

LIBERTY UNIVERSITY

INSTITUTIONAL ANIMAL CARE AND USE
COMMITTEE HANDBOOK



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I. LIBERTY UNIVERSITY MISSION STATEMENT

PHILOSOPHY OF EDUCATION

Liberty University is a Christian academic community in the tradition of evangelical institutions of higher education. As such, Liberty continues the philosophy of education which first gave rise to the university, and which is summarized in the following propositions. God, the infinite source of all things, has shown us truth through scripture, nature, history, and above all, in Christ. Persons are spiritual, rational, moral, social, and physical, created in the image of God. They are, therefore, able to know and to value themselves and other persons, the universe, and God. Education as the process of teaching and learning, involves the whole person, by developing the knowledge, values, and skills which enable each individual to change freely. Thus it occurs most effectively when both instructor and student are properly related to God and each other through Christ.

STATEMENT OF MISSION & PURPOSE

Maintaining the vision of the founder, Dr. Jerry Falwell, Liberty University develops Christ-centered men and women with the values, knowledge, and skills essential to impact the world. Through its residential and online programs, services, facilities, and collaborations, the University educates men and women who will make important contributions to their workplaces and communities, follow their chosen vocations as callings to glorify God, and fulfill the Great Commission.

LIBERTY UNIVERSITY WILL:

1. Emphasize excellence in teaching and learning.
2. Foster university-level competencies in communication, critical thinking, information literacy, and mathematics in all undergraduate programs.
3. Ensure competency in scholarship, research, and professional communication in all graduate programs and undergraduate programs where appropriate.
4. Promote the synthesis of academic knowledge and Christian worldview in order that there might be a maturing of spiritual, intellectual, social and physical value-driven behavior.
5. Enable students to engage in a major field of study in career-focused disciplines built on a solid foundation in the liberal arts.
6. Promote an understanding of the Western tradition and the diverse elements of American cultural history, especially the importance of the individual in maintaining democratic and free market processes.
7. Contribute to a knowledge and understanding of other cultures and of international events.
8. Encourage a commitment to the Christian life, one of personal integrity, sensitivity to the needs of others, social responsibility and active communication of the Christian faith, and, as it is lived out, a life that leads people to Jesus Christ as the Lord of the universe and their own personal Savior.

II. INTRODUCTION

The Institutional Animal Care and Use Committee (IACUC) is charged with ensuring that all vertebrate animals used in research or instruction at Liberty University are treated ethically and humanely in accordance with applicable Federal law. Federal law and university policy detail the authority of the committee to act in a manner that ensures the best possible care is given to every animal housed and used as a part of University research or instruction.

This handbook is designed to be a guide to the role of the IACUC at Liberty University, but should not be considered comprehensive or complete. For additional resources, please visit the IACUC website, www.liberty.edu/iacuc. Questions or concerns may be directed to iacuc@liberty.edu.

III. THE IACUC

MEMBERSHIP OF THE IACUC

Basic requirements of IACUC membership are outlined in both the Public Health Service Policy (PHS policy section IV.A.3.c) and the Animal Welfare Act (9 CFR 2.31 (a-b)). While each of these documents varies in its exact requirements, the Liberty IACUC has adopted the following rules to fulfill its obligations under these regulations and to establish and maintain a diverse, highly-qualified committee.

NUMBER & COMPOSITION OF MEMBERS

The IACUC will be chaired by an Associate or Full Professor of Liberty University, and shall have no less than five formal members with the qualifications listed below:

- One practicing scientist with experience in research involving animals.
- One Doctor of Veterinary Medicine with training or experience in laboratory animal medicine and with University-wide authority to direct activities involving animals.
- One member not affiliated with the University who represents the interest of the surrounding community with respect to care and use of animals in instruction and research.
- One member with expertise in a non-scientific area.
- One faculty, staff, and/or administrative professional from Liberty with experience and expertise in the care and use of animals in instruction or research.

