

Clemson University Institutional Animal Care and Use Committee (IACUC)

BYLAWS

Presented and Approved at the August 4, 2022 IACUC Meeting

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INTRODUCTION

I. PREAMBLE

The Institutional Animal Care and Use Committee, in accordance with the Clemson University Division of Research Policy 3.0.1, is responsible for the oversight of the University animal program, facilities for animal housing and procedures, and for the review of all research, teaching, testing and production activities involving vertebrate animals conducted at or in association with the University. The IACUC assures that animal care and use complies with all federal, state, and local regulations as well as university policies and assurances.

The basis of compliance and review includes the following:

- Animal Welfare Act (P.L. 89-544) and amendments and the Animal Welfare Act Regulations
- Public Health Service Policy on the Care and Use of Laboratory Animals
- The Guide for the Care and Use of Laboratory Animals
- The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching
- AVMA Guidelines for the Euthanasia of Animals
- Other applicable regulations
- Guidance from reputable species-specific scientific societies.

In conjunction with the Office of Research Compliance, the IACUC will establish policies to provide guidance, procedures, and requirements to implement these bylaws and clarify operational procedures.

II. DEFINITIONS AND ACRONYMS

Animal	“Animal” and “vertebrate animal” are used interchangeably in this document.
IACUC or Committee	Institutional Animal Care and Use Committee
University	Clemson University
Policy 3.0.1	Division of Research Policy: Responsibilities and Authority of the Institutional Animal Care and Use Committee (IACUC)
AWA	Animal Welfare Act
AWAR	Animal Welfare Act Regulations
PHS Policy	Public Health Service Policy on the Care and Use of Laboratory Animals
Guide	The Guide for the Care and Use of Laboratory Animals
Ag Guide	The Guide for the Care and Use of Agriculture Animals in Agriculture Research and Teaching
ORC	Office of Research Compliance
IO	Institutional Official
Chair	IACUC Chairman
Vice-Chair	IACUC Vice Chairman
AV	Attending Veterinarian
PI	Principal Investigator
SOP	Standard Operating Procedure
Administrator	IACUC Administrator
AUP	Animal Use Protocol

COMMITTEE GENERAL INFORMATION

III. COMMITTEE RESPONSIBILITIES

The IACUC shall fulfill the following responsibilities:

1. Review the institutional program for humane care and use of animals using the PHS Policy, AWAR, the Guide, and the Ag Guide as a basis for evaluation at least once every six (6) months.
2. Inspect all institutional animal facilities, (including satellite facilities) using the PHS Policy, AWAR, the Guide, and the Ag Guide as a basis for evaluation at least once every six (6) months.
3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit reports to the Institutional Official.
4. Review concerns involving the care and use of animals at Clemson University and/or its satellite facilities.
5. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C.
6. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.
7. Supply the IO with the necessary reports and make recommendations regarding any aspect of the institution's animal program, facilities, or personnel training.
8. Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals or of modifications required to secure approval as set forth in the PHS Policy at IV.C.4.
9. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.
10. Collaborate with the Medical Surveillance Program by withholding approval of protocols pending confirmation by the Occupational Health Nurse of protocol personnel enrollment in the program.

IV. COMMITTEE MEMBERSHIP

The Committee must be sufficiently qualified through the experience, expertise, and diversity of its members to maintain oversight of the University animal program, animal facilities, and procedures and to provide complete and adequate review of all animal activities conducted within the University. Candidates for IACUC appointment will be compiled by the ORC and forwarded to the IO for review. Candidates may be nominated by faculty and staff. The composition and size of the Committee will be determined by the IO and the President of the University. All final membership appointments are made in writing by the President.

The Committee will consist of a minimum of 5 voting members to include:

1. the Chairman
2. the Attending Veterinarian
3. at least one practicing scientist experienced in animal research

4. at least one individual having no affiliation with the University (other than as a member of the IACUC) and no immediate family member affiliated with the university.
5. at least one individual whose primary concern is non-scientific in nature.

If an individual meets the requirements of more than one of the categories detailed above, that member may fulfill more than one category. However, in accordance with PHS Policy, at no time will the Committee consist of fewer than 5 voting members. The Committee must not include more than three voting members from the same department.

The Committee may include non-voting ex-officio members and may invite consultants, as needed.

Alternate members are appointed by the President and must be listed on the Committee roster. An alternate may be appointed for each voting position on a specific one-to-one designation. Alternates will assume full voting privileges when the corresponding member is unavailable for one or more meeting or activity.

V. MEMBER APPOINTMENT TERMS

Voting members are generally appointed to serve up to a three-year term with the exception of the AV, whose term is indefinite. Members may be eligible for reappointment to the Committee at the end of their term. Members may serve consecutive terms as needed as determined by the ORC and as appointed by the President.

VI. MEMBER ROLES AND RESPONSIBILITIES

1. Chairman (Chair)

All Committee activities are presided over by the Chair. The Chair assigns reviewers, appoints and charges subcommittees, reviews reports of animal concerns, and serves to facilitate all activities of the Committee.

The Chair is appointed by the President and is notified in writing of this appointment. A member may be reappointed to consecutive terms as Chair. Once a member steps down from the Chair position, the role is assumed by the Vice Chair following written appointment by the President. If the Vice Chair is unable or unwilling to serve as Chair, the newly appointed Chair will have served a minimum of six months on the IACUC to be eligible for the position.

2. Vice Chairman (Vice Chair)

The Vice Chair serves as the Chair in the following instances:

- as requested by the Chair for a planned absence
- in the event the Chair has a conflict of interest with materials under review
- in the event that the Chair is unreachable or incapacitated

The Vice Chair will assume all duties, rights, and responsibilities of the Chair when serving as the Chair. The Vice Chair should have a minimum of six months (current or previous service) on the committee to be eligible for the office and is appointed by the

President. The Vice Chair will replace the Chair with the approval of the President upon resignation of the Chair. At which time, a new Vice Chair is appointed by the President. In the event a suitable Vice Chair cannot be appointed, the previous Chair may assume Vice Chair responsibilities until a suitable Vice Chair can be appointed.

3. Attending Veterinarian (AV)

The AV is a voting member of the committee whose responsibilities to the animal program are defined in the Division of Research Policy 3.0.2, Responsibilities and Authority of the Attending Veterinarian.

It is the responsibility of the AV or his/her designee to review all protocols. Additionally, the AV consults with the principal investigator and any other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, euthanasia, pre- and post-procedural care, surgical procedures and any other procedure that may cause pain and or distress during animal activities conducted within the University.

The AV may recommend, and will review and approve, or require modifications (to secure approval) all SOPs regarding care and use of University animals.

The AV has the authority to institute immediate actions to protect the welfare of animals in the care of the University, including the authority to institute "emergency care". Upon the institution of "emergency care," the Director of the ORC, the Chair, appropriate facility managers, and appropriate investigators will be notified that such authority has been exercised.

4. Committee Members

To assure high quality animal care and use, the following is expected of all Committee members:

- a. be familiar with all documents pertinent to the performance of duties as a Committee member
- b. attend and participate in meetings, facility inspections, and program reviews
- c. if unable to attend a meeting or activity, notify the Chair or the Administrator and the alternate (if appropriate) as soon as possible
- d. conduct thorough reviews of assigned AUPs and amendments in a timely fashion
- e. call for continuing review or full committee review of any AUP or amendment to an AUP at any time if regulatory or welfare standards are not being met
- f. perform duties as assigned by the Chair
- g. maintain appropriate confidentiality.

All members are expected to exhibit high ethical standards of conduct. If the conduct of any Committee member is brought to the attention of the ORC by any other Committee member, faculty, or staff, the ORC will evaluate allegations and make recommendations to the IO.

5. Alternate Members

Alternate members assume the responsibilities of the assigned member when that member is not available for one or more meetings or activities.

