# Informed Consent Form

Principal Investigator:

Other Investigators:

Participant ID:

## Introduction

## Section 1. Purpose of the Research

## Section 2. Procedures

## Section 3. Time Duration of the Procedures and Study

## Section 4. Discomforts and Risks

You may choose not to participate in this study due to the potential risks outlined above.

## Section 5. Potential Benefits

## Section 6. Statement of Confidentiality

This section contains information about the confidentiality of information collected during this study. Note that, as applicable, a description of this clinical trial may become available on http:///www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

## 6a. Privacy and confidentiality measures

## 6b. The use of private health information

## Section 7. Costs for Participation

## 7a. Costs:

## 7b. Treatment and compensation for injury:

## Section 8. Compensation for Participation

## Section 9. Research Funding

## Section 10. Voluntary Participation

Taking part in this research study is completely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Note that the Principal Investigator of this study may take you out of the research study at their sole discretion. Some reasons for this may include: 1) you did not follow the study procedures, 2) the risks of potential harm from the study became too high, or 3) the study was concluded earlier than expected. The Principal Investigator may have separate reasons instead of, or in addition to, those listed. If you do not sign this form, you will not receive research-related interventions.

## Section 11. Contact Information for Questions or Concerns

[Check this section carefully. Contact information may need to be manually filled in.]

You have the right to ask any questions you may have about this research study. If you have questions, concerns, or complaints, or believe you may have developed an injury related to this research, contact the study team immediately. The study team’s contact information is below:

Contact:

Phone:

Email:

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or, as applicable, about your privacy and the use of your personal health information, contact the applicable Institutional Review Board. Contact information is listed below:

Contact:

Phone:

Email:

## Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

Discussed this study with an investigator,

Reviewed the information in this form, and

Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant:By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

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| Signature of Participant | Date | Time | Printed Name |

Participant’s Legally Authorized Representative:By signing below, you indicate that you give permission for the participant to take part in this research.

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| Signature of Participant’s Legally Authorized Representative | Date | Time | Printed Name |

(Signature of Participant’s Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative’s Authority to Act for Participant:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Person Explaining the Research:Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

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| Signature of person who explained this research | Date | Time | Printed Name |

*Only approved investigators for this research may explain the research and obtain informed consent.*

*A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.*