# Community Healthcare System Central IRB
# Request to Renew a Humanitarian Use Device (HUD)
# (Form Date: 4/2019)

| Date Submitted: | **IRB use only**<br><br>IRB Number:<br><br>Date Received: |
|---|---|

**NOTE: All questions must be answered in full. The response "see attached" will not be accepted and the form returned for clarification.**

**Submit CHS CIRB Fee Invoice and check for $500.00 with submission for continuing review.**

Approved sites for use of HUD: Please check all that apply
☐ Community Hospital
☐ Saint Mary Medical Center
☐ Saint Catherine Hospital

## PART A: HUD/INVESTIGATOR/COORDINATOR INFORMATION

Name of HUD:

Manufacturer:

Principal Physician/Investigator:

Co-Physician/Investigators:

Name of Clinical Liaison/Coordinator:

Have there been any changes in physician/investigators or clinical staff since the last continuing review that you have not reported to the IRB?
☐ Yes ☐ No

Have all **new** physician/investigators and clinical staff completed the required "Physician/Investigator/Clinical Staff Acknowledgment" for use of a HUD?
☐ Yes ☐ No

Have all **new** physician/investigators and clinical staff completed the required "Humanitarian Use Device" (#21760) education in HealthStream?
☐ Yes ☐ No

## PART B: CONFLICT OF INTEREST

Have any of the Physician/Investigators and Key Personnel who have privileges to use the HUD discovered or acquired any new significant financial interest with regards to the HUD or its manufacturer since last completing their Financial Conflict of Interest Disclosure Form on file?
☐ Yes ☐ No

If the CHS CIRB determines that a financial conflict of interest exists, the consent document must disclose this information either in the body of the document or by attaching a "Financial Conflict of Interest Disclosure Addendum."

## PART C: STUDY STATUS

Did you adhere to all of the IRB Conditions of Approval received in the original approval or renewal letters?
☐ Yes ☐ No ☐ N/A
*If no, provide explanation.*

Have there been any changes to the approved indication(s) in the HDE since the last IRB review?
☐ Yes ☐ No
*If yes, provide explanation with corresponding documentation from the FDA.*

Have there been any changes in the cost/reimbursement of the HUD since the last review that may have a fiscal impact on the Community Healthcare System?
☐ Yes ☐ No
*If yes, provide explanation.*

Were all of the following submitted to the IRB? *If no, submit the documentation with the Renewal Request as an attachment.*

- Addition/deletions of physician/investigators ☐ Yes ☐ No ☐ N/A
- Addition/deletions of clinical staff ☐ Yes ☐ No ☐ N/A
- Reports of use for unapproved indications ☐ Yes ☐ No ☐ N/A
- Medical Device Reports (MDRs) ☐ Yes ☐ No ☐ N/A
- Internal AEs/Unanticipated Events ☐ Yes ☐ No ☐ N/A
- Changes in probable benefit or risk ☐ Yes ☐ No ☐ N/A
- Amendments or changes ☐ Yes ☐ No ☐ N/A
- Instructions for Use (IFU) Updates ☐ Yes ☐ No ☐ N/A
- Patient Education Material ☐ Yes ☐ No ☐ N/A

## PART D: PATIENT INFORMATION LOG

| Patient Initials | Medical Record # | Date of Use | HDE Approved Indication? | Non-HDE Approved Indication? (Report Submitted?) | Received consent, Patient education, or Product Insert (Yes or No) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**Complete for each patient who received treatment with the HUD since the last review.**

I certify that the above information has been reviewed by me and the co/sub-investigators for the study and that the information is correct.

_____ _____

Signature of Principal Physician/Investigator Date

***NOTE: The CHS CIRB office will return all incomplete submissions. The submission will not appear on the meeting agenda until the CHS CIRB office has received a complete submission packet.***