Members are allowed to fulfill multiple roles on the committee. No more than three members from the same department can be on the IACUC at a given time. Persons on the IACUC that do not meet one of the specific designations (veterinarian, scientist, non-scientific, non-affiliated) are referred to as a “member” of the IACUC. Liberty’s IACUC follows OLAW’s guidelines regarding the selection and use of alternate IACUC members.

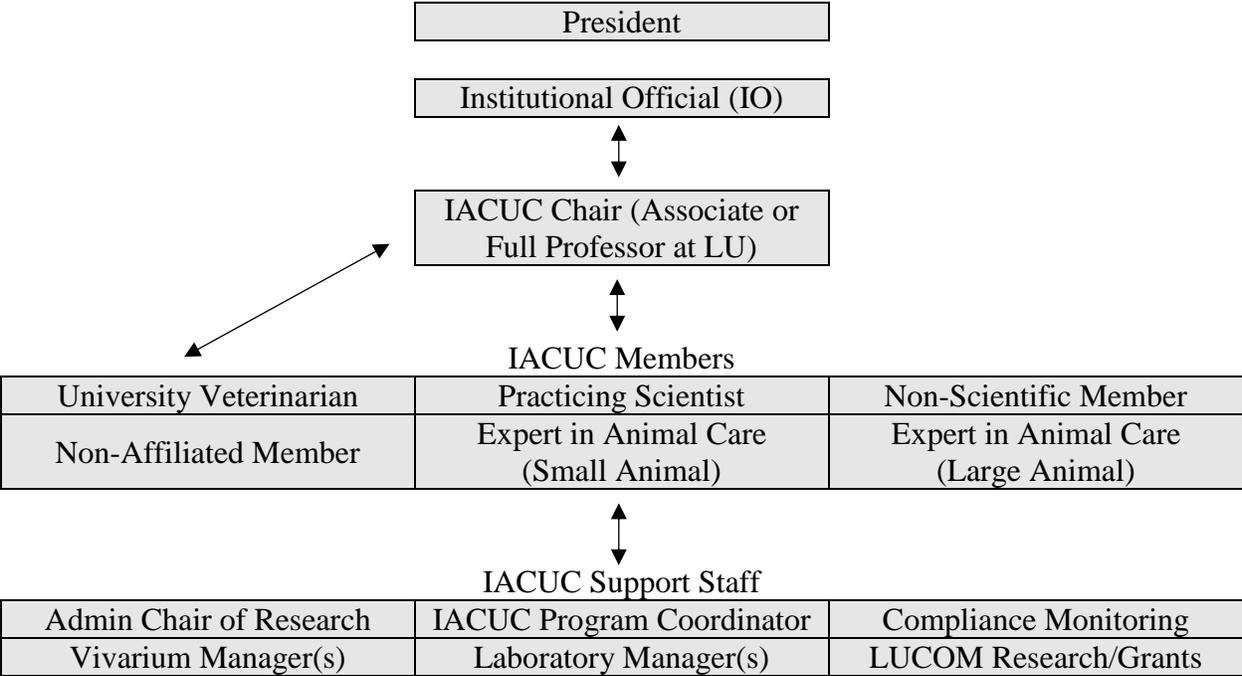
TYPES OF SUBMISSIONS TO THE IACUC

TYPE	DESCRIPTION	FORMS REQUIRED
New Protocol	New research project	Application & Appendices
Three Year Renewal	Continuation of the approved project beyond the 3 rd year	Application & Appendices
Annual Renewal	Progress report every 12 months, or as required by the IACUC	Annual Review Form
Amendment	Significant or minor change(s) to an existing protocol	Protocol Amendment Form

Forms are available on the IACUC website, www.liberty.edu/iacuc

IACUC ORGANIZATIONAL CHART

The IACUC is a presidential committee at Liberty University, appointed by the President, or his designee, the Institutional Official (IO).



