Regulation 3-32

Winona State University

Assurance of Compliance with Public Health Service Policy on Humane Care and Use of Laboratory Animals

(Mandated by Federal Regulations)

Winona State University, hereinafter referred to as WSU, 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.

I. APPLICABILITY

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals\(^1\) supported by WSU or the Public Health Service (PHS) and conducted at WSU, in the field, or at another institution as a consequence of the subgranting or subcontracting of a PHS-conducted or supported activity by WSU.

Faculty, staff and students at WSU may conduct research and/or teaching activities with laboratory-bred rats and mice, birds and lower vertebrates (fish, amphibians and reptiles). Activities may not involve on campus housing of species covered by the U.S. Department of Agriculture’s definition of animal, which includes any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit or other such warm-blooded animal, including wild species of rats and mice.

Ultimate responsibility for the care of any animal rests with the Principal Investigator, who shall name another faculty designee to be approved by the IACUC. This designee will assume responsibility for the care of the animals upon the absence of the Principal Investigator. If the IACUC receives a report of animals not receiving appropriate care and determines to the best of its ability that said care is inadequate, the IACUC will assume control of the animals and may care for or dispose of the animals, up to and including euthanasia, as appropriate. IACUC emergency / notification procedures are included in an attachment to the IACUC Protocol form and are updated annually.

II. INSTITUTIONAL POLICY

A. WSU will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

\(^1\) For the purposes of WSU, live, vertebrate animals include laboratory-bred rats and mice, birds and lower vertebrates (fish, amphibians and reptiles).
B. WSU is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. WSU acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, WSU 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.

D. WSU has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are:
B. The qualifications, authority, and percent of time contributed by the Veterinarian(s) who will participate in the program are:

The Veterinarian must be licensed in the State of Minnesota or Wisconsin. S/he is a full, voting member of the IACUC. S/he may advise individual researchers on appropriate animal care and may communicate directly with the President on issues of concern.

The Veterinarian is specifically required to participate in the semi-annual facilities’ inspections. Species currently used in research at WSU include laboratory-bred rats and mice, birds and lower vertebrates. Since these animals require relatively little specialized veterinary care, the percentage of the Veterinarian’s time dedicated to the program beyond IACUC membership will be minimal. When IACUC Veterinarian is not available, the Principal Investigators have the expertise to provide adequate care. Other local Veterinarians may be consulted by the Principal Investigator as needed.

C. WSU has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee WSU’s animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Faculty members are appointed by the WSU Faculty Association, then confirmed by the President.

D. The IACUC will:

1. Review at least once every six months WSU’s program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations are:

   A program review is conducted once a semester using the attached Semiannual Program Review Checklist. The review is conducted during a regularly scheduled IACUC meeting. Deficiencies are discussed and corrective actions to be taken are identified.

2. Inspect at least once every six months all of WSU’s animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are:

   All facilities housing animals used in research, research training or teaching are inspected once each semester. Inspections are conducted during a regularly scheduled IACUC meeting. After the inspection, IACUC members individually submit observations and recommendations to the IACUC Chair who compiles a report for IACUC review at their next scheduled meeting. Deficiencies are discussed and corrective actions identified.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3, and submit the reports to the President and Associate Vice President for Research, Graduate Studies and Assessment. The IACUC process for developing reports and submitting them to the Institutional Official is:
After each inspection, a program review and animal facilities inspection report is completed. The report identifies deficiencies and corrective actions taken and may make recommendations for additional corrective actions. Any dissenting viewpoints must be appended to the formal report. The report is submitted to the President and Associate Vice President for Research, Graduate Studies and Assessment. Copies of the report are filed in the office of the IACUC Compliance Officer (the Director of Grants & Sponsored Projects).

4. Review concerns involving the care and use of animals at WSU. The IACUC procedures for reviewing concerns are:

Any person may submit a request for IACUC action should s/he suspect violations of the animal care policy. Upon notification, the IACUC will immediately initiate an investigation of the suspected violation. A report of the IACUC findings will be prepared (including dissenting opinions) and will include recommended actions. The report will be forwarded to the President and Provost/Vice President of Academic Affairs (P/VPAA) through the President’s designee on the IACUC (IACUC Administration Representative). If appropriate, copies of the report will be sent to the Office of Laboratory Animal Welfare and other relevant granting agencies. A copy of the report will be kept on file in the offices of the Compliance Officer and the IACUC Chair and copies will be forwarded to affected parties. If warranted, WSU will take action to suspend the project and may require termination of the project. In extreme cases, WSU may place permanent restrictions on an individual’s ability to use or handle animals at WSU.

