

<b>Washington State University</b> <b><i>Institutional Animal Care and Use Committee</i></b>	
<b>Policy #2</b>	<b>“Protocol and Amendment Review”</b>
<b>Approval Date: 3/25/2020 (Replacing version: 3/27/2019)</b>	

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### **A. Purpose**

The Institutional Animal Care and Use Committee (IACUC) is responsible for reviewing the use of live vertebrate animals used in research and teaching at Washington State University (WSU). This policy describes the IACUC review process for new Animal Subjects Approval Forms (ASAFs) and amendments to existing ASAFs.

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### **B. Background**

Research and teaching activities involving live, vertebrate animals require approval before these activities can occur. PHS Policy and the USDA Animal Welfare Act/Regulations charge the IACUC with the responsibility to review, approve, require changes to secure approval, or withhold approval of proposals that involve live animals. The WSU IACUC will review each ASAF and amendment to ensure consistency with the USDA AWA/Rs and PHS policy and that exceptions/exemptions to these documents are scientifically justified.

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### **C. Submission and Pre-Review of Protocols**

New protocols must be submitted using the Online Animal Subject Approval Form using the myresearch.wsu.edu portal. Amendments for protocols in the old system must be submitted on the currently approved version of the protocol that includes all subsequent amendments since the last approval. Standalone amendments are not accepted for IACUC review. All the work proposed in the amendment must be approved by the IACUC before the work can begin. If the amendments fundamentally change the aim of the study, Principle Investigators (PIs) are encouraged, and may be required, to submit a new ASAF.

All protocols submitted to the IACUC will be subject to pre-review by the Animal Welfare Program (AWP) staff before submission to the IACUC for review. AWP staff will check for completion of mandated training of all personnel listed on the protocol, the approval of SOPs, housing areas, and inconsistencies in the submission. The mandatory training requirements are listed in [IACUC Policy #20](#). PIs will have 30 days from the date of submission to complete any deficient requirements.

#### **D. IACUC Review of Animal Care and Use Proposals**

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##### **1. Protocol Review (New, 3-year Resubmissions, Amendments)**

Protocols submitted for review are made available to all IACUC members. Any IACUC voting member may request Full-Committee Review of any protocol or amendment. If requested, any protocol nominated for Full-Committee Review will be discussed at the next convened IACUC meeting.

Newly submitted protocols and amendments to previously approved protocols that include animal research practices that constitute exceptions to the standards outlined in the Guide for the Care and Use of Laboratory Animals will typically be reviewed by Full-Committee review using the process described below. If an exception to the Guide is approved for a particular protocol, additional protocols submitted by the same PI or designee and requesting the same exception may be referred for Designated-Member Review (provided that no IACUC member calls for Full-Committee Review). The IACUC Chair or designee can decide to send these requests via designated review when justification is provided. The IACUC will be made aware of these requests and any member has the ability to call for full committee review.

Some amendments may qualify for administrative amendment or Veterinary Verification and Consultation (VVC). Refer to [Policy #24](#) for details regarding processing of amendments.

##### **2. Designated-Member Review**

Weekly assignments for Designated Member Review (DMR) panels are approved by the IACUC chair or vice chair and are sent to all IACUC members for review. If no member requests a Full-Committee Review during the 48-hour period following distribution to IACUC, the protocols are referred for DMR.

All panels include the Attending Veterinarian (AV) or his/her designated staff member(s) from the Office of the Campus Veterinarian (OCV). They are given the responsibility of reviewing the protocol and communicating any questions or concerns to other DMR members along with the Animal Welfare Program. The Animal Welfare Program then compiles the questions received from each reviewer and sends the questions to the PI and Co-Is. If a reviewer approves the protocol, the approval is recorded and is carried forth through all revisions of that version under review, but the reviewer is notified of all revisions returning to the DMR and has the opportunity to retract their approval to ask further questions.

Each member of the Designated-Member Review acts on behalf of the IACUC to evaluate the referred protocols for all of the criteria defined in the federal and institutional animal care and use regulations and policies. Particular attention is paid to the justification of the proposed animal use, the appropriateness of the treatments and animal numbers proposed, and to the possibility of modification by application of the 3 R's (Reduce, Refine, & Replace). Protocols are approved by unanimous vote of the DMR team. If one or more DMR members do not vote for approval, the protocol is referred for Full-Committee Review.

