

Department: UAMS Institutional Review Board
Policy Number: 18.2
Section: Drugs and Devices
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SUBJECT: Research Involving an Investigational Device

POLICY

Research conducted to determine the safety or effectiveness of a device must have an Investigational Device Exemption (IDE), unless the device meets the requirements for an abbreviated IDE or the protocol meets one of the exemptions from the requirement for an IDE.

All Investigator-initiated human research studies requiring an IDE are subject to UAMS Administrative Guide Policy 16.1.11. Local investigators proposing this type of study must consult the UAMS Office of Research Regulatory Affairs (ORRA) before the study is reviewed by the IRB.

DEFINITIONS

- A. **Device:** An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that:
1. Is recognized in the official National Formulary, the United States Pharmacopeia, or any supplement to them.
 2. Is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or other animals.
 3. Is intended to affect the structure or any function of the body of humans or other animals.
 4. Does not achieve any of its primary purposes through a chemical action within or on the body of humans or other animals, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
- B. **Significant Risk Device:** An investigational device that:
1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
 2. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
 3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or
 4. otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
 5. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- C. **Nonsignificant Risk Device:** An investigational device that does not meet the "significant risk device" definition. These devices are subject to the requirements at 21 CFR 812.2(b).
- D. **Abbreviated IDE devices:** Alternate term for a non-significant risk device.

PROCEDURE

A. Investigator Process for Device with an SR or NSR IDE.

1. For local-investigator-initiated device studies, the investigator shall consult with ORRA to determine the need for an IDE before the IRB reviews the study.
 - a. ORRA shall assess the proposal to determine the need for the IDE and will provide other support services, such as monitoring, required to meet FDA requirements.
2. For device studies that originate elsewhere, the investigator shall provide sufficient documentation to the IRB to verify the study underwent a device review and to support the decision made about an IDE.

3. For studies conducted under a valid IDE, the Investigator must provide the IDE number, when applicable, in the IRB e-system submission and submit documentation to confirm the validity of the IDE. The following documentation is acceptable:
 - a. Industry sponsored study protocol which includes the IDE number;
 - b. Written communication of the IDE number from the Sponsor; or
 - c. Written communication of the IDE number from the FDA.
 - d. Written documentation from the sponsor indicating the project meets the criteria for a non-significant risk (NSR) IDE or qualify for an abbreviated IDE
4. The investigator shall ensure the submission includes documentation supporting the sponsor's determination of whether the device is a significant risk or non-significant risk device.
5. For projects found to be exempt from IDE requirements, the investigator shall ensure the submission includes documentation supporting the sponsor's determination of exemption.
6. The investigator shall be responsible for the tracking and oversight of FDA-regulated devices in research.
7. The submission shall include a description of the device storage and accountability plans.
8. The investigator shall assure all of the following requirements are met:
 - a. The device shall be used only by the investigator or under his/her direct supervision.
 - b. The device shall be used only as described in the IRB-approved protocol.
 - c. The investigator shall not supply the investigational device to any unauthorized persons.
9. The investigator must provide a plan for secure storage of the device and the proper disposal or return of devices.
10. The investigator shall maintain the following accurate, complete, and current records related to the device:
 - a. Correspondence with the IRB, sponsor, monitor, other investigators and FDA
 - b. Records of receipt, use or disposition of a device that relate to:
 - i. The type and quantity of the device, dates of receipt, and batch numbers or code marks
 - ii. Names of all persons who received, used, or disposed of each device
 - iii. The number of units of the device returned to the sponsor, repaired, or otherwise disposed of, and the reason(s)
 - c. Records of each subject exposure to the device, including;
 - i. Informed consent form and associated documentation
 - ii. All relevant observations
 - iii. Adverse device effects
 - iv. A record of the exposure of each participant to the investigational device, including the date and time of each use and any other therapy
 - v. Dates and reasons for any protocol deviations

B. IRB Procedures

1. The IRB office staff shall, during pre-review, ensure device studies have undergone the appropriate regulatory review and that documentation supporting the review and related determinations are included.
2. The IRB will review research involving a device in accordance with this policy. It will confirm the device underwent the appropriate regulatory review and the review and related determinations are adequately documented in the submission.
3. For research involving a significant risk (SR) or nonsignificant risk (NSR) device, the IRB will consider and document whether it agrees with the sponsor's SR or NSR determination after reviewing relevant information at a convened meeting.
 - a. Information the IRB shall consider in making this determination includes:
 - i. What is the basis for the sponsor's risk determination? The determination is based on the proposed use of the device in an investigation, and not on the device alone.
 - ii. What is the nature of harm that may result from use of the device?
 - iii. Will the subject need to undergo an additional procedure as part of the study, for example, a surgical procedure?
 - b. This determination shall be made in accordance with the definitions above.
 - c. The determination, and reasoning behind the determination, will be documented in the meeting minutes.
 - d. If the FDA has been consulted regarding the risk level associated with a device, the FDA's determination is binding, and the IRB may not overrule it.

4. If the IRB disagrees with the sponsor's NSR assessment and decides the study involves an SR device, the IRB shall notify the investigator, and, where appropriate, the sponsor.
 - a. The investigator may appeal the decision to the IRB for reconsideration if additional information about the device is available.
 - b. The IRB may not approve the study until the discrepant determinations are resolved.
 - c. The sponsor may also contact the FDA directly regarding the need for an IDE.
5. If an IDE from the FDA is required, but has not yet been obtained, the IRB may review the research if it is submitted in accordance with the IDE regulations.
 - a. Such a study may not begin until it is allowed to proceed by the FDA and any FDA-required changes are submitted to the IRB for review and approval.
 - b. The IRB shall not review a study that has been submitted to the FDA for an IDE determination if the need for an IDE is not clear.

REFERENCES

21 CFR 50

21 CFR 56

21 CFR 812

AAHRPP Elements I.7.A and I.7.B

FDA Guidance titled *Significant Risk and Nonsignificant Risk Medical Device Studies*

FDA Guidance titled *Frequently Asked Questions about Medical Devices*

FDA Guidance titled *Guidance for IRBs, Clinical Investigators, and Sponsors IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed*