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## GUIDING DOCUMENT FOR THE USE OF IACUC FORMS

Texas Woman's University  
Institutional Animal Care and Use Committee (IACUC)

This document is intended to be used as a guide for Principal Investigators to manage animal research protocols at TWU. The TWU IACUC forms are located online at: <https://twu.edu/research/compliance/animal-care-and-use-committee/>. These documents are required of the TWU IACUC to assure that all animal use activity meets federal law mandates, Public Health Service policy, the Guide recommendations, and all accreditation expectations. It is the responsibility of the Principal Investigator (PI) to submit documents in a timely manner to allow for proper review.

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### **Animal Use Protocol Forms**

*These forms are used to submit new protocols, to request changes to existing protocols, to provide annual review of protocols, or for protocol closure. All animal use protocol forms should be submitted at least one week prior to the next IACUC meeting. Forms should be submitted to LeJuan Byford ([LByford@twu.edu](mailto:LByford@twu.edu)) and will be circulated for electronic signatures following final approval (hard copies or scanned forms with signatures are discouraged).*

#### **Animal Use Protocol Application**

This form is used to submit a new animal research protocol. This form is also used to submit a renewal protocol after a protocol has expired. Unless the PI requests for Designated Member Review (DMR\*) and it is approved by the IACUC, the protocol will be reviewed by the Full Committee Review (FCR\*\*). Following review, the PI will be notified of either (1) Full Approval of the document as is, (2) Modifications Required to Secure Approval with DMR for Final Approval, (3) Modifications Required to Secure Approval by Full Committee Review, or (4) Withhold Approval. PIs will receive notification and instructions for further submittal from the IACUC Chair. PIs are encouraged to attend the IACUC discussion of the submitted protocol and should notify the Chair of their intent to attend.

#### **Animal Use Protocol Amendment**

This form is used to make changes to an existing approved animal use protocol (parent protocol). Allowed changes include change in funding agency, request to temporarily inactivate the protocol, change in animal numbers, change of procedure(s), addition of procedure(s), and changes to personnel listed on the protocol. Additional procedures must be clearly related to the objectives of the parent protocol, otherwise a new protocol is required.

#### **Animal Use Protocol Annual Review**

An annual review form must be submitted by the first- and second-year anniversary of the protocol approval date each year the protocol is active. This form is used to notify the IACUC of the progress of the study and intent to continue the study. All studies

expire at the third-year expiration date. At the third-year anniversary, a new Animal Use Protocol Application will need to be submitted to renew the protocol. If the study will not be renewed at the third-year anniversary, the PI should use the Animal Use Protocol Closing Report. PIs will receive an email reminder from the TWU Office of Research and Sponsored Programs (ORSP) prior to protocol anniversary dates. If the protocol will be amended during an annual review, a separate Amendment Form should be attached.

### ***Animal Use Protocol Closing Report***

This form is to be used if the PI requests to close a study prior to the annual review. The form is intended to relay to the IACUC progress made on the protocol and to indicate the plan for any animals remaining in house. This form will also be required if the protocol expires (at the end of the 3<sup>rd</sup> year) and the protocol has to be administratively closed (e.g. a third-year annual review was not submitted by the PI by the deadline). If the protocol is administratively closed, any animals remaining in house will be transferred to the IACUC Animal Holding Protocol, in which no procedures may be conducted on the animals. If the protocol is administratively closed, then this form must be submitted within 30 days to remain in good standing with the IACUC. Once a protocol has been closed, it cannot be re-opened. If a PI wants to reinstate a closed protocol, a new protocol will need to be submitted. The IACUC may reserve the right to administratively close out protocols in which the PI is no longer able to fulfill the role as PI and there is no one available to take over the protocol as PI, but a Closing Report is still required within 30 days (this may be done administratively if needed).

### **Animal Order and Transfer Forms**

*These forms are used when animals or animal-derived tissues are transferred between protocols or to other PIs and require signature from either the IACUC Chair or the Director of the Vivarium.*

#### ***Animal Purchase Form***

This form is required to obtain approval from the IACUC Chair prior to requesting a Purchase Order (PO) for animal orders. This form will be submitted to procurement along with the quote and requisition form. This form is also used by the PI to account for animal usage on the protocol. When completing this form, consult with the Director of the Vivarium to get assigned animal housing and procedure rooms. It is recommended that PIs request that the PO is emailed to the PI so the PI can place the order directly with the vendor to obtain accurate animal numbers, strains, weights, and a delivery date. Once a delivery date is known, TWU Animal Husbandry should be notified to prepare cages and receive the delivery.

#### ***Animal Transfer Form***

This form is used to transfer animals between approved TWU IACUC protocols and is for internal transfers only. A transfer can occur between a single PIs protocols or between different PIs protocols. If transfers are planned, they should be stated in the parent protocol for approval or by an amendment. If transfers are unplanned, approval

is required by the IACUC Chair. The Director of the Vivarium must sign off on each transfer.

### ***Tissue Transfer Form***

This form is used to transfer post-mortem animal tissues (e.g. blood, organs, cells) from an approved TWU IACUC protocol to another investigator who may or may not be an approved animal user. The transfer is limited to post-mortem tissues and only approved personnel may handle the animals. Transferred post-mortem tissue may be handled by a non-animal user. If transfers are planned, they should be stated in the parent protocol for approval or by an amendment. If transfers are unplanned, approval is required by the IACUC Chair.

## **Obtaining Approval for Animal Research**

*These forms are used for PIs, graduate students, undergraduate students, lab technicians, and vivarium staff to become animal users prior to submitting or being listed on an animal use protocol.*

### ***Animal User Approval Request Form and Health Status Form***

PIs or graduate students that have taken CITI training at a previous institution may transfer that credit to the TWU IACUC. PIs must become approved animal users prior to submitting an animal use protocol. New graduate or undergraduate students must become approved animal users prior to being listed on IACUC protocols. Once a student becomes an approved user, the PI must submit an amendment adding the student to the appropriate animal protocol(s).

To start the process of becoming an animal user, go to ORSP to sign out a “Blue Folder” which will contain step-by-step instructions on how to become an approved animal user. The PI should sign the first page of the *Animal User Approval Request Form* found in the Blue Folder (or the TWU IACUC website). The PI should check the boxes for which CITI training is appropriate for the student (consult the IACUC Chair as needed). The Blue Folder contains instructions on *How to Sign up for CITI Training* (also located on the TWU IACUC website). All applicants are also required to submit the *Health Status Form* found in the Blue Folder (also located on the TWU IACUC website), which also requires the applicant to obtain or provide proof of tetanus shot received within the last 10 years. Graduate students, undergraduate students, and lab technicians must interview with and receive the signatures of two IACUC members and the IACUC Chair. PIs and vivarium staff only need the IACUC Chair’s signature.

Once signatures are obtained, return the form to ORSP who will then obtain approval from TWU Student Health and will notify the applicant of their approved animal user status. For PIs and vivarium staff, the Director of the Vivarium will give the PI a tour of the vivarium and will submit a request for the PI to have card access to the animal facility. Student and technician approval only permits the applicant to work with the PI or other trained animal users and does not permit the student to work alone in the vivarium. If independent access is required, use the Consent to Grant Access form below.

### ***Consent to Grant Access to the Animal Facility***

If the PI requires the student or technician to conduct independent research in the vivarium following appropriate training for at least two months, then the PI with the student/technician should complete the *Consent to Grant Access to the Animal Facility* form found on the TWU IACUC website. The form should be completed and submitted to ORSP and access is typically granted within 24 hours. Independent access should be reserved only for graduate students or advanced undergraduates. If access is needed at an earlier time frame (such as with a graduate student or lab technician already trained in animal work), the PI should consult with the Director of the Vivarium.

### **Term Definitions**

*\*Designated Member Review (DMR)*: The full committee votes to designate one member of the committee to perform the protocol review or review of requested modifications.

*\*\*Full Committee Review (FCR)*: The protocol is reviewed by and voted on by the full committee.