6. Ex-Officio Members

Ex-Officio members are non-voting members that provide the Committee with valuable information relevant to the review of materials or the animal program. Ex-Officio members typically included on the Committee roster include the occupational health nurse charged with oversight of the Medical Surveillance Program and the Bio-Safety Officer.

7. Consultants

Consultants may be invited to provide information relevant to materials under review or participate in committee activities as determined by the Chair or the Director of the ORC.

8. Director of the Office of Research Compliance (ORC)

The Director will provide support to all functions of the Committee through the administration of the ORC. The Director also serves as a conduit between the Committee and the IO. Committee administrative needs, special reports, and updates will be communicated to the IO by the Director.

9. IACUC Administrator (Administrator)

The Administrator is responsible for providing support to the Committee. These responsibilities include, but are not limited to:

- a. coordinating the review and approval of protocols, amendments, and annual reviews with guidance regarding reviewers and review type from the Chair
- b. coordinating and maintaining meeting information such as:
 - a. notices
 - b. agendas
 - c. minutes
 - d. review materials
- c. coordinating semiannual facility inspections and the semiannual program review
- d. preparing the semiannual report to the IO
- e. preparing annual reports to regulatory and accrediting bodies
- f. assisting in the evaluation of the Committee in fulfilling the responsibilities outlined in these Bylaws
- g. other related duties.

VII. RECORD KEEPING AND RETENTION

The ORC will maintain Committee records in-house for at least three years past any applicable expiration date. After three years, records will be sent to University archives for long-term storage.

VIII. TRAINING

1. Committee Members

All newly appointed members should complete the Collaborative Institutional Training Initiative (CITI) training course entitled *IACUC Chairs, Members and Coordinators*.

- CITI can be accessed at [Research, Ethics, and Compliance Training | CITI Program](#). New users must create a profile in order to access training modules.

The Chair and the IACUC administrator will conduct one on one training with new members. This training will include, but is not limited to:

- Providing reference materials (the Guide, the Ag Guide, AWA, PHS Policy, etc.) and introducing the member to guiding regulations
- Walking through the review process
- An introduction to the IACUC bylaws, policies, and the Assurance Statement
- Introducing the member to the InfoEd web-based protocol management system, Box drive navigation and granting access

A check sheet will be completed for each new member to assure all topics have been covered.

Returning Member Continuing Education

- Articles or announcements of interest will be uploaded to the meeting folder in Box each meeting month as continuing education materials.
- Travel to and registration for various meetings and professional programs may be provided to members and IACUC staff by the ORC.
- Various webinars may be registered for to provide additional opportunities for continuing education for members and IACUC staff.
- Web-based training modules on various animal welfare and regulatory subjects will be available through CITI Program.
- Presentations/discussion of emerging topics or case studies at IACUC meetings.
- While there is no Refresher version of the CITI course for IACUC members, the training should be repeated every 5 years as long as the member is active.

2. Faculty, Staff, and Students

The ORC and the Office of Animal Resources will provide appropriate training as mandated by the AWA and the PHS Policy to all faculty, staff, and students involved in the care and use of animals in research and teaching programs at the University.

The completion of animal welfare training, zoonotic training, and MSP enrollment will be confirmed by ORC staff for all personnel listed on an AUP or amendment. Approval will not be granted until all requirements are fulfilled.

The PI will verify that all students enrolled in classes requiring AUP's have successfully completed the required Animal Welfare Training, Zoonotic Training, and are enrolled in the Medical Surveillance Program.

The PI will be responsible for verifying that all personnel working on his/her protocol are qualified to perform their duties or will receive additional training based on that individual's role in the activities involving the use of animals.

IX. CHANGES TO THE BYLAWS

Any member may request a review of any part of these Bylaws. The Committee may amend these Bylaws by a two-thirds vote at any meeting at which a quorum is present, providing that all Committee members are sent notification of the pending vote a minimum of 5 business days prior to the meeting.

