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**SECTION: RESEARCH****AREA: RESEARCH ADMINISTRATION****SUBJECT: REGISTRATION OF CLINICAL TRIALS**

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**PURPOSE**

The purpose of this policy is to provide guidance on the requirements that certain types of clinical research conducted by UAMS faculty, employees, or students must register with a national clinical trials database (e.g. ClinicalTrials.gov).

**SCOPE**

This policy shall apply to all UAMS faculty, staff and students.

**DEFINITIONS**

**ClinicalTrials.gov** is a registry of clinical trials operated by the National Library of Medicine that captures:

- Key summary protocol information before/during the trial
- Summary results and adverse event information of a completed trial

**Designee** – The person designated by the Principal Investigator as responsible for registration and maintenance of the clinical trial in ClinicalTrials.gov.

**Device** – An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that:

- Is recognized in the official National Formulary, the United States Pharmacopeia or any supplement to them
- 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 animals
- Is intended to affect the structure or any function of the body of humans or animals
- Does not achieve any of its primary purposes through a chemical action within or on the body of humans or animals, and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
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**Drug** – An active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body.

**Principal Investigator--** The person responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

**Responsible Party** – This is the entity or individual who is responsible for registering a clinical investigation and submitting Clinical Trial Information to the Clinical Trial Registry Data Bank, (e.g. ClinicalTrials.gov). )<sup>1</sup>

**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. The IND/IDE holder is considered to be the person or entity that initiated the trial and, therefore, is the sponsor (regardless of how the trial is being funded).

## **POLICY**

The following clinical trials must be registered in ClinicalTrials.gov:

1. Trials of Drugs and Biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation
2. Trials of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance

For the purpose of this policy, UAMS serves as the sponsor for all investigator initiated studies being conducted on this campus that require either an IND or IDE. (UAMS Policies [12.1.10/12.1.11](#)) Also for the purpose of this policy, the Vice Chancellor for Research shall be designated by the Sponsor (UAMS) as the Responsible Party. Registration and Maintenance responsibility for a registered trial may be designated by the Vice Chancellor for Research to the Principal Investigator.

The Principal Investigator or their designee shall register and maintain the clinical trial within the ClinicalTrials.gov database.

Industry-sponsored and cooperative group sponsored studies are registered by the sponsor. It is the Principal Investigator's responsibility to ensure that the sponsor has complied with the registration requirement.

UAMS may assign, in writing, the obligation to register to another entity in accordance with Board of Trustees and UAMS policies.

**SPECIAL NOTE:** The International Committee of Medical Journal Editors (ICMJE) requirements for publication and registration are much more stringent than the requirements under federal law. The ICJME allows for registration in databases other than ClinicalTrials.gov. The ICMJE requirements and a non-inclusive list of member publications can be found at <http://www.icmje.org>. It is the investigator's responsibility to register their trial in the appropriate database for publication purposes.

**REFERENCES**

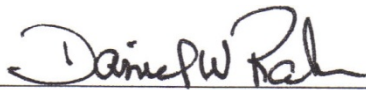
Review of IDE's for Feasibility Studies, FDA, CDRH May 17, 1989, Section 3 Public Law 100-85

<sup>1</sup>Elaboration of the Definition of Responsible Party, March 9, 2009

<http://clinicaltrials.gov/>

<https://register.clinicaltrials.gov>

<http://www.icmje.org>

Signature:  \_\_\_\_\_

**Date:** September 8, 2011