



MCW Office of Research Standard Operating Procedure

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 approved in accordance with the Federal regulations.

DEFINITIONS:

Investigational Device: Any healthcare product that does not achieve its primary intended purposes by chemical action or by being metabolized. A medical device that is the subject of a clinical project designed to evaluate the effectiveness and/or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

Investigational Device Exemption: An FDA-approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device.

Non-significant Risk (NSR) Device Project: A project of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety, or welfare of subjects.

Significant Risk (SR) Device Project: A project of a device that presents a potential for serious risk to the health, safety, or welfare of a participant and: 1) is intended as an implant; 2) is used in supporting or sustaining human life, or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.

Premarket Notification (510k) Status: A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA.

Premarket Approval (PMA) Status: Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with

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. Refer to *IRB SOP: Submitting New Projects* for further information. The MCW IRB is responsible to conduct initial reviews, grant approvals and maintain ongoing monitoring of all devices, used in human subjects research under its jurisdiction.
2. The Investigator must include the following information in the eBridge submission:
 - a. Approval status from the FDA such as 510k or Pre-Market Approval (PMA) or IDE number and; IDE Approval Letter from the FDA, or
 - b. Justification that the device meets the criteria to be considered Non-significant risk or exempt from IDE requirements.
3. IRB staff will confirm that there is an IDE and the IDE number is valid. Final IRB approval will not be granted until this has been confirmed.
4. For projects which involve investigational devices, the Investigator should make sure all advertising or recruitment documents follow federal guidelines and be in accordance with *IRB SOP: Advertisements*.
5. Investigators should ensure the Informed Consent document includes the following in accordance with federal regulations, be in accordance with *IRB SOP: Informed Consent for Human Subject Research* and to use the appropriate MCW Consent Form templates.
 - a. No claims are made which state or imply, directly or indirectly, that the device is safe or effective for the purposes under investigation or that the device is in any way superior to another device;
 - b. The informed consent document must contain a statement that the device, is “experimental”, meaning non-FDA approved;
 - c. The informed consent document must contain a statement that the FDA may have access to the participant's medical records as they pertain to the project.
6. Prospective IRB review and approval is required even if a waiver from IRB regulations has been granted by the FDA for use of the investigational device, unless the use meets the criteria of emergency use as described in federal regulations and *IRB SOP: Emergency Use of Investigational Devices*.
7. The Investigator is responsible for the tracking and oversight of FDA-regulated devices in research and must meet the following requirements in order to use an investigational device in research conducted under the jurisdiction of the MCW IRB
 - a. The investigational device must be used only by the Investigator or under his/her direct supervision;
 - b. The investigational device must be used only as approved by the FDA and as described in the currently approved IRB documents;
 - c. The Investigator must not supply the investigational device to any persons not authorized under the IDE; and
 - d. Investigational devices must be stored in accordance with FDA requirements at all times; and

- e. Informed consent from the participant or the participant's legally authorized representative must be prospectively obtained, unless waived by the IRB.
- 8. Failure to use or store investigational devices in this manner will be reported to FH Research Compliance along with the MCW IRB as noncompliance.

Significant Risk (SR) vs. Non-Significant (NSR) Risk Devices

1. Unless exempt by the IDE regulations, an investigational device must be categorized as either a Significant Risk (SR) device or a Non-Significant Risk (NSR) device. The initial risk assessment is determined by the sponsor, but the IRB must make a formal determination during a convened meeting regarding the appropriate SR/NSR category.
2. Research involving the use of a Significant Risk (SR) device must be conducted in accordance with the full requirements of the FDA and must have an approved IDE from the FDA.
3. Research involving the use of a Non-significant Risk (NSR) device must be conducted in accordance with the "abbreviated" requirements of the FDA as described in the FDA regulations 21 CFR Sec. 812.2(b). In some cases, the FDA may notify the sponsor that it does not agree with the NSR determination and will require the submission of an IDE.

Exemptions from IDE requirements

1. A device can be exempt from the IDE requirements. A claim that the device is exempt must reference the exemption category being claimed. There are seven exemption categories that may be claimed. The first two categories pertain to devices that were either manufactured before 1976 or similar products manufactured after 1976. Categories 3 and 4 are the most commonly applied for exemptions. Categories 5 and 6 are pertinent to the use of devices in animals. Category 7 pertains to custom devices and is rarely utilized. Full information regarding the seven exemption categories that may be claimed can be found in the FDA regulations 21 CFR Sec. 812.2(c).
2. The exemption category most commonly claimed is 21 CFR Sec. 812.2(c)(3). In addition to the sponsor's compliance with applicable requirements in 21 CFR Sec. 809.10(c), the device testing must comply with the following:
 - a. Is noninvasive;
 - b. Does not require an invasive sampling procedure that presents significant risk;
 - c. Does not by design or intention introduce energy into a subject; and
 - d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
3. Another common exemption category claimed is 21 CFR Sec. 812(c)(4). To qualify for this exemption, the device testing must not be for the purposes of determining safety and effectiveness and must not put subjects at risk. The device testing must be limited to the following:
 - a. Consumer preference testing;
 - b. Testing of a modification; or
 - c. Testing of a combination of two or more devices in commercial distribution.
4. The exemption under 21 CFR 812.3(b) is rarely used. The use of a defined custom device is exempt unless it is being used to determine safety or efficacy for commercial distribution.
5. It is the sponsor's responsibility to provide sufficient justification to support the exemption category being claimed, and the IRB will confirm the exemption based upon information provided.
6. An exemption from the IDE requirement is not an exemption from the requirement for prospective IRB review or informed consent.

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 Corporate SOP: Early Stage Research Regulatory Requirements (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

SUPPORTING DOCUMENTS:

MCW Corporate SOP: Early Stage Research Regulatory Requirements (RS.GN.170)

IRB SOP: Advertisements

IRB SOP: Informed Consent for Human Subject Research

IRB SOP: Submitting New Projects

IRB SOP: Emergency Use of Investigational Drugs, Device or Biologics

MCW Consent Form templates

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