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Care and Use of Animals in Research Policy

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Purpose and Scope

West Chester University (WCU) is dedicated to assuring the humane care and use of animals involved in research, teaching, and service performed by our faculty, staff, and students. To ensure that all members of the university community comply with federal and state regulations, policies, and guidelines for the ethical treatment of animals, this university policy charges the Institutional Animal Care and Use Committee (IACUC) with oversight of the designing, conducting, or reporting of all activities (research, teaching, testing, and demonstrations) involving vertebrate animal subjects on the WCU campus.

West Chester University is registered with the USDA and is assured with the National Institutes of Health, Office of Laboratory and Animal Welfare (NIH, OLAW). WCU provides annual program reports for both institutions.

Policy Statement

This policy applies to all WCU faculty, students, staff, and administrators who care for and use of vertebrate animals for the purposes of research, teaching, or service.

Policy Framework

A. Federal regulations, Policies, and Guidelines

Animal Care and Use at West Chester University falls under the purview of the United States Department of Agriculture, Animal Plant and Health Inspection Service (USDA, APHIS) and the National Institutes of Health, Office of Laboratory and Animal Welfare

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(NIH, OLAW). Regulations, policies, and guidelines provided by these agencies are provided below, along with a brief description of the agencies mission.

A.1. USDA, APHIS provides leadership in ensuring the health and care of animals and plants. In support of this mission, the agency performs routine, unannounced inspections of animal care facilities.

A.1.a. *Animal Welfare Act (AWA) and Animal Care Regulations*, <https://www.aphis.usda.gov> . Regulations established under the AWA set standards for the humane care and treatment for certain animals that are exhibited to the public, sold for use as pets, used in research, or transported commercially. Facilities using regulated animals for regulated purposes must provide their animals with adequate housing, sanitation, nutrition, water and veterinary care, and they must protect their animals from extreme weather and temperatures.

A.1.b. *Animal Care Policy Manual* (currently under review) further clarifies the intent of the AWA.

A.2 NIH, OLAW provides the Public Health Service (PHS) policies, regulations, and guidance that protect animals used in research, training, and biological testing.

A.2.a. *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, <https://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>.

A.2.b. *Guide for the Care and Use of Laboratory Animals*, 8th Edition, <https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>.

B. IACUC Membership

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Members of the IACUC will be appointed annually by the Vice Provost for Research and Creative Activity, who is the designated Institutional Official (IO), with approval from the Senior Vice Provost, Provost and Executive Vice President for Academic Affairs, and the President. In accordance with federal guidelines, the IACUC will consist of at least five members and include the following:

- At least one veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution
- At least one practicing scientist experienced in research with animals
- At least one member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy)
- At least one member who is not affiliated with the institution other than as a member of the IACUC

A chairperson will be elected by the members of the committee.

The role of the veterinarian includes, but is not limited to, providing for the health and welfare of the animals, assuring adequate veterinarian care of the animals, promoting regulatory compliance, and facilitating research. Based on her/his best clinical judgement and expertise the veterinarian has the authority to (a) modify a protocol; (b) euthanize any animal suffering unauthorized pain or distress; (c) report incidents involving breach of protocols to the other members of the IACUC; and (d) temporarily suspend conduct that has not been authorized by the IACUC or conduct that is not in compliance with federal and state regulations, policies, and guidelines for the ethical treatment of animals.

C. Responsibilities of the IACUC

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The IACUC reports directly to IO. The IO reports to the Senior Vice Provost who reports to the Provost and Executive Vice President for Academic Affairs and the President.

The members of the IACUC review the institution's program for humane care and use of animals and perform the following duties (a) reviewing initial and on-going protocols for all activities (research, teaching, testing, and demonstrations) involving vertebrate animal subjects; (b) approving or requiring modification in new or continuing protocols; (c) withholding approval of new or continuing protocols that do not meet with federal and state requirements; (b) notifying Principal Investigators (PIs) and the IO of its decision to approve or withhold approval of protocols; (c) inspecting the institution's animal facilities at least twice each year; and (d) providing annual reports regarding the number and types of protocols in place and making written recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training.

The IACUC is authorized to hear and adjudicate complaints related to the inhumane care and use of animals and to suspend activities that do not adhere to the APHIS and OLAW regulations, policies and guidelines. All meetings of the IACUC and its subcommittees are strictly confidential.

D. Responsibilities of the Principal Investigator

PIs assume responsibility for the legal and ethical conduct related to their work including that of all personnel working on their projects involving vertebrate animals. PIs conducting activities (research, teaching, testing, and demonstrations) involving animal subjects must be full-time faculty or staff at West Chester University. Undergraduate and graduate students cannot serve as a PI (or co-PI) on a project involving the use of vertebrate animals.

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Prior to the initiation of any activities (research, teaching, testing, and demonstrations) involving vertebrate subjects, the PI is responsible for requesting IACUC protocol review and approval and for the training of all personnel (other faculty, students, and staff) who will participate in the activities.

PIs are also responsible for the following:

- Assuring project adherence to state and federal regulations, policies, and guidelines for the ethical treatment of animals.
- Managing the development of the project in accordance with accepted scientific standards.
- Ensuring the integrity and safeguarding of all collected data.
- Notifying the IACUC of any changes made to the protocol.
- Meeting the renewal request requirements established by the IACUC.
- Immediately notifying the IACUC if a protocol is completed or withdrawn.
- Remaining aware of and complying with the IACUC policy and procedures.

D.1. Special Instructions for Research. Any individual conducting research, any activity designed to uncover new information, employing vertebrate animals as subjects must have IACUC approval, ***whether or not the project is funded by a federal grant.***

In order to assure that research activities do not unnecessarily duplicate previous research without scientific rationale or justification, a new protocol must be submitted for every research project even if an identical protocol has been previously approved. PIs will be asked to provide a scientific rationale for any duplication of an activity and a description of the appropriateness of the number of animals being used.

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D.2. Special Instructions for Classroom Demonstrations and Projects. Any individual conducting classroom demonstrations or projects where the sole purpose is to instruct students in methods of experimentation must have IACUC approval if the classroom demonstrations or projects involve vertebrate animals undergoing surgical procedures, discomfort, anesthesia, or euthanasia. Classroom demonstrations or projects that do not involve vertebrate animals and surgical procedures, discomfort, anesthesia, or euthanasia are exempt from IACUC review.

In order to assure that research activities do not unnecessarily duplicate previous research without scientific rationale or justification, a new protocol must be submitted for every classroom demonstration or project involving vertebrate animals and surgical procedures, discomfort, anesthesia, or euthanasia even if an identical protocol has been previously approved. PIs will be asked to provide a scientific rationale for any duplication of an activity and a description of the appropriateness of the number of animals being used.

E. Noncompliance

Vertebrate animal use for research, teaching, testing, and demonstrations in the absence of IACUC approval is a serious violation of this policy, and in some cases, a violation of federal law.

Vertebrate animal use for research, teaching, testing, and demonstrations conducted under the guise of an approved IACUC protocol but which are not specifically outlined in that protocol are considered a violation of this policy, and in some cases, a violation of federal law.

Failure to comply with federal and state regulations, policies, and guidelines for the ethical treatment of animals might result in prosecution by the federal government and the imposition of federal, civil, criminal, and/or administrative penalties or sanctions, denial of research privileges, and loss of reputation. It might also result in



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disciplinary action in accordance with the appropriate Collective Bargaining Agreement (APSCUF CBA articles 12, 14, 15, 42, *et. al.*)

Procedures

WCU is dedicated to assuring the humane care and use of animals involved in research, teaching, and service performed by our faculty, staff, and students. To ensure that all members of the university community comply with federal and state regulations, policies, and guidelines for the ethical treatment of animals, the IACUC will follow these university procedures for reviewing protocols, hearing and adjudicating complaints, and monitoring for all activities (research, teaching, testing, and demonstrations) involving animal subjects on the WCU campus.

A. Training

A.1.a. IACUC Chair. Every three years (or whenever a new IACUC Chair is appointed) The IO will earmark funds to support her/his attendance at a workshop for IACUC administration. The Chair will also complete online training for Animal Care and Use provided through CITI.

A.2. PIs and Students. All faculty, staff, and students who will participate in activities (research, teaching, testing, and demonstrations) involving animal subjects will complete online training for Animal Care and Use provided through CITI before those activities begin. CITI training must be renewed every three years.

B. Protocol Review, Determination, and PI Notification

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The IACUC will meet for a minimum of two in-person animal facility inspections and annual review meetings per year (one per semester). These meetings are required to conduct any formal business, such as adoption of policies or procedures, approval of semiannual reviews, and full committee protocol reviews. In addition, the IACUC will hold either in-person or virtual meetings for additional protocol reviews at the beginning and middle of each semester (as needed). A quorum of greater than 50% of all voting members must be present to conduct formal business. The IACUC may utilize full committee review or designated member review. A full committee review (FCR) requires a quorum of the IACUC to meet in person to review a protocol, whereas a designated member review (DMR) involves one or more IACUC members designated by the Chair to review a protocol. Any new protocols or significant modifications to a protocol (as defined by the NIH OLAW) will require a FCR, whereas a DMR can be used for protocol renewals (with no changes), protocol revisions, and/or minor modifications to a protocol (as defined by the NIH OLAW). Upon receipt of any protocol, the Chair will make the protocol available to all IACUC members for a period of five business days prior to any review and indicate whether it requires FCR or DMR. For a protocol undergoing DMR, each IACUC member has a right to request a FCR within this 5-day period. If no member requests a FCR after five business days, the protocol will remain as DMR. Any IACUC member with a potential conflict of interest must recuse her/himself from serving as a reviewer of a protocol. In the case of a FCR, the individual must leave the room while deliberations and voting occur. If the Chair has recused her/himself, the Chair will designate another member to serve as Acting Chair for that protocol and will not participate in the review process.

After review, the protocol will be given one of the following designations: approval, approval pending modifications, or approval withheld.

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B.1. Approval. IACUC has approved the protocol without a request for modification. An approval letter is sent to the PI. Animals may be purchased and used in the approved protocol only. Approval is given for a maximum of three years, with a continuing report of progress/status required annually.

B.2. Approval Pending Modifications. IACUC has determined that final approval of the protocol is contingent upon receipt of additional clarifications / information before the project can be initiated. A query letter is sent to the PI indicating the modifications that are required to secure final approval. The PI is advised to submit the requested information at his/her earliest convenience 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 designated member review 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. Animals may be purchased and used in the approved protocol only. Approval is given for a maximum of three years, with a continuing report of progress/status required annually.

B.3. Approval Withheld. IACUC did not approve the protocol due to significant deficiencies and concurred that the PI should resubmit a substantially revised protocol. A letter is sent to the PI indicating that the committee has voted to withhold approval of the study, the reasons for this determination, any issues that must be addressed in a revised protocol, and recommendations for consultation with the IACUC Chair or veterinarian for guidance and assistance prior to submission of a revised protocol. The letter also indicates that no animals may be ordered and no research may begin until approval is granted by the IACUC.

C. Protocol Renewal

Though protocols are approved for a three-year period, they must be reviewed and renewed annually. If there are significant proposed modifications to the initial protocol, the IACUC Chair will make the renewal request available for review as

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described in section II. B. Significant modifications include, but are not limited to, changes in study objectives, species or numbers of animals used, or experimental procedures. If no significant modifications are proposed, the IACUC Chair will review and approve any other changes. If the PI chooses to continue a project beyond the first year, but fails to submit the renewal form before the date of expiration, the PI is required to submit a new protocol before the project may continue. A reminder for the PI to submit a new protocol will be sent 30 business days prior to the protocol's date of expiration. A project continuing for more than three years must submit a new protocol at the end of the third year for the project to continue.

D. Amendments to Protocols

Any significant modifications to an approved project must be reviewed and approved by the IACUC before they may be implemented. Significant modifications include, but are not limited to, changes in: study objectives, species or numbers of animals used, experimental procedures, or personnel involved in the study. The IACUC Chair will make the amended protocol available for review as described in section II. B. For protocols that only include personnel changes, the IACUC chair will review and approve those changes.

E. Reporting and Post-approval Monitoring

E.1. Annual Progress Reports. The IACUC is required to conduct an annual review of each protocol every 365 days. An annual progress report should be submitted by the PI 30 business days prior protocol expiration. The annual report must be submitted whether or not any animal work was conducted in the past year.

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E.2. Final/Third-year Review. The IACUC will perform a *de novo* review every three years. Thus, the PI must submit a new protocol detailing the results of the last three years and the proposed work to be conducted in the future. The IACUC cannot administratively extend the expiring protocol.

E.3. Post-Approval Monitoring (PAM) is meant to ensure the safety of the research animals, appropriate applications and supporting documents are executed as approved, and any changes or adverse events are reported. During PAM a PI's research activities will be observed and the IACUC. The IACUC will also verify the project documents.

PAM subjects will be selected randomly from all approved and active protocols, without cause, no more than once per year. A study may be selected more than once in a given year if a "for cause" review is deemed necessary (i.e. At the IACUC's request from a review, part of an investigation for non-compliance, or upon PI's request). Protocols that are pain class E, have USDA covered species, are funded, or considered higher risk to the animals, are more likely to be selected. Should a PI have multiple protocols, it is possible that each protocol may be selected once per year individually or all protocols may be reviewed at once.

The IACUC will ask the PI to produce records/lab notebooks that demonstrate the protocol was followed as approved. PIs will also be interviewed by IACUC members about how the research project is progressing in relation to problems or adverse events.

The scope of the PAM varies greatly depending on the research, but it will include:

- Reviewing all records with the PI associated with animal care logs, animal health logs and drugs given to the animals.
- Reviewing all animal housing, protocol facilities and animals on the protocol.

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- Reviewing the names of all personnel working with the animals.
- Completion of the PAM Review Checklist.
- Viewing a procedure at a future date (by appointment).

The IACUC will provide the following feedback after the PAM:

- A highlighted best practice. The practice will be shared with the IACUC and may be incorporated into guidelines.
- Compliant with the protocol. No further information or follow up is needed.
- Minor deficiencies are noted. The PI provides a written plan in the resolution column to address the issues found within 30 business days.

Significant deficiencies are noted. The IACUC chair and the committee are notified of significant deficiencies. The PI provides a written plan to address the issues found within 15 business days. The protocol may be subject to a more in-depth review and monitoring to ensure all issues regarding compliance are met.

F. Compliant Hearing and Adjudication

All complaints must be submitted to the IACUC Chair in writing. Complaints should provide detailed information about alleged misconduct including date/time and the names of any potential witnesses. The IACUC Chair and veterinarian (or a designee if the complaint is directed to the Chair or veterinarian) will meet with the relevant Dean and the IO to evaluate the complaint to determine whether there is sufficient cause to warrant further investigation.

If there is sufficient cause to warrant further investigation the IACUC Chair and veterinarian (or designee if the complaint is directed at the Chair or veterinarian) will form a Hearing Panel to adjudicate all complaints related to animal abuse in research laboratories or teaching facilities at the university. Immediate steps will be

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taken to protect the animals involved. This may include veterinary or medical intervention.

F.2. The Hearing Panel.

- As the primary contact person for reporting charges of animal abuse, the IACUC Chair (or designee if the complaint is directed to the Chair) will be responsible for making all arrangements for a hearing, insuring that all meetings and deliberations occur in a timely manner, and chairing the Hearing Panel, unless there is a reason for recusal. The Chair or designee will not vote on a decision except in the event of a tie among members of the Hearing Panel.
- The veterinarian will be a voting member of all Hearing Panels unless there is a reason for recusal.
- Other Members of the Hearing Panel. The rest of the Hearing panel will consist of at least three other IACUC members and the IO.

If a member of the IACUC is the person to whom the complaint is being addressed or is bringing a complaint of animal abuse, he/she will recuse her/himself from participating on the Hearing Panel. All meetings and deliberations of the Hearing Panel are strictly confidential.

F.3. Notification of the Complaint and Invitation to Provide a Written Rebuttal. The IACUC Chair will notify the accused individual in writing that a complaint has been levied against him/her and inform him/her that a Hearing Panel will be formed to adjudicate the complaint. The individual who has been accused will immediately be provided with a copy of the complaint (with the personal data of the complainant redacted) in writing, and will be invited to provide a written response to the allegations to the Chair within three business days before the first meeting of the Hearing Panel.

F.4. Hearing Panel Schedule. The IACUC Chair will schedule three meetings of the Hearing Panel, each to occur within 21 working days, of receipt of the allegations.

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The person to whom the complaint is being addressed will be participate in the coordination of the meeting schedules so that an APSCUF representative will be able to attend on her/his behalf. The Hearing Panel will receive all relevant information for review from the Chair at least two business before the first meeting is scheduled including a copy of the complaint, a copy of the rebuttal by the person to whom the complaint has been addressed, and notification of the time and place of each meeting. The complainant will receive information in writing about the rebuttal and the time and place of the second meeting from the IACUC Chair at least two business days before the second meeting.

F.5. The First Meeting. During the first meeting, the person to whom the complaint has been addressed will respond to the complaint and to questions from the Hearing Panel. No evidence that has not already been provided to the person to whom the complaint is being addressed will be discussed at this meeting. The person to whom the complaint has been addressed will also be able to call any witnesses to support her/his perspective. If the person to whom the complaint has been addressed fails to attend the first meeting, it may proceed in her/his absence.

F.6. The Second Meeting. During the second meeting, the complainant will be allowed to further explain the complaint and to respond to questions by members of the Hearing Panel. The complainant will also be able to call any witnesses to support her/his perspective. The transcripts of this meeting (with the personal data of the complainant and her/his witnesses redacted) will be provided to the person to whom the complaint is being addressed within three business days of the second meeting.

F.7. The Third Meeting. During the third meeting, the person to whom the complaint is being addressed will have a second opportunity to respond to the information provided in the second meeting and to questions from the Hearing Panel. No evidence that has not already been provided to the person to whom the complaint is being addressed will be discussed at this meeting. The person to whom the complaint has been addressed will also be able to call any witnesses to support

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her/his perspective. If the person to whom the complaint has been addressed fails to attend the first meeting, it may proceed in her/his absence.

F.8. Deliberation and Conclusions of the Hearing Panel. When the members of the Hearing Panel are satisfied that they have all the pertinent facts, they will retire to a closed meeting to discuss the evidence provided to support or rebut the complaint. Members of the Hearing Panel will decide by hand vote if the charges are VALID or NOT VALID. The IACUC Chair will only vote to break a tie.

If the complaint is adjudicated as NOT VALID, the IACUC Chair will notify the person to whom the complaint has been addressed in writing within five business days. Furthermore, the Hearing Panel will issue a written report explaining the basis of the decision. The written report will be sent to the person to whom the complaint has been addressed and the relevant Dean.

If the complaint is adjudicated as VALID, the IACUC Chair will notify the person to whom the complaint has been addressed in writing within five business days. The Hearing Panel will issue a written report explaining the basis of the decision. The written report will be sent to the person to whom the complaint has been addressed and the relevant Dean.

If the decision is evenly divided between VALID and NOT VALID, the IACUC Chair may elect to cast the deciding vote or require the IACUC to conduct further investigations. If further investigations are required, the person to whom the complaint is being addressed will be notified immediately by the IACUC Chair.

F.9. Enforcement of a VALID Judgement. If the incident is judged to be minor, such as a simple oversight in procedure, the report of the Hearing Panel will explicitly tell both the person to whom the complaint has been addressed and the relevant Dean of any action necessary to prevent a recurrence of the incident (part of the written report). The relevant Dean will be responsible for ensuring that action is taken.

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If the incident is judged to be major (from careless practices to lax adherence to federal regulations to willful and serious animal abuse), the Hearing Panel shall comment in their report on the degree of the offense. The IACUC Chair will forward the Hearing Panel report to the IO, Provost, and the relevant academic Dean. The administrators will consult with each other and recommend appropriate sanctions based on federal rules and regulations to the WCU President along with their recommendation on how to proceed. The WCU President will determine and enforce appropriate sanctions based on federal rules and regulations (section A.) and will be responsible for notifying the person(s) charged. The degree of sanction shall be in relation to the degree of the offense.

The WCU President shall take whatever actions are necessary to remediate the violations. The Hearing Panel has the right to halt all animal use by an individual for up to 90 days, pending review by the entire IACUC.

At the quarterly meetings of the IACUC, the Chair will notify the entire committee of all allegations, the results of all Hearing Panel meetings, and all actions taken to correct situations that led to VALID complaints. If the Hearing Panel has suspended an individual's animal use privileges, the IACUC must vote to continue or halt such suspension at its next quarterly meeting. The IACUC also may impose an indefinite suspension. In those cases, further review by the IACUC is not necessary.

References

1. West Chester University, *Animal Care and Use*,
<https://www.wcupa.edu/admin/research/documents/IACUC2014.pdf>).
2. *Agreement Between Association of Pennsylvania State College and University Faculties and the Pennsylvania System of Higher Education*, Articles 12, 14, 15, and

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42. <https://www.apscuf.org/members/contracts/>.
3. Bloomsburg University, *Policy on Animal Subjects Research*, (https://intranet.bloomu.edu/policies_procedures/3995).
4. Slippery Rock University, *Responsibilities of the Principal Investigator*, (<http://www.sru.edu/offices/institutional-animal-care-and-use-committee/how-to-apply>).
5. George Mason University, *Policy for the Care and Use of Animals*, (<https://oria.gmu.edu/research-with-humans-or-animals/animal-care-and-use/iacuc-policies-and-procedures/policy-for-the-care-and-use-of-animals/>).
6. University of Maryland School of Medicine Office of Animal Welfare and Assurance, *Principal Investigator Manual*, (<http://www.medschool.umaryland.edu/iacuc/Policies--Procedures/>).
7. Appalachian State University, *Policy Manual*, (https://policy.appstate.edu/Policy_Manual).
8. Kutztown University, *Institutional Animal Care and Use (IACUC) Policy and Operating Procedures*, (<https://www.kutztown.edu/about-ku/administration/committees/institutional-animal-care-and-use-committee.htm>).
9. Pennsylvania State System of Higher Education, *PASSHE Procedures and Standards for University Operations, #2012-14-A, Compliance with United States Export Control Laws*, (http://www.passhe.edu/inside/policies/Policies_Procedures_Standards/Compliance%20with%20United%20States%20Export%20Control%20Laws%202012-14-A.pdf).

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10. Texas Tech University Health Sciences Center, Office of Research Institutional Animal Care and Use Committee, *IACUC Policy 11: Complaints of Mistreatment of Animals and Policy Noncompliance*,
<https://www.ttuhsc.edu/research/divisions/integrity-office/animal-care/policies.aspx>.
11. University of Montana, *IACUC Policies 7117: Complaints and Violations*,
<https://www.umt.edu/research/compliance/IACUC/policies/PLCYcomplaintsviolations.php>.
12. Louisiana Tech University, *Animal Care and Use Policy on Complaints*,
<https://www.latech.edu/about/administration/policies/p-7117/>.

Reviewed by: Office of Research and Sponsored Programs, WCU IACUC, Academic Deans Council, University Legal Counsel, and WCU APSCUF and WCU APSCUF Meet & Discuss.

Policy Owner: Office of Research and Sponsored Programs

Approved by:



Jeffery L. Osgood, Jr., Ph.D.

Deputy Provost and Vice President of Academic Operations

Date gets typed when signed

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