

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 1 OF 7	

1. PURPOSE

This policy documents the procedures for review of medical device studies in accordance with 21 CFR 50, 56, and 812.

2. DEFINITIONS

- 2.1. **A medical device** is defined as an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory that is:
 - 2.1.1. recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them;
 - 2.1.2. intended 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
 - 2.1.3. intended to affect the structure or any function of the body of man or other animals, and that does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals, and that is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
- 2.2. If a medical device is also a radiation-emitting product (e.g., laser products with medical claims), the device is subject to FDA regulation for both medical devices and radiation-emitting products.
- 2.3. Clinical investigations of medical devices must comply with the FDA informed consent and IRB regulations [21 CFR 50 and 56]. Except for certain low-risk devices, each manufacturer that wishes to introduce a new medical device to the market must submit a pre-market notification to the FDA. The FDA reviews these notifications to determine whether the new device is “substantially equivalent” to a device that was marketed prior to the passage of the Medical Device Amendment of 1976 and the Safe Medical Devices Act of 1990 (“pre-amendments device”). If the new device is deemed substantially equivalent to a pre-amendment device, it may be marketed immediately and is regulated in the same regulatory class as the pre-amendment device to which it is equivalent. If the FDA determines that the new device is not substantially equivalent to a pre-

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 2 OF 7	

amendment device, it must undergo clinical testing and pre-market approval before it can be marketed, unless it is reclassified into a lower regulatory class.

- 2.4. Clinical investigations undertaken to develop safety and efficacy data for medical devices must be conducted according to the requirements of the Investigational Device Exemption (IDE) regulation [21 CFR 812]. Certain clinical investigations of devices may be exempt from the IDE regulation [21 CFR 812.12(c)]. An investigational device must be categorized as either “significant risk” or “non-significant risk,” unless exempt from the IDE regulation. Examples of significant risk devices and non-significant risk devices are provided in IRB Document 110.2, “Examples of Non-Significant Risk Devices and Significant Risk Devices.”

3. DETERMINING THE RISK CATEGORY OF AN INVESTIGATIONAL DEVICE

The sponsor of a proposed study involving an investigational device makes the initial determination of whether the device presents a non-significant or significant risk. If the sponsor determines that the device presents a non-significant risk, the study must be submitted to the IRB for review. If the sponsor determines that the device presents a significant risk, the sponsor must apply for an IDE from the FDA. Exemptions from this requirement include the following:

- 3.1. The device fulfills the requirements for an abbreviated IDE (21 CFR 812.2(b)(1)):
 - 3.1.1. The device is not a banned device;
 - 3.1.2. The sponsor labels the device in accordance with 21 CFR 812.5;
 - 3.1.3. 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;
 - 3.1.4. 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;

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 3 OF 7	

- 3.1.5. The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
 - 3.1.6. 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);
 - 3.1.7. 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
 - 3.1.8. The sponsor complies with the prohibitions in 21 CFR 812.7.
- 3.2. The device fulfills one of the IDE exemption categories (21 CFR 812.2(c)):
- 3.2.1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the labeling in effect at that time.
 - 3.2.2. A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:
 - 3.2.2.1. Is noninvasive.
 - 3.2.2.2. Does not require an invasive sampling procedure that presents significant risk.
 - 3.2.2.3. Does not by design or intention introduce energy into a participant.
 - 3.2.2.4. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
 - 3.2.3. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 4 OF 7	

- 3.2.4. A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

4. NON-SIGNIFICANT RISK DETERMINATION

- 4.1. If the sponsor determines that the device presents a non-significant risk, the investigator shall provide the following information from the sponsor to the IRB along with the protocol and informed consent document:
- 4.1.1. Description of the device
 - 4.1.2. Reports of prior investigation with the device
 - 4.1.3. Proposed investigational plan
 - 4.1.4. Description of patient selection criteria and monitoring procedures
 - 4.1.5. Any other information that the IRB deems necessary to make its decision
 - 4.1.6. Statement regarding whether other IRBs have reviewed the proposed study and what determination was made
 - 4.1.7. Any FDA assessment of the device's risk, if such an assessment has been made
- 4.2. The IRB shall review the information provided and make a determination of risk. The risk determination should be based on the proposed use of a device in an investigation and not on the device alone. If, after review, the IRB agrees with the sponsor's initial determination that the device presents a non-significant risk, the IRB shall continue with its review of the proposed study.
- 4.3. If the IRB does not agree that the device should be classified as a non-significant risk device, the review shall be put on hold and the IRB shall notify the Principal Investigator and the sponsor of its determination. The sponsor shall then be required to submit the device study to the FDA for review. If the FDA determines that the device presents a non-significant risk, the IRB shall continue with its review of the study. If the FDA determines that the device presents a significant risk, the sponsor shall then apply for an IDE from the FDA. The FDA

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 5 OF 7	

has the ultimate authority in determining whether a device study presents a non-significant or significant risk.

