

WSU Manual for the Institutional Animal Care and Use Committee (IACUC)



**Office of research Assurances (ORA) and
Institutional Animal Care and Use Committee (IACUC)
Washington State University**

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Introduction

The Institutional Animal Care and Use Committee (IACUC) is charged with ensuring that *all vertebrate animals used in instruction or research at Washington State University (WSU) receive ethical and humane treatment*. The committee is bound by federal law and university policy to ensure that the best care is given to every animal housed and used at the university.

This manual is designed to be a guide for the IACUC process at WSU. While this manual hopes to illuminate many pertinent IACUC issues, it should not be considered definitive or comprehensive. Any questions regarding the IACUC process, or any material in this manual should be directed to the IACUC coordinator. Please visit the IACUC website: www.iacuc.wsu.edu for contact information.

I. The institutional authority under which the IACUC is established

The WSU IACUC is a Presidential Committee reporting to the President through the Vice President for Research and Dean of Graduate School. The Institutional Official (IO) for the IACUC is the Vice President for Research and Dean of Graduate School. The IO signs the Public Health Service (PHS) Assurance for WSU and thus commits the institution to abide by the Animal Welfare Act Regulations and the PHS Policy.

II. Purpose of the IACUC

The WSU IACUC is a Presidential Committee established to *protect the welfare of live vertebrate animals used in teaching or research* conducted under the auspices of WSU. The IACUC also assists researchers in conducting safe and *ethically* sound research involving animals.

III. Authority of the IACUC

a. Scope of authority defined

The WSU IACUC has the primary authority to approve, require amendments to an approved protocol, disapprove or suspend research and instruction on all live and dead vertebrate animals used in WSU. The scope includes WSU campus, campuses outside Pullman, satellite facilities, cooperative units and off campus facilities. The IO, the Vice President for Research and Dean of Graduate School, President and Regents also have the authority to suspend or disapprove research, even if the IACUC has approved it. The IACUC also has the authority to conduct Post-Approval Review (PAR) on all approved protocols.

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

b. Authority to inspect animal housing facilities and the University's animal care and use program.

The WSU IACUC has the authority to inspect and approve animal housing facilities prior to use; conduct semi-annual program review and regular inspection as mandated by federal laws. While WSU IACUC may inspect animal housing facilities on a semi-annual basis or in response as it deems appropriate, it must do so on a complaint or

statement of concern regarding a facility. The WSU site inspection must include at least two voting IACUC members. Experts or other consultants may be invited to help in the evaluation.

The program review covers all aspects of WSU's animal research and teaching program including, but not limited to facilities, veterinary care, occupational health and safety standards, and general IACUC functions.

The IACUC inspects all animal housing facilities and areas including locations where *any* surgery is performed or animals are held for more than 12 hours. IACUC also inspects facilities at all off site locations, regional campuses, satellite facilities and cooperative units. Irregular study sites may be visited only if a protocol is (or will be) approved and animals housed in the location. In facilities with an Animal Care and Use Committee, a report informing the WSU IACUC of the status of the project can be considered for the IACUC.

c. Authority to prepare and submit reports of the IACUC evaluations to the IO.

The IACUC will submit all inspection reports to the WSU's IO. The reports should include deficiencies both minor and major, and the program review. A majority of the IACUC members must sign the reports, and minority views (if any) must always be recorded. Members are requested to submit such minority views in writing.

d. Authority to prepare and submit report to regulating or accrediting bodies on behalf of the IO.

The OCV, on behalf of the IACUC prepares various reports to federal regulating agencies and accrediting bodies. These reports are forwarded to WSU's IO who then submits the report to the proper federal agencies. The OFFICE OF RESEARCH ASSURANCES receives copies of all reports and correspondence for the IACUC. For more information regarding the IACUC's reporting obligations please see section II of this manual.

e. Authority to make recommendations to the IO regarding the Institutional animal care and use.

The IACUC is authorized to make recommendations regarding all parts of the animal care and use programs. These includes (but is not limited to) facilities, training, or any other aspect of the animal care and use program at WSU.

f. Authority to disapprove, modify, or approve studies based upon consideration of the justification of animal use

Research reviewed and approved by the WSU IACUC may be subject to further review and disapproval by the IO. However, IO may not approve a research protocol if it has been previously disapproved by the WSU IACUC.

The WSU IACUC also functions independently of other committees in WSU. It makes an independent determination to approve or deny the protocol based upon *animal welfare and scientific merit*.

g. Authority to require progress reports from the investigators and oversee the conduct of the study

All approved research is subject to continuing WSU IACUC review and must be reevaluated at least annually (or more frequently, if specified by the IACUC). The WSU IACUC reviews all approved activities annually. The continuing review process is explained in detail in section I.a.iv of this manual.

h. Authority to conduct Post-Approval Review (PAR) on approved protocols

All protocols reviewed and approved by WSU IACUC are subject to PAR. The PAR will include review of all procedures and personnel listed in the protocols. The purpose of PAR is to document adherence to approved protocols and if necessary, to provide guidance to bring protocols into conformance with WSU standards for animal care and use. In addition, these reviews provide a mechanism for the IACUC to demonstrate to the accrediting agency (AAALAC) that WSU animal use practices match WSU policies. IACUC will receive the review results and then respond with a letter to thank the PIs for participation in this important process and summarizing the results of the review. If the review identifies areas which require either modification of an approved protocol or of animal use practices, the IACUC will work with the investigator to identify and implement potential solutions.

i. Authority to suspend or terminate approval of any approved activity

The WSU IACUC has the authority to suspend or terminate approval. Approval may be suspended or terminated for research that is not being conducted in accordance with the IACUC's requirements or is in violation of federal laws. This includes protocols that have been associated with unexpected serious harm to the animals or personnel. Any suspension or termination of approval shall include a statement of the reasons for the IACUC's action and will be reported promptly to the investigator and appropriate federal agencies.

j. Authority to review concerns involving animal care and use.

