OFFICE OF
RESEARCH
COMPLIANCE
CENTRAL MICHIGAN UNIVERSITY

IACUC-004:
IACUC REVIEW-
POLICIES AND PROCEDURES

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Institutional Policies and Regulations

I. BACKGROUND

In order to comply with the regulations for the care and use of animals in research, Central Michigan University (CMU) has established an Institutional Animal Care and Use Committee (IACUC) to review all research involving the use of vertebrate animals and to implement institutional policy regarding such research.

The IACUC is responsible for oversight of the Animal Care and Use Program as described in the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)[2] and the *Guide for the Care and Use of Laboratory Animals (The Guide)*[3]. The IACUC has jurisdiction over all animal subject research conducted under the auspices of CMU, regardless of funding source or performance site. Research conducted under the auspices of CMU includes research:

- Conducted at CMU
- Conducted by or under the direction of any CMU employee or agent (including students) in connection with their institutional responsibilities
- Conducted by or under the direction of any CMU employee or agent (including students) using any property or facility of CMU

According to the Animal Welfare Act Regulations (AWARs)[1], all activities involving the use of animals for research, testing or teaching, must be reviewed and approved by an IACUC. PHS Policy requires, "…institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities (hereinafter referred to as "activities") conducted or supported by the PHS."[2] Although PHS Policy specifically applies only to projects funded by the PHS, other funding agencies have formed agreements with PHS – specifically, with the Office of Laboratory Animal Welfare (OLAW) – requiring awardee institutions to review projects according to the criteria set forth in The Guide[3].

CMU may review any research protocol and reserves the right to terminate the implementation of a research protocol that has been approved by the IACUC, if in the opinion of CMU said research protocol would place its animal subjects, university, or community at undue risk. CMU may not, however, approve the implementation of any research protocol that has been rejected by the IACUC, nor may CMU override the decision of the IACUC to withhold approval for a research protocol per PHS Policy IV.C.8 and AWARs 9 CFR 2.31(d)8.

II. DEFINITIONS

Animal:

Animal Welfare Act Regulations[1], in Section 1.1 –

Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet. This term excludes birds, rats of the genus Rattus and mice of the genus Mus, bred for use in research; horses not used for research purposes; and other farm animals, such as, but not limited to, livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber. With respect to a dog, the term means all dogs, including those used for hunting, security, or breeding purposes.

Public Health Service Policy[2], in Section III.A –

Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.

For the purposes of these CMU policies, animals are defined as all vertebrate animals.

Principal Investigator (PI):

Researchers who utilize animals in their research or teaching and have the primary responsibility to ensure work conducted under their project following regulatory and institutional policies and procedures. CMU PI's also have the following responsibilities:

- Ensure that all personnel involved in animal use are listed on applicable IACUC protocols prior to initiating work with animals
- All personnel in their laboratory are trained in and familiar with the conduct of activities as described in the IACUC protocol
- Promote proper animal care and handling of animals in their studies

III. POLICY

A. Except for the activities exempted below, it is the policy of CMU that all activities involving the use of animals for teaching, research and outreach purposes must be approved by the IACUC before initiating the activity.

1. For approval, projects must adhere to the AWARs, PHS policy, and institutional policies and procedures, unless acceptable justification for a departure is presented to and approved by the IACUC.
2. IACUC review processes are conducted and documented in the electronic management system. Review actions or discussions occurring outside the system are added as part of reviewer checklists or supporting documentation.
3. Projects or forms reviewed outside convened meetings are communicated to the committee and program leadership through inclusion on meeting agendas and minutes.

B. Exempt Activities:
   1. Activities involving animal use that is not regulated by the AWARs or PHS policy, including projects using:
      a. Invertebrate animals only
      b. Vertebrate non-mammalian embryos that are at less than the half-way point of incubation period and are obtained from dams covered by an existing IACUC protocol
      c. Tissues or fluids obtained:
         i. From animals sacrificed for IACUC approved projects at CMU or other research institutions
         ii. From samples remaining from diagnostic tests performed by private diagnostic laboratories
         iii. Via a commercial source (e.g., slaughterhouse, butcher shop) from livestock killed for food
         iv. From wild animals that were sacrificed by governmental agencies
   2. Non-Intrusive Field Research
      a. Observation of wild vertebrates undisturbed in their natural habitat (with no manipulation of the animal or its environment)
      b. Observation of domesticated animals, undisturbed, and kept under generally accepted agricultural practices

      Note: Studies in which the behavior of a vertebrate animal is materially altered will require IACUC approval. By example, whereas telescopically observing birds in their natural environment requires no approval, teaching/research using feeders to draw birds in for observation requires approval.
   3. Animal use conducted by CMU researchers at another PHS-Assured institution and approved by that institution's IACUC.
      a. As described in CMU Policy 3-67, Off-Site Collaborative Research Activities, CMU researchers or students must contact the Office of Research Compliance or Office of Sponsored Programs prior to initiating collaborative research activities.
      b. The collaborative situation may require additional CMU involvement and review and will be assessed on a case-by-case basis.
   4. Other:
      a. Companion animal shows provided and overseen by reputable organizations (e.g., the American Kennel Club)
      b. Commercial entertainment involving live animals (e.g., circuses) on university property
      c. Outreach activities involving animals, provided approval is first obtained from the Office of Risk Management
      d. Retrieval and analysis of data from records

