

Chapter 18

USE OF MEDICAL DEVICES FOR RESEARCH PURPOSES

A. Definitions

- 1. Investigational Medical Device** means any instrument, apparatus, or other similar or related article, including component, part, or accessory, that is the object of a clinical trial and that has not yet received marketing approval by the FDA for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure of any function of the body of man or other animals.
- 2. Investigational Use of Marketed Products** means the investigational use of an approved marketed device or other health product with the principal intent of developing information about the safety and efficacy of the device or other health product for uses other than those for which it was approved by the FDA. The investigational use of marketed products requires an IDE and approval of the clinical trial by the IRB.

REGULATORY NOTE: If a physician uses a commercially available device, drug, or other health product for an indication not in the approved labeling as part of his/her practice of medicine and does not intend to collect any type of data, he or she has the responsibility to be well informed about the drug, device or other health product. Use of a device, drug or other health product in this manner as part of the practice of medicine (in a manner not designed to develop information about the safety and efficiency of the health product) for uses other than those for which it was approved, or conducted under an investigational protocol(IND/IDE) does not require review by the IRB.

- 3. 510(k) Device** means a medical device that is determined by the FDA to be substantially equivalent to a device that was or is being legally marketed (i.e., predicate device) and will grant FDA approval status typically after a 90 day review. The sponsor or company will provide this verification to the investigator in writing for IRB submission. A procedure that will involve a device with a 510(k) classification will require IRB full-review if not used as part of the practice of medicine only.

Note: A device that is under review by the FDA to receive a 510(k) status approval may not be used on a patient at CAMC until the FDA has approved the 510(k) status and that letter of FDA approval is on file.

- 4. IDE Number** is a number assigned to an Investigational Medical Device approved by the FDA for use in a clinical trial involving human subjects.
- 5. Significant Risk Device** means an Investigational Medical Device that presents a potential for serious risk to the health, safety, or welfare of the human subject. The study must have both FDA approval (IDE) and IRB approval for the investigation to begin. A Significant Risk Device is:

- intended for use as an implant and presents a potential for serious risk to the health, safety, or welfare of the patient; or

- purported or represented to be of use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the patient; or
- intended for a use that is of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the patient.

6. "Non-significant Devices" are subject to the abbreviated requirement which involves approval process differences. If the IRB approves an investigation as a nonsignificant risk, the investigation is considered to have an IDE under the abbreviated FDA requirements and the investigation can begin immediately following institutional research approval.

B. Determination of Device Risk by the Sponsor or Manufacturer

1. All clinical trials involving Investigational Medical Devices should include a written determination (i.e., protocol, memorandum, brochure) by the Sponsor of whether the Investigational Medical Device poses a "Significant Risk" or a "Non-significant Risk".
2. If the Sponsor has determined that the Medical Device presents a "Significant Risk", the PI must provide the IRB with evidence that the Investigational Medical Device has received an IDE from the FDA.

C. IRB Review Procedures for Medical Device Research

1. Medical Devices will be independently reviewed by the full-board IRB according to the standard format of the CAMC/WVU IRB and will receive a determination by the IRB of **"Significant Risk"** or **"Non-significant Risk"**. The IRB will review this information and may or may not agree with the Sponsor's determination. The IRB may consult the FDA for its opinion on the risks associated with the Investigational Medical Device.
2. In general, full-board IRB review is required for both "Significant" and "Non-significant Risk" devices. They may also be considered minimal risk studies, and thus may be reviewed through the expedited review procedure established by the IRB.
3. In addition, if the Investigational Medical Device is a "Significant Risk" Device or if the IRB disagrees with the Sponsor's determination that the Investigational Medical Device presents "Non-significant Risk" to human subjects, the Sponsor and/or the CAMC/WVU IRB will be required to notify the FDA that a "Significant Risk" determination was made by the IRB.

D. HCFA Policy: Financial/Patient Coverage of Investigational Devices

On November 1, 1995, the Health Care Financing Administration (HCFA) issued a Final Rule formally acknowledging that the Medicare program will cover certain investigational devices that the FDA has determined are safe and effective. Under this new policy, the FDA has categorized devices for which it has issued investigational device exemptions (IDEs) into two categories: Experimental/Investigational (Category A) or Nonexperimental/Investigational (Category B).

