|  |
| --- |
| **IRB Study Number:**  **Title:** |

**Expanded Access IDE (“Compassionate Use”)**

|  |  |
| --- | --- |
| NAME OF DEVICE | |
| CONDITION THAT WILL BE TREATED |  |
| IDE NUMBER | IDE HOLDER |

**Confirmatory Statements:**

I confirm that the following statements are true:

(1) The patient is (was) confronted by a life-threatening or serious disease or condition that is not an emergency. Life threatening: Diseases or conditions where (1) the likelihood of death is high unless the course of the

disease is interrupted or (2) there is a potentially fatal outcome. The condition need not be immediately lifethreatening or to immediately result in death. Serious diseases or conditions: Diseases or conditions involving risk or serious irreversible morbidity, such as sight-threatening or limb-threatening conditions, paralysis, stroke.

(2) There is no generally acceptable alternative for treating the patient.

(3) This particular use of the device is not already approved under an existing IDE.

(4) The patient does not qualify for the device through an ongoing clinical investigation.

**NOTE: *If all statements are not true, you must complete the full IRB application. If you intend to collect safety and effectiveness data for a use other than the IDE-approved indication(s), you must comply with the IND regulations at 21 CFR Part 812 in addition to complying with the requirements for IRB approval (21 CFR Part 56) and protection of human subjects (21 CFR Part 50).***

**Background**

1. Provide a brief description of the device:
2. What disease(s) or condition(s) will the device be used to treat or diagnose?
3. What alternatives are available to treat or diagnose the disease(s) or condition(s) described above?
4. Describe the patient or population who will receive the drug, including criteria for determining patient eligibility (i.e., screening procedures).

**Subject Population**

Requested number of patients:

Notes:

* This is a specific number and you must not exceed this number. To increase the number of approved patients, a modification must be submitted to the IRB and approved prior to using the IND in additional patients.

Age Range (check all that apply):

Newborn to 17 years of age\*

18 or older

**Procedures**

# Summarize the procedures for use of the device, including any ancillary procedures associated with use of the device such placement or implantation. Include any follow-up visits, tests or procedures.

1. Is any training required from the manufacturer or IDE holder (sponsor) prior to the health care practioner using the device?

No

Yes.

**If Yes**, Describe the training and indicate who will receive training.

1. Describe how the device will be controlled, including the storage location, the procedures for storage, dispensing, and limiting access to the individuals listed as personnel on this application to prevent the inappropriate use of the drug or the use by non-approved health care practitioners.

# Outline the schedule for monitoring the clinical use and safety of the device, including follow-up patient visits, tests, or procedures.

# What financial obligations will the patient incur as a result of receiving this drug?

**Risks and Benefits**

1. List the **possible risks** and/or adverse events associated with the clinical use of the device (include risks associated with ancillary procedures required for use of the device, such as placement or implantation) and how will risks be minimized:

2. List the **potential benefits** to the patient associated with the clinical use of the device:

3. Please describe how you will monitor the safety of the patient. (for example: sponsor medical monitor, AE reporting, protocol specific safety features like stopping rules, etc).:

**Patient Identification and Informed Consent**

1. How will potential patient(s) be initially identified?
2. Please describe the proposed consent process.
3. Please discuss whether there will be any waiting period between informing the prospective subject and obtaining consent, (e.g., does the indication for the IDE require consenting of potential patients emergently?).

**Notes:**

* *If the PI plans to delegate the responsibility for obtaining informed consent, please ensure that all individuals are listed on the study personnel list in IRBIS.*
* *Please upload the consent document(s) that you intend to use.*

**Required Attachments**

1. Documentation of IDE
2. Device Description
3. Informed consent form written for specific treatment (template available at \_\_\_\_\_\_\_\_\_\_)
4. Treatment protocol, if available