      Note: Refer to CMU Policy 13-5, Animals on Campus, for policy details for items a-c.
   5. Activities conducted by visiting or collaborating investigators at CMU may be exempt, based upon the following considerations and actions taken to evaluate the proposed activities:
      a. If the research is currently approved by the IACUC at their home institution.
      b. If their home institution holds a current assurance with OLAW.

c. The IACUC must be notified that such activities will be conducted at least 30 days prior to initiation at CMU.
   i. The IACUC will review the approved protocol to ensure that the species and methods used are appropriate for use at CMU.
   ii. The CMU IACUC reserves the right to withhold approval to conduct any animal activity conducted at CMU by visiting researchers.
d. The individuals working in CMU facilities must either:
   i. Adhere to the restrictions and rules outlined in the Vivaria Access: Visitor's Policy (5-10), or
   ii. Complete training and comply with the policy requirements of the Animal Research Occupational Health and Safety Program (13-6) at their personal cost.

IACUC Review of Research Proposals

This section defines the process for IACUC review of new animal use applications. IACUC protocols are approved for a period of three years. If the PI would like to continue the research beyond that time frame, a new application must be submitted for review with appropriate timing to permit IACUC review before the existing project expires.

I. ADMINISTRATIVE REVIEW

A. In order to initiate review, the PI must submit their protocol form within the electronic record system (e.g., IRBManager) using the appropriate application.

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. Administrative reviews will typically be completed within 3 business days.

C. During the administrative review process, the Chair, Co-Chair, IACUC Coordinator, or designee will assign two members as designated member reviewers for the proposal.
   1. A veterinarian will automatically be assigned as a designated member for all protocols involving experiments in humane use categories D or E.
   2. The designated reviewers will be notified of the assignment.
   3. The designated reviewers will notify the IACUC Coordinator if they decline the assignment to serve as designated reviewer.
   4. If the project is selected to go to FCR, the designated member reviewers will be expected to complete their review and be prepared to present a synopsis, questions, and concerns at the convened meeting.

D. At the conclusion of administrative review:
   1. If the administrative reviewer has no questions or comments, the submission is advanced to the committee open comment period.
   2. When appropriate, 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.
      i. The PI will make corrections to the form in the electronic record system and resubmit the application.
      ii. The process may be repeated until all issues have been addressed.
      iii. The administrative reviewer may invite the PI for a meeting to clarify any issues that prove difficult to resolve by electronic communication.
      iv. Once the issues have been addressed, the submission is advanced to the committee open comment period.

II. OPEN COMMENT PERIOD

A. All committee members are asked to review and evaluate the Animal Use Application within five business days (the "open comment period") of the document being made available for review. This time frame is based upon the time the notification in the system was sent to the committee members, not by the number of days or by close of business on the last day.
   1. 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.
   2. Protocols that have been acknowledged by all members may be advanced to the next review stage.
   3. Comments, recommended changes, and questions are to be submitted within the electronic record system. The questions or recommended changes must specify the location in the application pertaining to their question.
   4. At this stage, members may only:
      a. "Acknowledge"
      b. Add comments, questions, or recommended changes
      c. Recommend designated member review (DMR)
      d. Request full committee review (FCR) – members should provide details regarding the request
   5. Questions or comments submitted after the close of the 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.

B. If there are questions or recommended changes submitted by IACUC members, these will be sent to the PI via the application form and electronic record system to permit the PI to address those concerns before proceeding to the DMR or FCR processes.
   1. The questions or recommended changes that are added to the application form and provided to the PI will be anonymous (i.e., will not detail specific committee member names/contributions).
   2. Comments will be provided as written by the reviewer. If there are any questions or concerns, the IACUC Coordinator or designee, will confirm comment details with the committee member and/or IACUC Chair.
   3. The comments may be combined by conceptually similar comments and questions where appropriate.

C. Once the PI resubmits the proposal with their responses, the submission is advanced to the next review stage - DMR or FCR.

III. DESIGNATED MEMBER REVIEW (DMR)

A. The designated reviewer(s) will evaluate the proposal along with any responses/revisions from the open comment period review process within five business days.

B. The designated reviewer(s) will:
   1. Complete a reviewer checklist that:
      a. Addresses the acceptability of the protocol by section
      b. Provides additional feedback for the PI as appropriate
      c. Includes a recommendation for actions (see III.D)
      d. Includes a brief summary of the protocol (e.g., one paragraph)
   2. Reviewers should, when appropriate, include in their commentary:
      a. A summary of how the committee comments or questions have been addressed
      b. A summary of any additional dialogue with the PI (pertinent to the reviewer's decision) that occurred outside of the electronic record system processes
      c. For category D or E protocols requiring veterinary review/consultation, if any consultation between the PI and veterinarian took place outside of the electronic record system, a summary must be included in their review.

C. Possible DMR actions:
   1. Approval – The study is approved as submitted.
   2. Request further clarification to proposal submission details from the PI
      Note – DMR can be more than one round of review, to allow for dialogue with the PI in attempts to resolve concerns.
   3. Call for full committee review at a convened meeting

D. Recommendation for approval must be unanimous by all designated reviewers. If agreement cannot be reached, one of the reviewers should call for full committee review.

E. If both reviewers recommend approval, the IACUC Coordinator or designee, will notify the PI of the approval through the electronic record system.

