1.4.4 Review Process for Proposed Animal Activities and Modifications to Ongoing Activities

A. Purpose/Scope
This document describes the basis, background and means by which the Institutional Animal Care and Use Committee (IACUC) of Tulane University (TU) reviews, approves, requires modifications (to secure approval), and withholds approval of proposed animal activities or modifications to ongoing activities. It also describes the mechanism by which approved activities are subject to a continuing review.

B. Definitions
• Assured institution- an institution that has applied to the Office for Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) with documentation of assurance of institutional compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and has received subsequent approval.
• Animal activity- use of vertebrate animals for teaching, research, breeding, holding or demonstration
• Principal investigator - (PI) the person who has accepted responsibility for directing the conduct of animal activity as described in an approved IACUC protocol or amendment, and who has signed the assurance statement obliging him/her to conduct this activity in accordance with all animal welfare guidelines and regulation.
• Quorum - one more than half of the voting members of the IACUC
• Tulane University - The assured institution under one assurance number includes the Uptown Campus, Downtown Campus and the Tulane National Research Primate Center
• Institutional Official- Vice President for Research hereafter known as IO
• Full committee review (FCR) requires a meeting of a convened quorum of the IACUC. As outlined in the definition of convened quorum, full committee review is an example of an IACUC function that requires committee deliberation, interactivity, and voting, and which could be accomplished, in exceptional circumstances, through a carefully devised mechanism using telephone conferencing, audio-visual conferencing, or some other form of highly interactive electronic communication.
• Designated member review (DMR) is the other recognized procedure for protocol review. In this method, prior to review, all members are provided with the necessary information concerning the proposed research projects. All members are then given the opportunity to request full committee review. If no member calls for full committee review, then the IACUC Chair may designate one or more qualified IACUC members to review proposed research projects and to have authority to approve, require modifications in (to secure approval), or request full committee review of those research projects.
• Polling is an acceptable mechanism for providing all IACUC members with the prior opportunity to call for full review. It should be noted that the polling of IACUC members in this instance is not an approval vote on the proposed research. Records of such polling, however, are useful to document that the opportunity for members to call for full committee review has been provided.

C. References
• Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), 9 CFR, Subchapter A – Animal Welfare.
• National Research Council, Guide for the Care and Use of Laboratory Animals, National Academy Press, Washington, D.C., (most recent version)
• SOP 1.6 – Noncompliance and Suspension of Animal Activities
• P6.01 Designated Member Review Policy
• P6.03 General Program Policy

D. Background
Since the TNPRC is a PHS supported and assured institution, the review and monitoring of animal activities must adhere to the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy). This policy uses the Guide for the Care and Use of Laboratory Animals (Guide) and regulations (9 CFR, Subchapter A) issued by the USDA as the basis for the review of proposed and ongoing animal activities and the monitoring of such activities once approval has been secured.

E. Procedures
1. Submission of Protocols
   a. A faculty member must submit a current protocol form. An investigator who is not a faculty member must be listed as a co-investigator.
   b. Protocol must be submitted to the IACUC office by the submission deadline and must include any mandatory changes per the cursory review by administrative personnel in order to be placed on the agenda.

2. Review of Protocols
   a. A protocol submitted to the IACUC will be placed on the agenda for review at the next regularly scheduled (monthly) meeting.
   b. Prior to the IACUC review meeting, an agenda, minutes from the previous meeting, copies of all protocols, and other items listed will be distributed to all members. A primary reviewer will be assigned to each protocol listed.
   c. A quorum of the IACUC will be convened. If a quorum is not met, the meeting will be cancelled and rescheduled. Items on the agenda may be discussed but no vote can be taken.
   d. After the minutes from the previous meeting are approved, a review of the protocols will take place as listed on the agenda. Each protocol is assigned to a primary reviewer for presentation at the meeting. The primary reviewer summarizes the protocol for the committee members. After discussion of the protocol by all committee members, the primary reviewer makes a recommendation for approval, approval with administrative notations, modifications to secure approval (DMR), deferral or disapproval. A vote from all members present is taken and the status of the protocol is determined by a majority vote. If all members of the IACUC are not present at a meeting, the committee may use Designated Member Review (DMR) subsequent to Full Committee Review (FCR) when modification is needed to secure approval. All IACUC members agree that if they are not present at a convened meeting they agree to abide by the majority vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol. All members appointed after the approval of this SOP will be asked to agree with this provision.
   e. For any vote that is not unanimous, a count will be recorded and if necessary a minority view will be documented. Any member who has a conflicting interest in the activity under review will be excused from the discussion and will be recorded in the minutes as having abstained from the vote.

