**RESEARCH SUBJECT CONSENT FORM**

**Title:** Title

**Protocol No.:** Sponsor

**Sponsor:** Name

**Investigator:** Name

Address

City, State, Zip Code

Country

**Daytime Phone Number:** Phone Number

**24-hour Phone Number:** Phone Number (A 24-hour phone number is required for studies that are more than minimal risk)

Use the Short Form consent process for situations where you encounter a potential participant for whom a full-length version of the consent form is not appropriate for the participant and it is in the participant’s best medical interest to be enrolled in the research. Situations that generally meet this condition include:

o Low literacy

o Visual impairment.

The regulations require the following signatures when using the Short Form process

|  |  |
| --- | --- |
|  | **Required to Sign** |
| **Person obtaining consent** | Long Form |
| **Witness** | Short Form and Long Form |
| **Subject**  *If the subject is incapable of consent and either a legally authorized representative (as allowed by protocol) or parent(s) signature is required, replace the subject signature block below with the signature block from the IRB approved main ICF* | Short Form |

**Please fill out the study information above and DELETE these highlighted instructions**.

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; (v) how confidentiality will be maintained.

When applicable, the investigator will present key information to you before presenting other information.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; (vii) how many people will be in the study, (viii) use of your biologic specimens for commercial profit, (ix) whether you will be told about your research results, (x) whether the research might include whole genome sequencing (xi) information about the research has been or will be submitted for inclusion in a clinical trial registry, and (xii) future research use of your information or biologic specimens.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact the research team at the phone number above any time you have questions about the research.

You may contact the IRB at (phone number) if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

|  |  |  |
| --- | --- | --- |
| Your signature documents your consent to take part in this research. | | |
|  |  |  |
| Signature of adult subject capable of consent |  | Date |
|  |  |  |
| My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. | | |
|  |  |  |
| Signature of witness to consent process |  | Date |