



<b>SUBJECT: IACUC Application Submission Process</b>	<b>MWU IACUC SOP #AZ1</b>		
<b>APPROVED BY:</b> Institutional Animal Care and Use Committee (IACUC) – Glendale Campus	<b>ISSUED:</b> 9/30/2015	<b>REVISED:</b> 3/24/2021 <b>REVIEWED:</b> 3/24/2021	<b>PAGES: 5</b>

**Purpose**

The purpose of this document is to outline the process of animal subject research or teaching application submission and review, as conducted by the Midwestern University - Glendale Campus Institutional Animal Care and Use Committee.

**I. Application Submission**

**A. Is it research or teaching activity that utilizes animals?**

The Office of Laboratory Animal Welfare (OLAW) describes an animal as any live, vertebrate animal used or intended for use in research, research training, biological testing, or teaching. Research is defined as any systematic investigation designed to develop or contribute to generalizable knowledge. Teaching activities include the use of animals for the education of students at institutions of higher education.

**B. IACUC Forms**

All IACUC forms can be found on the MWU Intranet site under the “Administrative”, “ORSP” tab. Please note, all forms will be held to the same grammatical standards as internal and external grant applications.

- Form B Application: To be filed for new projects and triennial continuation of an approved project.
- Form B1 Annual Report: To be filed for annual review of approved protocols
- Form B2 Breeding Protocol: Application to maintain a breeding colony in the MWU animal facility
- Form B3 Breeding Consultation: Filed by the principal investigator (PI) with the MWU attending veterinarian for successful completion of Form B2
- Form B4 Protocol Amendment: Filed by the PI to acknowledge any changes to an already approved protocol
- Form B5 Training Certification: Filed by the PI with the ORSP, with a copy kept in the PI’s laboratory. Form B5 documents both general and laboratory-specific training for all personnel involved in animal research. Verification of completion of the online CITI training is automatically received from the provider.



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Form B6 Animal Transfer:

Filed by the PI with the ORSP whenever animals are going to be obtained for an active protocol by transfer from: another institution, the animal facility, or another MWU protocol.

**C. IACUC Training Expectations**

All personnel involved in animal research or the use of animals in teaching, including, but not limited to: principal investigators, researchers, research technicians, research assistants, teaching lab personnel, and IACUC members are expected to complete the Collaborative Institutional Training Initiative (CITI) online training program ([www.citiprogram.org](http://www.citiprogram.org)) including Working with the IACUC, Biosafety, and any relevant species specific modules. In addition, all personnel listed on active protocols are required to have an up-to-date Form B5 verifying facility- and research-specific training on file with the IACUC administrator and in the laboratory where the work is performed.

**D. IACUC Application Expectations**

Forms must be prepared and submitted electronically. Upon approval of the application, they must include the original signatures of all requested parties. As these documents must be available for external review and thus are a reflection of the PI's and Midwestern University's competency, it is requested that the PI ensures that proper formatting, composition, and grammar is maintained on all forms.

**E. Submitting Applications**

Completed applications must be submitted electronically to the ORSP Research Administrator.

**II. Application Review**

**New Applications**

Applicants are expected to submit all applications on the most recent version of Form B. All new applications should be submitted by the 1st day of the month in which the application will be reviewed (e.g., an application is due on August 1st for it to be reviewed in the August meeting). Applications submitted after that date may not complete the pre-review process in time to be included in the next IACUC meeting.

Upon submission, the application will undergo a pre-review process by the IACUC administrative staff, the Chair, and the attending veterinarian to assure that the protocol has no outstanding animal welfare or other issues. In order to be included at the next convened committee meeting, the pre-review process must be completed, and the final application must be submitted to the ORSP office no later than the 15th day of the month in which the application will be reviewed (e.g., August 15th in the example given above). Following final submission, applications will be handled by one of the following mechanisms:



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**Full Committee Review (FCR)**

This process is required for protocols requiring survival surgery, having death as an endpoint or are category E. In addition, a subset of applications will be selected to go to FCR for further review or IACUC training purposes. Each member of the IACUC will review the application to ensure compliance with the Guide for the Care and Use of Laboratory Animals. Based on the discussion in the convened meeting, the following actions can be taken by a simple majority of the committee quorum in reference to the application:

- 1) Approve as written
- 2) Require modification with review of modifications via FCR, DMR, or Chair review
- 3) Withhold Approval

**Designated Member Review (DMR)**

This review option can be used for any applications not requiring FCR. Additionally, DMR can be used subsequent to FCR to ensure that required modifications have been made prior to approval. This process requires the IACUC to review the application and unanimously approve of the DMR process prior to proceeding. The designated reviewers, chosen by the chair, will directly oversee the revision process and application approval and make the final approval decision.

