

Standard Operating Procedures (SOP) for the Institutional Animal Care and Use Committee

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I. New Protocol Submissions

Any investigator involved with the use of live or dead animals in research, teaching or other activities, regardless of where the work will be conducted must submit a protocol for Institutional Animal Care and Use Committee (IACUC) review. The PI must assure that all research personnel and/or students using live animals or animal tissues are adequately trained and experienced, and/or supervised to perform the procedures and are aware of all occupational health & safety practices associated with the use of live animals and/or animal tissues described in the application. If the work is being conducted at another institution, our IACUC will review the approved protocol to make sure that the procedures are acceptable. If acceptable, we will defer all oversight responsibilities to that institution (i.e. accept their review). If concerns are identified, a letter will be sent to the PI to revise the protocol to address those concerns, and have it re-reviewed and approved at the other assured institution. Once this process is complete, we will accept the institution's review. If the work is being conducted at our institution, our IACUC is responsible for ensuring compliance with all federal laws and regulations.

Principal Investigator Eligibility

Only full time faculty members qualify to serve as PI on a project. The faculty member's appointment must be as a Full Professor, Associate Professor, or Assistant Professor. Exceptions may be made for Full time (FT) Instructors or other FT faculty members.

Submission of Protocols

Requirements for the use of Live Vertebrate Animals

A completed *Salisbury University Animal Protocol forms* protocol forms must be submitted by the first day of each month. The IACUC meets on every month on the third Thursday in the month. All applications received on the deadline day are pre-reviewed by the IACUC Chairman, logged into the IACUC agenda prior to the assignment of an IACUC member(s), and forwarded for veterinarian.

The veterinarian shall pre-review all protocols before the formal review by the IACUC. The results of the veterinary pre-review will be forwarded to the IACUC chair and the PI will be notified of the comments. The veterinarian shall highlight specific issues regarding the protocol pre-review in writing and submit them to the IACUC chair. Prior to the formal review, the comments will be forwarded to the PI by the IACUC chair along with a statement indicating that "all, some, or none of the suggestions may be used prior to submission for a formal review by the IACUC." No other contact with the veterinarian is required by the PI, however all PI's will be invited to discuss their protocol with the veterinarian if they feel it's necessary.

Salisbury University Requirements for Animal Tissue Use

In order to document that appropriate practices of acquisition, use, and disposition of animal tissues are followed, and with appropriate consideration of occupational health and safety, a completed *Animal Tissue Protocol Form* must be submitted by the first day of each month whenever animal tissues are requested from an IACUC-approved protocol, another institution, or other source.

All Principal Investigators that desire to use animal tissues **only**, with no intention of using live animals must complete the Animal Tissue Protocol Form. In order for the IACUC to grant full approval, the PI must document appropriate practices of tissue acquisition, and the source of the tissue (e.g., from other IACUC approved protocols, slaughterhouses, zoos, or by-product of commercial/recreational fishing). The purchase and use of non-infectious materials such as formalin-fixed tissues, sterile cell cultures, and other preserved tissues or materials where no evidence or indication exists that they contain an infectious agent of animal or public health significance are not required to obtain a tissue protocol (e.g. fetal pigs, sheep hearts acquired from an approved commercial vendor). Occupational health and safety principles require that personnel using animal tissues know the hazards associated with their work, understand how these hazards are controlled, have safe practices, and use proper personnel protective equipment and supplies. The use of fresh or frozen animal tissue may pose a risk to the health of researchers and technicians through the transfer of disease (zoonosis). The PI must provide evidence that prior to beginning research involving animals and/or animal tissues, personnel/students are familiar with the health risks associated with the species involved in the work. In addition, The PI must have knowledge of all regulations pertaining to the acquisition of animal tissues under study, have obtained all permits necessary for carrying out the proposed studies prior to their initiation, and ensure that studies will be in accordance with all wildlife regulations. Tissue, either fresh or fixed, must be disposed in an appropriate manner. The IACUC requires that all tissue be disposed as biomedical waste. Please contact Wayne Shelton to arrange for the disposal of biomedical waste.