F. Upon receipt of the formal approval notification from the IACUC, the research team may begin working with animals for the proposed research.
   Note: There may be additional ancillary steps required before work may begin (e.g., animal acquisition or transfer procedures and approval, space availability, health status/clearance)

G. The proposal/project anniversary date is based upon committee approval date, not the date work is initiated.

IV. FULL COMMITTEE REVIEW (FCR)

A. During the Open Comment Period, any member may request review at a convened committee meeting (full committee review- 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. The PI is invited to provide further clarification ahead of the FCR after the OCP as indicated above. If PI responses result in further questions by committee members, those questions may be shared with the IACUC, but should be provided ahead of time to request PI feedback where appropriate.

D. 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.
   1. 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.
   2. This will ensure that all members' questions are consolidated into a single list by the IACUC Coordinator and;
   3. 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.
   4. 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.
   5. 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.

E. During FCR at a convened meeting, any member may make a motion for:
   1. 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 or designee, will notify the PI of the approval through the electronic record system.
      d. Upon receipt of the approval email, investigators may begin working with animals for the proposed research.
         Note: There may be additional ancillary steps required before work may begin (e.g., animal acquisition or transfer procedures and approval, space availability, health status/clearance)
      e. The proposal/project anniversary date is based upon committee approval date, not the date work is initiated.

   2. Request modifications or clarifications from the PI in order to secure approval

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 III.
d. If unanimous agreement for DMR subsequent to FCR is not achieved, PI responses will be reviewed at a subsequent convened meeting until either approval or withholding of approval is achieved.
e. The IACUC coordinator or designee will notify the PI of the decision to request modifications to secure approval through the electronic record system.

3. Failure to achieve either a motion to approve or a motion to request modifications to secure approval will lead to a withholding of approval by the committee.
   a. The IACUC coordinator or designee will notify the PI of the decision to withhold approval through the electronic record system and;
   b. Will advise the investigator that they may revise and resubmit their protocol as a new submission to restart the review process.

IACUC Review of Amendments

This section defines the process for IACUC review of amendments to IACUC approved animal use protocols. Based upon the type of modification, the amendment may be processed through either of these methods: Administrative Handling, Veterinary Verification and Consultation Review, or IACUC committee review processes. The information below helps to define the determining factors for which review will be employed for an amendment submission.

I. REGULATORY BACKGROUND

In accordance with the Office of Laboratory Animal Welfare (OLAW) Notice (NOT-OD-14-126) Guidance on Significant Changes to Animal Activities, CMU IACUC will follow the guidance regarding the types of protocol modifications that will be allowed to be reviewed and approved by designated administrative or veterinary staff as they will not result in a change in scope or alteration in humane use category. All other amendments will be reviewed through routine IACUC committee review processes.

II. ADMINISTRATIVE HANDLING

A. The following amendment types may be reviewed by this method:
   1. Personnel changes (except Principal Investigator) – for more details, refer to that section in this manual.
   2. Changes in project title or funding agency
   3. Typographical or grammar corrections
   4. Contact information changes
   5. Modifications to increase animal numbers for species already approved, provided that:
      a. The modification does not alter the scope or purpose of the study.
      b. The modification does not request a change in the humane use category.
      c. The modification must be approved by designated staff members with the expertise required to make these decisions.
      d. The changes in animal numbers must be justified under the original rationale or an acceptable justification related to the original rationale must be provided.

B. If the administrative reviewer has any uncertainty regarding changes in scope, purpose, or rationale, the amendment must be sent to the committee for review.

C. Procedures:
   1. In order to initiate review, the PI must submit their amendment form within electronic record system using the appropriate form.
      a. For approved protocol forms initiated prior to October 2020, the IACUC Amendment form must be used.
      b. For approved protocol forms initiated after October 2020, the PI may use the “Copy to Amend Feature”. Refer to Appendix A for additional guidance instructions.

2. An administrative review is conducted by the IACUC Coordinator, IACUC Chair or other appropriately trained IACUC staff member to ensure completeness of the submission. Administrative reviews will typically be completed within 3 business days.
3. At the conclusion of administrative review:
    a. If the administrative reviewer has no questions or comments, the submission is approved and the IACUC Coordinator or designee, will notify the PI of the approval through the electronic record system.
    b. When appropriate, the PI will be sent a list of questions, and requests for clarification or missing information.
        i. The PI will make corrections to the form in electronic record system and resubmit the application.
        ii. The process may be repeated until all issues have been addressed.
        iii. The administrative reviewer may invite the PI for a meeting to clarify any issues that prove difficult to resolve by electronic communication.

III. VETERINARY VERIFICATION AND CONSULTATION REVIEW

A. The following amendment types may be reviewed by this method:
    1. Modifications that request the addition of procedures within the scope of IACUC approved guidelines, provided the addition of those procedures will not:
        a. Adversely affect the health and welfare of animals or staff
        b. Cause a change in the humane use category
        c. Cause a change in the scope of the study
    2. Modifications that request the addition of routine or minor procedures that would positively affect the health or welfare of animals. The modification must not result in a change in the humane use category.
    3. Additional modifications regarding changes in:
        a. Anesthesia, analgesia, sedation, or experimental substances provided the changes do not change the scope of the study
        b. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals or institutional SOP's
        c. Duration, frequency, type, or number of procedures performed on an animal within the scope of an IACUC approved protocol

B. These modifications require approval by designated veterinary staff with the experience appropriate to make these decisions.

C. If the veterinary reviewer has any uncertainty regarding changes in scope, purpose, or rationale, the amendment must be sent to the committee for review.

D. Procedures:
    1. In order to initiate review, the PI must submit their amendment form within electronic record system using the appropriate form.

c. For approved protocol forms initiated prior to October 2020, the IACUC Amendment form must be used.
d. For approved protocol forms initiated after October 2020, the PI may use the "Copy to Amend Feature". Refer to Appendix A for additional guidance instructions.

2. An administrative review is conducted by the IACUC Coordinator, IACUC Chair or other appropriately trained IACUC staff member to ensure completeness of the submission. Administrative reviews will typically be completed within 3 business days.
3. At the conclusion of administrative review:
   a. If the administrative reviewer has no questions or comments, the submission is advanced to veterinary verification and consultation review.
   b. When appropriate, the PI will be sent a list of questions, and requests for clarification or missing information.
      i. The PI will make corrections to the form in electronic record system and resubmit the application.
      ii. The process may be repeated until all issues have been addressed.
      iii. The administrative reviewer may invite the PI for a meeting to clarify any issues that prove difficult to resolve by electronic communication.

4. Veterinary Consultation and Review
   a. If the veterinary reviewer has no questions or comments, the submission is approved and the IACUC Coordinator or designee, will notify the PI of the approval through the electronic record system.
   b. When appropriate, the PI will be sent a list of questions, and requests for clarification or missing information.
      i. The PI will make corrections to the form in electronic record system and resubmit the application.
      ii. The process may be repeated until all issues have been addressed.
      iii. The veterinary reviewer may invite the PI for a meeting to clarify any issues that prove difficult to resolve by electronic communication.

IV. IACUC COMMITTEE REVIEW PROCESS

A. Review and approval for amendments that do not fall under the list of approved types in sections II and III above, will be handled in the same manner as new protocol submissions (administrative review, open comment period, DMR, FCR).

B. Examples include, but are not limited to changes:
   1. In the objectives or scope of a study
   2. Addition of or modification of surgeries.
   3. From non-survival to survival surgery
   4. Resulting in greater discomfort or degree of invasiveness
   5. In the species or a notable increase in the number of animals requested
   6. In Principal Investigator

7. That impact personnel safety
8. To protocols that contain USDA covered species

C. Refer to the section for IACUC Review of Research Proposals for review and processing details for these types of amendments.

V. IACUC AMENDMENTS – COPY FOR AMEND

A. IACUC projects which had amendments submitted via the "Copy for Amend" procedure will incorporate the changes within the original document.

B. Reviewers or committee members may use the "View Audit" feature in the electronic record system to show changes made within any section of the form.

C. See Appendix B for guidance instructions.

IACUC Review of Continuing Review or Protocol Closure

This section defines the process for IACUC review of annual continuing review or protocol closure submissions to IACUC approved animal use protocols. Based upon the type of information included, the submission may be processed through either of these methods: Administrative Handling or IACUC committee review processes. The information below helps to define the determining factors for which review will be employed for a continuing review submission.

I. REGULATORY BACKGROUND AND PURPOSE

Federal regulations and policies mandate that institutions develop review procedures that are reasonable, meaningful, and efficient; such procedures should contribute directly to the welfare of the animals and/or provide significant information relevant to the role of the IACUCs.

The PHS Policy at IV.C.5. states "the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three years" while the USDA Animal Welfare Act & Regulations (CFR2.31 (d) (5)) states that the IACUC "conduct continuing reviews of activities...at appropriate intervals as determined by the IACUC, but not less than annually".

The purpose of continuing review is threefold:

- To inform the IACUC of the current status of the project
- To ensure continued compliance with PHS, USDA and institutional requirements
- To provide for re-evaluation of the animal activities at appropriate intervals

The use of continuing review is also a mechanism used to support the animal care and use program's post approval monitoring (PAM) program.

II. SUBMISSION TIMEFRAME

A. Continuing review of each approved animal use protocol must be completed by each of the first and second anniversaries of the protocol's initial approval.

B. The third anniversary should be completion of a protocol closure report.

C. If the PI wishes to continue the research beyond three years, a new application must be submitted for review with appropriate timing to permit completion of the IACUC review before the existing project expires.

D. If the project is completed prior to the 3rd anniversary date, the PI may submit a protocol closure at any time – it is not required to coincide with the anniversary timeframe.

III. CONTINUING REVIEW PROCEDURES

A. Approximately three months before the anniversary of a protocol's original approval date, Principal Investigators (PIs) will be alerted that the anniversary of their protocol's approval is approaching and will be sent an email with a link to initiate the continuing review process in electronic record system. Information requested on the form includes:
   1. PI name
   2. Protocol Identification (Number and Title)
   3. Current Project status:
      a. Project active and continuing
      b. Project completed
   4. Species/pain category of animals and total numbers of animal used thus far
   5. Unexpected problems or complication of the past 12 months that had not been reported to the IACUC
   6. Personnel changes for the project

B. If necessary, PIs will receive reminder emails at approximately two months, one month, and one week before the protocol's anniversary date.

C. Reviews, Approval, Requests for Additional Information
   1. The IACUC Coordinator, the Chair, the Co-Chair, or the Attending Veterinarian may approve continuing reviews if:
      a. No Unexpected Adverse Events (UAEs) are reported
      b. Reported animal usage remains within the number of animals approved for use in the PI's protocol
   2. Continuing reviews that include reports UAEs will be provided to the committee for review and handled in the same manner as new protocol submissions (administrative review, open comment period, DMR, FCR). Refer to the section for IACUC Review of Research Proposals for review and processing details.