The WSU IACUC has the authority to review all reports of concern regarding animal care and use at the University. The IACUC also has the authority to investigate these concerns and take any action necessary to protect the welfare of animals.

IV. Membership of the IACUC

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

i. Number of members

The IACUC will be chaired by an Associate Professor or a full Professor of WSU and shall have no less than five formal members with the qualifications listed below.

a. Composition of IACUC

The Committee shall include at least:

- One practicing scientist with experience in research involving animals.
- One Doctor of Veterinary Medicine with training or experience in laboratory animal medicine and with University-wide authority to direct activities involving animals. By local tradition and intent, this function is served by the Director, Office of Campus Veterinarian or his designee.
- One member not affiliated with the University who represents the interest of the surrounding community with respect to care and use of animals in instruction and research.
- One member with expertise in a non-scientific area.
- One faculty, staff, and/or administrative professional from WSU with experience and expertise in the care and use of animals in instruction or research.

Members are allowed to fulfill multiple roles on the committee.

No more than three members from the same department can be on the IACUC at a given time.

The advice on the use of alternate members is taken from regulations:

OLAW's (and USDA's) intent behind allowing "alternates" is to help IACUCs meet quorum so that they can conduct official business at a convened meeting. While use of alternates for designated review is acceptable, it would only be in those situations where the alternate's primary member is truly unavailable (i.e. on sabbatical, on vacation, away on business). Some institutions may be tempted to "abuse" the luxury of the provision of alternates and make alternates the individuals to review protocols via designated review. If your primary committee members are constantly defaulting to their alternates to conduct designated review on their behalf because they have no time, it is time to appoint a new primary member into those positions. Using your alternates for designated review should be a relatively rare event and truly in the absence of the primary member. Remember, OLAW (and USDA because they aligned with OLAW on this concept) introduced the concept of alternates to help IACUCs meet quorum, not to minimize the burden of designated review (or any other required activity) on primary members.

b. Liability coverage for IACUC members

The IACUC performs a vital University function. Thus, a member of the IACUC is either a state employee or an authorized volunteer acting for the benefit of WSU. See BPPM 60.81. As such, an IACUC member is eligible for state defense of tort and civil rights lawsuits if the acts or omissions of the IACUC member which gave rise to the suit were, or were purported to be, performed in good faith within the scope of that person's official duties RCW 4.92.060, 070.

c. Use of consultants

The WSU IACUC is encouraged to use non-member consultants for advice and information in specialized areas as needed. These consultants may be WSU

faculty or staff, or may be unaffiliated with WSU. The consultants may present their assessments in writing or in person.

IACUC is a presidential committee in WSU. Members are appointed by the president on the recommendation of the IO.

Institutional Official (IO)
Office of Research
*Vice President for Research
and Dean of Graduate school*

IACUC Chair
Associate or Full
Professor of WSU

Members (examples of types of expertise/experience sought)

Veterinarian
Office of Campus Vet
Director, OCV & designee

Practicing Scientists
Faculty members with
experience in Animal
research

Non-scientific member
Faculty with expertise in
ethics/philosophy

Non-affiliated Member
Member from the
surrounding community

Expert in Animal Care
Faculty with expertise in
large animal research

Expert in Animal Care
Faculty with expertise in
small animal research

Expert in Animal Care
Faculty with expertise
in Animal care

Expert in Animal Care
Faculty with expertise in
experimental research

Expert in Animal Care
Faculty with expertise in
clinical vet. medicine

Invited Attendees

Environmental Health &
Safety Specialist

Veterinary Technician

Alternate Members and
Post Approval Review
Team

Support Staff

Director, Office
of Research
Assurances

IACUC Program
Coordinator

PAR team,
located at OCV

V. Management of the IACUC

a. The IACUC Chairperson

i. Selection and appointment

The Chairperson is appointed by the President of the University, on the recommendation of the Vice President for Research and Dean of Graduate School.

ii. Duties

The Chair directs the IACUC meetings in accordance with institutional and federal requirements. The Chair works closely with IACUC members; Director, Office of Research Assurances; the Campus Veterinarian; the IACUC coordinator; institutional officials; and investigators to ensure that the research animals are protected. The Chair is the designated signatory for the IACUC. The Chair reviews all protocols, is involved in the pre-review process, and assigns reviewers for the protocols received for IACUC approval..

iii. Removal

The IACUC Chair may be removed or replaced *with or without cause* by the IO or the President of the University.

b. The IACUC members

i. Selection and appointment

All members to the IACUC are appointed by the President of the University, on the recommendation of the Vice President for Research and Dean of Graduate School. Alternate members appointed to the IACUC must have one-to-one designation with a voting IACUC member. The alternate member designation is made by the IO and is documented on the IACUC roster. The alternate member should meet the same qualifications as the member to whom they are appointed. For more information on alternate members see section C below.

Members are appointed to the committee for three years, but may be terminated sooner as provided in this section. These appointments typically begin August of the year appointed and end August three years later.

At the conclusion of their terms a committee member may be appointed to an additional term and/or year of service. There is no limit to the number of terms a member may serve on the IACUC.

ii. Duties

WSU IACUC members are responsible to ensure the humane care and use of animals in research and teaching. Their review of protocols should consider if the study is designed to minimize the ethical cost by following 3 R's: Replacement, Reduction, and Refinement and in a manner that is consistent with current federal regulations, state and local laws, and institutional guidelines and policies. In addition to the protocol review, the IACUC members are expected to participate in

the site visits, semi-annual program review, and other functions of the IACUC as needed.

iii. Removal

IACUC members may be removed or replaced with or without cause by the Institutional Official or the President of the University.

C. Alternate Members

i. Selection and appointment

All alternate members are appointed by the President of the University, on the recommendation of the Vice President for Research and Dean of Graduate School. There must be a specific one-to-one designation of the IACUC member to the alternate member. The specific alternate designation is made by the Institutional Official and is documented on the IACUC member roster and meets some qualifications.

Alternate members are appointed to the committee for three years, but the appointment may be terminated sooner, as provided in this section. These appointments typically begin August of the year appointed and end August three years later. The updated roster with all the members and alternate members are maintained by Office of Research Assurances.