[Shipping and receiving of animal tissues/specimens](#) must be conducted in accordance with federal safety and [importation guidelines and regulations](#). The PI must act in accordance with the United States Department of Agriculture, Animal and Plant Health Inspection Service regulations regarding the limits on [importation of animals or tissues](#) that may have been exposed to an exotic livestock or poultry disease agent, and the limits on the importation of plants and other vegetable matter. The PI must act in accordance with the Public Health Service Foreign Quarantine Regulations ([42 CFR 71.54](#)) which govern the importation and transfer of [etiologic agents and vectors of human disease](#). U.S. Fish and [Wildlife Service regulations](#) must also be followed. The movement of other non-infectious materials such as formalin-fixed tissues, sterile cell cultures, and other preserved tissues or materials where no evidence or indication exists that they contain an infectious agent of animal or public health significance are not governed by these regulations.

Full Committee Review Procedures

Routinely all protocol submissions undergo full committee review. Protocols submitted by PIs that have outstanding compliance issues will not be reviewed until all concerns are addressed and approved by the IACUC. Our IACUC utilizes a primary and secondary reviewer system such that at least two committee members with the appropriate expertise are responsible for an in depth review of a proposal and subsequently lead the discussion at the meeting. In rare instances, only a primary reviewer (usually the chair) may be assigned if a study involves minimal animal manipulations such as euthanize and harvest protocols. In all cases, the full

committee participates in the discussion. In situations where IACUC members have submitted protocols for review, that member must recuse themselves from voting on the outcome of the protocol and leave the room during the vote. They may be allowed to participate in the initial discussion. **[A quorum (>50%) of the members must be present at the meeting and the majority of the members present must vote in favor of the outcome for any action to be taken].**

The potential outcomes of review are:

- 1) Full Approval: The Committee has approved the protocol without question.
- 2) Conditional Approval: The Committee has approved the protocol contingent upon receipt of additional clarification before the project can be initiated.
- 3) Request More Information: The Committee has neither approved nor disapproved the protocol. Clarification, revisions and/or additions are needed to properly assess the proposed research. The revised protocol must come back to full committee review.
- 4) Disapproval: The Committee did not approve a protocol due to significant deficiencies and concurred that the Principal Investigator (PI) should start over.

Protocol Distribution Procedures

A copy of each protocol along with a meeting agenda, protocol assignments, veterinary pre-reviews, discussion and education materials, etc is distributed to all members one week in advance of the meeting. If a new protocol is added to the agenda following distribution of the packet, the materials are hand delivered or sent electronically to all members in advance of the meeting.

Post Meeting

Following the meeting, draft minutes are composed. Minutes include preprotocol review discussions (training, updates, etc) and detailed comments for each protocol reviewed. For each protocol, the following information is recorded in the minutes: PI Name; PI Department; Title; Species and Number Requested; Reviewers; Committee Decision; Committee Vote and Comments to the PI. IACUC number will be assigned to the protocol once approval has been received. Comments from each reviewer and IACUC Chair's notes for a given protocol are combined. The draft minutes are reviewed by the IACUC Chair. The minutes are revised to include any corrections/additions/deletions made by the IACUC Chair. From the minutes, letters are composed and sent to the PI for action as follows.

Full Approval: A full approval letter is sent to the Principal Investigator (PI). Animals may be purchased through the Office of Graduate Studies and Research and used in context of the approved protocol only. Approval is given for a maximum of three years from the meeting date with a continuing report of progress/status required annually.

Conditional Approval: A query letter is sent to the Principal Investigator (PI) indicating the study had been conditionally approved and includes those issues that must be addressed prior to final approval. The PI is advised to submit the requested information within fifteen (15) working days and is reminded that no animals may be ordered and no research may begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, a review (by the chair

and/or other members as warranted) will take place to determine if the response is adequate. If the information is satisfactory, a final approval letter will be sent to the PI. Approval is given for a maximum of three years, with a continuing report of progress/status required annually.

Request More Information: A query letter is sent to the Principal Investigator (PI) indicating that the committee requires further information to render a decision and includes those issues that must be addressed prior to further review. The PI is advised to submit the requested information to the IACUC as soon as possible and is reminded that no animals may be ordered and no research may begin until the final approval is granted by the IACUC. Upon receipt of the PI's response to queries, the protocol will be assigned to the original reviewers and put on the agenda for re-review at the next Committee meeting.