IV. PROTOCOL CLOSURE PROCEDURES

A. Approximately three months before the 3rd anniversary of a protocol's original approval date, Principal Investigators (PIs) will be alerted that the anniversary of their protocol's approval is approaching and will be sent an email with a link to initiate the closure process in electronic record system. Information requested on the form includes:
   1. PI name
   2. Protocol Identification (Number and Title)
   3. Project status
   4. Species/pain category of animals and total numbers of animals used on project
   5. Unexpected problems or complication of the past 12 months that had not been reported to the IACUC
   6. Personnel changes for the project

7. Confirmation if any live animals present in CMU facilities assigned to the study

B. If necessary, PIs will receive reminder emails at approximately two months, one month, and one week before the protocol's final anniversary date.

C. Reviews, Approval, Requests for Additional Information
   1. The IACUC Coordinator, the Chair, the Co-Chair, or the Attending Veterinarian may approve protocol closure reports if:
      a. No Unexpected Adverse Events (UAEs) are reported
      b. Reported animal usage remains within the number of animals approved for use in the PI's protocol
   2. Protocol closure reviews that include reports UAEs will be provided to the committee for review and handled in the same manner as new protocol submissions (administrative review, open comment period, DMR, FCR). Refer to the section for IACUC Review of Research Proposals for review and processing details.

IACUC Review of Personnel Addition Forms

This section defines the process for IACUC review of personnel addition submissions to IACUC approved animal use protocols.

I. BACKGROUND

To conduct animal research activities, individuals must be listed on an IACUC approved research protocol. Individuals observing only or performing only basic lab/benchwork type of functions, are not required to be added to the protocol but will need to refer to CMU Policy 5-10 (Vivaria Access: Visitors Policy) if they are entering the animal facilities. Visitors are NOT permitted to handle animals per CMU policy.

II. PROCEDURE

A. In order to initiate review, the PI must submit their personnel addition form within electronic record system using the appropriate form.

B. An administrative review is conducted by the IACUC Coordinator or designee to ensure completeness of the submission. Administrative reviews will typically be completed within 3 business days.
   1. The following are confirmed during administrative review:
      a. CITI training
      b. Laboratory Safety Training
      c. Status of animal research occupational health review
   2. If any of the items above are not appropriately completed for the research role of the individual, the form will not be approved and the form will be returned to the PI with instructions to resubmit once the necessary items are completed as indicated below.

C. At the conclusion of administrative review:
   1. If the administrative reviewer has no questions or comments, the submission is approved and the IACUC Coordinator or designee, will notify the PI of the approval through the electronic record system.
   2. When appropriate, the PI will be sent a list of questions, and requests for clarification or missing information.
      a. The PI or personnel will make the appropriate corrections and resubmit the form.
      b. The process may be repeated until all issues have been addressed.
      c. The administrative reviewer may invite the PI for a meeting to clarify any issues that prove difficult to resolve by electronic communication.

IACUC Review of Unexpected Adverse Event Forms

This section defines the process for IACUC review of unexpected adverse event submissions to IACUC approved animal use protocols.

I. REGULATORY BACKGROUND AND PURPOSE

The Institutional Animal Care and Use Committee's primary concern is the welfare of animals used in research, teaching or outreach programs conducted at Central Michigan University. Unanticipated outcomes or adverse events may occur which affect those animals. Animal users, as well as animal care staff, have a responsibility to report unexpected adverse events (UAE's). The IACUC, as part of post-approval monitoring, is required to perform continued review of approved protocols per PHS Policy (IV.C.5) and USDA Animal Welfare Regulations [9 CFR 2.31(d)(5)]. The UAE reports permit the evaluation into the cause of the UAE's and consider whether updates are required for protocol or standard operating procedures. Failure to report an adverse event by animal users or care staff is viewed as non-compliance and will be assessed for further actions on an individual basis by the IACUC.

An unexpected adverse event is an occurrence of an unforeseen event that negatively affects the welfare of research animal(s); that is, an event that involves pain, distress, and/or death of the animal. By definition, these are events that are not identified as a possible risk or outcome in the IACUC approved protocol.

II. PROCEDURES

A. Examples of occurrences that must be reported:
   1. Unexpected clinical signs, either related or unrelated to a protocol procedure
   2. Surgical complications, which may include recurring unexpected anesthetic deaths
   3. Animal morbidity or mortality in excess of that described in the approved animal use application, including endpoints prompting euthanasia that were cited in the protocol and found to be inadequately predictive resulting in unexpected animal deaths
   4. Unexpected circumstances that lead to animals being subjected to obvious harm or distress that is not justified and approved by the IACUC – e.g., facility or weather-associated events – HVAC or power failure, flooding, fire, housing malfunctions

B. Examples of occurrences that are <u>not</u> required to be reported:
   1. Death or morbidity of animals that has been described and approved in the animal use protocol (e.g., increased mortality rates due to described phenotypic characteristics of transgenic lines, post-operative complications)
   2. Since the chance of mortality increases as a function of age in all animals, the death of aged animals due to natural causes is not considered an adverse event; however, requires appropriate monitoring procedures detailed in the approved protocol.

