



SECTION: ACADEMIC AFFAIRS

AREA: RESEARCH ADMINISTRATION

**SUBJECT: DECLARATION OF SPONSORSHIP FOR INVESTIGATIONAL NEW
DRUG 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 New Drug (IND) 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

IND – Investigational New Drug application, a notice of claimed investigational exemption for a new drug.

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.

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

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; or
 - j. Nutritionals which make a drug claim.

2. UAMS will NOT be the IND sponsor for human research studies conducted for any of the following:
 - a. Industry funded studies conducted under the industry's IND;
 - b. Any National Cancer Institute studies such as Oncology Group studies;
 - c. Student research that does not involve a substance described in item 1;
 - d. Behavioral research that does not involve a substance as described in item 1;
 - e. Chart reviews;
 - f. Cellular products which fall under a "Bank" IND such as the National Cord Blood Registry;
 - g. 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. 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.

4. 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 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 IND applications, offering regulatory advice, providing a centralized, secure area for official IND 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 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, acting on behalf of UAMS, after consultation with appropriate institutional officials shall have the authority to terminate any IND study.

References

21 CFR 312

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

SIGNATURE: 
Chancellor

Date: July 30, 2009