Institutional Animal Care & Use Program - UTEP	
Title: Protocol Submission and Review Process	
Policy#: 011	**Date in Effect**: 27 August 2018
Version #: C	**Rev Date**: 24 April 2023
In Effect ☒ **Rescinded** ☐	**Date Rescinded**:

1. RESPONSIBILITIES

It is the responsibility of all personnel using animals at UTEP to abide by this policy. Exceptions to these policies must be approved by the IACUC before implementation.

2. APPLICATION

This policy applies to all faculty animal users engaged in research and teaching at UTEP.

3. PROTOCOL SUBMISSION AND REVIEW PROCESSES

3.1 SUBMISSION

The IACUC is responsible for local review and oversight of research involving animals 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 PI must have a faculty appointment at UTEP or be the Attending Veterinarian (AV) unless otherwise approved by the UTEP Institutional Official. 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 of 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.

All IACUC protocol submissions must be submitted electronically through IRBNet at www.irbnet.org. Protocols **MUST** be submitted by the **1st** of the month to be considered for that month's scheduled meeting unless published on the website.

3.2 USDA PAIN CATEGORIES – NON-USDA SPECIES

The University of Texas at El Paso will follow the following categories for pain and distress when describing pain/distress categories.

Category B	**Category C**	**Category D**	**Category E**
Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	Animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	Animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	Animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.
Examples			
1. Breeding or holding colony protocols	1. Holding or weighing animals in teaching or research activities 2. Injections, blood collection or catheter implantation via superficial vessels. 3. Animal identification procedures (eg. Ear punching/ micro chipping 4. Routine physical examinations 5. Observation of animal behavior 6. Feeding studies, which do not	1. Diagnostic procedures such as laparoscopy or needle biopsies. 2. Non-survival surgical procedures. 3. Survival surgical procedures. 4. Post operative pain or distress. 5. Ocular blood collection in rodent 6. Terminal cardiac blood collection. 7. Any post procedural outcome resulting in evident pain, discomfort or	1. Toxicological or microbiological testing, cancer research or infectious disease research that requires continuation until clinical symptoms are evident or death occurs. 2. Ocular or skin irritancy testing. 3. Food or water deprivation beyond that necessary for ordinary pre surgical preparation.

	result in clinician health problems 7. AVMA approved humane euthanasia procedures 8. Live trapping 9. Positive reward studies 10. Oral administration 11. Gavage	distress such as that associated with decreased appetite/ activity level, adverse reactions, to touch, open skin lesions, abscesses, lameness, conjunctivitis, corneal edema and photophobia. 8. Application of noxious stimuli or behavioral tests such as forced swim or exercise with intervention Exposure of blood vessels for catheter implantation. 9. Exsanguination under anesthesia. 10. Induced infections or antibody production with appropriate anesthesia and post-op/postprocedure analgesia when necessary.	4. Application of noxious stimuli or behavioral tests such as forced swim or exercise without intervention, fear conditioning, tail suspension, resident-intruder, inescapable electric shocks if the animal cannot avoid/escape the stimuli and/or it is severe enough to cause injury or more than momentary pain or distress. 5. Infliction of burns or trauma. 6. Prolonged restraint. 7. Any procedures for which needed analgesics, tranquilizers, sedatives, or anesthetics must be withheld for justifiable study purposes. 8. Use of paralyzing or immobilizing drugs for restraint. 9. Exposure to abnormal or extreme environmental conditions. 10. Psychotic-like behavior suggesting a painful or distressful status. 11. Any procedures for which needed analgesics,

			tranquilizers, sedatives or anesthetics must be withheld for justifiable study purposes. 12. Euthanasia by procedures not approved by the AVMA.

3.3 NEW SUBMISSIONS

Necessary forms can be found within the IRBNet Library or the IACUC website. For submission questions, the IACUC Office can be reached by e-mail at iacuc@utep.edu or by phone at 915-747-6056. Using the New Protocol/Triennial Renewal form, a complete description and justification (protocol or amendment) for the use of animals must be described. All submitted forms must be completed fully and accurately 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 must be received for review no later than the published receipt deadline in order to be placed on the agenda for that month's meeting.
- The PI may consult with the AV or the IACUC Office during the proposal preparation.
- For USDA pain categories D and E, the PI **must** meet with the AV during the drafting of the proposal or have the protocol pre-reviewed by AV prior to the electronic submission deadline

Upon receipt of the electronic submission, the IACUC Office and the AV will conduct a preliminary review within 3 days for completeness and animal welfare. The PI may be asked to submit additional information prior to review by the IACUC. If additional information is requested, comments will be sent electronically to the PI via IRBNet. The PI will need to submit clarifications within 10 days before that month’s scheduled IACUC meeting for the protocol to be reviewed at that month’s meeting.

3.4 AMENDMENTS

Any changes or modifications to approved protocols 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 in order to be placed on the agenda for

that month's meeting. Submitted amendments determined to meet the Designated Member Review (DMR) process will be administered as described below. Any modification not listed in the DMR categories may be considered as a significant change and will require FCR.