3. Injury or illness unrelated to approved research procedures – for example, dermatitis or species-specific behavior (among rodents could include fight wounds, barbering, and neonate cannibalization).
   Note: If these situations are noted to be increasing or in high numbers, it may be an indication of an issue and should be addressed with the veterinary staff.

C. Reporting process and expectations of research staff:
   1. All potential UAE's requiring immediate care for an animal and/or if the incident relates to husbandry or clinical care of animals must be promptly reported to the Attending Veterinarian (AV) or their designee.
   2. For UAE's that are larger-scaled and encompass multiple areas and/or protocols due to facility events, the Facility Manager will report the event to the AV. All other events will be reported by the PI (or designee).
   3. An Unexpected Adverse Event form must be completed and submitted to the IACUC within twenty-four (24) hours of the event being observed or identified.
      a. In order to initiate review, the PI must submit an Unexpected Adverse Event form within the electronic record system using the appropriate form.
      b. For facility or widespread UAE's, the AV in consultation with Facility Manager(s) will generate a summary of the event for review by the IACUC.
   4. Information to include within the reports:
      a. IACUC protocol number, if applicable
      b. Date and location
      c. The nature and severity of the event (describe what occurred)
      d. Any identified or potential contributing factors or additional details that may be pertinent to assessing the UAE
      e. Number of animals involved
      f. Any treatment(s) that were initiated or justification regarding why treatment not provided
      g. Suggestions or steps taken to correct and prevent future occurrence
      h. If a protocol amendment may be needed to address the event
   5. Concerns may be reported to the Office of Research Compliance directly or anonymously online:
      a. From any CMU web page, search for the "Office of Research Compliance" and select the "Report a Research Concern" link.
      b. Alternatively, a concerned individual could email – researchconcern@cmich.edu
      c. The Office of Research Compliance will review information presented via these formats.

D. UAE evaluation process:
   1. Any individuals involved in the evaluation process should be discreet and circumspect regarding communication of the reported situation.
   2. The Attending Veterinarian and the IACUC Chair (or designee) will be notified of the submitted UAE form by the IACUC Coordinator (or designee).

3. Initial questions raised during assessment review of the submission will be directed primarily to the PI.
4. Additional inquiries or assessment may be requested of the Office of Research Compliance by the IACUC Chair or Attending Veterinarian.

E. UAE determination and remediation process:
   1. Based upon determination during the assessment period, the report may be:
      a. Deemed as not an UAE, no further action.
      b. Accepted with no further action necessary. The IACUC will be notified of the report submission.
      c. Referred to IACUC to review for further assessment and determination. The IACUC will discuss submission, assessment findings, determine if further investigation is required, and potential modifications or corrective action necessary. The PI may be requested to participate in the meeting. Examples of corrective action may include:
         i. Training or adjustments to training
         ii. Veterinary consultation
         iii. Changes to vivarium staff support or research staff procedures

      Note: The IACUC will determine what submissions must be reported to regulatory agencies.
   2. The protocol will be updated to reflect the final determination and appropriate documentation within the electronic management system.

Review of Animal Acquisition, Transfer and Tracking Forms

This section defines the process for review of animal acquisition, transfer, and tracking form submissions to IACUC approved animal use protocols.

I. REGULATORY BACKGROUND AND PURPOSE

This section describes the expectations of the IACUC regarding acquisition and tracking of the number of animals used in teaching, research, and outreach activities at Central Michigan University. The intent is to ensure that animals are acquired and used in a manner that is consistent with the requirements of the Guide for the Care and Use of Laboratory Animals and the expectations of the Public Health Service Office of Laboratory Animal Welfare (OLAW) which are described below.

"Although the PHS Policy does not explicitly require a mechanism to track animal usage by investigators, it does require that proposals specify a rationale for the approximate number of animals to be used and be limited to the appropriate number necessary to obtain valid results. This implicitly requires that institutions establish mechanisms to document and monitor numbers of animals acquired and used, including any animals that are euthanatized because they are not needed. Monitoring should not exclude the disposition of animals inadvertently or necessarily produced in excess of the number needed or which do not meet criteria (e.g., genetic) established for the specific study proposal. Institutions have adopted a variety of administrative, electronic, and manual mechanisms to meet institutional needs and PHS Policy requirements."

II. DEFINITION

Acquisition- For the purposes of this policy, acquisition will mean purchase, transfer (from a breeding colony or another investigator), receipt by donation or gift from a collaborating institution or otherwise animals obtained for the purpose of conducting teaching, research, or outreach activities.

III. PROCEDURES

A. Animals may not be purchased or acquired until final approval of a Protocol has been obtained. If a delay in ordering could impact the research, contact IACUC leadership to discuss potential options.

B. <u>Once a Protocol has been approved</u>:
   1. Animals must be ordered or acquired under the appropriate protocol number and specific humane use categories indicated in the protocol.
   2. If the Principal Investigator finds it necessary to change the humane use category or increase the number of animals within an animal use category, an amendment must be

filed through the electronic management system and approved before ordering or acquiring the additional animals.

3. Veterinary approval is required for any animal obtained by means other than purchase from an approved vendor prior to the animal entering a CMU animal facility.
   Note: Please consult with the Attending Veterinarian and appropriate Facility Manager for additional information on approved vendors and approvals and considerations that are to be made prior to animals entering quarantine.

