

NUMBER: 16.1.06**DATE: 07/01/2003****REVISION: 02/23/2006; 01/20/10; 02/09/2016; 2/13/2018; 02/11/2020; 02/24/21; 10/23/2024 PAGE: 1 of 4****SECTION: RESEARCH****AREA: RESEARCH ADMINISTRATION****SUBJECT: MANDATORY EDUCATION POLICY FOR
INVESTIGATORS/STUDY PERSONNEL PARTICIPATING IN HUMAN
SUBJECT RESEARCH PROJECTS****PURPOSE**

To define the Institutional Review Board (IRB) and Institutional Human Research Protection Program (HRPP) educational requirements and to specify who must meet those requirements at the University of Arkansas for Medical Sciences (UAMS).

SCOPE

This policy applies to UAMS Workforce members who are Engaged in Human Subjects Research at UAMS or its Affiliate Institutions.

DEFINITIONS

Affiliate Institutions refers to Arkansas Children's, Inc. (AC) and Arkansas Children's Research Institute (ACRI).

Engaged is specifically defined by the Office for Human Research Protections at www.hhs.gov/ohrp/policy/engage08.html.

Human Subjects Research (HSR) refers to 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; and using analytic technologies that are considered by relevant federal agencies to generate identifiable private information

UAMS Institutional Review Board (IRB) refers to the office responsible for reviewing, approving, and overseeing Human Subjects Research conducted at UAMS, and for ceding review to another IRB.

Other Research-Affiliated Personnel refers to 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 refers to the person with direct responsibility for the design and/or oversight and conduct of a research project.

Research Staff refers to 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.

UAMS Workforce refers to physicians, employees, volunteers, trainees, students, and other persons whose conduct, in the performance of work for UAMS, is under the direct control of UAMS, whether or not they are paid by UAMS.

POLICY

UAMS shall require all Workforce members who are Engaged in Human Subjects Research at UAMS or its Affiliate Institutions to complete Human Subject Protection training as described in this policy. Education requirements for IRB reviewers are distinct from the Human Subject Protection training for individuals Engaged in Human Subjects Research and are detailed in IRB Policy 3.6, available on the IRB's website.

PROCEDURE

A. Human Subject Protection Requirements

All persons subject to this policy shall complete one of the web-based human subject protection (HSP) 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 completing one of the Human Subject Protection basic trainings described below, as appropriate for their research interests.

1. Basic Biomedical Research Course on HSP training, which is appropriate for persons whose research or potential research involves drugs, devices, and surgical/invasive procedures.
2. Social & Behavioral Research Course on HSP 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.

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

IRB submissions may include alternative HSP training proposals for Research Staff. Such a proposal must specify why the CITI program is not the preferred training. The IRB, in its review of the submission, will determine if the proposed training is adequate. The Office of Research Compliance (ORC), as part of its routine quality assurance activities, has the authority to confirm that training requirements are met.

Principal Investigators may also submit education plans for Other Research-Affiliated Personnel in their IRB submission for IRB review and approval. [The CIRTification program](#) has been preapproved for community partners who are Other Research-Affiliated Personnel. Other Research-Affiliated Personnel may also complete the CITI training as described above to meet these requirements.

B. Documentation of Training

All modules in the CITI 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 the IRB's electronic submission system .

Study teams are responsible for maintaining documentation of HSP 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 Research 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 Research Staff members adhere to this policy and that all new Research Staff members are listed in the IRB e-system for each study in which they may be involved.

D. Continuing Compliance

The CITI program will send out reminders for recertification to Principal Investigators and/or Research Staff members prior to the expiration of their HSP training. If Principal Investigators 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, and they may not interact with human subjects or access identifiable information until training is current. If Research Staff members other than the Principal Investigator allow their HSP training to expire, they may not interact with human subjects or access human subject material until they attain recertification. 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 IRB: IRB@UAMS.edu

UAMS ORC: 501-526-6270

Signature:  _____

Date: October 23, 2024