**Department: UAMS Institutional Review Board**

**Policy Number: 18.2**

**Section: Drugs and Devices**

**Effective Date: July 31, 2002**

**Revision Date: April 15, 2004; February 8, 2005; January 24, 2011; August 17, 2015; February 15, 2016**

**SUBJECT: Investigational Devices**

**I. Policy**

Research that is 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 12.1.11. Investigators proposing this type of study must work with the UAMS Office of Research Regulatory Affairs prior to submitting the study to the IRB.

**II. Definitions**

**Device:** An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that:

a. Is recognized in the official National Formulary, the United States Pharmacopeia, or any supplement to them.

b. 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.

c. Is intended to affect the structure or any function of the body of humans or other animals.

d. 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.

**Significant Risk Device:** An investigational device that:

a. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

b. 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;

c. Is for a use 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 a subject; or

d. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

**Nonsignificant Risk Device:** An investigational device that does not meet the definition for a significant risk device

**III. Process**

**A. Investigator Process for Device with IDE.** For studies conducted under a valid IDE, the Investigator must provide the IDE# 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.

**B. Investigator Process for study submitted under an abbreviated IDE.** In order for research to qualify for

an abbreviated IDE, the Investigator must provide sufficient information to the IRB to show that all of the following elements are met:

a. The device is not a significant risk device with a brief explanation from the Sponsor of why the device is not a significant risk device.

b. The device has not been banned.

c. The device is or will be labeled in accordance with 21 CFR 812.5;

d. The study will obtain written informed consent from each subject, unless documentation is waived by the IRB under 21 CFR 56.109(c)

e. The study complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;

f. The study will maintain the records required under 21 CFR 812.140 and make the reports required under 21 CFR 812.150;

g. The study complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

**C. Investigator Process for study submitted under exemption from the IDE requirements**. Investigators should provide sufficient information to the IRB to show that the study meets one of the following exemptions as outlined in

21 CFR 812.2(c):

1. Research involves a device that was in commercial distribution before May 28, 1976 and the FDA did not consider the device to be a drug prior to that date. The device is being used or investigated in accordance with the indications in labeling in effect at that time.

2. Research involves a device that was in commercial distribution after May 28, 1976 but where the FDA

has determined the device to be substantially equivalent to a device in commercial distribution prior to May

28, 1976. The FDA must not have considered the device to be a drug prior to that date. The device is being used or investigated in accordance with the indications in labeling in effect at that time.

3. Research involving a diagnostic device where the sponsor is in compliance with applicable requirements in 21 CFR Sec. 809.10(c). The device testing:

a. Must be noninvasive;

b. Must not require an invasive sampling procedure that presents significant risk;

c. Must not by design or intention introduce energy into a subject; and

d. Must not be used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

4. Research involving a device undergoing consumer preference testing, testing a modification of a device, or testing a combination of two or more approved devices. In order to meet this exemption, the device testing must not be for the purposes of determining safety and effectiveness and must not put subjects at risk.

5. Custom Devices may be exempt provided the research is not to test the safety or effectiveness of the device for commercial distribution. Custom device means a device that:

a. Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

b. Is not generally available to, or generally used by, other physicians or dentists;

c. Is not generally available in finished form for purchase or for dispensing upon prescription;

d. Is not offered for commercial distribution through labeling or advertising; and

e. Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

**E. Investigator Responsibilities for Investigational Device Studies**

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 IRB. If the protocol does not address the storage and accountability plans as outlined

below, the investigator should submit the Device Acknowledgement Form, found on IRB website, with the IRB Submission.

1. The investigational device must be used only by the Investigator or under his/her direct supervision.

2. The investigational device must be used only as described in the approved IRB protocol.

3. The Investigator must not supply the investigational device to any unauthorized persons.

4. The investigator must provide a plan for secure storage of the device and the proper disposal of or return of devices.

5. 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

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

d. Dates and reasons for any deviations from the protocol

**F. IRB Review Process**

The IRB will review research involving devices in accordance with this policy. It will confirm that the device; either has an IDE, that the research meets one of the identified exemptions, or the research meets the requirements for an abbreviated IDE; and that the device storage and accountability plans are appropriate.

For research involving a significant risk (SR) or nonsignificant risk (NSR) device, the IRB must document its agreement with the sponsor’s SR or NSR determination after reviewing relevant information at a convened meeting. The IRB should document its SR/NSR determination in the meeting minutes.

The IRB may ask the sponsor for proof (i.e. a copy of the FDA’s approval or conditional approval letter) that an SR study has an FDA-approved IDE application.

If the IRB disagrees with the sponsor’s NSR assessment and decides the study involves an SR device, the IRB must tell the clinical investigator, and where appropriate, the sponsor. In this case, the sponsor should approach the FDA with either an application for an IDE or for an FDA determination regarding whether the device is NSR or SR. The IRB may also direct the investigator or sponsor, as appropriate, to consult the FDA for an opinion regarding the device’s risk, if the IRB feels such a consultation is necessary.

The IRB may defer review of a study pending a response from the FDA.

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.