5. Make written recommendations to the President and Associate Vice President for Research, Graduate Studies and Assessment regarding any aspect of WSU’s animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:

Written recommendations may be made in the end-of-the-semester program review and facilities inspection reports or in investigatory reports. The IACUC may also make written recommendations at any other time, as needed. All written recommendations are prepared by the IACUC Chair and reviewed by the full IACUC.

6. 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 WSU staff, faculty and students planning to initiate a teaching or research project that involves the use of animals are required to submit via the approved electronic submission system Protocol For Animal Research and/or Teaching Activities prior to the initiation of any project. The Compliance Officer (the Director of Grants & Sponsored Projects) reviews the protocol for completeness and contacts the IACUC Chair to schedule a meeting to review the protocol. The Compliance Officer notifies IACUC members and Principal Investigator of the time and place of the next meeting and refers them to the electronic review system. Principal Investigators are invited to attend the meeting to answer questions IACUC members may have
during the review process, but they are asked to excuse themselves while IACUC deliberations take place. The committee has the option of rejecting, accepting or requiring revision and resubmission of the protocol. Action on a protocol may be taken if a quorum (a simple majority of members) is present at the meeting. Decisions require a majority vote by those in attendance.

All academic departments housing animals on campus for educational display purposes only (not to be explicitly used for research and/or teaching activities) are required to submit by September 30 each year, a memo indicating the animals are for display only. The memo should state: 1) the species and number of animals, 2) the location of the animals, and 3) who is responsible for their care.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of or care 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:

Descriptions of proposed changes are submitted via the approved electronic submission system to the IACUC. The Compliance Officer contacts the IACUC Chair to schedule a meeting of the IACUC and notifies IACUC members of the time and place of the next meeting and refers them to the electronic review system. Action on the proposed changes may be taken if a quorum is present at the meeting. Decisions require a majority vote by those in attendance.

8. Notify Principal Investigators and the Compliance Officer using the approved electronic system of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify Principal Investigators and WSU of its decisions regarding protocol review are:

With regards to approvals or withholding of approvals, the Compliance Officer will have 10 working days to electronically notify the investigator(s) of the IACUC decision. Notifications may provide for unqualified approval, deferral, approval pending clarification, qualified or conditional approval, limited approval or disapproval, all with explanation(s) as appropriate.

9. 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. The IACUC procedures for conducting continuing review are:

The IACUC Compliance Officer notifies Principal Investigators of upcoming review dates and requests submission of a Project Status Report on the prescribed form via the approved electronic submission system. The Project Status Report form and the original protocol request are reviewed by the IACUC at its next regularly scheduled meeting. If the original protocol was submitted on a protocol request form that is not longer in use, the Principal Investigator will be required to re-submit the protocol using the current form. Action may be taken if
a quorum (a simple majority) is present at the meeting. Decisions require a
majority vote of those in attendance. The IACUC Chair will have 10 working days
to electronically notify the investigator(s) of the IACUC decision.

10. Be authorized to suspend an activity involving animals as set forth in the PHS
Policy at IV.C.6. The IACUC procedures for suspending an ongoing activity
are:

The President’s designee on the IACUC (IACUC Administration
Representative) is authorized to recommend and initiate actions to suspend
activities. (See section D.4.)

E. The individual(s) authorized by WSU to verify IACUC approval of those sections of
applications and proposals related to the care and use of animals is the Director of
Grants & Sponsored Projects, who also serves as a non-voting member of the
IACUC and as the IACUC Compliance Officer, is authorized to verify IACUC
approval.

F. The occupational health and safety program for personnel who work in laboratory
animal facilities or have frequent contact with animals is:

Risk assessment for on campus laboratories indicates minimal risk since only
laboratory-bred rats, mice and birds are permitted in these facilities. Faculty are
responsible for providing occupational health and safety instructions to students.
All students are instructed as to the importance of personal hygiene and laboratory
attire appropriate to the work being performed. Smoking, drinking, eating, etc. is
prohibited in all laboratories. Chemical hoods are available as appropriate.
Eyewash facilities are installed in all laboratories along with first aid materials.
Hazardous materials are stored in appropriate containers and disposed of in
compliance with applicable State of Minnesota and federal regulations.

