**IRB-HSR#:**

**Consent to Participate in Research**

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; and (v) how confidentiality will be maintained.

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; and (vii) how many people will be in the study.

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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ phone number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ any time you have questions about the research.

You may contact the University of Virginia Institutional Review Board for Health Sciences Research (IRB-HSR) at phone number (434)-924-2620 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.

**Consent from Adult**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_\_  DATE |

*To be signed by the participant who is 18 years of age or older.*

**Interpreter**

By signing below, you confirm that the study has been fully explained to the potential subject in a language they understand, and all their questions have been answered.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

*NOTE: Study team member obtaining consent must sign long version of consent form.*

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

*If short form will be used in a study where children are enrolled, insert the following signature section(s) (where applicable) translated into the language of the short form.*

**Parental/Guardian Permission**

By signing below, you confirm you have the legal authority to sign for this child.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |
| ***Second parent/guardian signature section to be added if there is risk but no benefit to the participant.*** | | | | | | |
|  |  |  |  |  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |

*NOTE: Study team member obtaining permission must sign long version of consent form.*

**Assent from Child**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |
| **To be completed for any child aged 7 to <18.** | | | | | | |

*NOTE: Study team member obtaining assent must sign long version of consent form.*

**Interpreter**

By signing below, you confirm that the study has been fully explained to the parent/ guardian and the child (less than 18 years of age) in a language they understand and have answered all their questions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER  (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |  |  |

***Surrogate Consent (Giving approval for another adult to be in the study)***

*To be used in the event the adult participant is unable to give informed consent for participation in this study. This section may only be used if IRB has approved surrogate consent.*

**Surrogate Consent**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PERSON GIVING CONSENT FOR PARTICIPANT DATE

(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*NOTES: Study team member obtaining consent must sign long version of consent form.*

*If the study is approved by the full board, the attending physician must sign the long version of the consent form.*

**Interpreter**

By signing below, you confirm that the study has been fully explained to the surrogate in a language they understand and have answered all their questions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER  (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |  |  |

**Consent of the Participant to Continue to Be in the Study**

Your legal representative gave his/her permission for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this study. The decision is up to you. Before you sign this form, please ask questions about any part of this study that is not clear to you. When you sign below, you are saying you understand the information we gave you about the study and in this form.

**If you sign this form, it means that you agree to continue being in the study.**

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

PARTICIPANT PARTICIPANT DATE

(SIGNATURE) (PRINT)

*NOTE: Study team member obtaining consent must sign long version of consent form.*

**Interpreter**

By signing below, you confirm that the study has been fully explained to the subject in a language they understand and have answered all their questions.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER  (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |  |  |