Memorial Hermann Healthcare System(MHHS) *and* Principal Investigator(PI) *shared*

Checklist to Expedite Device Study Review Process

Please be advised that it is most beneficial if the items highlighted in red be addressed as early in the review process as possible to keep the study start up timelines to a minimum.

1	**What is the FDA status of the device?** Check one category : Approved □ IDE □ HDE □ 510K □ MA □
2	**Provide FDA approval letter:** *(Refer to: www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm. or request from sponsor)*
3	**Nature of device:** • Implantable □ • Interfaces with implantable device (ex: Console etc) □ • Minimal interface with patient (collects data, not diagnostic or interventional □
4	**Who is the sponsor? Please provide sponsor contact information**. (if sponsor is not a MHHS vendor, will initiate vendor vetting process)
5	**SITE AGREEMENT/ CLINICAL TRIAL AGREEMENT:** MHHS requires all investigational device study sponsors to enter into a site Agreement with the hospital. If the PI is MHHS employee a Clinical Trial Agreement will be used in lieu of site agreement. Does the sponsor have a template for Site Agreement or Clinical Trial Agreement (MHHS PI)? Y □ N□ Alternatively MHHS will provide a template for both types of agreement.
6	**PURCHASE AGREEMENT:** **Is sponsor asking MHHS to purchase the device** or is it provided to hospital for free? I**f the device is to be purchased by the hospital** a purchase agreement will be needed. Please provide the following information for the same: • Cost of Device • Number of Devices to be purchased • Are devices provided on consignment? • Payment Terms • Is there a need for a console associated with the device? • *If yes*, is console loaned or sold to site? Does the sponsor have a Purchase Agreement template? If so please provide copy to MH – CIRI.
7	Is there a same/similar device currently in use in MHHS? Y □ N □ If yes, please list:

8	What is the PI's current practice to treat patients with the same condition?
9	What are the associated billing codes and MS DRG for this study procedure?
10	What is the expected length of stay for this procedure?
11	**STUDY BUDGETING and COVERAGE DETERMINATION:** Please list study services under applicable categories in order to make a coverage determination and develop a study budget for hospital services: List services by category here: • **Service conducted by Memorial Hermann Hospital and paid by the sponsor** • **Service conducted by Memorial Hermann Hospital and billable to the patient or insurer** Tools: Most sponsors provide a template of coverage for study services based on study time and event schedule.
12	Will Sponsor's Physicians or Field Clinical Representatives be involved in proctoring or assisting with the procedure in MHHS? If yes, MHHS will initiate credentialing, Please provide the following information for each of the representatives: • Name: • Title: • Address • Email • Phone number • Purpose of requesting access to MHHS facility
13	**CMS/MAC (Medicare Intermediary) PRE-AUTHORIZATION:** MHHS – CIRI staff will assist the PI and research team to make determination if CMS preauthorization is required depending on the category of device. If required the **PI and Research Team will prepare a CMS submission packet** ahead of time and upon receipt of IRB approval, include such approval in the packet **and submit to Medicare.**

For questions or assistance with the process above please contact Director or Manager of Clinical Research Operations at MHHS Clinical Innovation and Research Institute at:
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