At the conclusion of their terms a committee member may be appointed to an additional term and/or year of service. There is no limit to the number of terms a member may serve on the IACUC.

ii. Duties

Alternate members receive training identical to the regular members. Alternate members receive all of the protocols and materials at each full meeting of the IACUC. They can attend any meeting, but their vote will not count at the meeting unless their appointed member is not present. The alternate members will be assigned protocols for review when their designated member takes a leave of absence from the committee or when the member becomes unavailable. They can participate in site visits and participate in the program review.

iii. Removal

IACUC alternate members may be removed or replaced with or without cause by the Institutional Official or the President of the University.

d. Training of IACUC Chair, Members, and alternate Members

i. Orientation

When a new member or Chair is appointed to the IACUC, the Director of OCV, Chair or Program Coordinator will conduct a New Member Orientation. This orientation will introduce new members to WSU IACUC meeting procedures, the protocol review procedures, functions of the IACUC, their responsibilities and the federal regulations that cover the use of vertebrate animals in teaching and research. Materials for New Member Orientation are available with the IACUC

Program Coordinator. Contact iacuc@wsu.edu; call: 509-335-7951 for more information.

ii. Continuing Education

Continuing education is held throughout the year regarding topics of special interest to the committee.

iii. Reference Materials

Members are given the current WSU IACUC roster, *brochure*, USDA Brochure on *Alternatives and the Animal Welfare Act*, NIH brochure on *Searching for Alternatives to painful procedures used on Research Animals*, WSU IACUC members handbook, Semi-annual inspection checklist and Pages from WSU IACUC Website. This manual can be downloaded from the website. Several resources are available online and will be provided to the IACUC members- OLAW website, the USDA website (for The Guide to the Care and Use of Laboratory Animals), and the ILAR website. More materials are listed and updated periodically online at: <http://www.iacuc.wsu.edu/resources.asp>.

e. Administrative support staff

An IACUC coordinator is housed within the Office of Research Assurances (and reports to the Director of the Office of Research Assurances. The IACUC Coordinator supports the IACUC and manages the privileged and confidential institutional review and approval process of proposed research activities involving animal use in research and instruction at the University. Among this position's duties are the following:

- Maintain current IACUC roster and membership letters
- Advise faculty, staff, and students in preparation of applications for IACUC approval.
- Maintain the IACUC database and keep track of protocols requiring annual and 3-yr Resubmissions. Notices for these protocols will be sent out three months, two months and a month before expiry.
- Provide administrative and database support for PAR by sending out notification of PAR (upon approval of a new protocol or a 3-yr Resubmission), maintaining records of PAR checklist in the database and sending out the appropriate letters (Attaboy! if no discrepancies were noted or Oops! when deviations are observed)
- Communicate sub-committee requests to investigators for additional information and revisions and review responses. While all members of the committee have the ability to communicate directly with investigators, the IACUC coordinator ensures that all requests for information or revision are resolved in a timely manner; and documented properly in the IACUC files.

An exception to this rule is the full committee review. When protocol is subjected to a full committee review, the Chair or his designee sends the comments out to the PI, unless the chair designates another IACUC member or the Coordinator to do so.

- Prepare correspondence, reports, agendas, minutes of meeting, and certifications of review for funding agencies related to review and approval process
- Facilitate the approval of administrative changes; coordinate semi-annual lab inspections and site visits, prepare the semi-annual program review document for the IO.
- Approve tissue use protocols and amendments to add/delete changes in personnel
- Support IACUC sub-committees as required

f. Responsibilities of the Office of the Campus Veterinarian

The Office of the Campus Veterinarian (OCV) has direct University-wide authority for all activities involving vertebrate animals. This office is responsible for ensuring appropriate care for all vertebrate animals involved in research and teaching.

The Director of OCV provides new member orientation to the chair, members of the committee and staff as required. The Director of OCV or his designee conducts the Animal Awareness Seminar (AAS) for the IACUC. Participation in AAS is a mandatory requirement for working with live vertebrate animals in any WSU campus and facilities.

The Director of OCV or his designee sits on the IACUC committee and is involved in the review of all protocols submitted to the IACUC.

The Director of OCV or his designee along with IACUC members carries out new facility inspection and participates in semi-annual site visits and program review. The PAR team also functions under the direction of Director of OCV.

The OCV is responsible for preparing and submitting various regulatory reports and maintain a variety of records of the IACUC for the University.

The Director of OCV conducts training, for the IACUC, a mandatory Animal Awareness Seminar that will explain the policies and principles of animal use in WSU. The training is required for all personnel listed on the research protocol and teachers/instructors/ staff on teaching protocol. The records will be maintained at OCV for the IACUC and verification of AAS for personnel on protocol will be provided by the OCV staff.

The Director of the Office of the Campus Veterinarian reports directly to the Vice President for Research and Dean of the Graduate School. The OCV works closely with the IACUC Program Coordinator, Director of Office of Research Assurances and the Chair of the IACUC.

g. Responsibilities of the Environmental Health and Safety Specialist.

The Environmental Health and Safety (EH&S) specialist administers the occupational health and safety program for animal workers and researchers. The Animal Contact Program (ACP) is one of the mandatory requirements for persons working with animals. The EH&S specialist reviews all IACUC protocols to evaluate and help address Environmental Health and Safety considerations (e.g. regulated substance, biohazards, etc). The EH&S specialist assists the animal care and use community address their IACUC and AAALAC EH&S expectations. This person also coordinates administration of the Animal Contact (medical surveillance) program at WSU to and ensures that all personnel on a protocol are offered this program.. The EH&S specialist contacts the investigators regarding health and safety issues, and reports the results of those discussions to the IACUC. The EH&S specialist is housed in the EH&S office and reports jointly to the Director of EH&S and the Director of the OCV.

h. Conflict of Interest Policy

a. Financial Conflict of Interest

Investigators (or other project personnel) involved in a research project or other activity involving live vertebrate animals must disclose a potential financial conflict of interest on the Animal Subject Approval Form.

b. Non-Financial Conflict of Interest

i. No selection of IACUC members by investigators

Principal Investigators cannot select which IACUC member will review their protocol. Additionally, any IACUC member must reclude himself or herself from a review if s/he has any real or apparent conflict of interest.

ii. Prohibition of participation in IACUC deliberations and voting by investigators

Reviews of applications will be conducted with objectivity and in a manner to ensure the exercise of independent judgment of each member. Members may not participate in a vote by the IACUC on actions concerning projects or activities in which they have an active role or conflict of interest. Failure to abide by these provisions may be cause for removal of a member from the IACUC.

