

TITLE: Institutional Animal Care and Use Committee Policy on the Handling of Active Protocols where the Principal Investigator is no longer working at the University of Arizona

PURPOSE: Standardize policy for handling active protocols where the investigator has left the University of Arizona without notification to the Institutional Animal Care and Use Committee (IACUC).

REVIEW/REVISIONS: Permanent amendment/revisions to this policy must be presented to the IACUC for review before implementation and should be developed by the Office of Animal Welfare Assurance (OAWA) staff and/or IACUC membership.

EFFECTIVE DATE: 11/06/2008

PERSON(S) RESPONSIBLE: Principal Investigator, IACUC Membership and Staff

POLICY/PROCEDURES:

NIH Grants Policy (12/03) section on Change in Status, Including Absence, of Principal Investigator and Other Key Personnel states:

The grantee is required to notify the GMO in writing if the PI or key personnel specifically named in the NGA will withdraw from the project entirely, be absent from the project during any continuous period of 3 months or more, or reduce time devoted to the project by 25 percent or more from the level that was approved at the time of award (for example, a proposed change from 40 percent effort to 30 percent or less effort). NIH must approve any alternate arrangement proposed by the grantee, including any replacement of the PI or key personnel named in the NGA.

The Principal Investigator(PI) must notify the IACUC of their intention to transfer their active protocols to another PI by submitting a Protocol Amendment form prior to leaving the University.

The following occurs when the OAWA staff becomes aware that a Principal Investigator (PI) is no longer at the University of Arizona (UA):

1. An email is sent to the PI's UA email account as well as to the protocol contact(s) listed on the protocol form.
 - a. The email includes instructions for the PI to submit an amendment to transfer ownership of the protocol to someone with current UA employment if they wish to leave their protocols in an 'active' status.
 - b. A response deadline of four weeks for receipt of the Amendment Form is set.
2. If no response from the PI or if a bounce back by the email system (address no longer exists) is received:
 - a. The protocol is placed in an 'on-hold' status with an entry in the Notes field in Sirius/eSirius stating why the protocol was placed on-hold.
 - b. A note is placed in the protocol file folder explaining the situation.
 - c. If animals are housed in the University Animal Care (UAC) facility:
 - i. An email is sent to the UAC Animal Facility Coordinators & Husbandry Purchasing Office staff stating that PI is gone and any active protocol in that PI's name has been placed on hold (no further animals may be ordered)
 - ii. If the PI can be located, they will need to transfer the protocol to a new owner within two weeks.
 - iii. Additional action is taken based on the conversation in accordance with standard UAC and IACUC practices and policies.
 - d. If the PI and no other protocol contact can be reached, the Department head will be notified to transfer the protocol to a new owner within two weeks. If the department head or PI still does not respond within two weeks, remaining animals will be euthanized.

JUSTIFICATION:

The Principal Investigator is responsible for all aspects of an approved animal use application. Investigators are responsible for informing the IACUC, and UAC, about anticipated clinical signs in animals, changes in any procedure, facilities, or changes in personnel (including the PI).

Failure to provide notification of departure from the University results in noncompliance in:

Ensuring adequate training of all personnel handling animals on project.

Ensuring that personnel familiarize themselves with all aspects of the animal application/protocol.

Ensuring that personnel adhere to all IACUC and UAC policies and regulations.

Establishing and identifying a lab coordinator to coordinate animal related activities of the laboratory and to train personnel in the laboratory in proper animal handling. (The laboratory coordinator may be the principal investigator.)

Reporting unanticipated adverse effects occurring in experimental animals to the IACUC. These are adverse effects that are not described in the animal use application.