

Department: UAMS Human Research Advisory Committee
Policy Number: 8.2
Section: Change in Protocol
Effective Date: July 31, 2002
Revision Date:

SUBJECT: Change in Principle Investigator

The HRAC must be notified within 30 days of a change in the principal investigator or the closure of the study. When changing investigators, please submit the following:

1. Protocol Amendment/Modification Form (found on the UAMS HRAC website)
2. A letter from the principal investigator indicating the change in responsibility
3. A letter from the new investigator accepting the responsibility for the research.

Any HRAC project associated with a Principal Investigator (PI) who has left the University of Arkansas for Medical Sciences cannot continue without modification. These projects must be closed or a new PI must be signed to take full responsibility for the project and the subjects enrolled in the project. If the study cannot be closed because of safety issues related to participant involvement, it is mandatory that a local, affiliated investigator be named as PI.

The HRAC considers a change in PI to be a major revision, usually requiring a full Board review before the change can be officially implemented. A change in sub-investigators must also be reported to the HRAC. It is the responsibility of the PI to notify the HRAC when a sub-investigator is dropped from a study and when a new sub-investigator joins an HRAC-approved project. Sub-investigator changes are considered minor revisions, but must also be approved before the change can be implemented.