Institutional Animal Care & Use Program - UTEP	
Title: Protocol Submission and Review Process	
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In Effect ☒ **Rescinded** ☐	**Date Rescinded**:

1. PURPOSE

   This policy provides clear guidance on the requirements and procedures for Principal Investigators (PIs), research staff, or the Attending Veterinarian (AV) for protocol submission through the IACUP (Institutional Animal Care and Use Program). All protocol applications and related submissions, such as triennial reports, amendments, etc., will be processed by the IACUP Office under the department of Research Compliance and Regulatory Assurances.

2. APPLICATION

   It is the responsibility of all personnel using animals at The University of Texas at El Paso (UTEP) to abide by this policy. The PI on the protocol(s) must be an appointed full-time faculty member or an appointed AV of the institution. The faculty member is the party responsible for the terms of protocol approval.

3. IACUC Criteria for Approval

   3.1 The IACUC will consider if the protocol meets the requirements of the Animal Welfare Act (AWA), the recommendations in *The Guide for the Care and Use of Laboratory Animals, 8th Edition,* and the following items as required by PHS policy IV.C

   3.2 Procedures that may cause more than slight pain or distress will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure has a proper justification in writing by the investigator to the IACUC.

   3.3 Procedures that may cause severe or chronic pain and/or distress that cannot be relieved will be humanely euthanized at the end of the procedure or, if appropriate, during the procedure.

   3.4 Location(s) for animal housing and procedures outside of the Laboratory Animal Resources Center (LARC) vivaria must be approved by the IACUC. Additionally, transport of animals between multiple locations requires prior approval by the IACUC. Documentation must be submitted through the IACUC office.

   3.5 The housing and feeding of the animals will be directed by a veterinarian or by another scientist trained in the proper housing procedures for the use of the species being maintained.

   3.6 Medical care for animals will be available from a qualified veterinarian or veterinary technician. They will provide medical care and advice on humane endpoints when needed.

3.7 Justification in writing must be provided by the PI for the use of non-pharmaceutical-grade chemical compounds, husbandry deviations, and the use of Category E

4. PROCEDURES FOR SUBMISSION

The IACUC is responsible for local review and oversight of animal research to ensure that institutional and federal regulations and guidelines are implemented. The IACUC can conduct a full committee review (FCR), designated member review (DMR), or an administrative review (if applicable). The IACUC has the authority to approve, request modifications to secure approval, or disapprove a protocol. The UTEP IACUC generally meets once a month. Meeting dates and submission deadlines are published on the IACUC webpage.

No **ACTIVITY** may begin with animals until all the following have occurred:

- Approval of the protocol application by the IACUC.
- Completion of IACUC-required training by all personnel listed on the protocol.
- Enrollment of all personnel listed on the protocol in the Occupational Health Program and/or an institutional waiver has been submitted and accepted.

All IACUC protocol and amendment submissions must be submitted electronically through the designated software platform (eProtocol). Protocols to be reviewed via Full Committee Review **MUST** be submitted by no less than 30 calendar days before the next scheduled meeting to be considered for that month's scheduled meeting, unless a change in meeting dates occurs, at which time the change will be noted on the website.

4.1 PROTOCOL SUBMISSIONS

For submission guidance or questions, the IACUC Office can be reached by e-mail at iacuc@utep.edu or by phone at 915-747-6056. All submissions must be fully completed for review. When submitting a new protocol:

- The PI must ensure that all listed study personnel have completed the required training/enrollment or are in the process.
- Submissions to be reviewed via Full Committee must be received for review no later than the published receipt deadline on the IACUC webpage to be placed on the agenda for that month's meeting.
- The PI must consult with the AV during the proposal preparation.

Upon receipt of the submission, the IACUC Office will conduct a preliminary review within 2 business days to assess completeness and animal welfare. The PI may be asked to submit additional information before the IACUC reviews it. The PI will need to submit clarifications within 10 calendar days (a request for an extension can be made to the IACUC if needed). Prior to using the DMR process, the IACUC at large is polled for 2 business days to determine the review type (DMR vs FCR). If any

member objects to DMR, the submission will automatically be reviewed via FCR. For any FCR protocols, the PI must submit clarifications at least 10 business days before the scheduled meeting to be placed on that month's agenda. PIs can request an extension before the deadline expires. If the PI does not meet the deadlines, the protocol may be withdrawn from the review process. The PI will be notified via email of submission withdrawal if clarifications requested by the reviewer are not returned or pre-review questions remain unanswered beyond the deadline.