Disapproval: A letter is sent to the PI indicating that the committee had disapproved the study, the reasons for disapproval, any comments the committee had that must be addressed in the next version, and recommend consultation with the IACUC Chair for guidance and assistance prior to submission of a new (revised) protocol. The letter also indicates that no animals may be ordered and no research may begin until the final approval is granted by the IACUC. Minutes are to be sent to the committee within seven working days after the committee meeting. Any comments/suggestions are to be returned to the IACUC Chairman. Revised minutes will be presented at the next scheduled meeting.

Designated Review Procedures

The designated review mechanism is not routinely used by the IACUC, although the following methods are implemented when the IACUC Chair has determined this method is appropriate. The IACUC prefers to review all protocols involving the use of animals at a fully convened meeting to discuss details of the proposed animal procedures.

The identified protocol can be submitted on the deadline date or at any point during the month. The protocol will be pre-reviewed by the IACUC Chair, and logged into the IACUC agenda prior to the assignment of an IACUC member(s). The protocol will be submitted to all members of the IACUC (in hard copy or electronically) identifying the two or more designated reviewers and providing a deadline for the opportunity for any member to request full committee review. If the reviewers or committee request full board review, a letter will be sent to the PI notifying him of the decision and the rationale for that decision. The designated reviewers may only vote to grant 1) full approval, or 2) disapproval.

The IACUC Chair will summarize for the committee the results of the designated review at the next upcoming bimonthly meeting for informational purposes only and this discussion will be documented in the minutes.

II. AMENDMENTS TO APPROVED PROTOCOLS

Any modification to the approved protocol must be submitted for IACUC review and approval. When an amendment is submitted to the IACUC, it is classified as either an administrative, minor or significant amendment.

Administrative Amendments

An administrative amendment is one that can be approved by the IACUC Chair. Examples of administrative amendments include changes to the protocol title, deletion of research personnel, change in office / laboratory location, etc. If the administrative amendment is approved, the approval date for the amendment will be the date of approval. The “Minor Amendment” approval letter will be issued. If a clarification is needed, an email will be sent to the principal investigator. Once a response is received and approved, the “Minor Amendment” approval letter will be issued. A copy of the approval letter and amendment is maintained in the protocol file.

Minor Amendments

A minor amendment is one that can be approved by the IACUC Chair. Examples of minor amendments include a change in animal numbers (<10%), a change to an anesthetic or an analgesic as recommended by veterinary consultation. If the minor amendment is approved, the approval date for the amendment will be the date of approval. The “Minor Amendment” approval letter will be issued. If a clarification is needed, an email will be sent to the principal investigator. Once a response is received and approved, the “Minor Amendment” approval letter will be issued. A copy of the approval letter and amendment is maintained in the protocol file.

Significant Amendments

A significant amendment must be reviewed via full committee or designated review, if warranted. Examples of significant amendments include change in objective of study, new species / strain, new procedures / experiments, a change in animal numbers >10 %, change in Principal Investigator, etc.

1. Full Committee Review of Significant Amendment

The amendment is pre-reviewed by the IACUC Chair, assigned to the original reviewers (or reviewers with the appropriate expertise) and put on the agenda for review at the next committee meeting. Our IACUC utilizes the primary and secondary reviewer system such that two committee members with the appropriate expertise are responsible for providing a brief summary of the approved study and an in depth review of the proposed modification. The full committee participates in this discussion and votes on the outcome of the review. **[A quorum (>50%) of the members must be present at the meeting and the majority of the members present must vote in favor of the outcome for any action to be taken].**

The potential outcomes of the full review are:

Full Approval: The Committee has approved the proposed modification without question.

Conditional Approval: The Committee has approved the proposed modification contingent upon receipt of additional clarification before the modification can be initiated.

Request More Information: The Committee has neither approved nor disapproved the proposed modification. Clarification, revisions and/or additions are needed to properly assess the proposed research.

Disapproval: The Committee did not approve the proposed modification due to significant deficiencies and concurred that the Principal Investigator (PI) should submit as a new study.