MEETING INFORMATION

X. RULES OF ORDER

The *Modern Edition of Robert's Rules of Order* shall guide all meetings of a quorum of Committee members.

XI. TYPES OF MEETINGS

1. Regularly Scheduled Meetings

The ORC will schedule monthly meetings for the Committee on a day agreed upon by a quorum of members. Members may attend in person or join the meeting via zoom. Remote participation is in adherence with NOT-OD-06-052. Members will be notified a minimum of five [5] calendar days prior to the meeting. An agenda listing all proposed activities to be reviewed along with written descriptions of all proposed activities involving the care and use of animals will be provided to all Committee members five (5) calendar days prior to the scheduled meeting. The names of respective primary and secondary reviewers on protocols requiring full committee review will be provided with the agenda.

2. Unscheduled Meetings – Emergency, to Address Time Sensitive Issues, or Member Requested

The Chair or the Director of the ORC may call an unscheduled meeting for an emergency or to address time sensitive issues.

An emergency is defined as any situation or condition that may jeopardize the health or safety of animal subjects or humans in association with animal subjects. If the AV declares "emergency care" of an animal or group of animals, an emergency meeting is scheduled as soon as a quorum of members can be convened.

Any member may request an unscheduled meeting by contacting the Chair or the ORC. Such requests should be in writing and explicit as to the reason and nature of the request. Requests will be judged by the Chair and the Director of the ORC to be legitimate or not. If the request is for a legitimate reason, notice is given to Committee members at least 48 hours prior to the meeting.

3. Status Meetings

The Chair, AV, Director of the ORC, and the Administrator will meet on an as need basis to discuss issues and prepare information for the Committee.

XII. CONFLICT OF INTEREST

A Committee member shall not participate in the review or approval of an activity in which that member has a conflicting interest. The member may provide information to the Committee, if the Committee so desires. However, the member must recuse himself/herself during deliberations and voting. Recused members will not count toward a quorum. The Chair will remind Committee members to self-identify conflicts of interest and recuse themselves from deliberations, if needed, and voting.

If any member perceives that another member has a conflict of interest that has gone unrecognized, the allegation may be brought to a vote by quorum of the Committee.

If an investigator submitting a protocol believes that a Committee member has a potential conflict, the investigator may request that the member be excluded. Either the member may voluntarily recuse himself/herself from the issue or a vote of the Committee quorum will be obtained to either sustain or reject the request from the submitting investigator.

Examples of conflict of interest include members that are:

- a. listed as PI, Co-PI, or listed personnel on a protocol under review
- b. involved in a potentially competing research program
- c. at an unfair competitive advantage with access to intellectual information.
- d. personally biased and unable to provide impartial judgment
- e. in a position to derive direct or indirect economic benefit from the outcome of a review.

XIII. VOTING

With the exception of Designated Member Reviews or Veterinary Verification and Consultation eligible amendments, approval on any motions or actions of the Committee may be granted only at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. All votes will be tallied and recorded in the meeting minutes as: For, Against, or Abstaining. Any minority views will also be recorded within or as an addendum to the meeting minutes.

XIV. MINORITY VIEWS

Majority vote determines the actions of the Committee. However, members who do not share the point of view of the majority have a right to have their ideas presented for consideration. If a member would like to have their opinion that contrasts with the majority vote documented, the member will submit the view to the Chair and Administrator in writing. Minority views will be included within or as an addendum to the meeting minutes and as an addendum to the semiannual report submitted to the IO.

XV. SUBCOMMITTEES

The Chair may appoint and charge subcommittees as needed.

REVIEW PROCEDURES

XVI. INITIAL PROTOCOL REVIEW AND APPROVAL

The following will be used as the basis for review and approval of all Animal Use Protocols:

- Animal Welfare Act (P.L. 89-544) and amendments and Animal Welfare Act Regulations
- USDA APHIS Animal Care Policies
- Guide for the Care and Use of Laboratory Animals
- Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching
- PHS Policy on the Care and Use of Laboratory Animals
- Guidance from species-specific scientific societies may also be considered.