E. Categorization of Investigational Devices

Category A - (Experimental/Investigational). Consists of innovative devices for which the FDA has not yet determined the safety and effectiveness of the device. This category includes devices for which "absolute risk" of the device has not been determined. **Medicare will not cover Category A devices that are used in patient care procedures.**

Hospital and Physician Services - The final rule reinforces HCFA's existing policy that hospital and physician services related to noncovered devices are not covered. Specifically, Medicare payment will not be made for services related to the use of a device that is not covered because HCFA decides that the use of the device is not "reasonable and necessary" or because coverage is excluded for other reasons.

The noncovered services include 1) all services furnished in preparation for the use of a noncovered device, 2) all services furnished during the use of the device; and 3) services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

Category B - (Non-experimental/Investigational). Consists of devices that the FDA has determined provide a reasonable assurance of safety and effectiveness or those for which underlying questions of safety and effectiveness have been resolved. Examples of Category B devices that qualify for coverage are the following:

1. Devices that have obtained a 510(k), those "substantially equivalent" to legally marketed device;
2. Devices whose technological characteristics and indications for use are comparable to a premarket-approved ("PMA") device;
3. Devices that are legally marketed, but later are required to obtain a PMA;
4. Devices that are under investigation for a new use;
5. Nonsignificant risk device investigations which require an IDE.

Once coverage is determined, *payment for a Category B device will not be able to exceed the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.* Consequently, the PI will need to advise hospital staff who will be assisting in the subsequent device-related procedure of the payment limitations prior to charging the patient.

F. Administrative Determination

Hospital areas should contact the Director of Research and Grants Administration when a decision is being made regarding the investigational or clinical use of a non approved medical device or device not approved for a proposed non indicated use.

G. Humanitarian Use Devices (HUD)

A HUD is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year. A HUD is not designated by the FDA as requiring a clinical trial or research study, but does require IRB oversight.

I. INITIAL REVIEW

- A. Complete the regular Full Board application, but include N/A on any items that do not apply. Be sure all administrative signatures are obtained before submitting the application.
- B. Attach a letter from the PI explaining the HUD process and requirements concerning the particular device. Explain why the HUD is needed, the situations for which the device will be used at this site, and any reporting requirements (serious and/or unanticipated AE's, annual summary of use, etc). Note if any training is required for use of the device and how that training will be done. Be sure that the letter indicates that the HUD is not being used as part of a research project or clinical investigation designed to collect data to support a FDA premarket approval application.
- C. Include a copy of the device brochure if one is available.
- D. Include a copy of a letter from the device sponsor which includes the following items:
 - a. the generic and trade name of the device
 - b. the FDA HDE number
 - c. the date of HUD designation
 - d. indications for use of the device
 - e. a description of the device
 - f. contraindications, warnings, and precautions for use of the device
 - g. adverse effects of the device on health
 - h. alternative practices and procedures
 - i. marketing history
 - j. summary of studies using the device
- E. Include a list of the physicians designated to use the device at our site.
- F. Complete, have signed and submit any necessary special clearance forms (such as the Form 6, Form 9, Nursing Participation Form, Form 10) if services from other departments are needed as a result of the HUD.
- G. Include a signed and completed copy of the Financial Disclosure Form for each physician designated to use the device.
- H. An IRB approved consent is required at this site. A HIPAA Authorization should be included with the consent document. Please follow the standard CAMC/WVU IRB consent guidelines altering the document to reflect that this is a HUD situation and not a research study.

II. UPON DEVICE USE AND CONTINUING REVIEW

- A. Following each use of the device, when physicians provide a letter to the sponsor concerning each use of the device, a copy of the letter should be provided to the IRB and to the original file. A contact person (similar to a study coordinator) must be designated to handle the file.
- B. At the time of continuing renewal, please be sure to fill out ALL items on the Continuing Review Packet. Put N/A if an item is not applicable. If Informed Consent is waived, indicate this on the form. Be sure to put NONE if there were no adverse events and include a brief summary as to the use and outcome of the device at the time of the renewal. With the packet include a copy of the original letter or document that describes the device, its purpose and indications for use. With a HUD all serious adverse events (SAE) need to be reported to the IRB. Use the IRB SAE forms and process and alter as necessary to meet the HUD situation.

Revised 5/04