A copy of each proposed significant modification is included in the meeting packet that is distributed to all members one week in advance of the meeting. If a modification is added to the agenda following distribution of the packets, the materials will be hand delivered or sent electronically to all members in advance of the meeting. A copy of the currently approved protocol is provided to both of the reviewers in addition to the amendment request.

Following the meeting, draft minutes are composed. Minutes include pre-protocol review discussions (training, updates, etc) and detailed comments for each protocol reviewed. For each protocol, the following information is recorded in the minutes: PI Name; PI Department; Title; Species and Number Requested; Reviewers; Committee Decision; Committee Vote and Comments to the PI. IACUC number will be assigned to the protocol once approval has been received. Comments from each reviewer and IACUC Chair's notes for a given protocol are combined. The draft minutes are reviewed by the IACUC Chair. The minutes are revised to include any corrections/additions/deletions made by the IACUC Chair. From the minutes, letters are composed and sent to the PI for action as follows.

Full Approval: A full approval letter is sent to the Principal Investigator (PI).

Conditional Approval: A query letter is sent to the Principal Investigator (PI) indicating the proposed modification had been conditionally approved and includes those issues that must be addressed prior to final approval. The PI is advised to submit the requested information within fifteen (15) working days and is reminded that the research proposed in the modification cannot begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, a review (by the chair and/or other members as warranted) will take place to determine if the response is adequate. If the information is satisfactory, a final approval letter will be sent to the PI.

Request More Information: A query letter is sent to the Principal Investigator (PI) indicating that the committee requires further information to render a decision and includes those issues that must be addressed prior to further review. The PI is advised to submit the requested information to the IACUC as soon as possible and is reminded that the research proposed in the modification cannot begin until final approval is granted by the IACUC. Upon receipt of the PI's response to queries, the proposed protocol modification will be assigned to the original reviewers and put on the agenda for re-review at the next Committee meeting.

Disapproval: A letter is sent to the PI indicating that the committee had disapproved the proposed modification, the reasons for disapproval, any comments the committee had that must be addressed in the next version, and recommend consultation with the IACUC Chair for guidance and assistance prior to submission of a new protocol. The letter also indicates

that that the research proposed in the modification cannot begin until final approval is granted by the IACU Minutes are to be sent to the committee within three working days after the committee meeting. Any comments/suggestions are to be returned to the IACUC Chair. Revised minutes will be presented at the next scheduled meeting.

2. Designated Review of Significant Amendment

The designated review mechanism is not routinely used by the IACUC, although the following methods are implemented when the IACUC Chair has determined this method is appropriate. In order for a modification to undergo this method of review, the Principal Investigator must provide documentation justifying the request. The IACUC prefers to review all proposed significant modifications involving the use of animals at a fully convened meeting to discuss details of the proposed animal procedures. The identified modification can be submitted on the deadline date or at any point during the month. The proposed modification will be pre-reviewed by the IACUC Chair and distributed to all members of the IACUC (in hard copy or electronically). The IACUC Chair will designate two or more reviewers and a deadline will be provided for the opportunity for any member to request full committee review. Designated reviewers will review the proposed modification and either grant full approval, conditional approval or require full board review at the next convened meeting (or an emergency meeting may be convened if warranted). The same procedures as noted above in the outcome section for full approval or conditional approval will be implemented. If the reviewers or committee request full board review, a letter will be sent to the PI notifying him of the decision and the rationale for that decision.

The IACUC Chair will summarize for the committee the results of the designated review at the next upcoming monthly meeting for informational purposes only and this discussion will be documented in the minutes

III. ANNUAL REPORTS

An email is sent to the Principal Investigator (PI) at least one month in advance of the protocol's anniversary date as a reminder that an annual report is due. The PI is required to report on the progress made to date, whether any complications have been observed and to address various questions regarding any proposed changes for the upcoming year. The completed form is to be submitted to the IACUC Chair prior to the anniversary date. [Delinquency in submitting an annual report will result in an administrative hold being placed on the protocol.]

Annual Report Review

The annual reports are reviewed by the IACUC committee and forwarded to the next committee meeting for informational purposes only. If complications or modifications are proposed, the IACUC Chair and/or other members, as needed, will review the annual report. An annual report requesting significant modifications will undergo full committee review or designated review.

Approvals

Once the annual report is approved, the “Annual Report Approval” letter is sent to the principal investigator. A copy of the approval letter and annual report is placed in the protocol file.

