



THE UNIVERSITY OF TOLEDO

SUBJECT: Standard Operating Procedure (SOP) for IACUC Protocol and Amendment Review

DATE: August 7, 2019

University of Toledo Standard Operating Procedure (SOP) for IACUC Protocol and Amendment Review

1. Introduction

The UT IACUC must review and approve all proposed components of a protocol involving the care and use of vertebrate animals or significant changes to previously approved protocols (Amendments) either through Full Committee Review (FCR) or through Designated Member Review (DMR), respectively. This SOP describes these procedures.

The UT IACUC is scheduled to meet monthly and will meet more frequently as required by workload. Most IACUC protocols and renewals go through FCR. Most amendments to active protocols go through DMR following review by IACUC membership.

The IACUC can send any amendment to an active protocol to FCR if an IACUC member specifically requests FCR. All IACUC members must be notified that DMR will be used. Otherwise, the amendment will be sent for FCR at an IACUC meeting. Administrative changes must be reviewed by DMR, and if any member requests, these changes will be reviewed FCR prior to approval by the IACUC.

2. Full Committee Review (FCR)

- a. **Most IACUC protocols** go through the FCR method. This is a review at a convened meeting with a quorum present (i.e., a majority of the IACUC voting members at a convened meeting) and is used for new protocols and renewals. A majority of the quorum present at a convened meeting may grant approval of those protocols only after review and vote.
- b. The IACUC protocol will be distributed to all IACUC members ten (10) business days before the meeting.

- c. The primary reviewer presents the protocol in detail, giving his/her comments and recommendations; the secondary reviewer adds his/her comments and recommendations.
 - d. If the primary and/or secondary reviewer is unable to attend the convened meeting, but provides his/her comments in writing, they may be read by any of the other IACUC members. However, if the committee believes that the protocol cannot be given adequate and fair review due to the absence of the primary and/or secondary reviewers, the review of the protocol is deferred until a future meeting. Committee members, once they received the upcoming IACUC agenda, have the responsibility to inform IACUC Administrator immediately when they know that they will not be able to attend the meeting and have been assigned as primary reviewer on one or more protocols. These protocols will be assigned to an additional reviewer that will be assigned as primary.
 - e. Following an FCR review, the UT IACUC has the authority to:
 - 1. Approve.
 - 2. Require modifications to secure approval – FCR. The IACUC may vote to use FCR to approve these modifications.
 - 3. Require modifications to secure approval - DMR subsequent to a FCR. The IACUC may vote to use DMR to approve these modifications. See explanation below.
 - 4. Withhold approval.
3. Procedures for DMR subsequent to a FCR
- a. DMR subsequent to a FCR is a procedure in which the IACUC designates one or more members to review information provided by Principal Investigators in response to a FCR of a protocol application. This procedure may proceed if approved unanimously by all IACUC members at the meeting at which the required modifications are developed and delineated, AND if the entire IACUC has previously approved that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval.
 - b. If, at the convened meeting, anyone votes against DMR subsequent to a FCR the protocol must be re-reviewed using FCR or at the next convened meeting.
 - c. Any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
 - d. Minor changes of an administrative nature (i.e, required signatures, removal of a student researcher, staff, or faculty from the protocol, etc.) may be confirmed by IACUC administrative/support personnel.

4. Designated Member Review (DMR)

- a. DMR is a procedure by which the IACUC chair designates at least one qualified member of the IACUC to review amendments to active protocols, SOPs, Breeding Protocols, Tissue Collection Protocols (or other Category A protocols), and other appropriate materials and make a recommendation regarding approval to the full committee.
- b. The DMR method can be used for the review of SOPs, amendments to active protocols, Breeding Protocols, Tissue Collection Protocols (or other Category A protocols), and other appropriate materials. In such instances, the material will be distributed via e-mail to all IACUC members. They are requested to respond within four (4) business days or less with their approval or other recommendations. Should ALL of voting members respond before the four (4) days are up, the DMR can approve the item, or follow other recommendations by the respondents. The IACUC will maintain e-mail records of the polling of members to obtain concurrence to use the DMR method or a record of concurrence by silent assent after four (4) working days have passed.
- c. The DMR has the authority to:
 1. Approve
 2. Require modifications to secure approval.
 3. Request FCR of the items in question. DMRs cannot withhold approval of a protocol.

5. IACUC Actions

- a. If the protocol is approved, the approval letter and protocol will be sent to the investigator indicating that research covered by the protocol may begin. A protocol is approved for a maximum of three years.
- b. If the protocol is approved pending modification:
 1. The IACUC Chair will notify the investigator in writing (via e-mail).
 2. Upon receipt of the revised protocol or amendment, based on the IACUC vote, the revised protocol or amendment will be: sent to the Chair or Acting Chair to review the response and either determine that it is:
 - i adequate and approved
 - ii requires further modifications
- c. If so determined by the IACUC at the meeting, the revised protocol or amendment will return for FCR.
- d. Investigators have 120 days (four months) to respond to modifications requested by the IACUC for a protocol or amendment. After 120 days, the investigator will be notified that the unapproved protocol will be administratively closed. If there is still no response, the unapproved protocol will be closed after 150 days (five months). After the protocol or amendment is closed, resubmission of the protocol or amendment will be accepted as a new submission.