SECTION: RESEARCH
AREA: SPONSORED RESEARCH ADMINISTRATION
SUBJECT: MANDATORY EDUCATION POLICY FOR INVESTIGATORS/STUDY PERSONNEL PARTICIPATING IN HUMAN SUBJECT RESEARCH PROJECTS

PURPOSE

The purpose of this policy is to define the UAMS IRB and Institutional Human Subject Protection (HSP) educational requirements and to specify who must meet those requirements.

SCOPE

UAMS has adopted the mandatory education program outlined below for the following personnel:

- All IRB Reviewers and Staff
- All Investigators engaged in human subjects research
- All Research Staff engaged in human subjects research
- All Research Pharmacists
- All UAMS Faculty engaged in human subjects research, including those supervising student research
- All Resident Physicians and Fellows engaged in human subjects research
- All Students engaged in human subjects research
- Any other person deemed to be engaged in human subjects research
- "Engaged" is defined by the Office of Human Research Protections at: www.hhs.gov/ohrp/policy/engage08.html

DEFINITIONS

Affiliate Institutions: Arkansas Children's (AC) and Arkansas Children's Research Institute (ACRI).

Faculty: Employees who hold academic rank of lecturer, master lecturer, assistant instructor, instructor, assistant professor, associate professor, professor, distinguished professor, University professor, or one of the above titles modified by clinical, research, adjunct, visiting, executive in residence, or emeritus, e.g., clinical professor, adjunct assistant professor.

- **Human Subject Research (HSR):** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. HSR activities include: investigational application of drugs, devices, or interventions;
- obtaining information or biospecimens through intervention or interaction with an individual, and using, studying, or analyzing such information or biospecimens;
- dissemination of information from research activities in humans;

- obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens;
- using analytic technologies that are considered by relevant federal agencies to generate identifiable private information

IRB: UAMS Institutional Review Board, the office responsible for reviewing, approving, and overseeing human subject research conducted at UAMS.

Other research-affiliated personnel: UAMS workforce members or non-affiliated individuals whose involvement in research is limited or incidental, such as nurses who administer investigational drugs but who are not part of research teams, or community members assisting with a particular research project.

Principal Investigator: The person with direct responsibility for the design and conduct of a research project.

Research Staff: Those persons whose responsibilities include, but are not limited to, day-to-day decision-making related to the protocol or study conduct; subject interaction, recruitment, selection and eligibility determination; clarification of the complexities of the protocol to the subject and others; or collecting, entering, or analyzing subject information or biospecimens.

POLICY

All persons within the scope of this policy are required to complete Human Subject Protection training as described in this policy.

PROCEDURE

A. Human Subject Protection Requirements

All persons listed in the "Scope" section of this policy shall complete one of the web-based Human Subject Protection training courses appropriate to their research discipline by registering with the CITI program at http://www.citiprogram.org, affiliating with the University of Arkansas for Medical Sciences or Arkansas Children's, as appropriate, and then enrolling in one of the Human Subject Protection Learner Groups. These courses are:

1. Basic Biomedical Research Course on Human Subject Protection Training, which is appropriate for persons whose research or potential research involves drugs, devices, and surgical/invasive procedures.
2. Social & Behavioral Research Course on Human Subject Protection Training, which is appropriate for persons whose research or potential research is relevant to those disciplines and does not involve drugs, devices or surgical/invasive procedures.

These courses will be updated as needed by the Office of Research Compliance in conjunction with the IRB.

This Human Subject Protection training must be renewed every three years by returning to the CITI program website and completing the relevant HSP Training Refresher Course.

On a case-by-case basis, the Office of Research Compliance Education Resource Specialist, in conjunction with the IRB Director and the Research Compliance Officer, may consider other programs with at least equivalent content to meet the HSP requirements for education, upon review of a Certificate of Completion from the other program.

Other research-affiliated personnel, or the investigators working with them, can contact the Office of Research Compliance and the IRB for suggestions regarding alternative educational requirements appropriate for these individuals. The ORC and the IRB will, on a case-by-case basis, assist with the development of alternative education methods appropriate for these individuals' specific roles. Other research-affiliated personnel may also complete the CITI training as described above to meet these requirements.

B. Documentation of Training

All of the modules in the HSP training courses and the related quizzes must be completed, with a score of 100% on the quiz at the end of each module. Learners' records are maintained by the CITI program, and completion information is automatically updated in IRB's electronic submission system.

Study teams are responsible for maintaining documentation of human subject protection training completed through a non-CITI system, such as any alternative education used by research-affiliated personnel. Study teams must also document that this training has been cleared by the IRB.

C. Responsibilities

Principal Investigators are responsible for assuring that all staff members for each research study are compliant with the mandatory education policy prior to beginning a research study, and that they remain compliant throughout the duration of the study. Principal Investigators are also responsible for assuring that all new staff members adheres to this policy and that all new staff members are approved by the IRB for each study in which they may be involved.

D. Continuing Compliance

The CITI program will send out reminders for recertification to investigators and/or staff members prior to the expiration of their HSP training. If investigators and/or staff members allow their HSP training to expire, their research studies will be ineligible for full approval until they attain recertification or are removed from the studies. Chairs, Division Heads, and Directors may request reports regarding the fulfillment of the mandatory education requirement by people in their areas from the Office of Research Compliance.

E. Affiliate Institutions Requirements

Any person within the scope of this policy working at a UAMS Affiliate Institution must ensure the education requirements of the affiliate institution are met.

F. For More Information

Questions concerning this policy should be directed to the following:

UAMS Office of Research Compliance: 501-526-6879
UAMS IRB: IRBQuestions@UAMS.edu

Signature:  **Date: February 11, 2020**