USE AND STORAGE OF INVESTIGATIONAL DEVICES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
It is the policy of the Medical College of Wisconsin (MCW) HRPP office and Institutional Review Board (IRB) that the use and storage of investigational devices be reviewed and

Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k).

Treatment IDE: A mechanism through the FDA for providing eligible subjects with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.

PROCEDURE:

1. When an Investigator wishes to conduct a project which may utilize a device, the Investigator must complete and submit an initial eBridge submission for IRB review.

Investigator-Sponsor responsibilities

1. When an Investigator serves as the sponsor for a project to be conducted to determine the safety or effectiveness of a device, Investigators must comply with the *MCW Cancer SOP: Early Stage Research (RS.GN.170)*.
    a. This process will ensure Sponsor-Investigators are aware of their regulatory requirements, provide support with submissions and annual reports.
2. When a Sponsor-Investigator seeks an NSR determination, the Sponsor-Investigator is responsible for assuring that the following FDA "abbreviated" requirements are met and information is provided to the IRB as part of their review:
    - The device is not a banned device;
    - The sponsor labels the device in accordance with 21 CFR 812.5;
    - The sponsor obtains IRB approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;
    - The sponsor ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, consent under 21 CFR 50 and documents it, unless documentation is waived;
    - The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
    - The sponsor maintains the records required under 21 CFR 812.140(b)(4) and (5) and makes the reports required under 21 CFR 812.150(b)(1) through (3) and (5) through (10);
    - The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a)(1), (2), (5), and (7); and
    - The Sponsor-Investigator complies with the prohibitions in 21 CFR 812.7 against promotion and other practices

REFERENCES:

21 CFR 50
21 CFR 807.92(a)
21 CFR 809.10(c)
21 CFR 812.140(a), (b)
21 CFR 812.150(a), (b)
21 CFR 812.2 (b), (c)
21 CFR 812.3 (b)
21 CFR 812.46
21 CFR 812.5
21 CFR 812.7
21 CFR 812.46
21 CFR 812.66
21 CFR 812.140
21 CFR 812.150
Federal Food, Drug, and Cosmetic Act Section 515