**[USE YOUR DEPARTMENT LETTERHEAD]**

**CONSENT FOR THE USE OF HUMANITARIAN USE DEVICE (NAME OF HUD)**

**Clinician:** [Add the Clinician’s name and credentials here (i.e., M.D., Ph.D., etc.).]

**INSTRUCTIONS:**

* **[BLUE]** highlighted text provides instructions to guide you in constructing the consent document.
* Delete all **[BLUE]** instructional text before submitting the document to the IRB.
* The consent document should be written in lay language.

This form is designed to provide you with information about the humanitarian use device used in the procedure you will have performed. Please take the time to review this information before you consent to its use.

**What is a Humanitarian Use Device?**

A Humanitarian Use Device is a device used to diagnose or treat a disease or condition that affects fewer than 8,000 individuals in the United States per year, for which no comparable device is available. Although the device is authorized by Federal law for use in the [choose treatment or diagnosis] of [specify the disease or condition], the effectiveness of the device for this use has not been demonstrated.

**Why is this procedure being done with this device?**

You are being asked to consent to the use of [name of device] because your doctor has determined that [provide a rationale for use and explain in lay terms the hypothesized mechanism of action of the HUD in relation to the disease or condition].

**What will be involved with the use of this device?**

[Prove a description of the use of this device and any additional procedures involved in its use.]

**What are the risks of harm from the use of this device in this procedure?**

[Specify all known risks or discomforts from the use of the HUD in the procedure.]

**What are the benefits of this procedure?**

[Specify the benefits to the patient from the use of the HUD in the procedure.]

**What are the alternatives to the use of this device?**

Instead of consenting to the use of [name of device], the following alternative treatments are available: [Itemize treatment alternatives to the use of the device. If there are no alternatives, state that here.]

**Who can I call for more information?**

Dr. [name of clinician] is available to answer any questions or concerns that you may have and can be reached at [phone number].

If you wish further information regarding the Institutional Review Board’s review of the use of this device in clinical care, contact the Rutgers Human Research Protection Program at (973) 972-3608 or (732) 235-9806 or email at IRBOffice@research.rutgers.edu.

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| **Agreement to the use of a Humanitarian Use Device in Clinical Care**I agree to the use of a Humanitarian Use Device in my clinical care. I have received a copy of the product labeling information from the clinician that was provided by the holder of the Humanitarian Use Device Exemption. **Signature Section:**[To document the patient's (or their legally authorized representative) consent to the use of HUD for clinical care. Follow the clinical site’s conventions for documentation of consent unless directed by the IRB to document following an IRB documentation template. At a minimum, the patient’s name, signature, and date the patient reviewed with the clinician the use of the HUD in their care and consented to its use must be documented.] |