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SECTION: ACADEMIC AFFAIRS

AREA: RESEARCH ADMINISTRATION

SUBJECT: DECLARATION OF SPONSORSHIP FOR INVESTIGATIONAL  
DEVICE EXEMPTION APPLICATIONS

### Purpose

The purpose of this policy is to establish the University of Arkansas for Medical Sciences as Sponsor for Investigator-initiated human research studies requiring an Investigational Device Exemption (IDE) filing with the Food and Drug Administration (FDA).

### Scope

This policy shall apply to all UAMS employees and students conducting Investigator-initiated human research studies irrespective of where the research is conducted.

### 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.

External Funding Agency – Any grantor, private organization, or pharmaceutical company providing funds or a device for an Investigator-initiated research study.

IDE – An exemption that allows an investigational device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device.

Investigational device – A device, including a transitional device, that is the object of an investigation.

Investigator – An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving a subject.

Principal Investigator - The responsible leader of a team in the event of an investigation conducted by a team of individuals. There is only one Principal Investigator per study.

Monitor – An appropriately trained individual who oversees an investigation and ensures that the trial is properly conducted and documented in accordance with the protocol, the Sponsor’s requirements, and all applicable laws and regulations.

Sponsor – An individual, pharmaceutical company, governmental agency, academic institution, private organization, or other organization which takes responsibility for and initiates a clinical investigation. The Sponsor does not actually conduct the investigation.

Transitional device – A device subject to section 510(l) of the Federal Food, Drug and Cosmetic Act, that is, a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

## **Policy**

UAMS will be the Sponsor for all Investigator-initiated research studies requiring an IDE. In the rare instance where the External Funding /Supporting Agency wishes to be the IDE sponsor, the Investigator-initiated study may be under that Agency’s IDE.

1. All UAMS Investigator-initiated studies requiring a significant risk IDE to be filed with the FDA or a non-significant risk IDE to be filled with the IRB will name the University of Arkansas for Medical Sciences (UAMS) as the Sponsor of the IDE. This includes studies with the following:
  - a. Approved device being used for a different indication.
  - b. A device that has not been cleared or approved by the FDA (unapproved device).
  - c. Combination device/drug, device/biologic, device/drug/biologic study where the device is not being used as approved.
  - d. Device studies deemed either NSR (non-significant risk) or SR (significant risk) by the IRB or FDA.
2. UAMS may NOT be the IDE Sponsor for human research studies conducted with any of the following:
  - a. Industry funded studies conducted under the industry’s IDE.
  - b. Studies exempt from the IDE regulations.
  - c. 510(k) cleared or PMA (Premarket Approval) approved devices, if being used as labeled.
  - d. Combinations of legally marketed devices, if being used as labeled.
  - e. Custom devices – As defined in 21 CFR 812.3(b).
  - f. Pre-amendment Devices – “devices in use prior to the Medical Devices Amendments of 1976 (FD&C Act as amended)”.

3. Newly hired Sponsor-Investigators who are a Sponsor-Investigator prior to coming to UAMS have the option of transferring IDE Sponsorship to UAMS or retaining that Sponsorship. Sponsor-Investigators who hold their own IDE prior to July 01, 2009, may, but will not be required to transfer the IDE sponsorship to UAMS.
4. If an Investigator conducting Investigator-initiated research under a UAMS held IDE leaves UAMS, transfer of Sponsorship of the IDE to the Investigator will be at the discretion of the Vice Chancellor of Research after consultation with appropriate institutional officials.

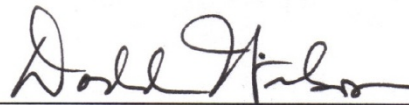
### **Procedures**

1. Any UAMS employee or student proposing to conduct Investigator-initiated research shall contact the UAMS Research Support Center for guidance before submitting their proposal to the UAMS IRB.
2. The Research Support Center will provide support to the Investigator by preparing and submitting IDE applications, offering regulatory advice, providing a centralized, secure area for official IDE documents, providing trial monitoring, and acting as liaison between UAMS and the FDA.
3. The Vice Chancellor for Research will sign all required documentation submitted to the FDA as the official signatory for UAMS.
4. The Research Support Center acting on behalf of the Vice Chancellor for Research will be responsible for ensuring that Sponsor obligations are fulfilled as described in 21 CFR 812. A study that does not comply with the protocol, FDA regulations or any conditions of approval imposed by the reviewing IRB or FDA, may be terminated.
5. The Vice Chancellor for Research, acting on behalf of UAMS, after consultation with appropriate institutional officials shall have the authority to terminate any IDE study.

### **References**

21 CFR 812

SIGNATURE: \_\_\_\_\_



Chancellor

Date: July 30, 2009