TITLE: Protocol Amendment Process

PURPOSE: To ensure that all minor and major protocol changes are approved by the IACUC prior to implementation by the investigator. The requested amendment must fit within the original objectives of the protocol.

REVIEW/REVISIONS: IACUC Office staff will review and revise this SOP as needed.

PROCEDURES:

Protocol Amendment

1. If the Principal Investigator (PI) wants to make a change to a currently approved protocol, a Protocol Amendment form must be submitted. The amendment must relate directly to the scope of the approved protocol. If not, a new protocol must be submitted.

2. Protocol amendments are reviewed by Designated Member Review (DMR) or at a fully convened IACUC committee meeting (FCR). Based upon the type of review, the amendment may be approved, may require modifications in order to secure approval (DMR, FCR) or approval may be withheld (FCR only).

   a. Examples of common protocol amendment requests reviewed by the IACUC:
      i. Addition of animal numbers, species or strains
      ii. Modification of surgical and non-surgical procedures
      iii. Changes to anesthetic regimen, post-operative care, palliative treatment, euthanasia
      iv. Changes to non-UAC housing location
      v. Request for 12 hours (or more) housing in a laboratory space
      vi. Request to change the funding source
      vii. Request to transfer protocol ownership between PIs

   b. Examples of minor protocol amendment requests processed directly by the IACUC Office:
      i. Addition of personnel (see below)
      ii. Removal of personnel (see below)
      iii. Changes to the protocol title
      iv. Minor changes to research location

Protocol Personnel Amendment

1. Only a protocol participant can submit a Personnel Amendment form in order to add or remove protocol personnel.

2. The IACUC Office confirms that the individual(s) to be added to the protocol meets the minimum requirements for inclusion on a protocol before adding them to the protocol. Personnel lacking adequate certification are not added to a protocol until all required certification has been complete.