

Title: IACUC Review Standard Operating Procedures
Effective Date:
Authorized by: IACUC, Vice President for Research
History: 25-August, 2016-JK, Revisions: 09/2016, 03/2017, 07/2018, 07/2019, 1/6/2020

I. Overview

The timeline for a typical IACUC review, after the Principal Investigator/Project Director (PI) has signed and submitted their protocol, is as follows:

1. **Administrative Review (AR)** by IACUC Coordinator/Staff: 3-6 business days plus time with PI
 - A. Protocol returned to PI for clarifications: undefined
 - B. Subsequent preliminary review phases: up to 3 business days per round, however;
 - C. The vast majority of preliminary reviews are completed in 1-2 rounds.
 - D. Veterinary consultation/review may occur at this stage or during OCP.
 - E. Designated reviewers are recommended and assigned: (up to) 1-2 business days
 - i. Administrative reviewer recommends reviewers during AR
 - ii. Chair or co-Chair accepts/assigns or replaces recommended reviewers.
2. **Open Comment Period (OCP)**: 7 business days
 - A. Designated members begin their reviews simultaneously with the OCP
 - B. Veterinary review/consultation of cat. D and E protocols occurs simultaneous with OCP
3. **Designated Member Review (DMR)** complete or clarifications requested from PI: 5 business days plus time with PI, 10 business days for 2 rounds
 - A. PI responses received: undefined
 - B. Subsequent rounds of questions/clarifications: Up to 5 business days per round
 - C. Chair may intervene and call for Full Committee Review (FCR) and/or invite the PI to attend meeting after 1 or more rounds of questions if it is clear multiple rounds of questions may not resolve issues.
4. **Full Committee Review**:
 - A. If FCR is requested during either OCP or by either designated reviewer or the Chair during DMR the timeline is variable depending on meeting schedule.
 - B. Reviewer questions and PI responses must be received at least 3 business days prior to convened meeting to be considered, late questions or responses may delay IACUC action.

By following this process the vast majority of protocols would be in the hands of the IACUC approximately 17-20 business days (3-4 weeks), with prompt PI responses, most protocols would be approved in one month.

II. Purpose

This SOP defines the process for IACUC Review of new animal use applications, continuing review forms and amendment requests and will ensure that protocol reviews are conducted effectively and according to the timeline outlined above. This SOP does not apply to minor amendments reviewed by designated administrative and veterinary staff via the Administrative Handling and Veterinary Verification and Review Process (see IACUC Policy P-0011-01 for more information).

III. Procedures:

1. Administrative Review

- A. In order to initiate review, the PI must submit their protocol, continuing review or amendment form within IRB Manager using the appropriate “xForm”.
- B. An administrative review is conducted by the IACUC Coordinator, IACUC Chair or other appropriately trained IACUC staff member to ensure completeness of the submission.
- C. Administrative reviews will typically be completed within 3 business days.
- D. At the conclusion of administrative review, the PI will be sent a list of questions, and requests for clarification or missing information. The administrative reviewer may also provide suggestions to expedite the review process once the application is sent to reviewers.
- E. The PI will make corrections to the xForm in IRB Manager
- F. The process may be repeated until all issues have been addressed. The administrative reviewer may invite the PI for an in person meeting to clarify any issues that prove difficult to resolve by electronic communication.
- G. If the administrative reviewer has no questions or comments, the submission is advanced to the open comment period.
- H. The IACUC Coordinator will recommend to the IACUC Chair and/or Co-Chair at least one IACUC member to serve as the designated reviewer, at least two members will be recommended for protocols involving category D or E procedures including one veterinary reviewer.
- I. The Chair or Co-Chair will respond within 48 hours and assign designated reviewers by either indicating acceptance or requiring changes to the members recommended by the IACUC Coordinator.

2. The Open Comment Period

- A. A veterinarian will automatically be assigned as a designated member at the beginning of the open comment period for all protocols involving experiments in humane use category D or E.
- B. All committee members are asked to review and evaluate the Animal Use Application or Amendment within 7 business days (the “open comment period”) of the document being made available for review.
- C. Acknowledgement, Comments, Questions and the “Add Comment” Dialogue
 - i. For record-keeping purposes, even those committee members who do not have questions/comments on an application/amendment should, at the very least, acknowledge each new submission. Protocols that have been acknowledged by all members may be advanced to the next review stage.
 - ii. Comments and questions are to be submitted Within IRB Manager.
 - iii. **At this stage, members may only “acknowledge”, add comments or request full committee review, they may not call for approval prior to DMR or FCR.**
 - iv. This is the only stage during which any member may call for FCR for any reason with the exception of a DMR process following an FCR (see D.4.b.i.2).
- D. At the end of the open comment period, the IACUC Coordinator will add the questions and comments compiled during the open comment period into the appropriate sections of the application. The investigator will be asked to address the questions and comments before the application is sent for designated member or full committee review.
- E. Late Comments/Questions: Questions submitted after the close of the open review period will be forwarded to the designated reviewers for consideration. The designated reviewers are not required to consider late responses, nor are they required to share late input with the PI.

