The University of Texas Southwestern Medical Center at Dallas

**HUMANITARIAN USE DEVICE CONSENT**

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| Name of Device: |
| Device Manufacturer: |
| Physician Name: | Telephone No.(regular office hours) | Telephone No.(other times) |
|  |  |  |

A Humanitarian Use Device (HUD) is intended for use in patients with conditions that affect less than 4,000 people in the United States.

Since the number of patients is so small, the Food and Drug Administration (FDA) has approved the use of HUDs for the clinical treatment of patients without the same amount of testing that other products get. The FDA believes that these devices are likely to be safe and will probably benefit patients.

**DESCRIPTION:** [insert the name of the device and describe its uses. Provide information on why the patient is a candidate for the use of the device].

**POSSIBLE RISKS:** [provide information describing the possible risks, side effects and/or adverse events associated with the HUD and its proposed use].

**POSSIBLE BENEFITS:** [provide information regarding the benefits associated with the use of the device].

**ALTERNATIVE TREATMENTS:** [describe alternative treatments that may be available to patients].

**ESTIMATED COSTS:** [provide the estimated costs to the patient for the device].

**YOU WILL HAVE A COPY OF THIS CONSENT FORM TO KEEP.**

Your signature below certifies the following:

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| --- | --- | --- |
| • |  | You have read (or been read) the information provided above. |
| • |  | You have received answers to all of your questions. |
|  |  | You have received and read the manufacturer’s information about this device. |
| • |  | You have freely decided to allow your doctor to use this device in your care. |
| • |  | You understand that you are not giving up any of your legal rights. |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient’s Name (printed) |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Patient’s Signature |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date / Time: AM-PM |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Legally authorized representative’s name (printed) |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Legally authorized representative’s Signature |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date / Time: AM-PM |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name (printed) of person obtaining Consent |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature of person obtaining consent |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date / Time: AM-PM |