IACUC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest related to any person or entity connected to a protocol. The IACUC member must make any conflict of interest known to the IACUC Chair. The member may provide information to the IACUC if requested. The fact that a protocol is submitted by another investigator from an IACUC member's Department or Section does not, in and of itself, constitute a conflict of interest.

VIII. Operations of the IACUC**a. Scheduling of meetings**

The full IACUC will convene monthly, unless there is no business that needs to be conducted at a convened monthly meeting. The meeting dates are listed on the IACUC website for the entire year. Cancellation of a monthly meeting will be provided at least 2 weeks before and posted on the website. Special meetings of the IACUC or subcommittee meetings may be called by the Chair.

Monthly meetings will be organized by the IACUC coordinator. The IACUC coordinator will make meeting sites available at each regional campus with a representative on the committee.

IACUC meetings are open to the public and meeting dates and deadlines for the calendar year are published on the Office of Research Assurances website <http://www.iacuc.wsu.edu/> and otherwise as required by law.

IACUC doesn't strictly follow the Roberts rule. The following is a sample SOP for conducting IACUC business during a convened meeting (from AALAS website):

1. The Chairperson will announce each item of business in order, following the agenda.
2. As each item of business comes up for consideration, the Chairperson shall then ask if any member has a conflict of interest, and allow any members that do to recuse themselves before deliberation begins.
 - a. The Chairperson will count the voting members left to make sure that a quorum is still present.
 - b. If a quorum is not present, business on that item cannot be conducted, and the Chairperson will notify the committee that the item has been tabled until the next meeting, and the Chairperson will introduce the next item of business (go to item 1). Otherwise, consideration of the item may continue.
3. If a primary or secondary reviewer has been assigned to lead the deliberations, the Chairperson shall ask for the primary reviewer's comments, followed by the secondary reviewer's comments. Otherwise, the Chairperson will appoint a member to review the pertinent background information on the item.
4. Following reviewer comments, the Chairperson will solicit comments about the business item from the entire committee, and will ensure that all opinions are heard as part of the deliberation. Once a consensus is apparent or a clear division in opinions is present, the Chairperson will ask the Primary reviewer to make a motion.
 - a. Acceptable motions for protocols are approve, require modification in to secure approval, or withhold approval. Motions made on protocols should include the review path that will allow approval. For instance, a valid motion is "I move that this protocol be assigned to the 'require modifications' category, with the primary

and secondary reviewers empowered to grant approval if a revised protocol is received from the PI that adequately addresses corrections and concerns noted during this meeting."

- b. Acceptable motions for other business items such as IACUC minutes are approve, approve with changes, disapprove, and table.
5. Once the reviewer makes a motion, it must be seconded by another voting member to remain active.
- a. If the motion is seconded, then the Chairperson shall ask for further discussion. The reviewer who made the motion may alter the motion if further discussion prompts a change. If the motion is altered, it must be receive another second to be valid.
 - b. If the motion does not receive a second, then the Chairperson will ask for a motion from any voting member of the IACUC (go to item 4.a.). This process will continue until a motion has been successfully seconded.
6. The Chairperson will then ask each member to vote "yea", "nay", or "abstain."

b. Protocol submission and review process
i. Description of Initial review process

The WSU IACUC reviews all projects involving live vertebrate animals conducted under the auspices of Washington State University regardless of funding source. Investigators are required to submit an Animal Subject Approval Form (ASAF) which addresses the following points:

- The amount of pain and distress
- The rationale for the use of animals
- Justify number of animals used in the experiment
- The experimental design or design of the instruction
- Alternatives to procedures listed
- The adequacy of veterinary care
- The method of euthanasia or disposition of animals
- Personnel qualifications of those involved in performing research and animal care

The IACUC then reviews this document for adherence to federal regulations and university policies. For guidance and more information on filling out forms, call IACUC Program Coordinator at 509-335-7951, email: iacuc@wsu.edu or visit: <http://www.iacuc.wsu.edu/forms.asp>.

Pre-IACUC Meetings

Meetings of the Pre-review committee are typically held a week before IACUC meeting to discuss various issues related to animal care. These meetings help the

committee to stay ahead of potential deficiencies and to ensure that protocols are reviewed in a timely manner.

Materials to be presented at the Pre-IACUC include the meeting agenda, minutes of the meeting concluded, and materials to be handed out by the Program Coordinator at the meeting. The draft version of the meeting agenda should include any request received by the IACUC, and finalized after consulting the chair.

Pre-IACUC meetings are attended by the Chair, Director OCV, Director Office of Research Assurances or his designee, EH& S personnel, Coordinator and invited attendees. Copies should be supplied to all members at the meeting.

iii. **Weekly Designated Member Review (DMR)**

Distribution of Materials

Every Monday (or earlier if there are holidays), the Coordinator sends out electronic copy of the protocols to all the committee members. Hard copies of the protocols will be sent out to the community member.

The members have 72 hours, usually until noon on Wednesday to request a full committee discussion of a protocol at the convened monthly meeting. If no full committee discussions are called for, the assigned sub-committees will review the protocols. The members of the sub-committee can refer a protocol for full committee discussion at any time. Sub-committees assigned weekly quota of protocols has a minimum of 2 weeks to resolve them.