Risk of exposure to biological hazards in field research is minimal since activities
may only involve fish, amphibians and reptiles. In review of protocols involving
field research, the IACUC expects Principal Investigators to address issues of
water safety and hazards in the field, document the safety of equipment and
procedures, and provide evidence that appropriate instructions in health and safety
will be provided to student participants.

Prior to engaging students in research activities, faculty will screen students via a
self- assessment of general health status. Students should complete a form which
allows/prompts them to identify preexisting conditions which may put them at risk
(e.g. allergies, asthma, chronic health issues, etc.) and affirms current tetanus
inoculation. Faculty should instruct students on procedures and for reporting
injuries e.g. bites.

G. The total gross number of square feet in each animal facility (including each
satellite facility), the species of animals housed therein and the average daily
inventory of animals, by species, in each facility is provided.
<table>
<thead>
<tr>
<th>Laboratory, Unit, or Building*</th>
<th>Gross Square Feet</th>
<th>Typical Species Housed in Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stark Hall Facility 219</td>
<td>606</td>
<td>rats</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mice</td>
</tr>
<tr>
<td>Phelps Hall Facility 208A</td>
<td>182</td>
<td>rats</td>
</tr>
<tr>
<td></td>
<td></td>
<td>chicks</td>
</tr>
<tr>
<td>SLC - 2\textsuperscript{nd} floor hallway</td>
<td></td>
<td>Cuban Night Anole a and b</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chinese Water Dragon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Green Iguanas</td>
</tr>
<tr>
<td>Greenhouse</td>
<td></td>
<td>Convict Cichlids</td>
</tr>
<tr>
<td>SLC – 232</td>
<td></td>
<td>Guppies</td>
</tr>
<tr>
<td>SLC – 234</td>
<td></td>
<td>Firemouth Cichlids</td>
</tr>
<tr>
<td>SLC – 238</td>
<td></td>
<td>Boa</td>
</tr>
<tr>
<td>SLC – 264</td>
<td></td>
<td>Siamese Fighting Fish</td>
</tr>
<tr>
<td>SLC – 264</td>
<td></td>
<td>Standing Day Geckos</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Leopard Geckos</td>
</tr>
<tr>
<td></td>
<td></td>
<td>African Clawed Frog</td>
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<td></td>
<td></td>
<td>Terrestrial Frog</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Convict Cichlids</td>
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<tr>
<td></td>
<td></td>
<td>Guppies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Green Anoles</td>
</tr>
<tr>
<td>SLC – 291</td>
<td></td>
<td>Brown Anoles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plecostoma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Siamese Fighting Fish</td>
</tr>
</tbody>
</table>

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is:

All Principal Investigators are required to document training and expertise relevant to research proposed in protocols submitted to the IACUC. For example, protocols involving surgery, invasive procedures, anesthesia, etc., are only approved for Principal Investigators who have documented their training and expertise in these methods. To assure the currency of faculty expertise a resource center will be established in the library and maintained by the IACUC.

The training of students who will work with animals is the responsibility of the Principal Investigator. In behavioral research this will require the review of American Psychological Association (APA) guidelines and procedures for the use of animals in research and specific instruction by the research supervisor on the procedures to be used in the research project. Individuals supervising students involved in more invasive procedures will document how the students will be trained in the protocol request.
IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 2, all of WSU’s programs and facilities, including satellite facilities, for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of WSU’s adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC evaluations will be submitted to the President and Provost/Vice President of Academic Affairs (P/VPAA). Semiannual reports of IACUC evaluations will be maintained by WSU and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING REQUIREMENTS

A. WSU will maintain in the Office of the Compliance Officer for at least three years:

1. A copy of this Assurance and any modifications thereof, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.

3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld.

4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the President and the Associate Vice President for Research, Graduate Studies and Assessment.

5. Records of accrediting agencies’ determinations.

B. WSU 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.
C. All records shall be accessible for inspection and copying by authorized Office of Laboratory Animal Welfare (OLAW) or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. Once registered, at least once every 12 months, the IACUC, through the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare (OLAW):

1. Any change in the status of WSU, any change in the description of WSU’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, WSU will provide OLAW with written notification that there are no changes.

2. Notification of the dates that the IACUC conducted its semiannual evaluations of WSU’s program and facilities (including satellite facilities) and submitted the evaluations to the President and Associate Vice President for Research, Graduate Studies and Assessment.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the PHS Policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A. and VI.B. above shall include any minority views filed by members of the IACUC.