IV. AUTHORITIES & FUNCTIONS

AUTHORITY FOR ESTABLISHING THE IACUC

Liberty University's Institutional Animal Care and Use Committee is prepared to file an assurance with the Office of Laboratory Animal Welfare (OLAW) in accordance with the PHS Policy. The committee is regulated by the USDA under the Animal Welfare Act (AWA) as well as Public Health Service (PHS) Policy. In order to ensure proper laboratory animal welfare, a partnership has been established with the Institutional Official (IO), the IACUC, the University Veterinarian, and the Investigators.

AUTHORITY OF THE IACUC

The Institutional Animal Care and Use Committee (IACUC) is the University's central review body for matters relating to the care, use, and treatment of animals in research or classroom instruction. The IACUC's scope includes the main Liberty University campus, campuses outside of Lynchburg, satellite facilities, cooperative units, and off-campus locations.

The IACUC is responsible for the oversight of all animal care and use, and for ensuring compliance with federal, state, and local regulations. The IO and President reserve the right to suspend or disapprove research, despite IACUC approval.

The following are federally mandated functions of the IACUC, according to policies outlined in the Animal Welfare Act (9 CFR Ch. 1 Subpart C 2.31 (c) (1-8)), Guide for the care and use of Agricultural Animals in Agricultural Research and Training (Chap. 1), and the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Section IV. B. (1-8)).

AUTHORITY TO INSPECT ANIMAL HOUSING FACILITIES AND THE UNIVERSITY'S ANIMAL CARE AND USE PROGRAM

Either the full committee or a designated IACUC sub-committee of at least 2 voting members will conduct a semi-annual program review at least once every six months. No member will be involuntarily excluded from participation. Those in attendance will review and evaluate the animal care and use program at Liberty University using OLAW's Sample Semiannual Program Review Checklist ("The Checklist"). Other documents referred to for the review shall include: The Checklist, The Guide, PHS Policy, and previous program evaluation reports. At the conclusion of the review, deficiencies will be classified as minor or significant. Repeat deficiencies and program changes will be noted. A plan of action and schedule for correction will be determined, as applicable. Member comments and deficiencies will be compiled, summarized, recorded and reported to the IO in the Semiannual Report. A majority of the IACUC will review and sign the report prior to submission. A copy of the report will be maintained by the IACUC office. Program areas that will be evaluated during the program review include, but are not limited to: Animal Care and Use Program Overview, Disaster Planning & Emergency Preparedness, The IACUC, IACUC Protocol Review & Special Considerations, IACUC Membership & Functions, IACUC Training, IACUC Records & Reporting Requirements, Veterinary Care, Personnel Qualifications & Training, Occupational Health and Safety of Personnel, Personal Security, Investigating & Reporting Animal Welfare Concerns.

Either the full committee or a designated IACUC sub-committee of at least 2 voting members will conduct semi-annual facility inspections at least once every six months. No member will be involuntarily excluded from participation. Those in attendance will review and evaluate the animal facilities at Liberty University using OLAW's Sample Semiannual Facility Inspection Checklist ("The Checklist"). Other documents referred to for the inspection shall include: The Checklist, The Guide, PHS Policy, and previous facility inspection reports. Each animal room, service area, laboratory, or procedure area will receive a report regardless of whether any deficiencies were noted. At the conclusion of the inspection, deficiencies will be classified as minor or significant. Repeat deficiencies will be noted. A plan of action and schedule for correction will be determined, as applicable. The appropriate investigator(s) and/or facility managers will be made aware of any deficiencies and plans for correction. IACUC staff will follow-up to ensure that deficiencies are corrected on or before the assigned completion date. Member comments and deficiencies will be compiled, summarized, recorded and reported to the IO in the Semiannual Report. A majority of the IACUC will review and sign the report prior to submission. A copy of the report will be maintained by the IACUC office. Animal facilities and components that will be evaluated during the review include, but are not limited to: Terrestrial Animal Housing & Support Areas, Aquatic Housing, Cage Wash, Special Facilities—Aseptic Surgery, Special Facilities—Procedure Areas, Non-Survival Surgeries, Laboratories, Rodent Surgeries, Imaging, Whole Body Irradiation, Hazardous Agent Contamination, Behavioral Studies.

