 ROSS UNIVERSITY SCHOOL OF VETERINARY MEDICINE	IACUC Protocol and Amendment Review Process. Pol.011	Issued	September 2012
		Revised	September 2020
		Authority	IACUC

Purpose

To ensure a well-defined and consistent approach to reviewing protocols and amendments submitted to the Ross University School of Veterinary Medicine (RUSVM) Institutional Animal Care and Use Committee (IACUC). This Standard Operating Procedure (SOP) outlines the process used by the IACUC to review, request amendment to and approve or reject protocols and amendments.

Scope and Responsibilities

All IACUC members are responsible for implementing and following this SOP.

Protocol Review Process:

Upon receipt of a protocol, the IACUC administrator will categorize the protocol as:

- New protocol
- Amendment to existing protocol with major procedures and potential for pain or distress
- Amendment to existing protocol without major procedures and potential for pain or distress
- Annual review of existing protocol


The IACUC administrator is responsible for guiding the protocol through the review process. The administrator reviews all applications for accuracy and completeness. Incomplete applications or applications with administrative errors will be returned to the Principal Investigator (PI) for revision before the protocol is sent to reviewers.

If the protocol is outside of the expertise of all IACUC members, an external consultant can be asked to conduct an in-depth review, to consult with the PI and present the protocol at the IACUC meeting.

Once the administrative review is satisfied, protocol applications will be sent to all IACUC committee members for a one week period of time in which the IACUC members can review what has been submitted, ask for more information or call the protocol application to Full Committee Review (FCR) if deemed necessary. Once the week has passed and the protocol application was not called to FCR, the Chair assigns the application to Designated Member Review (DMR). The minimum number of DMR reviewers assigned for each protocol is two. Once DMR is assigned, reviewers will have three business days to either:

- Approve the application
- Request revisions to or ask questions about the application
- Call to Full committee review

Once all IACUC Designated Member Reviewers have returned their reviews of the application, the administrator sends any questions to the PI. The PI must answer all questions and revise their application accordingly. After the PI sends responses to reviewer questions together with applicable revisions to the protocol application, the IACUC administrator sends the materials back to the IACUC Designated Member Reviewers for further review. The second round DMR review is to be conducted within three business days. If after two DMR rounds the reviewers request further revisions, the IACUC Chair is notified, who may decide to either call the protocol to FCR or continue the DMR process.

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If the PI does not respond to the reviewer questions after four weeks, the IACUC administrator will send a reminder to the PI. If no response from the PI has been received after six weeks, the IACUC administrator may withdraw the protocol from review.

After the application is approved by the IACUC committee, the IACUC Chair validates the protocol by signing a letter of approval.

All personnel listed on a protocol must satisfy all IACUC and Environmental Health & Safety mandated training and safety requirements prior to approval.

No IACUC member can participate in the IACUC review of a protocol in which that member has a conflicting interest, except to provide information requested by the IACUC.

If a protocol is called to Full Committee Review (FCR), all decisions regarding the protocol will be made during an IACUC meeting. For a decision to be made by the IACUC committee, a quorum of the IACUC members must be present. For a protocol or amendment to be approved by the IACUC committee, a quorum of the members must vote in favor.

The IACUC has four options:

- Approve
- Request modification to obtain approval
- Table until further information can be obtained
- Withhold approval

The Following situations require Full Committee Review:

- New protocols involving procedures with pain and distress category E
- New protocols involving procedures with survival surgery
- New protocols involving major procedures with Non-Human Primates (NHP)


Amendment Review Process:

Using the protocol amendment form, the PI must clearly explain why the modification to the protocol is being requested and how it relates to the original specific aims of the previously approved protocol.

Amendments are reviewed using nearly the same process as new protocols.

The IACUC administrator sends the protocol amendment form together with all relevant forms/documents to the entire IACUC committee to be viewed. The protocol amendment application is then assigned to Designated Member Review, and an Environmental Health & Safety officer if necessary. Once all IACUC Designated Member Reviewers have returned their reviews of the amendment, the IACUC administrator sends any questions to the PI. The PI must answer all questions and revise the protocol amendment accordingly.

When all DMR reviewers have issued an approval of the protocol amendment, the amendment request is approved and after final review by the IACUC Chair, an approval letter of the protocol amendment is

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issued. The approved original protocol together with all approved protocol amendment forms and applicable updated IACUC application forms is kept together on file by the IACUC administrator.

