
Valdosta State University Institutional Animal Care & Use Committee

Standard Operating Procedure Number 003

REVIEW AND APPROVAL OF ANIMAL USE PROTOCOLS (AUPs) AND PROTOCOL MODIFICATIONS

PURPOSE: This Standard Operating Procedure (SOP) summarizes VSU's IACUC protocol application submission and review process.

SUBMISSION PROCEDURES: The IACUC Animal Use Protocol (AUP) and AUP Modification forms are available on the VSU Office of Grants & Contracts (OGC) website. The completed application form must be submitted to the OGC at least two weeks prior to the meeting at which the review is requested. IACUC meeting times are posted on the OGC website. All sections of the application form must be completed; items not applicable must be indicated as such. Incomplete or illegible forms will delay the review.

PROCEDURES FOR REVIEW AND APPROVAL OF NEW ANIMAL USE PROTOCOLS (AUPs):

1. The PI, Attending Veterinarian, and the Department Head must sign the application before the application is submitted to the IACUC Administrator. An application that lacks these signatures will be returned to the PI.
2. The Attending Veterinarian will initially screen the new AUP for appropriate designation of pain and distress category and for appropriateness of methods proposed to alleviate pain and distress and/or to euthanize the animals. He/she has the authority to request from the Investigator additional information or changes to the AUP. The Attending Veterinarian will sign the application before forwarding it to the IACUC Administrator for distribution to IACUC members.
3. The IACUC Administrator will screen the AUP for completeness. He/she has the authority to request additional information from the Investigator. Subject to IACUC approval, the IACUC Administrator may delegate such screening responsibilities to qualified staff.
4. If the AUP indicates a USDA Pain Level of E (Pain or distress or potential pain or distress that is not relieved with anesthetics, analgesics, and/or tranquilizer drugs or other methods for relieving pain or distress, the IACUC Administrator or his/her designee will electronically distribute the AUP to the entire IACUC membership (both voting and alternate members) and shall place discussion of the AUP on the agenda for the next IACUC meeting. Category E AUPs must be approved by a majority of the voting members at a meeting in which a quorum is present.
5. The IACUC Administrator or his/her designee will electronically distribute the new AUP with USDA Pain Level of B, C, or D to the entire IACUC membership (both voting and

alternate members) and shall allow no less than three (3) working days for preliminary review. Any voting member wishing to refer an AUP for full committee review must indicate so to the IACUC Administrator or his/her designee within the stated preliminary review period. If no requests for referral are received from voting members during that time period, the AUP will be forwarded to a designated review team. Inasmuch as possible, Voting Members are expected to respond either affirmatively or negatively when polled regarding the need for full committee review. Responses not received by the end of the review period are assumed to be negative.

6. If no voting member requests a full committee review, the AUP will be assigned to a designated review team of three voting members, who will be assigned by rotation through the membership roster. If any member of the designated review team has a potential conflict of interest, the IACUC Administrator or his/her designee will adjust the rotation schedule as necessary to alleviate the potential conflict.
7. When review by a designated review team is not practicable or time constraints warrant, the Chair or the Vice-Chair may individually conduct a designated review.
8. Designated review teams, the Chair, and the Vice-Chair are authorized to request additional information and/or revisions from the Investigator, approve the AUP, and/or refer the AUP for full committee review. Approval by designated review of the original AUP and/or the revised AUP requires unanimous decision of all review team members; otherwise, it is referred for full committee review. If the AUP is approved by the designated review team, the approval will be reported at the next regular meeting of the IACUC.
9. Designated review teams, the Chair, and the Vice-Chair may not disapprove a protocol application. Such action requires require consideration at a convened IACUC meeting at which a quorum is present, and the protocol must be disapproved only when a majority of those present vote for disapproval.
10. If any voting member requests a full committee review as a result of the preliminary review, the AUP will be reviewed by the full committee at the next regularly scheduled meeting. If any member has a potential conflict of interest, he/she shall recuse him/herself from the meeting during discussion of, and action on, the protocol.
11. All reviews will be conducted in accordance with the Guide and/or VSU's policies and procedures on animal care and use. The review will focus on the humane and ethical treatment of animals, appropriateness of the animal species and number of animals intended for use, adequacy of the investigator's skills related to animal use, and the adequacy of the procedures the investigator has taken to reduce or alleviate pain and distress.
12. If the AUP is approved, the IACUC Administrator will issue an approval letter to the Investigator. If the IACUC requests revisions or clarification, the Investigator will be instructed by the IACUC Administrator to submit an updated AUP, with changes electronically highlighted, to the IACUC Administrator. The resubmitted AUP will be returned to the reviewers for action. If the IACUC withholds approval of an AUP, the IACUC Administrator shall include in the written notification a statement of reasons for the decision. The Investigator will be given the opportunity to submit a new AUP.

13. Approvals are given for a three-year period, with the requirement for annual review and/or review of any proposed significant modifications to the approved protocol prior to their implementation.