**AUTHORITY TO PREPARE AND SUBMIT REPORTS OF THE IACUC
EVALUATIONS TO THE IO**

The IACUC will submit all inspection reports to Liberty's Institutional Official (IO). The report includes both major and minor deficiencies, and the program review. A quorum of the IACUC voting members must sign the reports, and minority views (if any) must be submitted in writing. Such views will be duly recorded and incorporated into the final report.

**AUTHORITY TO PREPARE AND SUBMIT REPORTS TO REGULATING OR
ACCREDITING BODIES ON BEHALF OF THE IO**

The IACUC will convene to review any findings or departures identified as a result of a semi-annual program review or facility inspection. The findings will be summarized and submitted in a semiannual report to the Institutional Official. Prior to submission, a majority of the IACUC will sign the report. The IACUC office will maintain a copy of the report. The report will follow the format of OLAW's sample semi-annual report and shall include, at minimum: the date and outcome of each review or inspection; observed deviations from PHS Policy or the Guide; rationale for any IACUC-approved departures from PHS Policy or the Guide; classification of deficiencies as minor, significant, and/or repeat; a schedule and plan for correcting deficiencies; any minority views.

**AUTHORITY TO MAKE RECOMMENDATIONS TO THE IO REGARDING THE
INSTITUTIONAL ANIMAL CARE AND USE**

Any recommendations made to the Institutional Official as a result of a semi-annual review or inspection will be communicated to the IO using the semiannual report. Recommendations that are made at other times shall be sent in writing via the IACUC Chair or IACUC office. Any recommendations must be supported with appropriate documentation and/or justification.

**AUTHORITY TO DISAPPROVE, MODIFY, OR APPROVE STUDIES BASED UPON
CONSIDERATION OF THE JUSTIFICATION OF ANIMAL USE**

The IACUC meets as needed throughout the year to review protocols and to discuss other pertinent business.

Submission of Protocols: Investigators will submit protocol applications to the IACUC electronically. A protocol number will be assigned and the training status of all associated personnel will be verified.

“Exempt” Review Process: Certain activities do not require IACUC oversight. The LU IACUC has explicitly defined such activities and will review exemption request submissions to confirm that an activity does not require IACUC review and approval. These activities include non-invasive field studies, studies that do not involve the use of live animals (such as the use of tissues, cadavers, blood, etc. obtained from an approved source), and studies that solely involve invertebrate animals. In such cases, only the IACUC can determine whether a protocol is exempt from oversight. The IACUC reserves the right to require that an approved protocol be in place prior to starting any animal activity if the IACUC determines it is in the best interest of the University, and/or the animals being used.

Preliminary Review Process: Upon receiving a protocol application, IACUC staff will conduct an administrative pre-review to ensure that all documents have been submitted properly and that the application is complete. During this pre-review period, the Attending Veterinarian may choose to review the protocol and will forward any comments or requests to the IACUC office. IACUC staff will then compile any preliminary feedback and return it to the investigator for review. This process may be repeated as necessary until the submission is deemed acceptable. At the discretion of the Attending Veterinarian, the veterinary protocol review may take place in person with the investigator in advance of protocol submission; during the pre-review period; or at the time of a convened IACUC meeting.

Conducting Protocol Reviews: Protocols that have completed the pre-review process will be electronically distributed to all committee members for an initial committee review. During the initial committee review period (typically 3 business days), members will be polled as to whether each protocol should be reviewed using the Full Committee Review process or the Designated Member Review (DMR) process. Committee members are informed that if no response is received during this initial committee review period, their non-response is considered a passive endorsement of designated member review. If no single member calls for a full committee review of a protocol, the protocol may be reviewed via the DMR process described below. If any

single member calls for a full committee review of a protocol, it will be presented for review at the next scheduled IACUC meeting. Any discussion, feedback, or revision requests from the initial committee review will be presented at a full committee meeting, to be recorded in the minutes in accordance with PHS Policy, IV.E.1.b. If a protocol is to be reviewed by Designated Member Review, any such comments will be saved in the protocol's electronic file and will be provided to the designated reviewer(s) for consideration.