The weekly assignments are maintained in separate DMR Agenda for every week. This agenda is to be uploaded into the database to enable all members to provide feedback. Separate agenda is prepared for the monthly meeting.

When Amendments are presented to the committee, the previously approved protocol should be made available to all the members to facilitate a complete review.

Designated-Member Review (DMR)

Most review is accomplished by DMR. The IACUC coordinator works with the IACUC Chair to designate a sub-committee for each protocol on the agenda before sending the materials to the full committee for review. . . Subcommittee size is determined based on the pain classification of the protocol in question.

B or C classification protocols, annual renewals, and amendments are reviewed by two members of the IACUC. The current practice is that these forms are reviewed by the Chairperson and the Director of OCV or designate.

D classification protocols and amendments are reviewed by three members of the IACUC. The third reviewer is the Director of OCV or his designate.

E classification protocols and amendments are reviewed by four members of the IACUC. The fourth reviewer is the Director of OCV or his designate.

Primary reviewer (the first named in the sub-committee) of a sub-committee acts on behalf of the IACUC to review the protocol, seek consensus opinion from the other members of the sub-committee, request clarification or further information from the PI. Any member of the sub-committee can call for a Full Committee review, and vote to approve the protocol. However, the sub-committee reviewers cannot withhold approval. Only a full committee review can vote on the suspension.

When protocols are submitted for emergency review, all members will still be given the opportunity to review each protocol and request for full committee review.

Minor Amendments and requests to add personnel (not a change in PI) are approved by the IACUC Coordinator after submitting them to the whole committee (See section v for further details).

IACUC Exemption Determination

Two categories of protocols are determined to be under IACUC exemption, but PIs often request letters from the IACUC regarding the same:

1. When there is no contact with live animals, when no animals are being manipulated, when it involves field observations, or when only urine and dung samples will be collected from wild
2. When working with dead animal tissue, when no animals were euthanized for the purpose of the study, or when samples are obtained from commercial sources.

Exemption determination will be provided by the Chair of IACUC and Director of OCV. Such protocols are assigned an ASAF number, but no annual renewals are required for them.

Full Committee Review

Any member of the IACUC can call for Full Committee review of any protocol on the agenda. This means that this protocol will be discussed at the next meeting of the IACUC, and must be voted on by a quorum of the full committee.

If any questions or concerns arise during a full committee review, the IACUC chair or designated member will be responsible for requesting clarifications from the PI.

A full committee review and approval is also called on new policies to be adopted by the IACUC, pass the semi-annual program review to be presented to the IO, new protocol submission forms and other changes that affect the functioning of the IACUC.

iv. Continuing Review

The Public Health Service policy and the Animal Welfare Act (AWA) require at least triennial review of all IACUC approved activities. The AWA also calls for annual review in addition to the triennial requirement for activities using AWA regulated animals. Such animals may be housed under OCV's Holding Protocol. No procedures can be performed for the animals under the Holding protocol, although

routine veterinary care will be provided for the animals. Per Diem will be charged for housing animals under the OCV's protocol. When the Holding Protocol has been used, the IACUC will be informed of this development and listed on the Agenda.

Washington State University policy expands the AWA requirement of annual review to all IACUC approved projects regardless of the species of animal involved.

Continuing review process

The WSU IACUC approved protocols require annual and three-year reviews. Amendments may be submitted to facilitate modifications to approved protocols at any time. The failure to meet any of these renewal requirements will result in the termination of IACUC approval regardless of the species (USDA regulated vs. non-USDA regulated) involved in the project.

Annual Renewal

After a protocol has been approved by the IACUC, an investigator must submit an annual renewal form at the first and second anniversary of approval. This gives the committee an indication of the investigator's intentions for the upcoming year. Annual renewal documents are sent to the whole committee and allowed for 72 hours of time to call for a full committee review. The sub-committee to review annual renewal consists of the Chairperson of the committee and the Director of OCV or designate. When the Chairperson or the Director of OCV has a protocols coming for Annual Renewal, other committee members will be assigned to the Annual Renewal.

Three-year Re-submission

After two annual renewals on a protocol, it is due for a 3-year Resubmission by the Investigator. The investigator must resubmit the entire protocol and all supporting documents to the IACUC for review. These resubmissions are reviewed as a new protocol.

Renewal Notices

Three reminders for continuing review are sent via e-mail from the database by the IACUC coordinator. The first email is sent three months before the expiry, the second notice is sent two months prior to the anniversary date and the last notice is sent on the month a renewal is due. IACUC Coordinator will inform the Chairperson, Director OCV, and Director Office of Research Assurances if there is no response to any of these emails and two phone calls have not resolved the issue. Any protocol past the original three year approval date will have a new number assigned to it upon resubmission for the IACUC approval. Investigators wishing to continue their research are responsible for submitting at the appropriate time for review before the annual or three year expiration date.

v. Review of Amendments

All changes to approved research with animals must be approved by the IACUC prior to implementation. Changes to an approved protocol should be submitted by

the Principal investigator on an amendment form to the IACUC coordinator. The type of review required for an amendment depends on the type of change being made.

Minor Amendments

Minor Amendments can be approved by the Coordinator (voted in July 2008 meeting) after submission to the committee and waiting for 72 hours.

Examples of Minor Amendments

- A small (less than 20%) increase in animal numbers to be used
- A minor change in technique, drug, diet, and the like which is consistent with the intent of the original ASAF, if it will not change the level of pain or distress.
- Request to add a new strain of a specific species or to use of a closely related species, defined as those animals that require similar housing and care. NOTE: ***This does not extend to any USDA covered species.***

Examples of closely related species (for the purpose of minor amendments):

- *Rats and mice*
- *Different species of songbirds*
- *Different species of nonpoisonous snakes*
- *Different species of nonpoisonous lizards*
- *Different species of frogs*
- *Different species of salamanders*
- Change in titles of grants covered by protocol
- Change in funding agencies
- Request for new antibody generated specifically for the investigator by a commercial vendor
- Change in location for housing or animal use
- Change in blood volume drawn, but within the approved range
- Change in suture materials, but with no changes in approved procedure
- Change in brand name of feed, but not the type of feed
- Request to administer a new compound closely related to other compounds already approved

Major Amendments

Major Amendments must be reviewed by the sub-committee or full committee at the convened monthly IACUC meetings.