C. Acquisition of Animals through Animal Orders, Animal Imports, and Animal Transfers:
   1. All animal orders, animal imports, and animal transfers are generated through the electronic management system using the Animal Acquisition, Transfer, and Tracking Form.
      a. Animal orders – through routine vendors, may require periodic veterinary review for vendor approval status
      b. Animal imports – international movement or wildlife collection tracking
      c. Transfer – movement of animals between IACUC-approved protocols, including breeding and hatchery protocols.
   2. Once the Animal Acquisition, Transfer and Tracking Form is received in the system, the IACUC Coordinator, or designee, will confirm the following within the approved protocol:
      a. Protocol status
      b. Animal numbers
      c. Species, strain, sex, and age
   3. Once confirmed, the PI and the Veterinarians and appropriate Facility Manager or designee for that area will be notified.
   4. The Facility Manager, designee, and/or Veterinarian will coordinate the animal movement with the appropriate research personnel as needed.
   5. If there are any concerns or disputes regarding the animal movement requests, the Veterinarian or Facility Manager will discuss with the appropriate research personnel. If an agreement cannot be reached, the final determination will be made by the Attending Veterinarian.
   6. If for any reason, the animals are not received, ordered, or transferred, the IACUC Coordinator must be notified to update the electronic management system records appropriately.
   7. The animal numbers that are generated through this process are not required to be included in the quarterly report for animal use tracking as they have already been reported to the IACUC for tracking purposes.

D. Breeding Colony Reporting Expectations:
   1. Projects with animals born under a breeding or hatchery protocol or protocols with approved breeding are required to track and report animal numbers quarterly.
      a. The reporting quarter periods are ending March 31, June 30, September 30, and December 31.
      b. These reports must be received by the IACUC within two weeks of the end of each quarter.

c. The reports are submitted through the same electronic management system form (Animal Acquisition, Transfer, and Tracking Form) indicated above for animal transfers, orders, and imports.
d. The IACUC Coordinator or designee will send a reminder email to PI's with active protocols.

2. Breeding colony numbers are generated through the following methods:
   a. Rodents and avian – number of offspring born (if doing research pre-parturition, feti will require tracking)
   b. Aquatics - once the offspring are capable of being counted and transferred out of the hatchery into the general population

E. Field Research Reporting Expectations:
1. Projects with animals observed or handled under a field or wildlife protocol are required to track and report animal numbers quarterly.
   a. The reporting quarter periods are ending March 31, June 30, September 30, and December 31.
   b. These reports must be received by the IACUC within two weeks of the end of each quarter.
   c. The reports are submitted through the same electronic management system form (Animal Acquisition, Transfer, and Tracking Form) indicated above for animal transfers, orders, and imports.
   d. The IACUC Coordinator or designee will send a reminder email to PI's with active protocols.
2. Numbers are generated through the following methods:
   a. Numbers of wild animals, by species, where their behavior was materially altered to observe for research purposes
   b. Numbers of wild animals, by species, where the animals were caught or handled for research purposes

F. Expiring Protocols
1. If a Protocol is expiring, any remaining animals must be:
   a. Transferred to a new IACUC-approved protocol for the research
   b. Transferred to a different IACUC-approved research protocol
   c. Utilized before the expiration date of the existing protocol
   d. If appropriate, adopted per CMU policy 13-7 (IACUC Policy on Adoption of Research Animals)
2. These actions must be appropriately documented in the electronic management system, contact the IACUC Coordinator for any questions regarding the appropriate documentation method.

IACUC Policy on Standard Operating Procedures for Animal Care and Use

This policy describes the expectations of the Vice President for Research and Innovation and the IACUC regarding the procedures required for acceptable evaluation and implementation of Standard Operating Procedures (SOPs) or any other reference documents that impact the Animal Care and Use Program at Central Michigan University.

I. BACKGROUND AND PURPOSE

The intent of this policy is to ensure that SOPs are used in a manner that is consistent with the requirements of the Guide for the Care and Use of Laboratory Animals (The Guide) and the expectations of the Public Health Service Office of Laboratory Animal Welfare (OLAW). OLAW offers significant guidance on the appropriate use of SOPs including the following from The IACUC Handbook, Third Edition page 238, OLAW guidance:
http://grants.nih.gov/grants/olaw/faqs.htm

> "The Guide clearly defines the animal care and use program as including SOPs and assigns responsibility for regular review of the program to the IACUC. The PHS Policy and AWARs allow the IACUC to determine the best means of evaluating the research facility's programs and facilities. The IACUC should approach this responsibility by developing a policy that gives reasonable latitude for changes deemed necessary by the animal facility management and also limits the burden to the committee. Some research facilities refer to SOPs in their training programs for scientists, research technicians, animal technicians and other personnel involved in animal care and treatment. Such SOPs should be evaluated by the IACUC to ensure that personnel are qualified to carry out their duties. Some IACUCs allow investigators to reference SOPs in their protocols rather than provide a written narrative of common animal use procedures. Such SOPs should be reviewed by the IACUC at appropriate intervals for proposed activity review (at least once every three years according to PHS Policy or semiannually, if they involve USDA-regulated species) to ensure that they are up-to-date and accurate."