Per PHS Policy IV.2., any IACUC member(s) involved in the protocol or those with any potential conflicts of interest shall recuse themselves from deliberation and voting and shall not count toward the quorum; these individuals may be present to provide information requested by the IACUC, however, once deliberations and voting begin, they must recuse themselves. Any conflicts of interest will be recorded in the minutes. Absent members' comments may be presented for the purpose of discussion. However, absent members are unable to vote. The committee may determine that an outside consultant is needed to provide appropriate discipline-specific guidance and may invite that consultant to participate in the review and approval process; these consultants are unable to vote and do not count toward the quorum.

Full Committee Review: All members will receive advanced notice of the meeting and will be provided access to any protocols scheduled for review. The IACUC chair or designee presides over the meeting and presents any protocols scheduled for review. In order to review protocols, a quorum of voting members must be present. In certain cases, the IACUC Chair may request that the PI be present for the discussion. However, once deliberation begins, the PI will be asked to leave the room. After adequate discussion of each protocol, the full committee may move to vote in the following ways: approve, modifications required to secure approval, defer or table, or withhold approval. A voice vote will be taken, and the majority vote of the quorum present shall represent the decision of the committee. The outcome of the vote and any dissenting votes, abstentions, or minority views will be recorded in the minutes.

Designated Member Review following Full Committee Meeting: Per Liberty University IACUC policy, a quorum of voting members present at a convened IACUC meeting may unanimously vote to have any requested modifications reviewed and approved by DMR following the full meeting. If such a vote is received at the convened meeting, the IACUC Chair will appoint one or more qualified voting members to serve as designated reviewers. The IACUC office shall serve as the intermediary between the designated reviewer(s) and the principal investigator. Modification requests shall be sent to the principal investigator, and revised protocols will be returned to the IACUC office. The IACUC office will then distribute the revised protocol to the designated reviewer(s). Designated reviewers may then make the following decisions: approve, modifications required to secure approval, or refer protocol to full committee. Decisions made by designated reviewers must be unanimous. Any additional modification requests or protocol revisions must be reviewed by all designated reviewers. If designated reviewers do not come to a unanimous decision, a protocol must be returned to full committee. Designated reviewers are not allowed to withhold approval.

Designated Member Review (DMR): Assuming no single member has called for a full committee review of a protocol, the IACUC may use the DMR process following initial committee review (as described above, *Conducting Protocol Reviews*). The IACUC Chair will

appoint one or more qualified members to review the protocol via DMR, considering any potential for conflicts of interest. The IACUC Chair can assign any number of qualified reviewers to the protocol. This process will proceed as described above in “*Designated Member Review following Full Committee Meeting*” with the same possible outcomes.

Appeals Process: If a protocol is not approved using the above processes, a principal investigator may request an appeal in writing. When such a request is received by the IACUC office, the committee will convene to interview the investigator and attempt to resolve any issues prior to written appeal to the IO. Should the appeal process result in a written appeal to the IO, the following process will be followed:

- The IO will review the committee’s original decision to withhold approval. He or she may agree with the IACUC’s decision, or the IO may determine that further review is warranted.
- If the IO agrees with the IACUC’s decision to withhold approval, the decision is final.
- If the IO decides that further review is warranted, the protocol will be reviewed a second time by the IACUC in full committee. The PI will have the opportunity to revise the protocol and/or provide additional information, opinions, or consultation prior to the protocol being re-reviewed by the IACUC. If present, the PI must recuse him or herself from the meeting during deliberations and voting.
- After deliberation, the committee may vote to either “approve” or “withhold approval.” Decisions made a result of this vote will be final.

A letter announcing the final decision will be provided electronically to the investigator and the IO. The IACUC office will maintain a copy of this letter.