As general guidance, Protocol Amendments with significant changes to Animal Activities as described by NIH Notice NOD-14-126 (August 26, 2014), *Guidance on Significant changes to Animal Activities*, will be handled by the RUSVM IACUC as follows:

Full Committee Review:

Certain significant protocol amendments are administratively flagged for Full Committee Review; these include, but are not limited to:

- change in objectives of a study
- proposals to switch from non-survival to survival surgery
- resulting in greater pain, distress, or degree of invasiveness
- change in species

Designated Member Review:

Protocol amendments with significant changes to Animal Activities that are allocated to Designated Member Review (but not excluded from FCR) includes, but are not limited to, changes:


- in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- in Principal Investigator (PI)
- that impact personnel safety

Veterinary Verification and Consultation (VVC):

Certain categories of significant changes to Animal Activities may be handled administratively according to IACUC-reviewed and approved policies in consultation with the Attending Veterinarian (AV) or a Clinical Veterinarian (CV) authorized by the IACUC.

The AV/CV is not conducting Designated Member Review, but is serving as a subject matter expert to verify that compliance with the IACUC reviewed and approved policies is appropriate for the animals in this circumstance. The AV/CV may refer any request to the IACUC for review for any reason and must refer any request that does not meet the parameters of the IACUC reviewed and approved policies.

Consultation with the AV/CV must be documented by submitting a protocol amendment form to the IACUC administrator. The consulting AV/CV must submit an approval of the protocol amendment to the IACUC administrator. Upon final review of the protocol amendment by the IACUC Chair, the IACUC Chair issues an approval letter.

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Significant changes to Animal Activities that may be handled through Veterinary Verification and Consultation (VVC) is limited to changes in:

- anesthesia, analgesia or sedation, protocols that use referenced dosages for the species
- Experimental substances administration that does not exceed guidelines published by Diehl et al. A good practice guide to the administration of substances and removal of blood, including routes and volumes. J. App Tox. 2001; 15-23
- Duration, frequency, type (e.g. blood collection site or volumes, route of administration, volumes, and dosages) performed on an animal contingent upon them not exceeding guidelines published by Diehl et al (2001).
 - i. Blood collection site or volume
 - ii. Route of administration, volumes, and dosages
 - iii. Increasing food/fluid restriction prior to a procedure to more than 12 hours with adequate justification
- Euthanasia by any method approved in the most recent AVMA Guidelines for the Euthanasia of Animals
- Changes to space requirements if restriction is justified and not excessive based on veterinary consultation.

Requests for an increase in animal numbers will be handled by FCR, DMR or VVC depending on the nature of the request.

Administrative handling by IACUC administrator:

Significant changes that may be handled administratively by the IACUC administrator:


- Increase in animal number of non-USDA covered species, not to exceed 10% of the approved protocol number.
- Change in housing location within an IACUC approved facility.
- Change in personnel (not PI)
 - Including review that all personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs and meet other criteria by the IACUC
- Updated contact information
- Typographical errors or grammar
- Change in funding information

Communication of IACUC approvals to the IACUC committee:

The IACUC Administrator communicates all IACUC approvals obtained through DMR, VVC and administrative review to the IACUC committee.

Review of Protocol or Protocol Amendment

The review of a protocol or a protocol amendment will be conducted in accordance with applicable local and US federal laws, regulations, policies and guidelines outlined in the RUSVM IACUC policy “General Policy on the Care and Use of Animals” as well as RUSVM IACUC Policies, Standard Operating Procedures and Guidelines.

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Section C.1, Table A (Regulatory Criteria Applicable to Protocol Review as Defined in PHS Policy and USDA Regulations) and Section C.2. (Protocol Review Criteria) in the OLAW Institutional Animal Care and Use Committee Guidebook summarizes main criteria in use:

- Assessment if alternative methodologies are available and the benefit versus risks of studies normally relies on the description provided by the PI and literature search from the PI
- Group sizes are evaluated based on published literature, guidelines (e.g., FDA, VICH) and/or power analysis
- Several members of the IACUC are veterinarians and their input is provided during the IACUC discussion of the protocol
- All studies and especially those with concerns regarding adverse events or pain or distress, are required to specify endpoints, events that would require removal of an animal from a study and/or events that would require study termination

Documentation of Protocol and Protocol Amendment Review Process

The following review process steps, as a minimum, must be documented:

- Categorization of protocol as New protocol; Amendment to existing protocol with/without major procedures or potential for pain or distress; Annual review of existing protocol
- Assignment of protocols or amendments to an IACUC member to present to the IACUC
- Assignment of protocols or amendments to a consultant for review and presentation to the IACUC
- Assignment of amendments to AV/CV for VVC
- Assignment of amendments to IACUC administrator for administrative handling
- Assignment of protocols or protocol amendments to an IACUC member for Designated Member Review
- Assignment of protocols for Full Committee Review
- Outcome of the decision regarding a protocol or protocol amendment

Review

This SOP is subject to annual review.

Records

All IACUC records that relate directly to protocols are kept for the duration of the study activity and for an additional 3 years after completion of the activity.

Policy Approval:

Signed

Date