### **3. Full-Committee Review (FCR)**

Following careful review of the protocol under evaluation for all of the criteria defined in the federal and institutional animal care and use regulations and policies, the IACUC discusses/deliberates and each committee member votes for approval, to withhold approval or abstains from voting. Particular attention is paid to the justification of the proposed animal use, the appropriateness of the treatments and animal numbers proposed, the welfare of the animals, and to the possibility of modification by application of the 3 Rs. Protocols are approved by a majority vote at the IACUC meeting with a quorum of members in attendance. Any objections or abstentions to a protocol are recorded in the minutes.

If additional information is required in order to secure approval, the IACUC may elect one of the following three options:

- 1) DMR subsequent to FCR: A quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modifications are required to secure approval. However, any member of the IACUC may, at any time,

request to see the revised protocol and/or request FCR of the protocol. This option requires that all members have agreed in writing to the use of DMR subsequent to FCR. These agreements will be maintained by the AWP office.

2) Request that the revised protocol be sent out to DMR using the process described in D2 above (revised protocol sent out to full committee and if after 48 hours no member calls for FCR then the protocol is referred to DMR).

3) Request the protocol be deferred/tabled until the next convened IACUC meeting.

If the IACUC votes to withhold approval, the PI will be provided written notification of the IACUC's decision along with the reasons for denial. The PI has an opportunity to respond in person or in writing and the IACUC can re-consider the decision based on any additional information provided.

#### **4. Continuing Review**

The USDA AWA/R require that the IACUC conduct continuing reviews of activities involving animals at intervals as determined by the IACUC, but not less than annually. A complete review (de-novo) is required every three years by both the AWA/R and PHS Policy.

To meet the requirements for protocols covered by the Animal Welfare Regulations, PI's are required to submit an annual renewal request for the first two years after approval. Protocols submitted for annual renewal will be reviewed by the IACUC using the DMR process described above.

Animal Welfare Program staff will perform annual renewals for protocols not covered by the AWA/R administratively.

A complete re-submission and de-novo review will be required every three years for all protocols.

#### **5. Conflict of Interest**

For Full-Committee reviews, IACUC members who are the PI or otherwise directly involved in protocols will be excused from the meeting room during consideration of those protocols and cannot contribute to the constitution of a quorum.

For Designated-Member reviews, IACUC members who are PI or otherwise directly involved in protocols will not be assigned to review panels for those protocols.

If a member is inadvertently assigned to a protocol for which they have a conflict of interest, it is their responsibility to notify the IACUC Chair and/or the AWP staff and excuse themselves from review of that protocol.

## **E. Protocol Review Flow Chart**

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### **Step 1—Protocol Submitted**

1. Received by AWP staff
  - a. From the PI or designee
  - b. From OCV Veterinarian for VVC process
  
2. AWP staff then:
  - a. Pre-reviews submission for completeness
  - b. Informs the PI that the protocol has been received
  - c. Upon completion, the protocol will be submitted to IACUC Chair for approving DMR reviewers
  - d. Receives the IACUC chair's approval of DMR assignments
  - e. Updates the Agenda to inform the IACUC that the protocol is received and the suggested DMR assignment

When an amendment is received from an OCV Veterinarian for VVC approval process, the changes will be administratively incorporated into the protocol. A written description of the VVC approved amendment must be provided to the AWP office within two business days, and then the AWP office has 30 business days to add the change to the protocol.

### **Step 2—IACUC Review**

1. If any IACUC member calls for FCR, the protocol is added to the agenda of the next scheduled IACUC meeting.
2. If FCR is not requested within 48 hours, DMR panel members can move forward with review process.
3. Regular reminders are provided to reviewers to ensure timely review completions.

4. DMR or FCR proceeds to voting.
5. If DMR does not result in consensus approval, the protocol is referred for FCR review at the next scheduled meeting.

### **Step 3—Approval**

1. Protocols approved by DMR or FCR are reviewed for appropriate animal housing, SOPs, addendums, training, permits or assurance of permit application (collection cannot begin unless permit is acquired), and other required supporting documents
2. The PI and Co-I are notified of the approval.
3. The PI is notified regarding the Post Approval Review process.

### **Step 4—Post-approval Review**

All approved protocols are subject to Post-approval Review to ensure that the procedures in use are in agreement with the procedures approved in the IACUC approved protocol. Post-approval reviews may include tabletop exercises, inspection of surgical or animal housing facilities, and/or direct observation of animal procedures, at the discretion of IACUC. Details of Post-approval Review are found under IACUC [Policy #25](#).