

Department: UAMS Institutional Review Board
Policy Number: 8.2
Section: Change in Protocol
Effective Date: July 31, 2002
Revision Date: May 20, 2004

SUBJECT: Change in Principal Investigator

The IRB 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 through ARIA.
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, and the new investigator's CV if not already part of the study file.
4. Revised protocol, consent forms, HIPAA authorizations or advertisements, as applicable.
5. Revise FDA Form 1572 if applicable.

Any IRB 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 IRB 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 IRB. It is the responsibility of the PI to notify the IRB when a sub-investigator is dropped from a study and when a new sub-investigator joins an IRB-approved project. Sub-investigator changes are considered minor revisions, but must also be approved before the change can be implemented.