Any proposal for animal use approved by the Committee may be subject to further approval by the IO or President. However, neither the IO nor President may allow the commencement of activities involving the care and use of animals that have not been approved by the Committee.

1. Pre-Review

A pre-submission review by the AV is required for all new and triennial renewal protocols. This consultation will cover, but is not limited to:

- experimental design and timeline
- the use of animal subjects and animal wellbeing
- project personnel and training requirements
- the source of animals and any quarantine requirements
- housing and husbandry needs including special housing or equipment requirements
- surgical procedures
- the use of analgesia and/or anesthesia
- euthanasia methods and humane endpoints

The AV will assign a USDA pain category to the study after the pre-review is complete.

The IACUC Administrator performs an administrative review of the AUP. When projects are funded, the AUP and the proposal are reviewed for congruency by the IACUC

Administrator. If needed, the IACUC Administrator provides the PI with a listing of information or sections of the AUP that need to be modified before it can be sent to the Chair.

2. Full Committee Review (FCR)

a. Submissions must receive FCR under the following conditions:

1. Major survival surgical procedure
2. Exceptions to recommendations in the ILAR Guide or Ag Guide
3. Euthanasia methods that are not consistent with AVMA Guidelines
4. Studies where death is the experimental endpoint
5. Experiments that involve burn studies or head/spinal trauma
6. Potential for more than minimal or transient pain, distress, or discomfort not relieved by drugs
7. Any procedure involving non-human primates, dogs or cats.

b. Full Committee Review Procedure (FCR)

1. The Chair assigns the review type and a primary and secondary reviewer. If a member of the IACUC has been identified as having a conflict of interest, that member is not eligible for assignment as the primary or secondary reviewer.
2. The ORC will notify all Committee members that a new submission has been posted and will list the members assigned to the reviewer roles.
3. The secondary reviewer and all other members shall post comments in InfoEd within 5 business days of posting.
4. The primary reviewer shall review the submission as well as comments from Committee members. The PI receives a list of modification requests from the IACUC in order to make corrections before the meeting. The primary reviewer will strive to ensure all items identified as unsatisfactory are corrected before the Committee meeting during which the protocol or amendment is discussed. Minor changes agreed to by the PI and the primary reviewer may be corrected in the submission by the Administrator or primary reviewer. Significant or extensive modifications will be made by the PI.
5. The primary reviewer should complete the review in a timely fashion, but not before the general review period has ended (i.e., 5 business days).
6. During a convened meeting, the primary reviewer, secondary reviewer or Chair shall present the protocol and the recommended action. After the Committee deliberates, the protocol presenter will make a motion to either approve the protocol as is, require modifications to secure approval with a second motion to allow a subsequent DMR to evaluate those modification, withhold approval, or table the protocol until a later meeting. After the motion is seconded, the Chair will call for a vote. The motion will only be passed if a majority of the quorum of Committee members present vote "for" the motion. All voting results are recorded in the meeting minutes. Minority views are also recorded within or as an addendum to the meeting minutes. Members attending

remotely participate in voting by visually providing their response to the voting prompts during the meeting.

7. The Administrator will prepare the approval letter for the Chair's signature. A copy of the signed correspondence and a copy of the AUP approved by the Committee will be sent to the PI. Copies will be maintained by the ORC.