4.2 AMENDMENTS

Any changes or modifications to approved protocols require an amendment that must be reviewed and approved by the IACUC prior to initiation. Amendments requiring full committee review must be received for review no later than the published receipt deadline to be placed on the agenda for that month's meeting. The amendment will clearly explain and document what changes are being proposed in agreement with PHS Policy IV.C

4.3 DESIGNATED MEMBER REVIEW

Designated Member Review (DMR) is the process by which protocols, amendments, or closure reports without renewal may be reviewed at times other than the regularly scheduled monthly meetings of the IACUC. The review can be conducted by as few as one IACUC member, designated by the IACUC Chair for this specific task. All new protocols and related submissions are eligible for DMR. The PI will follow the submission guidelines as described above.

The submission is received by the IACUC office, and a preliminary review will be performed as described above and completed within two business days. If the submission falls into the approved Administrative Review categories, the IACUC office will appropriately process the request. All others will be polled for 2 business days, as described above. If any IACUC member fails to respond within the designated timeframe, the lack of response will constitute silent assent to proceeding with the DMR process.

- If polling supports the DMR, the IACUC office will initiate the DMR process. Reviewers will conduct a review within 5 business days.
- If the designated reviewer(s) have not completed the review in the required timeframe, the Chair has the option to re-assign another reviewer(s). The IACUC may consider a shorter period to accommodate special circumstances, such as *Just-In-Time* requests from a funding agency.

- During the DMR review process, IACUC members can call for Full Committee Review (FCR) at any time.
- *Recommend Approval:* The submission complies with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines, and USDA regulations,

and is written in such a way that only administrative questions or clarifications are required.

- *Required Modifications for approval by DMR*: The submission complies with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines, and USDA regulations, but is written in such a way that minor questions and/or clarifications must be resolved to secure approval.
- *Required Full Committee Review*

4.4 FULL COMMITTEE REVIEW

Prior to the monthly meeting, the Chairperson (or designee) assigns at least one reviewer and the veterinarian to each Full Committee Review (FCR) submission. The submissions are provided to the full IACUC. The reviewers are responsible for reviewing the entire submission and summarizing the protocol for the committee. Prior to the meeting, IACUC members can pose questions and, if needed, request additional information or clarification for formal discussion of the protocol. All questions and comments will be communicated to the PI by the IACUC Office via eProtocol. The submission will be placed in one of four categories at the committee's discretion. They are:

- ***Recommended for Approval***: The submission complies with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines, and USDA regulations, and is written in such a way that only administrative questions or clarifications are required.
- ***Require modifications for approval by DMR:*** the IACUC may request modifications to comply with the regulatory requirements or improve procedures relating to the care of the animals in the project to be reviewed by DMR. The DMR method may be used only after all members present have been given the opportunity to call for full committee review. If any member requests a full committee review, then FCR must be used.
- ***Tabled, Require FCR*****:** The submission either does not comply with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines, or USDA regulations, or is written in such a way that there are serious questions that must be resolved to secure approval. Subsequent approval must be decided by Full Committee Review at a convened meeting.
- ***Approval Withheld*****:** The submission either does not comply with all requirements of the *Guide for the Care and Use of Laboratory Animals*, PHS guidelines, or USDA regulations, or the PI will not agree to comply with the IACUC's requirements. The PI will be notified in writing of the IACUC's decision to withhold approval to include reasons. The IACUC Chair may request a meeting with the PI to discuss the IACUC's concerns and provide guidance on the PHS Policy IV.C requirements.

4.5 ADMINISTRATIVE REVIEW

Submissions received by the IACUC office will be reviewed and checked against pre-approved administrative categories. If the submission falls into the approved Administrative Review categories, the IACUC office will appropriately process the request.

The following changes are approved for administrative review

- Personnel amendment - removal/addition (other than PI).
- Animal increase less than 40% of the protocol-approved number.
- Change of telephone number, room number, location, or building name.
- Misspellings &/or typographical errors.
- Adding/replacing/changing from the approved vendor list.
- Changes in funding source.
- Change in gender.
- Title change.

Location change will be in consultation with the AV and may be due to relocation, construction, or other events that may need to cause the relocation of animals outside their normal habitat area for longer than 12 hours and approved by the IACUC

5. PROTOCOL CLOSURE FOR DEPARTING INVESTIGATORS

PIs leaving UTEP are responsible for notifying the IACUC Office in advance of their departure date to plan for any current IACUC protocol(s) and animals. All IACUC projects under a departing PI must be closed, and arrangements must be made for the transfer or disposition of animals under the project(s) (prior to closure), or the protocol(s) must be transferred to another PI through a personnel amendment.

If a PI departs without making prior arrangements, any animals remaining on a departed PI's IACUC proposal(s) will be transferred to the Holding Protocol, and the proposal(s) will be administratively closed. Studies may not continue with animals assigned to an IACUC proposal that has been closed. If no prior arrangements were made for the disposition of the animals (export, transfer, or euthanasia), their disposition will be determined by the AV. All expenses incurred while assigned to the Holding Protocol will remain the responsibility of the original PI and/or department.

Review History	
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A	27 August 2018
B	28 October 2024
C	24 November 2025