Examples of Major Amendments

- A change in the overall aim or objective of the study
- Change in Principal Investigator
- Change of species of animals to be used
- Change in pain level or addition of a procedure that will increase the pain level or distress
- Large (greater than 20%) increase in animal numbers to be used
- Addition of survival surgery, or a change from non-survival to survival surgery.

A note on major amendments

In some situations it is easier to submit a new Animal Subject Approval Form, instead of an amendment form. This is because major changes require a good deal of justification and explanation. While the ASAF asks for these details, the Amendment form does not. Examples of major amendment include:

- Change in the aim and scope of the protocol
- If the protocol involves multiple changes
- Change in animal species
- Increase of more than 25% of animals
- Adding a new procedure
- The use of a new chemical, environmental condition or biological agent that induces disease or other substantial change in animal health, including new class of test therapeutics, toxic chemicals, disease agents, hormones, radiation, or recombinant organism
- Addition of a strain or transgenic-line that has a severe disease or disability

The amendment process is designed to help researchers make small changes in their current research, however if major changes are called for it is easier for a new ASAF to be submitted. Please ask the IACUC coordinator if you have questions regarding which forms you should submit.

Submitting Amendments to the IACUC

Changes to a previously approved ASAF must be typed and submitted on the Amendment form. Amendment forms can be found on the forms section of our website (<http://www.iacuc.wsu.edu/forms.asp>). The amendment should thoroughly describe the change and include a justification for the change.

Amendments should be submitted to the IACUC coordinator before the deadline for the weekly submission. Forms can be submitted electronically and a signature is required to complete the form.

The IACUC may only approve amendments submitted during a current approval year to the end of that period. For example, if the new, renewal, or continuing approval is issued on January 1, 2010 it will have an expiration date of December 31, 2010. If an amendment is approved during this time, the approval still lasts only until December 31, 2010.

Major amendments are sent out for DMR and typically require 2 weeks for review and approval. PIs may request an expedited review from the Chair of the IACUC. Expedited reviews must be sent to all members for review so that any member may request full board review within 3 days (72 hours). After 72 hours the amendment will be assigned to a DMR committee.

A note on the Training requirements of personnel listed in the protocol

WSU IACUC requires all personnel working on *research* protocols to undertake two mandatory requirements: Animal Awareness Seminar (AAS) offered by the Director, Office

of Campus Vet on behalf of the IACUC and the Animal Contact Program (ACP) provided by the Office Environmental Health. Currently only students and faculty listed on *research* protocols are offered this training. Instructors and Principal Investigators on the teaching protocols are required to undertake AAS and ACP, while students require to sign up for ACP. Optional online training program is also offered in specific areas. Personnel on tissue use protocols should have ACP.

b. Voting requirements

i. Quorum required

A quorum of more than half of the voting membership is required to conduct business.

ii. Full voting rights of all reviewing members

Each member has one vote.

iii. No proxy votes

No proxy votes are allowed.

iv. Prohibition of conflict-of-interest voting

IACUC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol. Since they don't vote, their votes cannot be counted towards the quorum.

c. Communication from the IACUC

Any member of the IACUC can have direct communication with the Investigator, although most communications are routed through the first reviewer. The IACUC coordinator facilitates all communication and is responsible for ensuring the completion of the review process.

Any questions regarding IACUC review or the content of the manual should be directed to the IACUC coordinator at the Office of Research Compliance.

d. Appeal of IACUC decisions

If an IACUC application is disapproved, the Chair will notify the PI. The investigator may request the IACUC to reconsider by responding in writing, and may request an opportunity to appear before the IACUC.

e. Requirement for Other Presidential Committee Approval Prior to IACUC Protocol Approval

In order to comply with AAALAC accreditation requirements and Public Health Service Policy (PHS Policy), the IACUC will coordinate approvals with other committees (i.e. Radiation Safety Committee, Institutional Biosafety Committee, and/or Environmental Health & Safety) as necessary.

For protocol modifications, the modified portion of the protocol cannot be approved until the necessary safety committee has approved it.

- The IACUC office is responsible for sharing the details of the pending IACUC protocol to the appropriate presidential committee.
- The respective presidential committee is responsible for ensuring the Principal Investigator completes the required paperwork, if any.
- The presidential committee will notify Principal Investigators and the IACUC office of safety approval, which does not indicate IACUC approval of the animal protocol.
- If using radiological or biosafety hazards, Principal Investigators are strongly advised to check with the Radiation Safety Committee or Institutional Biosafety Committee (respectively) prior to the submission of animal protocols to the IACUC.

II. IACUC record requirements and activities

The table represents the documents to be maintained for the IACUC at various locations in WSU

Documents	Responsible	Location	Oversight
IACUC Meeting Agenda	Coordinator, IACUC	Office of Research Assurances	IACUC
Minutes of IACUC Meeting	Coordinator IACUC	Office of Research Assurances	IACUC
Protocols considered by IACUC	Coordinator IACUC	Office of Research Assurances	IACUC
Standard Operating Procedure (SOP)	Coordinator IACUC	Office of Research Assurances	IACUC
Records of Semiannual site visits by IACUC	Coordinator IACUC	Office of Research Assurances	IACUC
Report of facilities by OCV	Campus Vet	Office of Campus Veterinarian (OCV)	IACUC
Dog and cat purchased, acquired, owned, held or possessed	Every research facility	Animal managers	OCV for IACUC
Transport			OCV for IACUC
Sold or adopted			OCV for IACUC
APHIS 7001	International Health certf.		OCV for IACUC
APHIS 7006	Record of Disposition of Dogs and Cats		OCV for IACUC
APHIS 7005	Record of Acquisition and Dogs and Cats on Hand		OCV for IACUC
USDA INSTITUTIONAL REPORT	OCV	OCV & copy to ORA	
OLAW ANNUAL REPORT	OCV	OCV & copy to ORA	
Statement by OCV to AAALAC	OCV	OCV & copy to ORA	

on Veterinary care			
PHS Assurances Statement	OCV	OCV & Copy to ORA	
AAALAC REPORT	OCV	OCV & copy to ORA	
Permits to study wild animals	Copy with ORA	PI to have originals	

a. IACUC membership roster

Purpose

The purpose of the roster is to keep track of the IACUC membership, and to ensure compliance with federal regulations regarding membership requirements.