Principal Investigators must submit protocol amendments for review whenever a change to an approved animal use protocol is considered. Any changes must be approved by the IACUC prior to being implemented by the PI. Once received, the IACUC office will inform the PI that the amendment has been received and that the review process will begin shortly. Significant changes include, but are not limited to:

- Change in the purpose, aim, or objectives of a study
- Change in Principal Investigator
- Change or addition of a new species
- Significant increases in animal number
- Repeating an experiment with more animals
- Adding hazardous agents
- Changing an approved procedure (duration, frequency, invasiveness)
- Adding or changing therapeutic/analgesic/anesthetic agents
- Change in housing or husbandry
- Change in the method of euthanasia

Once an amendment request form has been received, it will be processed by the IACUC office. Significant amendments will be distributed to the committee electronically for initial committee review. The committee will be asked to respond the same way they would for receipt of a new protocol; the amendment review process is handled in the same manner as a new protocol. These processes are described above in III.D.6.

Certain significant amendment requests may be reviewed using VVC, depending on the nature of the proposed change, current IACUC policy, and the discretion of the IACUC Chair and/or Attending Veterinarian.

Changes in personnel (other than the PI) and other minor amendments may be reviewed administratively. The IACUC office will review any personnel amendments to ensure that listed individuals are properly trained, qualified, and enrolled in the Occupational Health Program.

Any amendments considered administrative or minor may be referred to the full committee for review. All amendment requests, correspondence, annual reviews, and reviewer comments shall be recorded and saved in the protocol's file.

AUTHORITY TO APPROVE PROTOCOLS, REQUIRE PROGRESS REPORTS FROM THE INVESTIGATORS, AND OVERSEE THE CONDUCT OF THE STUDY

Notice of Approval: Investigators will be informed of any IACUC approval decisions electronically. An approval letter will be provided and shall include the following: date of approval, Principal Investigator's full name, protocol number and title, and period of approval (three years maximum). The IACUC office maintains copies of all approval letters, which may be printed and provided in hard copy by request.

Notice of Tabled Review: If the IACUC chooses to table a protocol review for an extended period of time, the decision to do so will be provided to the Principal Investigator electronically. This notification will include a brief description detailing the committee's rationale along with any recommendations to the PI regarding resubmission or revision.

Notice if a Protocol is Not Approved: If the IACUC chooses not to approve a protocol, the decision will be delivered to the Principal Investigator electronically. This correspondence will include a letter detailing the committee's rationale, any recommendations to the PI regarding resubmission or revision, and methods for how to respond to the IACUC's concerns, whether in person or in writing.

Notification of the Institution: The IACUC office maintains records of all IACUC decisions regarding protocol review. These records are made available to the committee or the IO upon request.

AUTHORITY TO CONDUCT POST-APPROVAL MONITORING ON APPROVED PROTOCOLS

Annual Reviews: If a protocol includes a USDA-covered species, an annual review must be submitted to the IACUC by the Principal investigator prior to the date of the first and second anniversaries of the protocol's original approval. The annual review shall include: the number of animals used to date, any previously unreported updates to personnel, any previously unreported changes in protocol or unreported adverse events, and a summary of key developments from the past year. Investigators are reminded to submit any amendments for IACUC approval prior to implementation. Annual reviews are distributed for initial committee review and are then

reviewed using either Full Committee Review or DMR (see above for this process). Upon receiving an annual review, the IACUC office will verify the animal use totals against the approved number, and verify the training and occupational health status of all personnel. If an annual review is submitted after the expiration date, all animal work must cease and all animals shall be transferred to the Attending Veterinarian's holding protocol until a new protocol is approved by the IACUC.

Three-Year Renewals: On the third anniversary of original protocol approval, a protocol is considered expired unless it has been re-approved by the IACUC. Should the PI wish to continue animal work on an existing protocol, a renewal application must be submitted and approved in advance of the expiration date. If a protocol renewal request is submitted after the expiration date, all animal work must cease and all animals shall be transferred to the Attending Veterinarian's holding protocol until a new protocol is approved by the IACUC. The protocol renewal process is *de novo* and follows the review procedures listed above.