3. Review Outcomes and Investigator Notification
   a. The investigator is notified by email of the review outcome:
      i. Investigators, whose protocols receive, approved as submitted, do not need to make any changes.
ii. Investigators, whose protocols receive *approved with administrative notations*, must provide an updated protocol with the notations highlighted, underlined or bolded. The IACUC director checks the notations for completeness and accuracy and approves the protocol.

iii. Investigators, whose protocols receive *modifications to secure approval*, must provide an updated protocol with the modifications highlighted, underlined or bolded. The revised protocol must be received in the IACUC office within 3 months from receipt of the disposition letter. If a protocol has not been resubmitted with revisions the protocol is considered voided and must be resubmitted for full committee review. The primary reviewer receives the revised version of the protocol and makes sure that all modifications have been completed and then assigns an approval for the protocol. If the primary reviewer decides that all modifications have not been adequately addressed it is returned to the IACUC office with a request for follow up modifications. This request is sent to the PI who will need to address the modifications and send in a revised protocol.

iv. Investigators, whose protocols receive *deferred*, must provide an updated protocol that will be reviewed at a convened meeting.

v. Investigators, whose protocols receive *disapproval*, will be notified in a written notification the reasons for this decision. If the committee allows a revision of the protocol, it would then be reviewed at a convened meeting.

a. Once a protocol is approved, approval letters are sent to the PI via email. All protocols are entered into LAMBS (IACUC database) with a sequential outline of the history of the protocol.

b. It is the responsibility of the PI to notify support agencies and collaborators of any modifications that are required to secure approval.

4. Amendment Review

Any changes to a proposed research protocol must be submitted to the IACUC for review and approval.

a. Minor amendments - Amendments are reviewed by the chair and if determined to be minor; the amendment is sent to a veterinarian for consultation. If the veterinarian does not agree that the amendment is minor, it is sent to the IACUC for review and steps under b. are followed. If the veterinarian agrees that the amendment is minor, then s/he becomes the designated reviewer (see 4.c-e).

b. All other amendments are sent to the IACUC for review.

i. A copy of the amendment, the protocol and all other amendments are sent to committee members by email. Each committee member must review the amendment and vote for DMR or FCR in a timely manner.

ii. Any committee member may request to be a designated reviewer or submit comments after reviewing the amendment. Comments may be sent to the PI or forwarded to the designated reviewer.

iii. If any member calls for full committee review, the amendment will be scheduled for review at the next scheduled meeting and the PI will be notified.

iv. If no member calls for full committee review, the chair will appoint one member of the committee as the designated reviewer. The reviewer should submit his/her recommendation in a timely manner. A designated reviewer has the right to approve, require modifications or refer it for full review. The designated reviewer does not have the right to withhold approval; in such cases the protocol is referred to full committee review.

c. The designated reviewer approval will have equal validity to full committee review approval and does not require subsequent approval or notification by a convened meeting.
d. All amendments approved within a three-year period are bound to the protocol they amend. After three years, all procedures and aspects approved via amendment that are anticipated to remain a component of the study must be included in the renewal protocol.

e. It is the responsibility of the PI to notify support agencies and collaborators of any modifications to their original protocol.

5. Investigator Appeals

a. In the event an investigator disagrees with the decision of the committee, the following options will be available:
   - Submission of a revised protocol
   - Written appeal to the committee
   - Written appeal to the authorized IO

b. The authorized IO may request that the full committee reconsider the protocol. However, the decision of the committee, in review of appealed protocols initiated by the investigator or the IO is final.

6. Continuing Review of Animal Activities

a. To comply with continuing review requirements, the IACUC office will generate annual review letters and expiration notices every two weeks. For each approved protocol an annual review letter will be sent to the PI for completion and must be returned to the IACUC office. For each protocol that was approved three years ago, an “Expiration Notice” will be sent to the PI 120 days prior to the expiration of the protocol. On this form, the PI will be requested to indicate the status of the protocol and his or her plans for renewal. This notice is then sent again at 90 and 60 days prior to expiration, if the subsequent notice is not returned to the IACUC office. Any protocol indicated as “In Progress” will require the submission of a renewal protocol by the date of expiration (see Policy for Expired Protocols). Failure to submit a renewal protocol by the expiration date will constitute a condition of investigator noncompliance.

b. Completed Annual Review forms and Expiration Notices will be added in the protocol files according to record keeping requirements

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