SECTION: RESEARCH
AREA: RESEARCH ADMINISTRATION
SUBJECT: DECLARATION OF SPONSORSHIP FOR INVESTIGATIONAL DEVICE EXEMPTION APPLICATIONS

PURPOSE

To outline the process to establish the University of Arkansas for Medical Sciences ("UAMS") as Sponsor for Investigator-initiated human research studies requiring an Investigational Device Exemption ("IDE") filing with the United States 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 shall mean 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.

Compassionate Use shall mean the use of an Investigational Device to treat or diagnose an individual patient or a small group of patients with a serious disease or condition when there are no available alternative options

Emergency Use shall mean the use of an Investigational Device when an individual patient is in a life-threatening situation and needs immediate treatment (there are no alternative options and no time to use existing procedures to get FDA approval for the use)

Expanded Access shall mean a potential pathway for patients with a serious or life-threatening disease or condition to access an investigational medical device that has not been approved or cleared by the FDA for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available through one of three mechanisms: Emergency Use, Compassionate Use, treatment Investigational Device Exemption.

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

Investigational Device Exemption ("IDE") shall mean 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 and allows an Investigational Device to be used in a clinical study in order to collect safety and effectiveness data.

Investigational Device shall mean a Device, including a Transitional Device, that is the object of an investigation.

Investigator shall mean 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. The responsible leader of a team in the event of an investigation conducted by a team of individuals. A Sub-Investigator is any other individual member of that team.

Principal Investigator shall mean the lead Investigator responsible for the conduct of an investigation. The term Principal Investigator or Co-Investigator is not defined in FDA regulations. Generally, there is only one Principal Investigator per study. In the event there are Co-Principal Investigators, each Co-Investigator is fully responsible for fulfilling the Investigator obligations in 21 CFR 812 Subpart E.

Monitor shall mean 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 shall mean 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.

Subject shall mean a human who participates in an investigation, either as an individual on whom or on whose specimen an Investigational Device is used or as a control. A Subject may be in normal health or have a medical condition or disease.

Transitional Device shall mean 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.

Treatment IDE shall mean the use of an Investigational Device to **treat or diagnose a group of patients** with a serious or immediately life-threatening disease or condition when the Device is also being studied for the same use under an approved Investigational Device Exemption.

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 filed with the IRB will name 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; or
   e. Expanded Access Compassionate Use or Treatment IDEs.

2. UAMS may **NOT** be the IDE Sponsor for human research studies conducted with any of the following:
   a. Expanded Access Emergency Use;
   b. Industry funded studies conducted under the industry's IDE;
   c. Studies exempt from the IDE regulations;
   d. 510(k) cleared or PMA (Premarket Approval) approved Devices, if being used as labeled;
   e. Combinations of legally marketed devices, if being used as labeled.
   f. Custom devices – As defined in 21 CFR 812.3(b); or
   g. Pre-amendment Devices – "devices in use prior to the Medical Devices Amendments of 1976 (FD&C Act as amended)".

3. The Principal Investigator will serve as the Sponsor-Investigator for individual patient, Compassionate Use by default. If necessary, UAMS may be the Sponsor for individual patient, Compassionate Use at the discretion of the Vice Chancellor of Research and Innovation in consultation with the Office of Research Regulatory Affairs and the IRB.

4. 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.

5. 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 and Innovation after consultation with appropriate institutional officials.

PROCEDURES

1. **Any UAMS employee or student proposing to conduct Investigator-initiated research shall contact the Office of Research Regulatory Affairs for guidance before submitting their proposal to the UAMS IRB.**

2. The Office of Research Regulatory Affairs 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 and Innovation or their designee will sign all required documentation submitted to the FDA as the official signatory for UAMS.

4. The Office of Research Regulatory Affairs acting on behalf of the Vice Chancellor for Research and Innovation 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 and Innovation, acting on behalf of UAMS, after consultation with appropriate institutional officials shall have the authority to terminate any IDE study.

REFERENCES

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 USC 321 (h))

21 CFR 812

FDA Expanded Access for Medical Products

FDA Expanded Access for Medical Devices

Signature:  **Date: November 9, 2022**