Contents

The roster contains the names, affiliation and term of every member on the IACUC board.

Mandated by

The Animal Welfare Act Regulations (9 CFR Part 2 Subpart C 2.35 (a)(1)) and the Public Health Service Policy (Section IV. E).

Department Responsible

The Office of Research Assurances is responsible for maintaining and updating the IACUC roster. The Office of Research Assurances coordinates with the Vice President for Research and Dean of Graduate School for Research and the President's Office to ensure that the IACUC roster is up to date.

b. Meeting Minutes

Purpose

The minutes are used to record the business of the committee at each meeting. The IACUC Coordinator will take minutes at each meeting of the IACUC.

Contents

The minutes will contain:

- Date and location of meeting
- Attendance
- Committee Activities
- Committee Deliberations
- Motions Made and Seconded
- Record of Voting

Mandated by

Public Health Service policy and the Animal Welfare Regulations

Department Responsible

The Research Compliance Office is responsible for creating and maintaining the minutes of all IACUC meetings.

c. Public Health Service Institutional Assurance

Purpose

This is a written document intended to explain in detail the Universities Animal Care and Use Program, and commits the University to comply with Public Health Service policies.

Contents

This report will list information regarding every aspect of the animal care and use program. It will include information regarding the lines of authority in the institution, the qualifications of those involved in the IACUC, occupational health and safety program, training programs at the institution, IACUC membership list and explanation of IACUC procedures.

Mandated by

Public Health Service Policy Section IV.A.

Department Responsible

The Office of the Campus Veterinarian is responsible for creating and maintaining this assurance.

d. Annual Report to OLAW

Purpose

This document is submitted in order to update the Office of Laboratory Animal Welfare (OLAW) on the changes in the Universities Animal Care and Use Program.

Contents

This report will detail all changes that have occurred in the Universities animal care and use program. If there are no changes to the program, then the university must report to OLAW that there have been no changes.

Mandated by

Public Health Service Policy Section IV. F.

Department Responsible

The Office of the Campus Veterinarian is responsible for creating and maintaining this document.

e. IACUC Protocol to Grant Comparison

Purpose

This comparison is designed to ensure that all grant activities using animals have been approved by the IACUC.

Method

In order to facilitate the comparison process, researchers at WSU are asked to submit a protocol to match each different grant activity. A small number of grants are then

compared to protocols on a random basis each month to ensure that grant activities are being reviewed by the IACUC.

Mandated by

Public Health Service Policy Section V. B.

Department Responsible

The Office of Research Assurances is responsible for comparing grants to protocols.

f. Post Approval Monitoring

Purpose

Post Approval Monitoring is carried out to ensure that activities described on the ASAF are being carried out in the same manner in the laboratory.

Method

Protocols are chosen at random to receive review. The protocol is brought to the site where procedures are being performed or animals are being housed. The post approval monitoring team checks to ensure that the procedures laid out in the Animal Subject Approval form are being followed.

Mandated by

Although the Guide and PHS recommend that monitoring is required, the requirement of a PAR is not listed on these.

Department Responsible

The Office of the Campus Veterinarian is responsible for post approval monitoring at WSU.

g. USDA Registration

Purpose

To inform the United States Department of Agriculture of the USDA regulated activities that occur at Washington State University.

Contents

This document will contain the location of all facilities; the number of covered species used annually, sources of Federal funds.

Mandated by

Animal Welfare Act (9 CFR Part 2, Subpart C 2.30)

Department Responsible

The Office of the Campus Veterinarian is responsible for maintaining this report.

h. USDA Annual Report

Purpose

To update the United States Department of Agriculture (USDA) on the current status of the animal care and use program at WSU

Contents

This report must contain the location of all animal facilities, name and number of animals being used in each of the USDA pain classification categories, and all endorsed assurance statements.

Mandated by

Animal Welfare Act (9 CFR Part 2, Subpart C 2.36)

Department Responsible

The Office of the Campus Veterinarian is responsible for filing this annual report.

i. AAALAC Accreditation Materials

Purpose

Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) helps to certify institutions animal care and use programs. AAALAC accreditation at WSU means that the program for animal care meets the requirements of the accrediting body. WSU voluntarily seeks AAALAC accreditation to ensure that the University is achieving the highest level of animal care possible.

Mandated by

AAALAC is a voluntary accreditation process and therefore is not mandated by federal law. AAALAC uses the Guide for the Care and Use of Laboratory animals to assess animal care and use programs for accreditation.

Department Responsible

The Office of The Campus Veterinarian is responsible for filing and maintaining accreditation materials (with copies to the Office of Research Assurances).

j. Reports of Suspensions and Noncompliance

Purpose

To keep all funding agencies and regulatory bodies aware of animal care and use issues at the University. The IACUC, through the Institutional Official is required to report any serious or continuing noncompliance with Public Health Service policy, the Guide for the Care and Use of Laboratory Animals, or the Animal Welfare Act. The IACUC is also responsible for reporting when they suspend any activity at the institution.

Contents

The report to the Institutional Official will contain a full explanation of the circumstances, description of corrective action taken, and any minority views filed by the IACUC.

Mandated by

Public Health Service Policy (Section VI. F) and the Animal Welfare Act (9 CFR Part 2, Subpart C 2.31(d)(7)).