Post Approval Monitoring: Post approval monitoring (PAM) is conducted throughout the life of a protocol to ensure compliance with regulations and adherence to the IACUC-approved protocol. Post approval monitoring may be performed using the above continuing review methods, or by in-person audit. Any identified issues or concerns will be reported to the Chair and/or the IACUC, and appropriate action will be taken to promptly correct any deficiencies. If PAM identifies any issues that pose an immediate threat to the health or welfare of the animals or personnel, the Attending Veterinarian and/or Chair may take appropriate action to promptly resolve the issue.

AUTHORITY TO SUSPEND OR TERMINATE APPROVAL OF ANY APPROVED ACTIVITY
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The IACUC may suspend an activity involving animals only after review at a convened IACUC meeting with appropriate quorum. The suspension vote must be a majority vote. Depending on the situation, an emergency meeting may be called by the IACUC Chair. Criteria for suspension and timelines for resolution will be recorded in the minutes, along with the final vote and any minority views. The PI will receive a letter electronically informing them of the committee's decision. This letter shall include a rationale for the suspension, actions to be taken to lift the suspension, and timelines for resolution. At a minimum, the IACUC Chair and IO will be copied on the notification. Upon receipt, the IO will review the action taken by the IACUC and if warranted, provide a preliminary written report to OLAW. The IO has the ability to impose additional sanctions for lifting the suspension. If a suspension was the result of significant animal welfare concerns, the PI must explain to the IACUC, in writing, the steps have been taken to reduce the likelihood of recurrence prior to the suspension being lifted. Once a suspension has been lifted, the IO shall submit a final report to OLAW (and any other applicable funding agencies) describing the reasons for suspension and the actions taken to remedy the situation.

Investigators with a pattern of non-compliance may be denied IACUC review or the use of animals for teaching/research/testing at the discretion of the IACUC Chair, University Veterinarian, IO, and/or PI's Department Chair. Those with a history of ignoring the direction of

the IACUC, Chair, Attending Veterinarian, or the provisions of the Guide or the Animal Welfare Act are also covered under this statement.

AUTHORITY TO REVIEW CONCERNS INVOLVING ANIMAL CARE AND USE

All new and existing IACUC personnel will be informed of how to report concerns related to animal care and use at the University, including the whistleblower policy. Information for reporting concerns shall be available on the IACUC website, which includes a mechanism for anonymous reporting. Other mechanisms that enable individuals to report concerns include: in-person, by phone, or by email to the IACUC Chair, IACUC Office, Attending Veterinarian, Principal Investigator, and/or Lab/Facility Managers. Posters with how to report concerns and the contact information for these individuals and offices will be prominently displayed in all animal housing facilities and procedure areas.

How Concerns are Handled & Reported by the IACUC: Once received, all reported concerns will be promptly forwarded to the IACUC Chair for review. The IACUC Chair or designee will then investigate the claim. If the Chair or designee finds that a claim is substantiated, the Chair or designee shall promptly contact the responsible party in order to come to a resolution or to devise a plan to correct the deficiency. If the Chair or designee determines that the complaint poses an immediate threat to animal welfare, the Chair may choose to take immediate action, consult with the Attending Veterinarian, or convene the committee to present the problem for immediate discussion. If a claim is brought before the full committee, the committee will review the claim, make recommendations, and vote on appropriate action up to and including a vote to suspend the activity either indefinitely, or until the problem is resolved. If, at the Chair's discretion, a claim does not warrant immediate attention, it will be presented at the next scheduled IACUC meeting for discussion.

The IACUC chair, the attending veterinarian, and/or the IO will take appropriate action(s) to ensure that there is no reprisal against an individual reporting a concern. Significant animal welfare issues will be promptly reported to the IO, who may choose to take additional action. As required, OLAW, USDA, and other funding agencies will be notified of the deficiency and timeline for correction.