Meeting Minutes

Any annual report with a significant modification undergoes committee review, and the discussion and comments are noted in the minutes. See procedures for committee review of significant modifications. An annual report agenda noting all annual reports approved since the last meeting is included in the final minutes.

IV. FINAL REPORTS

All studies are approved for three years. Three months in advance of a study’s expiration date, the PI is sent an email reminder indicating that a final report is due and if he/she wishes to continue the research a new protocol must be submitted for review prior to the current study’s expiration date (noted on the reminder).

Final Report Review

The final report is reviewed and approved by the IACUC committee. Any final report noting complications is reviewed by the IACUC Chair. New protocols undergo full committee review.

Closure / Approval

Once the final report is approved, the study is closed. The expiration date is removed from the database and a “Final Report Approval” letter is sent to the investigator. A copy of the approval letter and final report is placed in the protocol file.

Procedures if no final report is submitted

Final report review takes place on the date of expiration, unless otherwise requested by the PI (e.g. early closure). All final reports are reviewed, approved and the study is closed. All studies for which a final report has not been submitted are identified and administratively closed. A “Close” letter is sent to the investigator. A copy of this letter is placed in the protocol file. All closed / completed protocols are archived in the Office of Graduate Studies and Research.

V. SEMI-ANNUAL INSPECTIONS

Every six months, all facilities in which animals are housed or used are inspected by representatives of the IACUC. Inspection teams consist of at least two IACUC members accompanied by the IACUC Chair. The inspections are assigned by building and then broken into laboratories, animal housing facilities or satellite facilities. The IACUC database includes the location of animal usage for each protocol. Prior to each semiannual inspection, the database is queried for each building and a report is printed out to assist inspectors in assuring all areas have been seen. Each room inspected is documented on the inspection form noting room number, PI, species used, whether surgery is conducted and if so surgical procedures and logs are inspected, drug inventory inspection, vermin control, cleanliness of room and a section to note any deficiencies or guidance, etc. When an apparent deficiency is noted, it will be

discussed with the principal investigator or research staff. The principal investigator may choose to send a formal letter to the IACUC noting what corrective action he/she has taken or they may wait to respond to the IACUC letter documenting a deficiency was found in his/her lab, etc. If immediate veterinary care is warranted, the IACUC Chair will contact veterinary services to follow up and provide a report back to the IACUC of their findings, discuss actions taken, etc.

Inspection Report and Deficiency Notices

The IACUC Chair gathers information recorded on the inspection forms and composes a formal inspection report. The report briefly summarizes the IACUC's responsibilities set forth in the PHS Policy, what guidance was used as a basis for evaluation, what areas were inspected and how. The report is separated into two sections: facility inspections and program review. Under facility and lab inspections, a brief summary is included addressing whether any significant deficiencies were noted and a description of the information to follow. This section of the report is broken into sections: labs / satellites and animal housing facilities. Each section is further divided to address deficiencies, comments, or recommendations per building. Items identified in the report include building, room, principal investigator, significant or minor deficiency and its corrective action. Under program review, each element reviewed is documented noting version date. The draft report is reviewed and approved at a monthly IACUC meeting and documented in the minutes. Upon approval, corrective action letters are sent to the principal investigators, as well as those parties responsible for the animal housing facilities noting the deficiency, the corrective action to be taken and the deadline for correction. The final report is forwarded to the Institutional Official for review, discussed as needed and signed off.

VI. SEMI-ANNUAL PROGRAM REVIEW

Every six months, during monthly IACUC meetings, a review is done of the Institution's program for humane care and use of animals. The committee utilizes the OLAW Semi-Annual Program Review Checklist to aid in this evaluation. This checklist and a detailed list of the reviews including the date of the IACUC meeting in which it was reviewed and approved are included with the semi-annual inspection report and in the monthly minutes for that month.

Additionally, the IACUC conducts a review of its program on a continuing basis throughout the year. As modifications are made, review and final approval by the full IACUC is required and is documented in the meeting minutes.

Pre-Meeting Procedures

The IACUC Chair pulls all necessary documents. Each responsible party is asked to review the document(s) and ascertain that the current version on file in the IACUC is still applicable. If a document is updated, the revisions will be discussed and approved at the meeting. The updated version(s) will replace the current version on file in the IACUC.

VII. GRANT APPLICATIONS

Grant / Protocol Congruency

For most grant agencies, the institution is required to provide assurances that the protocol approved by the IACUC is consistent with the information contained in the grant. This process occurs by the following procedure:

If an IACUC protocol is already in existence at the time of routing, the Office of Graduate Studies and Research will review the grant and assure that all procedures are contained within the animal use protocol on file in the IACUC. The IACUC Chair may also participate in this process as needed. The Office of Graduate Studies and Research administrator will initial the appropriate space on the routing form. If the grant is being submitted to NIH, the Office of Graduate Studies and Research administrator will initial the face page of the submission attesting that the latest approval date is correct and the assurance number is included in the appropriate space. If the grant is being submitted to an agency other than NIH and this agency requires an IACUC letter of approval for this submission, the Office of Graduate Studies and Research administrator will provide this letter for the grant.

To Be Submitted Tracking Procedures

All grant applications are routed through Office of Graduate Studies and Research. The Office of Graduate Studies and Research will maintain a database for IACUC information (IACUC #, status, and latest approval date). For grants indicating the animal protocol is "to be submitted," a copy of the grant must be included in this IACUC submission.

The grant / protocol comparison is conducted by Office of Graduate Studies and Research and reviewed by the IACUC Chair, as needed. If the animal procedures in the grant are included in the animal protocol, then the grant is filed with the protocol. No further action is taken. If there are any discrepancies, the investigator is emailed for clarifications. The clarification will be filed with the grant in the protocol. The investigator may or may not need to submit an amendment depending on the situation.

Special Notes Regarding Animal Protocols and Grants:

1. The following statement regarding information on the veterinary care of the animals should be included in all grants:
"Animals are maintained in the animal facilities of Salisbury University. Animals are housed, cared for and used strictly in accordance with the NIH Guide for the Care and Use of Laboratory Animals."
2. An IACUC protocol may include additional procedures which are not included in the grant, but must include at a minimum the animal work proposed in the grant.
3. One IACUC protocol may be used for multiple grants, as long as the scientific aims are related and all the animal work proposed in the grants is approved under the specified IACUC protocol.

VIII. ANIMAL CARE CONCERNS

Individuals can report any concerns regarding animal research procedures and/or animal care to the IACUC via the following methods: telephone followed by written documentation, email or a written correspondence. The IACUC prefers that the initial contact be made via telephone so that the appropriate action to ensure the well-being of the animal(s) in question can be taken immediately. Subsequently, a written description of the concern should be submitted for further action. When a concern is reported, the Office of Graduate Studies and Research is the first point of contact. The Office of Graduate Studies and Research will obtain as much information as possible from the party lodging the concern, and contact the IACUC Chair immediately. (Anonymity of the individual initiating the concern will be respected if requested.) The chairman will follow up to obtain any additional information necessary from the individual initiating the concern and from all individuals involved in providing care or responsibility for the animals in question. If warranted, visitation to the location or immediate veterinary care will be initiated. If it is decided that further action should be taken, the IACUC Chair may call an emergency meeting of the IACUC to discuss the issue at hand and whether to suspend the investigator's research until all issues with relation to the concern have been resolved. If the latter action is necessary, the IACUC will inform the appropriate Institutional Official and any other agency as required of the initial allegation. The IACUC will coordinate a plan to maintain compliance with university policies and consult with all parties as needed during the process. The IACUC will follow up with all parties regarding the final outcome.

In general, all issues affecting the care and use of animals are brought to the attention of the IACUC at its regular monthly meeting, or on an emergency basis as noted above when necessary. Issues are discussed, and resolutions are documented in the IACUC minutes.

In an attempt to protect the complainant from possible reprisal, the IACUC will maintain anonymity of the individual initiating the concern, if at all possible. The individual will be kept informed of the final findings of the investigation relative to the concern of the event.

IX. PROTOCOL SUSPENSIONS

Animal use can be suspended as result of noncompliance with the IACUC approved protocol, with the federal regulations and/or university policies, etc., or as result of jeopardizing animal health and well-being.

The IACUC Chair has been given the authority to initially suspend animal use utilizing their best judgment if animal health or well-being is being jeopardized or as a result of noncompliance with the IACUC approved protocol, etc. Following such action, the members will convene for a meeting to discuss the initial suspension, devise a plan to move forward, and vote to determine whether the suspension should remain in effect until the issue is resolved. The suspension could put all animal use on hold, or just certain procedures on hold. Alternatively, the IACUC Chair may call a meeting of all members to discuss an issue at hand and to decide whether a suspension is warranted. Once a determination has been made to suspend animal use, the PI, the Institutional Official, and other agencies will be notified as required. The contact with the PI and Institutional Official will be in person or via telephone. All conversations will be followed up with a written correspondence. In order for a suspension to be lifted, the PI must address all

committee concerns, as well as establish and implement a plan to avoid any such problems in the future. The committee will meet to vote on whether the suspension should be lifted and whether any additional stipulations should be implemented. A final report documenting reasons for suspension, procedures followed, corrective actions taken, timelines, etc. will be kept and a copy forwarded to the appropriate institutional officers and other federal or accrediting agencies as required.

X. ANIMAL ACTIVIST

The University Police and the IACUC must also be informed of any proposed protest against animal research. If an unscheduled protest, notice of an unapproved protest, or animal activist threat occurs, the University Police Department must be immediately notified. The University Police Department will determine what action should be taken in the event of a protest /animal activist threat.

XI. FILMING

An investigator who desires media coverage of their research that involves animal usage must contact the Office of Graduate Studies and Research to issue a press release. A copy of the press release must be forwarded to the IACUC with a cover memo indicating the approved IACUC protocol under which the research was accomplished. Investigators must immediately notify the Office of Graduate Studies and Research of any request by the news media to view, photograph, film or videotape animal usage. Concurrently, the investigator must immediately notify the IACUC Chair to inform the IACUC of any such requests. Any request by the news media to view, photograph, and film or videotape animal usage must be approved in advance by the IACUC and the Office of Graduate Studies and Research. No filming by the news media may take place without prior approval. Any filming, photographing or videotaping of animal usage must be coordinated with the Office of Graduate Studies and Research. The IACUC must also be informed of the filming schedule. A member of the IACUC and a representative from the Office of Graduate Studies and Research must be present during filming. In addition, a veterinarian may be present if the filming involves a surgical procedure, or if it is recommended by the IACUC. Stock video footage of several species is/or will be available for media use. If you cannot use this stock footage, please provide justification for the necessity of additional filming. Please contact the IACUC for information regarding all stock video footage.

XII. RECORD KEEPING

All animal use protocols and IACUC documents are kept on file by the Office of Graduate Studies and Research. All files are secured within an internal office under separate lock and key. During non-working hours, the external office is alarmed. All record keeping procedures are in accordance with PHS Policy, AWA and other applicable laws, regulations or policies.

All documents such as semi-annual inspection and program review reports, USDA site visits, meeting minutes, AAALAC program description, OLAW Assurance are maintained on site for at least three years, after which point they are archived. All protocols are maintained on campus

while active. Once a protocol is closed, it is archived. All closed protocols are maintained in the archive for 4 years following its closure.

All files can be retrieved from archives in a timely fashion. No files are destroyed without prior consent issued by the IACUC Chair or the Office of Graduate Studies and Research.

XIII. IACUC COMMITTEE MEMBERSHIP AND REPORTING

Committee membership is evaluated at least once every six months. The IACUC will determine whether there is a need for additional expertise. If needed, the IACUC Chair will discuss it with the committee at the next convened meeting. If the committee is in agreement, a candidate will be pursued.

Potential committee members are identified as follow:

- a. Contact the Department Chair for recommendation of a faculty member
- b. The committee identifies a specific faculty member
- c. Follow-up with a faculty member that has expressed interest in serving on the committee if and when a need arises.

If a current member resigns, he/she will be asked to recommend another faculty member from their department if possible. The IACUC Chair will contact the identified member, discuss the responsibilities, expectations, and the amount of time required to serve as an IACUC member. If the faculty member is willing and able to commit to serving on the IACUC, the following information is obtained: updated CV and confirmation of willingness to serve on the committee. The following information will be forwarded to the Office of Graduate Studies and Research and then to the Provost for consideration and final approval / disapproval:

1. A formal letter including the need for the additional member and a brief description of the faculty member's qualifications and training.
2. A copy of the updated CV,
3. An IACUC appointment letter for the Dean's signature.

Once a faculty member's appointment has been approved, the appointment letter is sent out. As soon as an acceptance letter is received, the faculty member will be scheduled to meet with the IACUC Chair for new committee member orientation.

Committee Attendance

It is the expectation that all IACUC members be present at each meeting unless unforeseen circumstances arise. If a member has been assigned a review and cannot attend at last minute, the review must be faxed or emailed to the IACUC Chair so that the other reviewer and the chair can present the review to the committee.

Membership

Members of the IACUC are appointed by the Provost, generally for 3-year terms except as indicated below.

Chairperson.

Appointment:

The Chairperson will generally serve a term of 3 years, but may serve a term of 1 year if approved by the Dean of Graduate Studies and Research. The Chairperson's appointment is renewable by the Dean of Graduate Studies and Research for additional terms, and may be extended to provide continuity.

Qualifications:

- i Knowledgeable and effective leader;
- ii Has been a member of the IACUC for at least two years
- iii Responsibilities:
 - a. Works with School Administration to ensure compliance with all applicable regulations.
 - b. Recommends membership changes to the Dean of Graduate Studies and Research.
 - c. Reviews and writes policies and Standard Operating Procedures as needed
 - d. Reviews all incoming protocols and amendments and assigns committee members as appropriate
 - e. Convenes/chairs meetings; designates acting chair if unable to attend meetings or inspections
 - f. Acts as spokesperson on behalf of the IACUC.

Members

Terms

Faculty members will be appointed for a term of three years. Faculty members may be reappointed by the Provost as deemed necessary and for one additional consecutive term. Staff members representing specific campus units may serve multiple 3 year terms. Non-Affiliated Members representing the interests of the community at-large may serve multiple three year terms.

Alternate Members

Alternate members will be appointed to the IACUC by the Dean of Graduate Studies and Research in accordance with PHS policy. An IACUC member and his/her alternate may not count toward a quorum at the same time or act in an official member capacity at the same time.

Ad-hoc

Non-voting attendees may be invited as needed. Examples of such attendees include, but are not limited to, representative(s) from Environmental Health Services, and the Dean of Graduate Studies and Research .

Meeting Attendance Requirements

The IACUC Chair will maintain IACUC member attendance records based on the calendar year. All members are required to do the following:

1. Attend approximately in total 75% of the regularly scheduled meetings and inspections. Notify the IACUC Chair if attendance at a meeting or inspections is not possible. This notification does not preclude the member from meeting the 75% attendance requirement.
2. All IACUC members are expected to participate in the required IACUC inspections and IACUC subcommittees.
3. Removal of Delinquent Members
If a member does not meet the 75% attendance requirement his/her membership on the committee can be suspended.

Reporting

The IACUC reports to the Dean of Graduate Studies and Research.

Minutes

- a. Minutes of meetings are provided to IACUC members prior to the next scheduled convened meeting.
- b. Changes or additions to the meeting minutes will be made during regularly scheduled meetings and will be approved by the IACUC members.
- c. Minutes of all IACUC meetings will be maintained by the Office of Graduate Studies and Research.

Semi-Annual Program Review

- a. Semi-annual reports are sent to the Dean of graduate studies and research. Any minority reports will be attached.
- b. Copies of all semi-annual report will be kept on file by the Office of Graduate Studies and Research.

Deficiency Memos

- a. Will be issued and signed by the IACUC chair.
- b. All deficiency memos will be sent to the Dean of Graduate Studies and Research, the PI and the PI's Department Chair.
If same or identical deficiency is found on subsequent three (3) inspections the IACUC has the right to remove or suspend the active protocol until the deficiencies are corrected.
Notification will be sent to the Dean of Graduate Studies and Research, the PI, PI's Department Chair, and Vet Service of the removal or suspension.
- c. Deficiencies affecting animal health and being will corrected immediately. All others deficiencies will be corrected with three days of notification. Copies of all deficiency memos will be kept on file by the Office of Graduate Studies and Research.