SECTION: RESEARCH
AREA: RESEARCH ADMINISTRATION
SUBJECT: DECLARATION OF SPONSORSHIP FOR INVESTIGATIONAL NEW DRUG 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 New Drug ("IND") Application 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

Drug shall mean an article intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease; an article (other than food) intended to affect the structure or function of the body; a substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device; a substance recognized by an official pharmacopoeia or formulary. This term also includes biological products.

Emergency Use shall mean the use of an Investigational Drug with a human Subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

Expanded Access shall mean a potential pathway for patients with a serious or immediately life-threatening disease or condition to gain access to an Investigational Drug for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. This is also known as "compassionate use" or "treatment use".

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

Investigational New Drug ("IND") Application refers to a request from a Sponsor to obtain authorization from the FDA to administer an Investigational Drug to humans. INDs allow an Investigational Drug to be studied in humans, exempts the Drug under the IND from the premarketing approval requirements that are otherwise applicable and allows it to be shipped lawfully for the purpose of conducting clinical investigations of that Drug.

Investigational Drug shall mean a Drug that is used in a clinical investigation, or a biological product that is used *in vitro* for diagnostic purposes. The terms "investigational drug" and

"investigational new drug" are synonymous in the regulations.

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.

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.

Principal Investigator ("PI") shall mean the lead Investigator responsible for the conduct of an investigation. Co-Investigator and Co-PI are not defined in FDA regulations. Generally, there is only one PI per study. In the event there are Co-PIs, each Co-PI is fully responsible for fulfilling the Investigator obligations in 21 CFR 312.60.

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 a recipient of the Investigational Drug or as a control. A Subject may be a healthy human or a patient with a disease/condition.

POLICY

UAMS will be the Sponsor for all UAMS IITs requiring an IND without regard for funding source. In the rare instance where the External Funding Agency or an Agency providing a Drug for the study wishes to be the IND Sponsor, the IIT may be conducted under that Agency's IND.

1. Unless otherwise provided for in section 2 below, all IITs requiring an IND will name UAMS as the Sponsor of the IND. This includes studies with the following:
   a. New Chemical Entity ("NCE");
   b. Marketed products which are not exempted from the IND regulation as determined in 21 CFR 312 including Drugs;
   c. Cells and cellular products;
   d. Botanicals;
   e. Combinations that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
   f. Drug/device;
   g. Biologic/device;

h. Drug/biologic;
i. Drug/device/biologic;
j. Nutritionals which make a Drug claim; or
k. Expanded Access INDs, except Emergency Use

2. UAMS will NOT be the IND Sponsor for human research studies conducted for any of the following:
   a. Emergency Use INDs;
   b. Industry funded studies conducted under the industry's IND;
   c. Any National Cancer Institute studies such as Oncology Group studies;
   d. Student research that does not involve a substance described in item 1;
   e. Behavioral research that does not involve a substance as described in item 1;
   f. Chart reviews;
   g. Cellular products which fall under a "Bank" IND such as the National Cord Blood Registry; or
   h. Oncology studies which fit the FDA Guidance, "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer." NOTE: The Investigator for such studies must review the guidance to determine if their study qualifies and must then write a letter informing the Office of Research Regulatory Affairs ("ORRA") and Institutional Review Board ("IRB") of the exemption.

UAMS will serve as the Sponsor for single patient, non-emergency use INDs ("SPINDs") by default. The PI may be allowed to serve as the Sponsor-Investigator for SPINDs at the discretion of the Vice Chancellor of Research and Innovation ("VCRI") in consultation with ORRA and the IRB.

Newly hired Investigators who were a Sponsor-Investigator prior to coming to UAMS have the option of transferring IND Sponsorship to UAMS or retaining that Sponsorship. Sponsor-Investigators who held their own IND prior to July 01, 2009, may, but will not be required to, transfer the IND Sponsorship to UAMS.

If an Investigator conducting an IIT under a UAMS held IND leaves UAMS, transfer of Sponsorship of that IND 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 that involves a Drug shall contact ORRA for guidance before submitting their proposal to the UAMS IRB.
2. If it is determined that an IND Application is necessary, ORRA will provide support to the Investigator by preparing and submitting IND Applications, offering regulatory advice, providing a centralized and secure area for official IND 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 312. A study that does not comply with

the signed agreement (Form FDA 1572), 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 UAMS-Sponsored IND study.

REFERENCES

Section 201 of the Federal Food, Drug, and Cosmetic Act (21 USC 321 (g)(1)).

Section 21 of the Code of Federal Regulations (CFR) Part 312 – Investigational New Drug Application.

21 CFR 56.102(d) – Institutional Review Boards.

FDA Guidance: "IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer." January 2004.

FDA Guidance: "Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND". September 2013.

FDA Guidance: "Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers" June 2016; Updated November 2022.

https://www.fda.gov/drugs/investigational-new-drug-ind-application/investigator-initiated-investigational-new-drug-ind-applications

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