

**STANDARD OPERATING PROCEDURE  
UTAH STATE UNIVERSITY  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

**IACUC SOP#: 5**

**Inception Date: January 30, 2007**

**Modification Date:**

**Title: IACUC Review of Submitted Applications for Live Animal Use**

- I.** Applications or Amendments to Applications for Live Animal Use in Research, Teaching, or Training at Utah State University (Applications) will be submitted in writing or electronically to the IACUC office in the Laboratory Animal Research Center (LARC, UMC 5600) using the most current form available.
  - a.** Current applications are available on the IACUC web site.
- II.** Applications will be reviewed for completeness by the LARC Supervisor and/or the IACUC Administrator prior to distribution to the IACUC committee.
  - a.** At this point the Primary Investigator (PI) may be asked for additional information to complete the Application.
- III.** Applications are distributed to the full IACUC committee (usually via e-mail attachments) for review.
  - a.** All members of the IACUC MUST have access to ALL Applications submitted for IACUC review.
- IV.** IACUC members have 7 working days after distribution of an Application to request a committee review to be conducted at the next convened IACUC meeting, or to approve the use of a Designated Reviewer (DR).
  - a.** Committee members may respond using the attached form by mail (campus mail or US Postal Service), e-mail, or personal delivery.
    - i.** Although not required, committee members are encouraged to list any concerns the attached form they may have regarding the proposed animal work listed in the Application.
  - b.** Committee members may only request a full committee review or approve the use of DR. An Application may not be disapproved outside of a convened committee meeting.
  - c.** A lack of a response from a committee member within the 7 working days is considered to be a tacit approval of the DR process by that committee member.
    - i.** On the 8<sup>th</sup> working day, following distribution of the Application, the IACUC chairperson will be notified of the status of the Application and, if appropriate, assign a designated reviewer.
  - d.** Request for a committee review by any one member of the IACUC will automatically require review by a convened quorum of the committee.
- V.** Following approval of the DR process, the IACUC Chair will appoint one or more members of the Committee to serve as Designated Reviewers.
  - a.** Immediately following approval of the DR process the IACUC office will notify the IACUC committee chairperson regarding the approval. The chairperson in turn will identify the Designated Reviewer(s).

- b.** Any voting member(s) of the IACUC may serve as Designated Reviewer(s) provided there is no conflict of interest associated with the Application presented for review.
  - c.** Actions available to the Designated Reviewer(s) in relations to the Application being reviewed are:
    - i.** Approve the Applications as written
      - 1.** A DR is considered to represent the entire IACUC. Approvals granted by the DR are considered equal to those granted by a committee vote.
    - ii.** Request additional information from the submitting PI to clarify any questions or concerns, and then approve the Application.
      - 1.** If information received from PI is inadequate the Application may still be referred for review by a convened quorum of the committee
    - iii.** Refer to the Application for review by a convened quorum of the committee
      - 1.** If referred to a committee meeting, it is at the discretion of the IACUC chairperson to either quickly convenes a meeting or to wait until the next regularly scheduled IACUC meeting.
  - d.** A Designated Reviewer may not disapprove and Application.
  - e.** Designated Reviewers are encouraged to seek expert advice (from within or outside of the IACUC) when reviewing Applications with procedures or information unfamiliar to the reviewer.
  - f.** The DR has 5 working days to begin the application review process.
    - i.** If the DR is unable to conduct an Application review in a timely manner, the IACUC chairperson will assign the Application to another member of the IACUC to serve as a DR.
    - ii.** The time restriction noted here assumes the PI is available to reply to questions or concerns raised by the DR.
    - iii.** The DR is encouraged to complete the review process in a quick and timely manner.
    - iv.** The DR should forward the recommendation regarding the Application to the IACUC office as soon as the review process is complete.
  - g.** The DR is asked to forward copies of all correspondence (e.g. e-mails, notes on phone conversations, etc.) conducted during Application review to the IACUC office.
    - i.** This will allow a more complete understanding of the review process during protocol renewal, post-approval monitoring, or inspection by regulatory agencies.
- VI.** Upon request of any IACUC member during the initial review period, or upon recommendation of the Designated Reviewer(s), an Application will be reviewed and voted upon in a convened meeting of a quorum of the IACUC.
- a.** Actions available to the IACUC during an Application review during a convened meeting in relation to the Applications are:

- i. Approve the Application as written.
    - ii. Approve the Application providing the PI is willing to make specific changes to the protocol as requested by the IACUC (i.e. Approval with Modification).
    - iii. Disapprove the protocol.
  - b. All actions taken by the Committee in relation to Applications will be approved by a majority vote of a convened quorum of the committee.
  - c. Any dissenting votes (i.e. Minority Opinions) will be appropriately noted in the meeting minutes.
  - d. The PI has 30 working days to reply to questions or concerns raised by the IACUC or the DR.
    - i. If no reply has been received within 15 days, the PI will be notified by the IACUC office and reminded of concerns.
    - ii. If no reply is received in 30 working days the committee members may vote to disapprove the protocol due to lack of response.
- VII.** There are no specific laws, regulations, or guidelines dictating which Applications may be reviewed by a Designated Reviewer or those which must reviewed by the full committee; however, Committee review generally results in a closer scrutiny of Application details and procedures. Therefore, Committee members should consider some criteria as potentially requiring Committee review. These criteria may include:
- a. Use of species covered under the Animal Welfare Act (AWA).
  - b. Studies of Federally protected animals (i.e. endangered species).
  - c. Use of non-human primates.
    - i. USU does not currently house or own any non-human primates.
  - d. Applications involving painful procedures (i.e. Category D and E).  
Specific examples include:
    - i. Survival surgery
    - ii. Death as an endpoint studies
    - iii. Food deprivation studies
  - e. Applications containing new and/or complicated procedures
  - f. Applications submitted by PIs who have previously had problems with the compliance.
- VIII.** The USU IACUC has previously granted the IACUC Administrator the authority to conduct an Administrative Review process to speed the approval of commonly submitted changes or additions to Protocols. This authority has been granted for a few specifically designated areas which include:
- a. Addition of new personnel to Protocols upon completion of appropriate training.
  - b. Approval of strictly Observational protocols.
  - c. Approval of Protocols from outside IACUCs.
- IX.** The USU IACUC does not conduct any form of Expedited Review.
- X.** The IACUC does not conduct after-the-fact reviews.
- a. Animal Use conducted in the absence of an approved IACUC protocol is in violation of the USU Animal Use Policy (Policy #309) and may require disciplinary action by either the IACUC or by Utah State University.

- i. Any actions taken by the IACUC in regard to inappropriate use of animals will be conducted in accordance with IACUC SOP# 1 **IACUC Response to Animal Care and Use Concerns** and IACUC SOP# 2 **Sanctions of Animal Users for Issues of Non-Compliance**
- XI. This SOP is written in accordance with the regulations of the Animal Welfare Act and the Health Research Extension Act.