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 Trials ("IITs") requiring an Investigational Device Exemption filing with the United States Food and Drug Administration ("FDA").

SCOPE

This policy shall apply to all UAMS employees and students conducting IITs, 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 that has not received FDA approval or clearance for individual patients or a small group of patients with a life threatening or serious disease or condition for whom the treating physician believes the Device may provide benefit in diagnosing, monitoring, or treating their disease or condition.

Emergency Use shall mean the use of an Investigational Device with a Subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain Institutional Review Board ("IRB") approval.

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 IDE

External Funding Agency shall mean any grantor, private organization, or pharmaceutical company providing funds or a device for an IIT.

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). In the event an investigation is conducted by a team of individuals, the Investigator is the responsible leader of the team (*i.e.*, the Principal Investigator). A Sub-Investigator is any other individual member of that team.

Investigator-Initiated Trial (IIT) shall mean a clinical investigation in which the investigator conceives the research and develops the protocol and the investigation is sponsored by an independent Investigator or academic sponsor.

Principal Investigator ("PI") shall mean the lead Investigator responsible for the conduct of an investigation. Co-Investigator ("Co-I") is not defined in FDA regulations. There will be only one PI per study. In the event there are Co-Is, each Co-I 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 usually does not 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 a healthy human or a patient with a medical disease or condition.

Transitional Device shall mean a device regulated as a drug prior to May 28, 1976, the date the Medical Device Amendments were signed into law; a device that FDA considered to be a new drug or an antibiotic drug before May 28, 1976. They are subject to section 520(l) of the Federal Food, Drug and Cosmetic Act.

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 and there is no comparable or satisfactory alternative device available to treat or diagnose the disease or condition in the intended patient population.

POLICY

UAMS will be the Sponsor for all IITs requiring an IDE without regard for funding source. In the rare instance where the External Funding/Supporting Agency or an Agency providing the Device for the study wishes to be the IDE sponsor, the IIT may be under that Agency's IDE.

1. Unless otherwise indicated below, all UAMS IITs requiring a significant risk ("SR") IDE to be filed with the FDA or a non-significant risk ("NSR") IDE to be filed with the UAMS Institutional Review Board ("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; or
    d. Device studies deemed either NSR or SR by the IRB or FDA.

2. UAMS may NOT be the IDE Sponsor for human research studies conducted with any of the following:
    a. Emergency Use and Treatment IDEs;
    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 PI will serve as the Sponsor-Investigator for individual patient, Compassionate Use IDE studies by default. If necessary, UAMS may be the Sponsor for individual patient, Compassionate Use IDE studies at the discretion of the Vice Chancellor of Research and Innovation ("VCRI") in consultation with the Office of Research Regulatory Affairs ("ORRA") and the UAMS IRB.

4. Newly hired Investigators who were a Sponsor-Investigator prior to coming to UAMS have the option of transferring IDE Sponsorship to UAMS or retaining that Sponsorship. Sponsor-Investigators who held 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 an IIT under a UAMS held IDE leaves UAMS, transfer of Sponsorship of the IDE to the Investigator or the Investigator's new institution will be at

the discretion of the VCRI after consultation with ORRA and other appropriate institutional officials.

PROCEDURES

1. Any UAMS employee or student proposing to conduct an IIT shall contact ORRA for guidance before submitting their proposal to the UAMS IRB.

2. If it is determined that an IDE application is necessary, ORRA will provide support to the Investigator by assisting with relevant document development, preparing and submitting IDE applications (SR), offering regulatory advice, providing a centralized and secure area for official IDE documents, providing trial monitoring, and acting as liaison between UAMS and the FDA.

3. The VCRI or their designee(s) will sign all required documentation submitted to the FDA as the official signatory for UAMS.

4. ORRA, acting on behalf of the VCRI, 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, Sponsor-Site Agreement, FDA regulations or any conditions of approval imposed by the reviewing IRB or FDA, may be terminated.

5. The VCRI, acting on behalf of UAMS, after consultation with ORRA and any other 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)(1)).

Section 21 of the Code of Federal Regulations (CFR) Part 812 – Investigational Device Exemptions.

FDA Expanded Access for Medical Products

Investigational Device Exemption (IDE) - https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide

FAQs about Investigational Device Exemption - https://www.fda.gov/medical-devices/investigational-device-exemption-ide/faqs-about-investigational-device-exemption

Signature:  **Date:** **May 12, 2026**