3. Designated Member Review

- A. As indicated in section 1.H above, at the beginning of the open comment period, the IACUC Coordinator will recommend, and the IACUC Chair or co-Chair will confirm, at least one IACUC member to act as designated reviewer for type B and C protocols and two IACUC members to act as designated reviewers for type D and E protocols.
- B. The designated reviewers will, within 24 hours, notify the IACUC administrator whether they accept or decline the request to serve as designated reviewer. If no response is received within 2 business days, another reviewer will be selected and the IACUC Coordinator will

- notify the Chair or co-Chair of any re-assignments following the process described in section 1.H-I above.
- C. Once a member has accepted the assignment he/she will evaluate the proposal/amendment, make comments, and/or ask questions **during the same open comment period as the rest of the committee.**
 - D. **Even if a member calls for FCR during the open comment period, it is expected that the designated member(s) will complete their review and be prepared to present a synopsis, questions and concerns at the convened meeting.**
 - E. For **applications that evoke no suggestions/criticism/inquiry or calls for FCR**, the designated reviewers are asked to summarize the proposal, and submit the summary with their decision within 5 working days following the end of the open comment period. The submission must be documented in IRB Manager in the form of:
 - i. A completed IACUC reviewer checklist;
 - ii. This submission is in addition to the acknowledgment and any comments that the review may have brought up during the open comment period.
 - iii. **For category D or E protocols requiring veterinary review/consultation, the consultation between the PI and the veterinarian may take place in person or by phone, however a summary of the consultation or veterinary review must be documented in IRB Manager by the designated veterinary reviewer.**
 - F. For applications that evoked questions/comments, the designated reviewer(s) will evaluate the responses/revisions and either recommend approval, request further clarification, or call for full committee review **within 5 business days of receipt of the responses from the PI.**
 - i. When recommending acceptance, the designated member reviewers will:
 - a. Complete a reviewer checklist that:
 - 1. Addresses the acceptability of protocol by section
 - 2. Provides additional feedback for the PI as appropriate
 - 3. Includes a recommendation for approval, deferral or referral for FCR
 - 4. Includes a brief (e.g., 1 paragraph) summary of the protocol;
 - b. Reviewers should, when appropriate, include in their commentary a summary of how the committee comments/questions have been addressed and
 - c. a summary of any additional dialogue with the investigator (pertinent to the reviewers' decision).
 - ii. Recommendation for approval must be unanimous by all designated reviewers
 - iii. If the designated members cannot reach consensus, one of the assigned designated reviewers should call for FCR.
 - G. If a response is not received from the reviewer(s) within 5 business days, the protocol will be re-assigned to another reviewer. **For this reason, if the reviewer has contacted the PI directly (e.g. outside of IRB Manager or not through the IACUC Coordinator) and is awaiting a response the reviewer must notify the IACUC Coordinator to avoid having the protocol re-assigned to another reviewer after 5 days.**
 - F. Should it appear that investigator responses to reviewer/committee inquiry will lead to multiple rounds of questions, the chair may invite the investigator to the next IACUC meeting or call for FCR.
 - G. Once the designated reviewers (or the full committee) recommend approval, the IACUC coordinator will notify the investigator via email of the approval and generate an approval letter. Upon receipt of the approval email, investigators may begin working with animals for the proposed research.
 - H. At the completion of DMR, any IACUC member may request/review the entire protocol package and all review documents.

4. Full Committee Review

- A. During the Open Comment Period, any member may request FCR.
- B. The designated reviewer(s) assigned at the start of the open comment period are asked to evaluate the proposal/amendment **and be prepared to present a synopsis, questions and concerns at the convened meeting.**

- C. **For all protocols referred to FCR, members are encouraged to submit their questions as early as possible in order to facilitate sending them to the PI and having responses from the PI prior to the convened meeting.**
- i. **Members are asked to submit their questions as early as possible in order to allow time for the PI to respond prior to the convened meeting. Members must submit their questions at least 3 business days prior to the date of the convened meeting for them to be included in the discussion.**
 - ii. **This will ensure that all members' questions are consolidated into a single list by the IACUC Coordinator and;**
 - iii. **Will facilitate the Chair having access to all questions to be posed to the PI in the event they have been invited to attend the convened meeting.**
 - iv. **PI responses to any questions sent to them prior to the meeting will be included in the agenda items only if they are received at least 48 hours prior to the meeting.**
 - v. **Late Comments/Questions:** Because the agenda at convened meetings is often full, any questions or responses submitted after the deadline for inclusion for consideration at the convened meeting will be forwarded to the Chair. The Chair will not be required to consider late responses but may, at their discretion, allow a specified amount of time for discussion of questions at the meeting.
- D. **During FCR, any member may make a motion for:**
- i. **Approval**
 - a. Following a motion for approval, the Chair will call for discussion prior to a vote.
 - b. Approval will carry if a majority of the convened quorum votes in favor of approval.
 - c. If approval is granted, the IACUC coordinator will notify the investigator via email of the approval and generate an approval letter for the IACUC chair to sign. Upon receipt of the approval email, investigators may begin working with animals for the proposed research.
 - ii. **Request modifications or clarifications from the PI in order to secure approval and then either step i or ii below:**
 - a. By unanimous agreement the protocol may be returned to DMR for review of modifications and clarifications
 - b. Any member may request access to review materials, including investigator responses, during DMR subsequent to FCR and May call for the protocol to be returned to FCR.
 - c. The DMR process is carried out as indicated in section 3.
 - d. If unanimous agreement for DMR subsequent to FCR is not achieved, PI responses will be reviewed at a subsequent convened meeting by repeating steps 4.C and 4.D until either approval or withholding of approval is achieved.
 - iii. **Failure to achieve either a motion to approve or a motion to required modifications to secure approval will lead to a withholding of approval by the committee.**
 - a. The IACUC coordinator will notify the investigator via email of the decision to withhold approval and;
 - b. Will advise the investigator that they may revise and resubmit their protocol as a new submission to restart the review process.

Additional Information:

For questions, additional details or to request changes to this policy, please contact the IACUC Office IACUC_Admin@cmich.edu or Office of Research Compliance RESCOMPLIANCE@cmich.edu with questions.