**Application for Continuing Review / Progress Report Submission**

**For a HUD for Clinical Use ONLY**

|  |
| --- |
| **Use this Progress Report only to request continuation approval by the IRB to use a HUD for clinical use only.** **CAUTION: If an HUD is part of a Clinical Investigation, please use the regular progress report form – DO NOT USE THIS FORM.****The progress report and all required materials must be provided to the IRB within at least three (3) weeks in advance of the expiration date.** |

1. **GENERAL INFORMATION**
2. **Protocol Title:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **Principal Clinician**
 |       | **Dept:** |       | **Box:** |     |
| 1. **Contact Information:**
 | **Phone # (required):**       **Email (required):**      **Alternate E-mail (optional):**       |

1. **Status:**

[ ]  Downstate Clinician

[ ]  NYC H+H, Kings County Clinician

[ ]  Other. Specify:

1. **If someone, other than the PI, is the main contact for this study, please provide his/her contact information below:**

|  |  |
| --- | --- |
| **Name (if not PI):**      **Role on Study:**       | **Phone:**       **Email:**       |

1. **TABLE OF CLINICAL STAFF:**

 *If additional space is needed, please continue on a separate page using the same format.*

|  |  |  |
| --- | --- | --- |
| a. Name & degree | b. Place of employment | c. Will this person be obtaining verbal or written Informed Consent/Authorization |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |
|       | [ ]  SUNY Downstate[ ]  NYC H+H, Kings County[ ]  Other:       | [ ]  Yes [ ]  No |

 ***Attach additional pages if needed.***

1. **CURRENT STATUS (Check all that apply)**

 **[ ]  No patients have used the HUD**

 **[ ]  There are still plans to use the HUD**

 **[ ]  There are no longer any plans to use the HUD**

1. **ADDITIONAL INFORMATION:**
2. **Since the last IRB review, was the HUD used for an “off label” purpose?**

**[ ]  Yes [ ] No If yes, provide a summary:**

1. **Since the last IRB review, how many patients were diagnosed or treated with the HUD?**
2. **Since the IRB originally approved the HUD use, how many patients were diagnosed or treated with the HUD?**
	1. **How many patients died during their participation period?**
	2. **How many patients have completed diagnosis/treatment and are no longer being followed?**
3. **Since the last IRB review, please describe the clinical experiences with the device. As applicable, include information regarding 1) impact on clinical care, 2) whether the patients received any benefits, and/or 3) types of patients diagnosed or treated with the HUD:**

1. **Since the last IRB review, was informed consent obtained from all patients or their legally authorized representative?**

**[ ]  Yes [ ] No [ ]  N/A If no, explain:**

1. **Since the last IRB review, have all appropriate follow-up precautions, monitoring, and evaluations with the patients been completed?**

**[ ]  Yes [ ] No [ ]  N/A If no, explain:**

1. **Since the last IRB review, where there any changes with indications, locations, or patient populations? [ ]  Yes [ ] No**
	1. **If yes to (F):**
		1. **[ ]  All changes implanted have been previously reported to and approved by the IRB**
			1. **Provide a summary of previously approved amendments:**
		2. **[ ]  The changes described below have been implemented but were not submitted to or approved by the IRB.**
			1. **Give a brief description of the change(s) made:**
			2. **Explain why the IRB approval was not obtained prior to making the change(s):**
2. **Since the last IRB review, check if any of the following have occurred:**
	1. **[ ]  FDA Actions**
	2. **[ ]  Changes to the HUD**
	3. **[ ]  HDE amendments/supplements submitted to the FDA**
	4. **[ ]  New indications for use**
	5. **[ ]  FDA withdrawal of approval of HDE**
	6. **[ ]  Temporary suspension of FDA approval**
	7. **[ ]  Complaints about the use of the HUD**
	8. **[ ]  Any publications in the literature relevant to the risks or potential benefits of the HUD**
	9. **[ ]  Newly identified risks**
	10. **[ ]  Change of risks or potential benefits (in the opinion of the clinician)**
	11. **[ ]  Discontinued use of the HUD**

**If any boxes above are checked, provide a summary:**

**Please attach any relevant supportive literature or materials.**

1. **Since the last IRB review, check if any of the following have occurred:**
	1. **[ ]  Device related malfunctions**
	2. **[ ]  Unanticipated adverse device effects**
	3. **[ ]  Serious adverse events**
	4. **[ ]  Serious injury**
	5. **[ ]  Deaths**
	6. **[ ]  Patient withdrawn by clinician**
	7. **[ ]  Patient who decided not to continue**

 **If any of the boxes in (I) where checked, provide a summary:**

**If any of the boxes in (I) where checked, have all occurrences been reported to the applicable oversight bodies (e.g., HDE-holder, HUD manufacturer, FDA, or IRB) within the required reporting period?**

**[ ]  Yes [ ] No**

**If any of the boxes in (I) where checked, was there any remedial action required to prevent an unreasonable risk or substantial harm to a patient or to the public health?**

 **[ ]  Yes [ ] No If yes, explain:**

1. **Since the last IRB review, do any of the employees in the table above have any stock or patent position with the device company, participate in the product design or development of this device, serve as consultant to the HUD manufacturer, have their contact information listed a company directory with the HUD manufacturer, or have any financial interest related to the use of this HUD?**

 **[ ]  Yes [ ] No If yes, explain:**

1. **If you wish to add additional information for the IRB to consider, please add it here:**

 **The IRBNet package must be electronically signed by the Primary Clinician before submitting the package to the IRB.**