**Consent to Receive Treatment Involving a Humanitarian Use Device (HUD)**

You are being asked to consider treatment involving the use of a Humanitarian Use Device (HUD), which is a medical device intended to benefit patients in the treatment or diagnosis of a disease that affects or is manifested in fewer than 8,000 individuals in the United States per year.

Before you agree, the investigator must tell you the following things:

1. that the effectiveness of the device for this use has not been demonstrated;
2. that the HUD is designed to diagnose or treat the disease or condition described in the device labeling and that no comparable device is available to treat the disease or condition;
3. any additional procedures associated with the use of the HUD;
4. a description of the use of the HUD;
5. all known risks or discomforts associated with the use of the HUD; and
6. an explanation of how the HUD will work in relation to your disease or condition.

If you agree to receive treatment with the device, you must be given patient labeling (such as a brochure) that includes all of the information listed above.

You may contact \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ at phone number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ any time you have questions about your care.

Signing this document means that the above information has been provided to you, you have had a chance to ask questions, and that you voluntarily agree to receive treatment with the device.

**Consent from Adult Patient** *(To be signed by patients who are 18 years of age or older)*

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

Adult Patient’s Name (Printed) Adult Patient’s Signature Date

**[NOTE: DELETE THE LEGALLY AUTHORIZED REPRESENTATIVE LINES UNLESS THE PROTOCOL ALLOWS FOR THE INVOLVEMENT OF ADULTS WHO ARE UNABLE TO PROVIDE CONSENT]**

**Consent from Legally Authorized Representative (LAR) for an Adult Patient**

(*To be signed when an adult participant is unable to give informed consent)*

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

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

LAR’s Name (Printed) LAR’s Signature Date

LAR’s Relationship to the Adult Patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[NOTE: DELETE THE PARENT/LEGAL GUARDIAN AND ASSENT LINES UNLESS THE PROTOCOL ALLOWS FOR THE TREATMENT OF CHILDREN]**

**Permission from Parent/Legal Guardian for a Child Patient**

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

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

Parent/Legal Guardian’s Name (Printed) Parent/Legal Guardian’s Signature Date

**Assent from Child Patient** *(To be signed by child patients ages 7 to <18)*

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

Child Patient’s Name (Printed) Child Patient’s Signature Date

**[NOTE: INCLUDE THE FOLLOWING SIGNATURE LINES IN ALL CONSENT FORMS]**

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

Person Conducting Consent Discussion’s Name (Printed) and Signature Date

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

Principal Investigator Signature (if different from above) Date