Department Responsible

The Office of The Campus Veterinarian is responsible for investigating these situations and submits the necessary reports. The OCV prepares the report for the Chair, IACUC who submits it to the IO.

k. Records of Semi-Annual Site Visits and Program ReviewPurpose

The semi-annual site visits are designed to help the IACUC identify problems or deficiencies in its animal care and use program.

Contents

The report must include any departures from the regulations, deficiencies both minor and major, a plan and schedule for correcting each deficiency found, and any minority view point's expressed by the IACUC. It should also include the semi-annual program review as performed by the IACUC.

Mandated by

Public Health Service Policy (Section IV.B. (1-3))

Department Responsible

Members of the IACUC are responsible for performing the Program Review. The OCV prepares the inspection report on behalf of the IACUC. The Office of the Campus Veterinarian creates the semi-annual report. Records of site visits are maintained in Office of Research Assurances by the Coordinator. Program report to IO is drafted by IACUC Chair and Program Coordinator. It is edited, voted and signed by a quorum of IACUC members.

I. Animal Subject Approval Forms (ASAF) and all ChangesPurpose

To inform the IACUC regarding proposed research or instruction using live vertebrate animals at WSU. These forms contain information such as level of pain and distress, veterinary care, procedures to be used, personnel qualifications, and explanation of final disposition of all animals involved.

Contents

The ASAF contains information necessary for the review and approval of animal activities. These records will also include whether or not each protocol received IACUC approval. For further information regarding the Animal Subject Approval Form call IACUC Program Coordinator at 335-7951. To view the current forms click here (Hot link: <http://www.iacuc.wsu.edu/forms.asp>)

Mandated by

Public Health Service policy (Section IV.C.1) and the Animal Welfare Act

Department Responsible

All approved forms are maintained by the IACUC coordinator in the Office of Research Assurances. Please contact IACUC Program Coordinator with your questions at (hotlink) iacuc@wsu.edu; or call 335-7951.

m. Standard Operating Procedures (SOP)

IACUC identifies areas of importance to researchers and develops SOP to cover these areas. Three main types of SOP will be recognized and certified by the IACUC:

1. IACUC guidelines and methods for common procedures
2. SOPs that are related to an animal housing or other facility that is to be approved by the IACUC, but authored by the respective managers and caretakers of the facilities.
3. SOP for species that are maintained by researchers, either singly or in collaboration shall be authored by the researcher and attached to all the protocols using the species. IACUC approves such SOPs as a part of the researchers ASAF.

Chemical SOPs are required and often specific to the protocol. Environmental Health and Safety will provide the input specific to the protocol. Since the chemical SOP will be attached to a protocol, researchers are requested to work with EH & S personnel for a chemical SOP before the protocol approval can be processed.

All general and facility SOPs approved by the IACUC will be displayed online for use by researchers. While filling out an ASAF form, the mention of SOP# will be sufficient to complete the procedure instead of having to detail it all over again. The SOPs will be reviewed and renewed every 3-years by IACUC.

n. Continuing Review

Purpose

To ensure that approved protocols remain in compliance with all animal subjects' regulations, and WSU policies.

Contents

Annual renewal documents will contain the intentions of the Investigator for the next year of the project. Annual renewal of an IACUC approved protocol is due in the calendar year. Every protocol can be renewed twice and will require a three-year Re-submission for continuing work after that. The three-year expiration date is set at the time of approval and work on the protocol can't be extended beyond that date *for any reason*. Three year resubmissions will consist of a new Animal Subject Approval form.

Mandated by

The Public Health Service policy and the Animal Welfare Act (AWA) require at least triennial review of all IACUC approved activities. The AWA also calls for annual review in addition to the triennial requirement for activities using AWA regulated animals.

Washington State University policy expands the AWA requirement of annual review to all IACUC approved projects regardless of the species of animal involved.

Department Responsible

All continuing review materials are maintained by the Research Compliance Office.

o. Retention of records

All protocols reviewed, and related materials will remain on file at the Office of Research Assurances for three years after the date of first approval for the protocol.

Meeting minutes and IACUC rosters will remain on file at the Office of Research Assurances as a permanent record of the committee's activities.

Policy guidance and forms will be disseminated from and stored at the Office of Research Assurances.

III. Investigator responsibilities

a. Principal Investigator requirements

WSU policy requires the following things for a person to be principal investigator (PI) on any project submitted to the IACUC. In order to be PI you must be:

- WSU employee
- Individual who bears primary responsibility for the project
- Completed the WSU Animal Awareness Seminar and
- Decided on participating or declining to participate in Animal Contact Program.

- b. While graduate students can meet the above criteria, the student's primary advisor should bear ultimate responsibility for the student's work. Therefore, the advisor should be listed as PI. **Education requirements**

All members of a project involved in animal care and use are required to have training in WSU policies and the Animal Welfare Act. This training is provided through the Office of the Campus Veterinarian. All members involved in performing research procedures on an IACUC protocol are required to attend the mandatory Animal Awareness Seminar at WSU at least once. Additional training in specific procedures or training on specific species is also available through the Office of the Campus Veterinarian.

Student Training

The WSU IACUC has recognized that it is difficult for all students involved in courses that require IACUC approval to receive the proper training. In response to this problem the IACUC has developed a policy specifically related to animals used in an instructional setting {see Policy #20 at: <http://www.iacuc.wsu.edu/resources.asp>.}

c. Animal Contact Program or Medical Surveillance

The WSU Animal Contact Program provides information and training to individuals regarding the occupational health risks associated with animal contact (i.e. zoonotic diseases, allergens, animal bites, scratches, biological hazards, physical hazards, etc.) and invites all individuals with animal contact to participate in the Medical Health and Risk Assessment element of the program. All individuals at Washington State University who have contact with research and teaching animals (this includes handling, cleaning, feeding, exposure to unfixed tissues, and exposure to animal waste or bodily fluids) must register in the WSU Animal Contact Program. Principal investigators and animal facility supervisors are responsible for ensuring ALL individuals (i.e. classified staff, faculty, AP, students, time-slip, work study, collaborators, and volunteers) exposed to animals are informed of this program and are registered in the WSU Animal Contact Program.