3. Designated Member Review (DMR) Subsequent to Full Committee Review (FCR)

- a. A quorum of members at a convened meeting may decide by motion and unanimous vote to use DMR subsequent to FCR following a motion and majority vote for modifications required to secure approval. DMR review may result in approval, modifications to secure approval, or referral to the full committee at the next convened meeting.
- b. Any Committee member may request at any time in writing or subject to recording in the official minutes of a called meeting a DMR subsequent to FCR be changed back to a FCR prior to approval. Written requests will be submitted to the Chair and the Administrator.
- c. Designated Member Review Subsequent to Full Committee Review Procedure
 1. The designated reviewer will be identified during the meeting where the DMR subsequent FCR motion was made. The reviewer will contact the PI after the meeting in a timely fashion and discuss modifications needed to secure approval. The modifications will be made by the PI and submitted in InfoEd as a revised protocol. If the revised material has satisfied the recommendations of the Committee, the reviewer will complete their review.
 2. If a member requests a FCR, a secondary reviewer will be assigned by the Chair and the protocol or amendment will return to the FCR procedure.
 3. The IACUC Administrator will prepare the official correspondence for the Chair's signature. A copy of the signed correspondence and a copy of the AUP or amendment approved by the Committee will be sent to the PI. Copies will be maintained by the ORC.

4. Designated Member Review (DMR)

- a. Submissions that do not require FCR will be assigned to DMR.
- b. Any Committee member may request at any time in writing or subject to recording in the official minutes of a called meeting a DMR be changed to a FCR prior to approval. Written requests will be submitted to the Chair and the Administrator.
- c. Designated Member Review Procedures
 1. Submissions for DMR will be processed as described for FCR. If there are no calls for full committee review within 5 business days, the designated

reviewer can approve the protocol or require modification to secure approval. Protocols that cannot be approved by the designated reviewer will be reviewed by the full committee.

2. The designated reviewer will review the submission, as well as comments from Committee members, and may contact the PI to resolve any potential problems. The designated reviewer should complete the review in a timely fashion, but not before the general review period has ended (i.e., 5 business days). Minor changes agreed to by the PI and the primary reviewer may be corrected in the submissions by the Administrator or primary reviewer. Significant or extensive modifications will be made by the PI and submitted to the designated reviewer and IACUC Administrator as a revised protocol.
3. If a member requests a FCR, a primary and secondary reviewer will be assigned by the Chair and the protocol or amendment will be reviewed in accord with FCR procedures.
4. The IACUC Administrator will prepare the official correspondence for the Chair's signature. A copy of the signed correspondence and a copy of the AUP or amendment approved by the Committee will be sent to the PI. Copies will be maintained by the ORC.

5. Safety Review

- a. If certain fields within the protocol indicate hazards, a safety review will be assigned to the Biosafety Officer. The Safety Review will identify potential hazards and the Biosafety Officer will work with PI's to receive appropriate training and/or have documentation in place.

XVII. PRINCIPAL INVESTIGATOR APPEAL PROCESS

To ensure timely review and approval of AUPs, a PI must work with the primary reviewer of their AUP to assure that requests for clarifications, recommendations and concerns are fully addressed during the review process and before the scheduled meeting of the IACUC.

If the PI has concerns about the review process or the preliminary recommendations of the primary reviewer or the AV, the PI may schedule to meet with the full committee at the monthly Committee meeting. The PI will be given an opportunity to present information, discuss the proposed protocol and to ask and answer questions prior to the Committee's vote on the protocol.

In order for an item to be placed on the agenda of an upcoming Committee meeting, the PI must contact the ORC by email or telephone at least five days before the meeting. The Chair or the Administrator may be contacted in special circumstances.

XVIII. CHANGES TO APPROVED PROTOCOLS

Changes to approved protocol are accomplished through the submission of an amendment. The review of amendments will be conducted in accordance with IACUC Policy #2.6 and IACUC Policy #1.10.

XIX. ANNUAL REVIEW PROCEDURES

Approved protocols must be reviewed at least annually. Four to six (6) weeks prior to the anniversary date of an approved protocol, the PI is notified that the annual review form must be completed and returned in sufficient time to assure review and approval before the anniversary date of the initial approval.

PIs are encouraged to submit the annual review form at least two weeks prior to the anniversary date of the approved protocol. If the annual review has not been received by the anniversary date, the Committee may take action to ensure animal care and use is in compliance with federal law.

Completed annual review forms are reviewed and approved by the AV and the Chair and are made available to all Committee members. Any member may request that an annual review be presented to the full committee for review.