AUTHENTICATED BY:

[Signature]
Judith A. Ramaley
President
March 5, 2012
Date of Adoption

Authoritative References:
President
Code of Federal Regulations – Title 9, Animals and Animal Products, Chapter 1, Part 3, Standards – U.S. Department of Agriculture
IACUC Guidebook – Office of Laboratory Animal Welfare (OLAW)

Initial Date of Adoption: December 3, 2008
Dates of Revisions: November 4, 2011

LIST OF ATTACHMENTS:
• Semiannual Program Review checklist (attached)
• Read Me First – Instructions
• IRBNet – Electronic submission system – http://www.irbnet.org – Forms and Templates includes:
  o Read Me First - Instructions Faculty Sponsor Instructions File Reports (If Required) How To Do Everything
  o Modifications and Information Required Notices from IRBNet
  o Student Co-Investigators Instructions
  o “Unlocked” Protocols and IRB Office Requests for Missing Information
  o Working with Co-Investigators and Faculty Sponsors
• WSU IACUC Protocol for Animal Research and/or Teaching Activities
1. **IACUC Membership and Functions**

- at least 5 members, *faculty appointed by WSUFA and non-faculty* appointed by President
- members include Veterinarian, scientist, non-scientist, and non-affiliated non-lab animal user
- responsible for oversight and evaluation of WSU’s program
- reports to Institutional Official (IO)
- conducts semiannual evaluations of institutional animal care and use program
- conducts semiannual inspections of institutional animal facilities
- reviews and investigates concerns about animal care and use at WSU
- procedures for review, approval and suspension of animal activities
- procedures for review & approval of significant changes to approved activities
- policies for special procedures (e.g. restraint, multiple survival surgery, fluid restriction)

2. **IACUC Records and Reporting Requirements**

Reports to Institutional Official (IO)
- reports of semiannual program reviews & facility inspections are submitted to IO
- include minority IACUC views
- describe departures from *Guide* or PHS Policy and reasons for departure
- distinguish significant from minor deficiencies
- include plan and schedule for correction of each deficiency identified

Reports to Office of Laboratory Animal Welfare (OLAW)
- reports include any minority IACUC views
- annual report to OLAW documents program changes & dates of IACUC semiannual review
- promptly advises OLAW of serious/ongoing *Guide* deviations or *PHS Policy* noncompliance
- promptly advises OLAW of any suspension of activity by the IACUC

Records
- minutes of IACUC meetings and semiannual reports maintained for 3 years
- IACUC review documentation maintained for 3 years after end of study
- IACUC review of activities involving animals includes all required information

3. **Veterinary Care** *(See also next section - Veterinary Medical Care)*

- institutional arrangement for Veterinarian with training or experience in lab animal medicine
- veterinary access to all animals
- provision for backup veterinary care
- must provide guidance on handling, immobilization, sedation, analgesia, anesthesia, euthanas
- must provide guidance/oversight on surgery programs and oversight of postsurgical care
- veterinary authority to oversee all aspects of animal care and use

* = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)
4. PERSONNEL QUALIFICATIONS AND TRAINING

- WSU has established and implemented an effective training program
- includes professional/management/supervisory personnel
- includes animal care personnel
- includes research investigators, instructors, technicians, trainees, students

Training program content
- humane practices of animal care (e.g. housing, husbandry, handling)
- humane practices of animal use (e.g. research procedures, use of anesthesia, pre- & post-operative care)
- research/testing methods that minimize numbers necessary to obtain valid results
- research/testing methods that minimize animal pain or distress
- use of hazardous agents, including access to OSHA chemical hazard notices where applicable

5. OCCUPATIONAL HEALTH AND SAFETY OF PERSONNEL

Institutional program for a safe and healthy workplace
- program is established and implemented
- covers all personnel who work in laboratory animal facilities
- based on hazard identification and risk assessment
- personnel training (e.g. zoonoses, hazards, pregnancy/illness/immunosuppression precautions)
- personal hygiene procedures (e.g., work clothing, eating/drinking/smoking policies)
- procedures for use, storage & disposal of hazardous biologic, chemical, and physical agents
- specific procedures for personnel protection (e.g., shower/change facilities, injury prevention)

Program for medical evaluation and preventive medicine for personnel
- pre-employment evaluation including health history
- immunizations as appropriate (e.g. rabies, tetanus) & tests
- zoonosis surveillance as appropriate (e.g. Q-fever, tularemia, Hantavirus, plague)
- procedures for reporting and treating injuries, including bites etc.

Notes:

*A = acceptable; M = minor deficiency; S = significant deficiency (is or may be a threat to animal health or safety)