3.5 DESIGNATED MEMBER REVIEW

Designated Member Review (DMR) is the process by which protocols or amendments may be reviewed at times other than the regularly scheduled monthly meetings of the IACUC, and by as few as one IACUC member, designated for this specific task by the IACUC Chair. The PI will follow the submission guidelines as described above. The submission will be reviewed by the IACUC office and checked against the approved DMR categories. If the modification falls into the approved Administrative Review categories, the IACUC office will appropriately process the request. If the request falls into the approved DMR categories, the following procedures will occur:

- Within 7 days of the submission, the IACUC Office will conduct an administrative review and the AV and/or designee will review for any animal welfare issues and the IACUC Chair will verify the submission for DMR authorization and designate a reviewer(s).
- Once approved by the Chair, the IACUC office will share the submission with the IACUC member(s) via IRBNet, where they will have access to all applicable documents for their consideration of an expedited review. Each IACUC member will have an opportunity to call for a FCR of the submission.
- IACUC members will have 72 hours from the time the application is shared in which to individually reply (without copy or blind copy to anyone else) to the IACUC office by e-mail to iacuc@utep.edu. This maintains the confidentiality of the member's decision while avoiding any possible intimidation. If any IACUC member does not respond within that time, that lack of response will be considered as that member's agreement to exercise the DMR process. After the 72 hour response time, records of the polling will be filed within the appropriate protocol submission.
- If any IACUC member calls for a FCR, the DMR process will not be exercised, and the submission will be placed on the Agenda for the next appropriate IACUC meeting for which the agenda is still open. The IACUC office will notify the investigator of the IACUC's decision.
- In the event that polling supports the DMR, the IACUC office will initiate the DMR process. The IACUC office will remove shared access from the committee members

and only leave review access to the designated member reviewer(s). A subcommittee consisting of at least one primary reviewer will be authorized to review, approve, require modifications or request FCR of the submission. The designated reviewer(s) may consult with the AV during the DMR process. Subcommittee communications between members shall be entered in the comments section for "Reviewers" within IRBNet. Reviewers will conduct a review within 5 working days. If the designated reviewer(s) has not completed the review in the required timeframe, the Chair has the option to re-assign another reviewer(s). If more than 15 days have passed, the submission will be called back for FCR.

- If the designated members cannot fully agree with the contents of the protocol or amendment, they may, at any time during the DMR process, request FCR.
- Once the DMR process is complete, the primary reviewer will notify the IACUC office of the review decision and any recommendations. The IACUC office will notify the investigator of the Designated Reviewer's decision and/or any recommendations for corrections or clarifications. Once requested revisions have been made by the PI, the Designated Reviewer(s) will re-review the application for approval.
- The IACUC will be notified of the results of the DMR at the next IACUC meeting.

The following may be approved for Designated Member Review (DMR)***

- Triennial protocols
- Animal increase $\leq$ than 49% of the protocol approved number
- Change of PI
- Closure report without renewal
- Adding/replacing/changing different species
- Adding/replacing/changing from a non-approve vendor list
- Change in housing arrangements-single vs. group
- Change is euthanasia method**
- Change in anesthesia, analgesia, sedation or experimental substances**
- Procedural amendment-addition of non-invasive, non-surgical procedure**

**May be handled via DMR with an already IACUC reviewed and approved protocol and in consultation with the AV. The AV is not conducting DMR but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. Consultation with the veterinarian must be documented. The veterinarian may refer any request to the IACUC for review for any reason and must refer to any request that does not meet the parameters of the IACUC-reviewed and -approved policies. **

***The following triennials/amendments need to be reviewed full board:**

- **USDA category D and E**

- **Non-USDA category E**

3.6 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 are approved for administrative review

- Personnel amendment - removal/addition (other than PI)
- Animal increase less than 20% of the protocol-approved number**
- Change of a telephone number, room number, location or building name*
- Misspellings &/or typographical errors.
- Adding/replacing/changing a strain within the same species (with either IACUC Chair and/or AV verification)
- Adding/replacing/changing from the approved vendor list
- Changes in funding source
- Change in gender.
- Change in title

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

May be handled administratively with an already IACUC-reviewed and approved protocol and in consultation with the AV. The AV is not conducting DMR but is serving as a subject matter expert to verify that compliance with the IACUC-reviewed and -approved policy is appropriate for the animals in this circumstance. The veterinarian may refer any request to the IACUC for review for any reason and must refer to any request that does not meet the parameters of the IACUC-reviewed and -approved policies. It is required that the study objectives and the rationale for using animals are unchanged by the increase. If the rationale or study objectives change, an IACUC review by DMR or FCR is required.

3.7 CONTINUING REVIEW

In accordance with the 21st Century Cures Act to harmonize USDA, FDA, and NIH forregulation and policies for animal care, annual reports are no longer required.

3.8 FAILURE TO SUBMIT CLOSING REPORTS

Failure to submit completed forms in sufficient time to be placed on the IACUC agenda for consideration of approval before the study expiration date will result in the study becoming expired. No research or teaching activities may continue in animals under an expired protocol. Continuation of research or teaching activities on an expired protocol will be reported to the appropriate funding and regulatory agencies. Animals already in the

experimental queue should remain in the study until protocol procedures for their use have been completed. Furthermore, for other animals (refer to Policy 21), no procedures other than routine husbandry care can be carried out until the protocol is reapproved. If a closing report is not submitted within 60 days after the expiration date, the PI will be notified by the IACUC office alerting them the protocol will be administratively closed.

3.9 PROTOCOL CLOSURE FOR DEPARTING INVESTIGATORS

PIs leaving UTEP are responsible for notifying the IACUC Office in advance of their departure date to make arrangements 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 and approved using the Change of PI personnel form.

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 closed. Studies may not continue on 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 still remain the responsibility of the original PI.

Review History	
Revision Version:	**Revision Date**:
A	24 February 2017
B	27 August 2018
C	22 August 2019
D	21 October 2019
E	27 July 2020
F	24 January 2022
G	23 May 2022
H	24 April 2023