CLINICAL CONSENT FOR USE OF A HUMANITARIAN USE DEVICE

TITLE: Humanitarian Use Device: [Device Name]

What is a Humanitarian Use Device?

*Use the following standard clause:*

A Humanitarian Use Device is a device used to diagnose or treat a disease or condition that affects fewer than 4,000 individuals in the United States per year and for which no comparable device is available. The U.S. Food and Drug Administration (FDA) approves the use of Humanitarian Use Devices based primarily on evidence that it does not pose a significant risk of injury to the patient and that the potential benefit of the device to the health of the patient outweighs the risks of its use. The use of the Humanitarian Use Device, “[name of device]” for [name of disease or condition] is approved by the FDA.

The use of [name of device] does not involve research.

Why does my doctor want to use this device?

*This section should describe the specific indication for use of the HUD.*

What will be involved with the use of this device?

*This section should describe the placement and use of the HUD. Describe procedures chronologically using simplistic language, short sentences (1-3 lines) and short paragraphs (less than 6 sentences). Use subheadings as appropriate to organize this section and increase readability.*

What are the possible risks associated with the use of this device?

*Describe the risks associated with placement and use of the device, using simplistic language. The most serious and common risks should be addressed first followed by disclosure of uncommon and less serious risks in a separate paragraph, if warranted. Provide incidence data if available and appropriate.*

Conclude with the following standard clause:
It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

What are the possible benefits associated with the use of this device?

Describe the potential benefits of use of this device, with particular reference to the patient’s disease or condition.

What alternative treatments or procedures are available?

Describe, in reasonable detail, therapeutic alternatives the patient may have available.

What will use of this device cost you?

Use the following standard clause:

You or your insurance provider will be responsible for all costs associated with the placement and use of the [name of the device]. You will also be responsible for all costs related to the treatment of your [name of disease or condition].

Documentation of Consent

Use the following standard clauses:

You are freely making a decision whether to allow your physician to use this device. Signing this form means that (1) you have read and understood this consent form, (2) you have had the consent form explained to you, (3) you have had your questions answered and (4) you have decided to use this device.

If you have any questions, you should talk to one of the physicians listed below. You will be given a copy of this consent form to keep.

Signature of Patient:     Date:
My signature certifies that all the nature and purpose, the potential benefits and possible risks associated with the [name of device] and its proposed clinical use have been explained to the above individual and that any questions about this information have been answered. In my judgment, the participant possesses the legal capacity to give informed consent and is voluntarily and knowingly giving informed consent.

Signature of Physician:     Date: