



POLICY & PROCEDURE DOCUMENT

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SECTION: Research
TITLE: Policy on the Use of Vertebrate Animals
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AUTHORIZED BY: Dr. Cheryl Stevens, Provost and Vice President for Academic Affairs

I. Purpose and Scope

Western Kentucky University (WKU) hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, involving live, vertebrate animals conducted at WKU, or at another institution as a consequence of the sub-granting or subcontracting of a supported activity by WKU.

The policies and procedures herein apply to all parts of WKU including satellite facilities, regional campuses, facilities run by affiliated and related foundations and so forth.

II. Policy

A. General Principles

1. WKU is committed to the highest standards of ethical and humane treatment of animals used in research, teaching and other institutional functions.
2. WKU will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
3. WKU is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training."

4. WKU acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this assurance. As partial fulfillment of this responsibility WKU will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
5. WKU has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (hereinafter "The Guide").

B. Responsibility

Institutional responsibility is delegated from the Provost and Vice President of Academic Affairs (Institutional Official) to the Associate Provost for Research and Graduate Education who oversees the Compliance Manager. The Compliance Manager works with the Institutional Veterinarian and the Chair of the Institutional Animal Care and Use Committee (IACUC) to ensure compliance.

C. Institutional Veterinarian

1. The Institutional Veterinarian is a full member of the WKU IACUC committee.
2. In the event that the Institutional Veterinarian is not available, arrangements for animal care will be deferred to a list of veterinarians on file with the WKU IACUC chair or the WKU farm.
3. Due to the small size of our animal program, the services of an Institutional Veterinarian are required only on a part-time consultant basis. Approximately 0.05 FTE is currently spent in animal care at Western Kentucky University.
4. The Institutional Veterinarian has direct program responsibility at Western Kentucky University for activities involving animals.
5. In addition to serving as a member of IACUC, the Institutional Veterinarian attends to animal care appropriate to our institutional needs, administers health care to animals found to be ill or injured and oversees procedures for disease containment and surveillance. He/she is consulted regarding the proper use of drugs, surgical procedures and proper euthanasia procedures.

III. Procedure

This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures.

A. Creation of an Animal Care and Use Committee (IACUC)

1. The IACUC consists of six members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b.
2. Members are appointed to the IACUC by the Associate Provost for Research and Graduate Education with the advice and consent of the IACUC Chair and the Compliance Manager.
3. The Associate Provost for Research and Graduate Education will respect the impartial and independent nature of the IACUC and will not interfere in its actions or deliberations.
4. The Associate Provost for Research and Graduate Education may suspend or dissolve the IACUC in order to curtail or prevent an actual or imminent crime, breach of regulations, or a grossly unethical or inhumane act.

B. Operations of the IACUC

The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC will review the functions and procedures, our institution's occupational health program, veterinary care procedures, and the personnel qualification process. This program review uses a checklist adapted from the "Sample Semiannual Program and Facility Inspection Checklist" recommended by the Office of Laboratory Animal Welfare, hereafter, OLAW.
2. Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the Guide as a basis for evaluation: a quorum of members must participate and will perform an official physical inspection of our institution's animal facilities and complete a checklist adapted from the "Sample Semiannual Program and Facility Inspection Checklist" recommended by the OLAW.
3. Prepare reports of the IACUC evaluations as set forth in the PHS policy at IV.B.3. and submit the reports to the Associate Provost for Research and Graduate Education. Following each semiannual program review and animal facility inspection, the IACUC chair prepares a report which contains a description of the nature and extent of the institution's adherence to the Guide and PHS Policy and identifies specifically any departures from the provisions of the Guide and PHS Policy and states the reasons for each departure. The reports distinguish significant deficiencies from minor deficiencies. A significant deficiency is one, which, in the judgment of the IACUC, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports contain a reasonable and specific plan and schedule for correcting each deficiency.
4. Make written recommendations to the Associate Provost for Research and Graduate

Education of Western Kentucky University regarding any aspect of the institution's animal program, facilities, or personnel training. Recommendations regarding the animal program, facilities, or personnel training will normally be included in the Semiannual Program and Facility Inspection Report. Additional recommendations (approved by a majority of IACUC members) not included in the Semiannual Report may be sent directly to the Associate Provost for Research and Graduate Education (in writing – including email) at any time.

5. Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are: All proposals for the use of animals in teaching and research will be forwarded to the Chair of IACUC.
 - a. Proposals must be completed on an application form entitled "Research and Educational Animal Use Protocol". An investigator may submit a protocol to the Chair of IACUC for review at any time during the academic year.
 - b. All applications will be distributed electronically (hard copies may be copied and forwarded upon request) to all committee members by the Chair of IACUC. In most cases, protocols will be distributed to IACUC committee members within one week of receipt by the IACUC Chair. Any member of the IACUC may obtain, upon request, full committee review of any project.
 - c. If full committee review is not requested, after a period of one week, at least one member of the IACUC, designated by the chair and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects.
 - d. If full committee review is requested, approval of those research projects will be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflict of interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflict of interest contribute to the constitution of a quorum.
 - e. All proposals will be reviewed according to the criteria in the PHS Policy, and further elaborated in the Guide for the Care and Use of Laboratory Animals and in Sections B-1 and B-2 of the IACUC Guidebook. As a result of this review process, IACUC will give unqualified approval for a proposal as submitted, defer decision due to lack of sufficient information, approve pending clarification of specified minor points, or reject the proposal outright.
 - f. If the IACUC cannot give an unqualified approval at the meeting and requests specific modifications on the part of the principal investigator, then the IACUC must meet again to approve those changes or the "designated reviewer" method could be used to approve the modifications provided that all members of the IACUC, including those not present at the previous meeting, be given sufficient information and the opportunity to call for a full committee meeting. In all cases in which there is a lack of Committee unanimity, the reason(s) for disapproval

by the majority or minority membership will be presented to the investigator in writing. The committee records will reflect any diversity of opinion. Investigators will be notified of the review results (in writing) within 1 week following the review date. Investigators must make all revisions as requested by the board prior to beginning the proposed activity.

6. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are: If significant changes in ongoing projects are proposed by an investigator, a new "Research and Educational Animal Use Protocol" form must be completed and submitted to the IACUC chair with changes from the original proposal clearly indicated. Once submitted, the same procedure will be followed as specified in section 6 above for original submissions.
7. Notify investigators and the institution in writing of its decision to approve or withhold approval of those sections of applications or proposals related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are: The Chair of the IACUC will notify investigators and the Institutional Official of the review results (in writing) within a period of 1 week following the IACUC review. If an investigator chooses to resubmit a proposal, which has previously been disapproved, the revised proposal should include the provision of additional evidence by the investigator, which addresses the original concerns of the IACUC committee. Disapproved proposals cannot be administratively approved by a higher authority.
8. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4, at least once every three years. All investigators at the institution who have IACUC-approved animal use protocols will be contacted by the IACUC chair each year by email or by written memorandum. At this time, the investigator will be asked to notify the IACUC chair if the project is: 1) Ongoing, or 2) Completed. Animal use protocols that continue for more than 2 years will be re-reviewed in the third year by the IACUC committee members using the criteria specified in the in the PHS Policy, in the Guide for the Care and Use of Laboratory Animals, and in Sections B-1 and B-2 of the IACUC Guidebook. Prior to the review, the protocol will be distributed to all IACUC committee members and will be handled in the same manner as a specified in section 6 for a new proposal.
9. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.
 - a. If it is determined that an animal-use activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy, a meeting of the IACUC will be called by the Chair or by the Institutional Official.

- b. An activity will typically be suspended only after review by a quorum of the IACUC members and only if a majority of the quorum present votes for suspension. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and report that action with a full explanation to the OLAW.
 - c. In the case that it is believed that immediate suspension of an activity is needed to prevent significant harm, suffering, or other risk, the Chair of the IACUC may request that the Institutional Official (Provost and Vice President for Academic Affairs) affect an immediate temporary suspension. The final disposition of such a temporary suspension will proceed as in the previous subsection.
10. Review concerns and **allegations of noncompliance** involving the care and use of animals at the institution.

Noncompliance: Failure (either intentional or unintentional) to comply with applicable federal regulations, state or local laws, the requirements or determinations of the IACUC, or university policy regarding institutional biosafety. Noncompliance may be minor (non-serious), serious, and may also be continuing.

Minor or non-serious noncompliance: Noncompliance that does not increase risk to research participants/subjects or affect the integrity of the research/data. Examples of minor noncompliance may include, but are not limited to the following: lapses in continuing IACUC approval, minor changes in or deviations from an approved protocol, or administrative errors.

Serious noncompliance: Noncompliance that increases risk to researchers, research subjects, or affects the integrity of the research/data. Examples of serious noncompliance may include, but are not limited to the following: conducting or continuing non-exempt research without IACUC approval; inappropriate oversight of the research to ensure the safety of researchers or research subjects; inappropriate oversight of the research to ensure the integrity of the research/data.

Continuing noncompliance: Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of IACUC requirements. Examples of continuing noncompliance may include, but are not limited to the following: repeated failures to obtain IACUC approvals for research, inadequate oversight of ongoing research, or failure to respond to or resolve previous allegations or findings of noncompliance.

11. Procedures for Handling Allegations of Noncompliance

- a. Any concerns or allegations of noncompliance in regard to the use of animals in teaching and research at Western Kentucky University are constantly solicited, and should be directed to the attention of the Chair of IACUC, Institutional Official, Associate Provost for Research and Graduate Education, or Compliance Manager without delay.

- b. There are no restrictions on who can report an alleged incident and there will be no threat of reprisals against those reporting perceived mistreatment or noncompliance. The report should include a factual description with date, time, location, animal species, numbers and identifications of animals, and personnel involved, as well as any other relevant details.
- c. All allegations will remain confidential to the furthest extent possible.
- d. The IACUC Chair, in consultation with the Compliance Manager, will conduct an initial inquiry to determine if further investigation and review by the IACUC is warranted. The Compliance Manager will notify the Associate Provost for Research and Graduate Education and institutional official when an initial inquiry is initiated.
- e. Persons named in the complaint/allegation will have the opportunity to respond in writing. If an investigator is contacted for a response during the inquiry, a written response will be requested by a specified date.
- f. If further investigation or convened IACUC review is not warranted (e.g. dismissal of the allegation or referred to another University process), the allegation will be considered resolved. The IACUC will be informed of all allegations and outcomes of any initial inquiry at the next convened meeting and the Office of Research Integrity.
- g. If further investigation is deemed warranted, the allegation will be reviewed by all members of IACUC according to section D-4 of the IACUC Guidebook, the Guide for the Care and Use of Laboratory Animals, and PHS Policy. Any individual with a potential conflict of interest may not participate in the investigation.
- h. In all cases, researchers will be informed in writing of the further investigation. The institutional official, Associate Provost for Research and Graduate Education, and the researcher's dean and department chair (or equivalent), will also be notified that an IACUC investigation will take place. A written response from the researcher will be requested, depending upon the nature of the alleged noncompliance, to facilitate the review and conclusion of the investigation.
- i. The results of the investigation will be considered IACUC actions and all members will have the opportunity to present minority views. Recommendations will be sent in writing to the Associate Provost for Research and Graduate Education and to the Institutional Official.
- j. The institutional response will be based upon recommendations specified in section D of the IACUC Guidebook. Specifically, "if the violation is verified by the IACUC, then the IACUC is empowered under USDA Regulations and PHS Policy to suspend a previously approved project. If the activity is supported by PHS funds, the IACUC through the

Institutional Official must file a full report to the Office of Laboratory Animal Welfare (OLAW). In cases where there is sufficient evidence of serious noncompliance, the IACUC will suspend the activity pending the outcome of full investigation. In these cases, a preliminary report will be sent to the OLAW, through the Institutional Official, with a promise of a full report upon completion."

- k. Corrective action(s) will be based on the nature of the noncompliance, extent to which animals were placed at risk, previous noncompliance, etc. The range of possible corrective actions that the IACUC may consider includes, but is not limited to:
 - Modification(s) of the animal use protocol through amendments initiated by the researcher
 - Monitoring of animal use activity (including audits or assessments of technical abilities)
 - Education or training for the researcher and/or research staff
 - Additional reporting requirements
 - Limitations on research activities, use of research facilities, or use of research data
 - Suspension or termination of IACUC approval for one or more of the investigator's protocols
 - Suspension of personnel from working with vertebrate animals
- l. When approval of animal use activities is suspended or terminated, an explanation will be communicated to the researcher(s) and their dean and department chair (or equivalent), along with any corrective actions required to ensure future compliance with the regulations.
- m. The researcher will have 14 days to appeal the IACUC decision in writing. The appeal will be considered during a scheduled IACUC meeting, and the researcher may be invited to attend, or may request to speak at the meeting. The researcher will be notified of the IACUC decision within 14 days. The IACUC decision will be final.
- n. If the researcher does not comply with required corrective actions, additional action(s) may be taken, including suspension of IACUC approval(s) for ongoing animal use activities. The researcher and the convened IACUC will be notified of resolution of corrective actions or the need for additional actions.
- o. Consideration for reinstatement of approval for activities will be based on whether there are remaining concerns about potential pain or distress to animals or continuing noncompliance on the part of the researcher or research staff.

C. Occupation Health Related to Animal Research

1. A pre-placement physical examination will be performed at Health Services or at a community outpatient health clinic for individuals with direct regular contact (8 hrs/weeks or more) or direct contact limited exposure (less than 8 hrs/week) with rodents. Tetanus immunization will also be required at 10-year intervals. In addition, tetanus immunization is available for any student, faculty, or staff member who is injured while working at Western Kentucky University.
2. Individuals with direct regular contact or direct contact limited exposure to rodents will be provided with a suitable laboratory coat and other necessary protective equipment, including dust masks, disposable gloves, and safety goggles or face shields. If required for the work performed, signs will be posted inside the animal facility indicating environmental or biohazards and emergency phone numbers. In addition, the animal facility will have appropriate first aid kits, which will be inspected and re-stocked each academic semester.
3. Faculty researchers are required to provide basic training to their students and employees on topics such as: zoonoses; personal hygiene; occupational hazards (such as animal bites and scratches); allergy; and first aid. Students and employees must report any unusual incidents, including accidents, animal bites, animal scratches and sick or dead animals, to their faculty advisor immediately.
4. Students or employees requiring medical attention should be transported immediately to Health Services or to a community Outpatient Clinics—or in the case of serious injury, the emergency room of one of our two local hospitals. Faculty advisors should make certain that an official university accident report form is completed for any accidents, which occur related to the animal facilities or animal use. Non-employee and employee accident forms are available in all departmental offices and on-line. Forms should be completed and submitted to the Environmental Health and Safety Office and to Human Resources.

D. Training in the Care and Use of Animals

1. Faculty serving as principal investigators on research projects involving vertebrate animals will be required to complete appropriate Collaborative Institutional Training Initiative (CITI) Programs training determined by the WKU IACUC Chair or the committee, and encouraged to attend workshops, seminars or otherwise consult with experienced researchers at institutions (e.g., University of Kentucky, Vanderbilt University) with larger animal facilities in order to continually update their knowledge in the proper care and use of laboratory animals.
2. The faculty will in turn train all students, technicians and other faculty involved in the humane practice of animal care and use and will also complete appropriate CITI Program training, determined by the WKU IACUC Chair or IACUC committee.
3. All students and employees with direct animal contact will be provided with a copy of the second edition of "Essentials for Animal Research, A Primer for Research Personnel", by B.T. Bennett, M.J. Brown, and J.C. Shofield or

equivalent current text. Faculty will be required to keep records documenting their own training, and student training in the proper care and use of laboratory animals. At the conclusion of each academic year, faculty members will provide copies of the training records to the IACUC Chair. Furthermore, all IACUC members are given a copy of the Guide for the Care and Use of Laboratory Animals and are required to complete the CITI Laboratory Animal Welfare Course, "Essentials of IACUC Members". Also, they are required to participate in an in person orientation conducted by the IACUC Chair.

E. Record Keeping Requirements

1. This institution will maintain for a minimum of three years:
 - A copy of the Institutional Assurance, any modifications there to, as approved by PHS.
 - Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
 - Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
 - Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Associate Provost for Research and Graduate Education.
 - Records of accrediting body determinations if appropriate.
2. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.
3. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner when requested.

F. Reporting Requirements

1. At least once every 12 months, the IACUC, through the Institutional official, will report in writing to the Office of Laboratory Animal Welfare (OLAW):
 - a. Any change in the status of the institution (e.g., if WKU becomes accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, WKU will submit a letter to OLAW stating that there are no changes.
 - b. Notification of the date that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluation to the Associate Provost for Research and Graduate Education.

2. The IACUC, through the institutional official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
 - a. Any serious or continuing non-compliance with the PHS Policy.
 - b. Any serious deviations from the provisions of the Guide.
 - c. Any suspension of an activity by the IACUC.
3. Reports filed under the previous section shall include any minority opinions filed by members of the IACUC.

IV. Resources

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>)

V. Reason for Revision

November 2010

A non-substantive revision to this policy included the numbering system.

March 2011

Change of “six months” to “one year” in II.C and the addition of the requirement to inform

June 2011

Non-WKU Policies were added to the purview of the document

January 2012

Revised to new policy format

May 2016

Revised to reflect re-organization of the Office of Research and Creative Activity.

November 2017

Revised to more fully describe the IACUC procedures for handling allegations of noncompliance.

June 2021

Non-substantive changes resulting from fifth year review in accordance with Policy 0.000V.

VI. Related Policies

Policy 2.730V *Research Misconduct and Non-compliance*