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 human research studies requiring an Investigational New Drug ("IND") 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

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.

Emergency Use shall mean the use of an Investigational Drug (including biologic) for by an individual patient in a life-threatening situation that requires the patient be treated before a written submission can be made.

Expanded Access shall mean a potential pathway for patients with a serious or life-threatening disease or condition to access an Investigational Drug or biologic that has not been approved or licensed by the FDA 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 Investigator-initiated research study.

IND shall mean an Investigational New Drug application, or a notice of claimed investigational exemption for a new Drug, which allows an Investigational Drug or biologic to be studied in humans and 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 new Drug or biological Drug that is used in a clinical investigation. The term also includes 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. 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 – 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 312.60.

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 participate in an investigation, either as a recipient of the investigational new 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 Investigator-initiated research studies requiring an IND without regard for fund source. In the rare instance where the External Funding/Supporting Agency wishes to be the IND sponsor, the Investigator-initiated study may be conducted under that Agency's IND.

1. Unless otherwise provided for in section 2 below, all Investigator-initiated studies 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 both Drugs and biologicals;
    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;
   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 Institutional Review Board (IRB) of the exemption.

3. UAMS will serve as the Sponsor-Investigator for single patient, non-emergency use INDs by default. The Principal Investigator may be the Sponsor-Investigator for single patient, non-emergency INDs at the discretion of 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 IND Sponsorship to UAMS or retaining that Sponsorship. Sponsor-Investigators who hold their own IND prior to July 01, 2009, may, but will not be required to transfer the IND sponsorship to UAMS.

5. If an Investigator conducting Investigator-initiated research under a UAMS held IND leaves UAMS, transfer of Sponsorship of that IND 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 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 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 312. A study that does not comply with the signed agreement (Form FDA-1572), 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 IND study.

REFERENCES

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

21 CFR 312 – Investigational New Drug Application

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

FDA Guidance: "Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers" June 2016; Updated October 2017

FDA Expanded Access for Medical Products

FDA Expanded Access Keywords, Definitions and Resources

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