

HARBORVIEW MEDICAL CENTER
NEW or INVESTIGATIONAL IMPLANT or DEVICE REQUEST

Background: The purpose of this new formal process for devices (new technology, implantable or investigational) is to assure compliance with billing regulations. Improper billing can lead to organizational as well as individual liability. Financial reimbursement may be hindered if the process is not followed. This would include not only the device, but also the physician's fee and entire inpatient and outpatient services.

New Process: HMC Physicians & Surgeons desiring to bring in a new device (new technology, implantable, or investigational) that is not currently in inventory must first obtain authorization from Surgical Council.

Financial reimbursement to the vendor will occur only if the device has been formally authorized by Surgical Council. For surgical implants, the purchase order requisition must also be submitted by the OR Business Manager for the vendor to receive reimbursement.

Forward this completed request to: Don Millbauer, Director of Operative Services, Box 359890 or fax to 744-6577. Phone # is 744-8094.

Medicare Billing Eligibility & Device Classification: Under current Medicare rules, no bill may be submitted for any "services related to the use of" a "Investigational Device Exemption (IDE) Category A" device. Medicare guidelines specify that a bill may be submitted for services related to use of a "IDE Category B" device, but only if specific information has been previously submitted to Medicare and if Medicare has provided a billing authorization code. HMC will forward the information to Medicare and will work with the agency to expedite receipt of the billing authorization code. **(This form gathers this required information.)** Other insurers may also adopt these guidelines. The FDA will have informed the manufacturer of the device's categorization; the manufacturer should have passed this information on the Principal Investigator. Any device being used for other than its FDA approved purpose is also considered investigational and can only be used as part of an FDA approved clinical trial.

FDA Letter (obtained by the Business Manager from the device manufacturer) will state whether the device:

- A. has FDA pre-market approval for commercial marketing;
- B. has a FDA declaration of substantial equivalence (a 510(k) clearance);
- C. is a Class I, II or III;
- D. is subject to an FDA-approved Investigational Device Exemption (IDE) and identifies the actual IDE number; or
- E. is Category A or Category B.

Financial Interests Disclosure (for investigational devices involving clinical trial): This disclosure is intended to ensure that potential financial conflicts of interest involving devices are recognized, disclosed, and managed. For purposes of this form, "Financial Interests" means any direct or indirect beneficial interest in the company manufacturing or selling the device or in the device itself. It includes the requesting surgeon but also the requesting surgeon's spouse and children.

Please Print all Responses:

Attending Physician: _____ Department/Division: _____

E-mail address: _____

Phone #: _____ Pager #: _____

Generic Name of Device: _____

Brand Name/Manufacturer: _____

Device cost (each): _____

Intended Clinical Use: _____

Placement Frequency: _____

Date of Earliest Desired Use: _____

How is this device similar to and/or different from other comparable products on the market? (e.g. similarity to 1st generation device that this evolved from) _____

What device, if any, will this replace that is currently in inventory? _____

Do you want to bring in the device for a trial period or to immediately add to inventory? _____

Please provide the following information for ALL devices:

1. Is this device being used for the indication approved by the FDA? _____ YES, _____ NO

Explanation: _____

2. Is this a device that is custom-made for the use by a particular physician or patient? _____ YES, _____ NO

Explanation: _____

If the device is in a Clinical Trial, proceed to questions 3-15:

3. What is the Human Subjects Approval Number: _____ Approval Date: _____
(attach a copy of the approval letter).

4. Who is the Principal Investigator? _____

5. **Attach a description** of all actions taken to conform to any applicable FDA special controls (*FDA letter will state the need to conform to any special controls. Examples are performance standards and post-market surveillance. Please define what controls you have put in place.*)

6. **Attach an explanation** of the protocol for obtaining informed consent. (*refer to and attach section III D 6 of the Human Subjects Application.*)

7. **Attach a copy of the Final Informed Consent** form as approved by the Human Subjects Review Committee.

8. **Attach a copy of the study protocol**, including patient inclusion criteria.

9. **Attach a copies of all agreements** between the sponsor and the provider, especially but not limited to, financial agreements.

10. **Attach a copy of the Principle Investigator's (PI's) budget** for the study, showing allocation of all funds from all sources.

Financial Interests (within the past 5 years, currently or expected):

YES NO

11. Salary or other monetary recognition for services (e.g. consulting fees, honoraria, travel, and accommodations) _____

12. Equity interests? (e.g. stocks, stock options, or other ownership interests) _____

13. Intellectual property rights? (e.g. patents, copyrights, and/or royalties from those rights) _____

14. Other financial interests that could benefit or be perceived to benefit from the acquisition of the device? _____

15. Is the acquisition of the device expected to lead to financial benefit or perceived benefit to HMC, University of Washington or any component of the University of Washington? _____

Physician Signature: _____ Date: _____

Please also forward copies to Don Millbauer of any of the following: device adverse events, sponsor safety reports, substantive changes in approved Consent forms, and manufacturer changing the device FDA categorization.