DISAPPROVAL OF ANIMAL USE PROTOCOLS:

1. A designated review team cannot disapprove an AUP. The AUP must be referred for full committee review. The ICAUC can disapprove an AUP only at a convened meeting in which a quorum is present and a majority of the members present vote for affirmatively for disapproval. (In accordance with Robert's Rules of Order, abstentions will be counted "nay" votes.)
2. The IACUC has the final authority to disapprove an activity involving the use of animals. The IACUC's decision cannot be overruled at any administrative level.
3. Investigators whose AUPs have been disapproved are invited to work with the Attending Veterinarian and the IACUC Chair to revise the protocol and to submit a new AUP.

ANNUAL REVIEW PROCEDURES:

1. Approved AUPs will be reviewed no less frequently than annually. Approximately two (2) months prior to the anniversary date of the most recent review, the IACUC Administrator will notify the Investigator of the upcoming annual review. The Investigator is required to submit an Annual Review form that indicates the number of animals used in the previous year, any minor modifications made to the protocol during the previous year, if the animal activity is completed or if continuation is planned, and any proposed significant modifications in the protocol for the coming year.
2. If the initial AUP approval was given by a designated review team, the annual review will be assigned to a designated review team (unless a protocol modification is proposed that elevates the USDA Pain Level to Category E, which will trigger review by the full committee).
3. If the initial AUP approval was made by the full committee but no significant protocol modifications are requested for the ensuing year, the annual review will be assigned to a designated review team.
4. If the initial AUP approval was given following review by the full committee because of a Pain Level of E, the annual review will be undertaken by the full committee at the next regular meeting.
5. Annual review paperwork must be submitted by the Investigator in sufficient time to allow for the review to be completed by the IACUC prior to the anniversary date of the approval or most recent review. Failure to submit the annual review request in sufficient time to allow the review prior to the anniversary date of the approval or most recent review will result in termination of the AUP. If the Investigator wishes to continue the animal activity, a new AUP will be required.
6. At the end of the third year, the Investigator must submit a new AUP in order to continue the animal activity.

PROCEDURES FOR REVIEW AND APPROVAL OF MODIFICATIONS TO APPROVED ANIMAL USE PROTOCOLS: A new AUP is required if there is a change in the purpose or specific aim of the research or a change in Principal investigator. Other proposed modifications will be reviewed in the following manner:

1. Significant Modifications

- A. Significant modifications include, but are not limited, to the following:
- ◆ A substitution or addition in the PI involved in a research study
 - ◆ A change in objectives of the research
 - ◆ A change in the animal species (requires evidence of an additional search for alternatives)
 - ◆ Addition of any new vertebrate species (requires evidence of an additional search for alternatives)
 - ◆ Change in sex of animal to be used (if relevant)
 - ◆ A significant increase in the number of animals to be used, i.e., a 5% or greater increase (requires evidence of an additional search for alternatives)
 - ◆ Addition of survival surgery
 - ◆ Addition of a painful procedure
 - ◆ Any other change that involves a pain and distress category of D or E (requires evidence of an additional search for alternatives)
- B. The Investigator must request approval of significant modifications by submitting an AUP Modification Request. The request should be submitted to the IACUC Administrator, who will determine the review process based on previous IACUC action.
- C. If the initial AUP approval was given by a designated review team and the proposed modification does not elevate the USDA Pain Level to Category E, the modification request will be assigned to a designated review team.
- D. If the initial AUP approval was given by a designated review team and the proposed modification adds a USDA Pain Level Category E procedure, the modification request will be considered by the full committee at the next regular meeting.
- E. If the initial AUP approval was given after review by the full committee because of a Pain Level of E, the protocol modification request will be considered by the full committee at the next regular meeting.

2. Procedural Modifications

- A. Procedural modifications are changes in procedures performed on the animals. Depending on specifics, they may or may involve significant modifications of a protocol. Procedural modifications include, but are not limited to, the following:
- ◆ Minor modification to a surgical procedure
 - ◆ Modification of a non-surgical procedure

- ◆ Change in type or dosage of drugs used
 - ◆ Repeat of an experiment without a change in the number of animals
 - ◆ Change in euthanasia agent or method
- B. Investigators proposing procedural modifications should indicate the proposed changes on the AUP Modification Request. The request should be submitted to the IACUC Administrator, who will forward the request to the Attending Veterinarian and the IACUC Chair.
- C. The Attending Veterinarian and the IACUC Chair may jointly approve the procedural modification or they may consider the proposed change a significant modification and refer the request for review as a regular request for approval of a significant modification.

C. Minor Modifications

- A. Minor modifications are those that do not significantly change the protocol or the procedures used in the protocol and thus do not impact the number of animals used, pain and distress category, or the well-being of the animals. Minor modifications include, but are not limited to the following:
- ◆ Changes in personnel, other than the PI, who will be involved in the research protocol. Personnel includes faculty collaborator, student or technician.
 - ◆ Substitution or addition of students on an instructional protocol
 - ◆ Addition of another strain of the same animal species providing the number of animals used does not exceed a 5% increase
- B. Minor modifications to an approved protocol may be implemented by the Investigator without prior review and approval and should be reported after the fact on the Annual Review form.