Department:	**UAMS Institutional Review Board**
Policy Number:	**10.4**
Section:	**Principal Investigator Responsibilities**
Effective Date:	**July 31, 2002**
Revision Date:	**May 7, 2004; February 8, 2005; January 24, 2011, March 31, 2020**

SUBJECT: Principal Investigator Responsibilities and Qualifications

POLICY

Each human subject research study will be carried out under the oversight of a local Principal Investigator (PI). PIs are responsible for the conduct of all research activities in a study they oversee, including activities they may have delegated to research staff.

PROCEDURE:

A. Each study shall list only one PI in the submission e-system's staff list.

B. The PI should have the necessary training and background to conduct studies in accordance with the protocol; organizational policies and procedures; and applicable regulations and policies, including but not limited to those concerning IRB review, informed consent requirements, reporting requirements, maintenance of records, retention of records, and supervision of research conduct. This training and background shall be documented in the curriculum vitae, resume, or other equivalent document uploaded to the PI's CLARA profile.

C. The PI will complete and remain current on research-specific training courses as required by UAMS Administrative Guide Policy 16.1.06, titled "Mandatory Education Policy For Investigators/Study Personnel Participating In Human Subject Research Projects.

D. PIs shall know how to access UAMS IRB and institutional policies related to research.

E. Before undertaking a project, PIs must verify they have the resources, including but not limited to time, equipment, and necessary staff in terms of numbers and qualification in order to conduct the research in a way that minimizes risks to participants.

F. PIs will ensure all study staff are appropriately trained on study procedures and will delegate study responsibilities only to qualified personnel.

G. All PIs must indicate on their application to the IRB whether they or any other person responsible for the design, conduct, or reporting of the research has a competing interest related to, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research. The IRB will use this notification of a potential conflict in its review of research, as described in IRB Policy 2.2, and may require certain study changes in response to a management plan or for other reasons intended to maintain subjects' rights, safety, and welfare.

H. Student PIs, including fellows and resident physicians, must list their faculty adviser as a co-investigator or responsible study staff member. The adviser should be given the ability to manage the e-system submission.

I. PIs agree to conduct approved research in accordance with the approved protocol, applicable regulations and institutional policies, and finalized IRB determinations and decisions.