**Single Member DMR or Chair Review**

This review option can only be used subsequent to FCR or DMR to ensure that required modifications have been made prior to approval. This process requires the IACUC to review the application and unanimously approve of the single member DMR review process prior to proceeding. This single member DMR (i.e. the Chair) will directly oversee the revision process and application approval and make the final approval decision.

**Protocol Amendments**

In the amendment process, the applicant should directly amend their currently approved Form B Application. All changes to the protocol should be clearly indicated to allow reviewers easy discernment of the amendment. Additionally, the applicant must complete the protocol amendment form (Form B4) detailing each change and explaining why the amendment was made. Be aware that all personnel additions will require inclusion of their training certification forms (Form B5) and completion of the online CITI training requirements.

Upon receipt of the amended protocol application, the chair of the IACUC will determine if the protocol has undergone a significant revision or not. The amended application can be reviewed



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either by FCR or DMR. Non-PI personnel changes and location amendments can be reviewed and approved administratively by the IACUC research coordinator.

**Requested Modifications**

If the IACUC has voted to require modifications on an application, the PI will be informed of this decision and given a list of the specific modifications requested in a letter from the IACUC chair. If no response is received within 90 days of receipt of the letter, the application will be considered withdrawn. Resubmission of the application after this deadline will be treated as a new submission. Please note that if an annual review application is withdrawn, there may not be sufficient time to approve a new one may before the deadline and the protocol would be found deficient in its post-approval monitoring requirements (see below).

**III. Annual Reviews and Renewals**

**A. Annual Reviews**

One month prior to the anniversary of the date of the protocol's approval, an annual review will be due. The PI must submit a Form B1 Annual Review to the ORSP administrative staff. This will be initially reviewed by the chair and then sent out to all IACUC members for approval via DMR or FCR. This annual review must be submitted for each year of the application's existence, including the third year, even if a triennial renewal is being submitted. If a PI wishes to close the protocol prior to the three-year anniversary of its approval, they must submit a final report (Form B1) stating they wish to close the protocol.

**B. Triennial Protocol Submission**

Applications submitted to the IACUC are approved for three years. Within that time the protocol will undergo two annual reviews. On the third anniversary date of the protocol, the PI must submit a final annual review. If the PI wishes to continue the protocol, a triennial protocol renewal application (a new Form B) must be submitted along with the annual review. The continuation application will be treated as a new application and will be valid for an additional three years upon IACUC approval.

**C. Facility Inspections**

The Public Health Service Policy requires the IACUC to conduct semi-annual reviews of the animal facility and animal research activity areas. Included in this is the inspection of drugs or chemicals that are administered to animals. Therefore, in addition to animal use areas, areas in which these substances are stored must also be inspected. Members of the IACUC must have access to all of these areas for the review.

**D. Deficiencies**

Protocols must satisfy the requirements of all of the methods listed above at all times. If, at any time, a protocol does not satisfy the above requirements, animal work under that protocol may be suspended until such time as the deficiency can be corrected and the correction has received IACUC approval. Examples of deficiencies include, but are not limited to: failure to submit and



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secure approval of an annual report before the anniversary date of the protocol's approval, unacceptable conditions in rooms where animal work is conducted, or failure to close a protocol or submit and secure approval of a triennial protocol renewal application after the third year. Any animal work that occurs during this period of suspension will be considered an instance of noncompliance and will result in disciplinary action. If no action is taken to correct the deficiency within 2 months of notification by the IACUC, the protocol may be deemed inactive and will be closed. All animals currently held under that protocol will revert to ownership of the animal facility, and the PI informed by letter from the IACUC chair. Further work on that protocol will require submission of a new protocol application.