- 4.4. The minutes of IRB meetings shall document the rationale for the IRB's determination of risk for investigational device studies.

5. SIGNIFICANT RISK DETERMINATION

The FDA must review any device categorized as a significant risk device either by the sponsor or by the IRB after initial review. If the FDA agrees that the device presents a significant risk, the sponsor shall obtain an IDE from the FDA. The Principal Investigator shall have an IDE and IRB approval before proceeding with clinical studies. The IRB shall not give final approval until the IDE has been received from the FDA.

6. IRB REVIEW OF INVESTIGATIONAL DEVICE STUDIES

After the risk determination has been made, the IRB shall review the research study using the same criteria [21 CFR 56.111] applied to any research involving an FDA-regulated product. To ensure that risks to the subjects are reasonable in relation to the anticipated benefits, the risks and benefits of the investigation shall be compared to the risks and benefits of alternative devices or procedures. Minutes of IRB meetings shall document the rationale for approval or disapproval of the clinical investigation.

7. NON-SIGNIFICANT RISK DEVICE STUDIES

If a non-significant risk device study qualifies as a "minimal risk" study, the IRB may choose to review it using the expedited review procedures outlined in IRB Policy 109, "[Expedited Categories](#)," Section 5. In all other cases, the project shall be subject to full IRB review. If the IRB approves the study, the sponsor and Principal Investigator shall comply with the "abbreviated requirements" of the IDE regulation [21 CFR 812.2(b)], informed consent regulations, and IRB regulations. Unless otherwise notified by the FDA, a non-significant risk study is considered to have an approved IDE if the sponsor fulfills the abbreviated requirements. The abbreviated requirements address, among other things, the requirement for IRB approval and informed consent, recordkeeping, labeling, promotion, and study monitoring. Non-significant risk studies may commence immediately following IRB approval.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 6 OF 7	

8. SIGNIFICANT RISK DEVICE STUDIES

Significant risk device studies shall be conducted in accordance with the full IDE regulation [21 CFR 812] and shall not be commenced until: 1) 30 days after the FDA receives the IDE application or the FDA approves, by order, an IDE for the investigation, and 2) the IRB has approved the study. The FDA considers all significant risk studies to present more than minimal risk, and thus full IRB review is necessary.

9. HUMANITARIAN USE DEVICE (HUD)

A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

9.1. Humanitarian Device Exemption (HDE)

- 9.1.1. A Humanitarian Device Exemption (HDE) is an FDA approval for a physician to use an HUD in the clinical treatment of patients. All of the following FDA requirements must be met for FDA to approve an HDE:
 - 9.1.1.1. The device is to be used to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year;
 - 9.1.1.2. The device would not otherwise be available unless an HDE application were approved;
 - 9.1.1.3. No comparable device, other than another HUD approved under the HDE regulation or a device being studied under an approved IDE, is available to treat or diagnose the disease or condition; and
 - 9.1.1.4. The device will not expose patients to an unreasonable or significant risk of illness/injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 110	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 9/2009; 3/2011; 11/2013
POLICY: Medical Devices	PAGE 7 OF 7	

9.2. Procedure

The Creighton University IRB (IRB-01) shall review and approve the use of all HUDs. The IRB does not generally require review/approval of each individual use of an HUD device as long as the uses of the device fall into the FDA-approved indication and IRB protocol approval, as applicable.

9.3. Initial IRB Review/Approval

9.3.1. HUD use shall be reviewed and approved by the full board prior to the initial use of the device at a facility operating under the jurisdiction of the Creighton University IRB. The physician requesting initial use of a HUD device shall include the following forms in addition to the Initial Application:

9.3.1.1. The HUD product labeling, clinical brochure, and/or other pertinent informational materials;

9.3.1.2. The FDA HDE approval letter; and

9.3.1.3. Information sheets (a research consent form is not required).

Note: Because the use of an HUD is for diagnosis or treatment purposes only, the HIPAA regulations for research are not applicable. Therefore, a HIPAA Research Authorization and/or Waiver of Authorization is not required.

9.4. Continuing IRB Review/Approval

9.4.1. Continuing review of HUD use by the IRB is required at least annually. Continuing review at a convened meeting is required.

9.4.2. Additional information regarding the FDA requirements for medical devices may be found online at the following addresses:

9.4.2.1. [Frequently Asked Questions about IRB Review of Medical Devices](#)

9.4.2.2. [Device Advice: Device Regulation and Guidance](#)