if you consent to the disclosure, including for your medical treatment;
3. if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
4. for the purpose of auditing or program evaluation by the government or funding agency.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[***If the study involves genetic testing or the tracking of a particular disease or disorder in an individual’s family***, insert the following:] This research follows the Genetic Information Nondiscrimination Act (GINA), a federal law that generally makes it illegal for health insurance companies, group health plans, and most employers to request the genetic information we get from this research and to discriminate against you based on your genetic information.

[***If the study involves the collection of biospecimens***, insert the following as appropriate:] We may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. [Insert a description including what information will be gained, how the information will be used and stored, any risks of whole genome sequencing, and whether the information will be provided back to the subject, and, if so, whether it may be clinically relevant.]

**WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?**

[***If a physical injury is reasonably foreseeable as a result of participation***, insert the following:] In the event of physical injury resulting from your participation in this study, [Insert description of plan to provide care to subjects injured during research]. It is your responsibility to determine the extent of your health care coverage. [Insert one of the following two options:] There is/There is not a program in place for other monetary compensation for such injuries. You will be responsible for seeking medical care and for any necessary expenses associated with any care received.

[***If a source of funds for payment of treatment costs is available*,** insert a description of the source and conditions for payment of those costs.]

**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.

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**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:**