AUPs are approved for up to a three-year period. Projects that continue past the three-year period require a new AUP. These reviews are conducted using the same methods as a new protocol.

XX. DEPARTURE OR ABSENCE OF A PRINCIPAL INVESTIGATOR

Departure or absence of a PI will be handled in accordance with IACUC Policy #1.4.

XXI. POST APPROVAL MONITORING

All members are authorized to observe and evaluate approved activities for compliance with the approved protocol.

INSPECTIONS AND REPORTING

XXII. INSPECTION OF ANIMAL FACILITIES AND ANIMAL ACTIVITY AREAS

The Committee will inspect all University animal facilities (as defined in the PHS Policy and AWA) at least once every 6 months. Inspection of animal facilities and animal activity areas will be scheduled by the Administrator. A team of at least 2 Committee members will conduct the facility inspections/evaluations. The team must include at least the veterinarian or his/her designee and one or more voting members. Any member wishing to participate in a facility inspection may not be excluded.

A summary of inspection findings shall be reviewed and approved during a convened meeting of the Committee. Any minority views will be included in the meeting minutes.

Any failure to correct significant deficiencies found during inspections will be reported in accord with federal regulations to the IO, OLAW, USDA, and/or the funding agency as applicable.

XXIII. ANIMAL PROGRAM REVIEW

The IACUC shall review, at least once every 6 months, the University's program for the humane care and use of animals, using the ILAR Guide and the OLAW Semiannual Program and Facility Review Checklist as a basis for the evaluation. The Chair may assign a subcommittee to complete the animal program review. One member will serve as the chairman of the subcommittee and will present review findings to the Committee at a convened meeting.

XXIV. OTHER REPORTS TO THE COMMITTEE

The Committee shall review monthly reports on the veterinary care program from the AV.

XXV. SEMIANNUAL REPORT TO THE INSTITUTIONAL OFFICIAL

The Committee shall submit a report of the program review and facilities inspection to the IO at least every 6 months. This report shall identify all facility and program deficiencies. The Committee shall refer to the ILAR Guide, AWA Regulations, and the PHS Policy regarding definitions of deficiencies and reporting requirements. The report shall also include a plan of action and timelines for resolution of all deficiencies.

The Semiannual Report will be presented to the Committee and signed by a majority of members prior to submission to the IO.

XXVI. ANNUAL REPORTS

Annual reports will be made available for review by Committee members.

1. United States Department of Agriculture – Animal Health and Inspection Service (USDA APHIS)
 - a. An annual report will be prepared by the ORC according to the provisions of 9 CFR 2 (Subpart A, 2.36).
 - b. The report will be submitted according to guidelines set forth by the USDA APHIS.
2. Public Health Service (PHS), Office of Laboratory Animal Welfare (OLAW)
 - a. An annual report will be prepared according to the requirements of the PHS Policy at least once every 12 months.
 - b. This report will be reviewed and submitted to the IO for signature.
 - c. The ORC will submit, through the IO, the report to OLAW.
 - d. The report will provide OLAW with a full explanation of the circumstances and actions regarding:
 1. Serious or continuing noncompliance
 2. Serious deviations from the Guide
 3. Suspension of any PHS funded activity by the IACUC.
3. Association for the Assessment and Accreditation for Laboratory Animal Care International (AAALAC)
 - a. An annual report will be prepared and sent to AAALAC at least once every 12 months.

- b. The ORC will submit the report to AAALAC per guidelines established by AAALAC.

ANIMAL CONCERNS OR NON-COMPLIANCE

XXVII. REPORTING ANIMAL CONCERNS OR NONCOMPLIANCE

Reports of concerns regarding the care and use of animals will be addressed in accordance with IACUC Policy #1.5 Procedures for Reporting and Investigating Animal Care and Use Concerns.

Reports of non-compliance with IACUC policies and procedures will be addressed in accordance with IACUC Policy #1.7, Procedure for Addressing Non-Compliance with IACUC Policies or Procedures.