The processes described below are designed to:

- Allow animal users to maintain control of their SOPs to enable the greatest degree of flexibility for implementation of required changes
- Ensures access of SOPs to animal users to minimize the chance of protocol drift (non-compliance)
- Ensure access to the IACUC to meet their obligations for review as described above and in the AWARs
- Ensure that SOPs and other reference documents are reviewed and updated at the appropriate intervals as described above and in the AWARs

II. PROCEDURES

A. Drafting Standard Operating Procedures:
   1. Anyone in the Animal Care and Use Community may draft an SOP. The individual drafting the SOP, or the faculty member whose laboratory they work in, will be considered the party responsible, or Responsible Party, for the purposes of the SOP.
   2. When drafting an SOP, animal users are encouraged to obtain a blank template from the IACUC Office. This will allow for uniformity of SOPs across the program.
   3. IACUC standard operating procedures will describe programmatic policies and are not guidelines.
   4. SOPs must be written in plain language and with enough detail that a new employee can easily understand the procedures described.
   5. Unless critical for the context of the SOP, IACUC SOPs will not include specific building references and are applicable campus wide.
   6. Electronic versions of the IACUC SOPs located on the ORC website represent the most current and accurate version.

B. Access to and Evaluation of Standard Operating Procedures:
   1. Whether developed for limited use, for multiple users, or for use by the entire animal care and use program, SOPs must be periodically reviewed. Often, SOPs will need to be revised for clarity and to comply with changes in, or in the interpretation of, animal use regulations, including PHS Policy and the AWARs.
      a. SOPs pertaining to animals covered by PHS policy must be reviewed every three years
      b. SOPs for animals covered by the AWARs must be reviewed every six months
   2. SOPs developed for limited use (single laboratory/single location):
      a. An SOP developed for single laboratory use should be made accessible to all members of the research team in the laboratory where the procedure is carried out. This can be accomplished by:
         i. Maintaining a binder of SOPs within the laboratory
         ii. By maintaining electronic copies of the SOPs on a shared drive or computer accessible to all members of the research team
         iii. The final draft can be maintained on the ORC web page
      b. If SOPs are to be referenced in an IACUC protocol, additional procedures will apply, see section C below.
   3. SOPs developed for multiple users (multi laboratory, department, or facility use):
      a. Multiple user SOPS must be made available to all researchers who will employ the procedures.
      b. The mechanisms employed to provide access can be the same as described above or can be accomplished by following the additional procedures outlined in section C below.
   4. SOPs developed for use by the entire animal care and use program:
      a. Due to their wide use, these SOPs must be made available to the entire animal care and use community.

b. Program wide SOPs must follow the additional review and access procedures outlined in section C below.

C. Additional procedures for SOPs or other documents that will be referenced in an animal care and use protocol or used by multiple users in different physical locations:
   1. To facilitate meeting their review responsibility, any SOP or other document referenced in an IACUC protocol must be accessible to the IACUC for review.
   2. Additionally, the IACUC must be able to confirm that the SOP or document has been reviewed and updated as needed in compliance with PHS or USDA policy.
   3. To facilitate access and confirmation of review, any new document or SOP referenced in an IACUC protocol or employed in multiple physical locations must follow additional steps related to evaluation and access.
      a. The party responsible for an SOP must submit the document to the Office of Research Compliance (ORC) or IACUC Office to initiate review.
      b. The SOP will be reviewed by the ORC and IACUC Office staff to ensure that it is in compliance with AWARs and in consultation with the AV to ensure it is consistent with acceptable animal care and use practices.
      c. If changes are needed, the ORC and IACUC Office will work with the Responsible Party to arrive at a final draft.
         i. The IACUC Office and ORC will provide the Responsible Party with specific regulatory references any time a change is requested.
         ii. If the regulatory reference is a requirement (a “must”) the owner will be required to edit in a specific manner to meet that requirement.
         iii. If the regulatory requirement provides non-specific direction (a “should”) the Responsible Party should decide the best approach to meet the requirement in consultation with the AV, IACUC Chair, or ORC as appropriate.
      d. The final draft can be maintained on the ORC web page.
      e. A database will be maintained by the IACUC/ORC to ensure that parties responsible for an SOP are notified when the document is due for review or update.
      f. Disputes regarding the acceptability of an SOP that cannot be resolved between IACUC leadership and the SOP’s Responsible Party will be referred to the IACUC.

D. IACUC Leadership may update policies and procedures due to administrative or regulatory change requirements.

E. IACUC Subcommittee Review Process:
   1. Existing SOP’s and policies will be reviewed and updated as per PHS and USDA policy. New IACUC policies and procedures will also be generated and reviewed similar to the process indicated below.
   2. The ORC will maintain a database with the SOP document listings and the dates of review or final approval.
   3. The IACUC Chair will create subcommittees to lead specific SOP reviews.
   4. The review process will consist of multiple stages:

a. Animal users and committee members may suggest recommendations for changes or additions to existing SOPs at any time. The responses will be provided to a SOP subcommittee for further review and consideration for implementation.
b. The subcommittee will prepare a revised draft to be presented to the IACUC Committee for review and approval. This draft will be provided to the IACUC Chair or Coordinator prior to a convened meeting to be included on the meeting agenda and allow members appropriate time for review.
c. If applicable, the Vice President for Research and Innovation and/or the General Counsel may be consulted for additional review and approval.

Note: Additional review is required for University Policies.

5. The final draft will be maintained on the ORC web page or on the General Counsel website for University Policies.
6. The IACUC Coordinator or designee will alert appropriate staff when the final version is posted.

Additional IACUC Protocol Oversight Activities

This section describes additional processes regarding IACUC review and oversight of the animal care and use program and research activities not previously communicated in this document.

I. SEMIANNUAL FACILITY INSPECTIONS

At least once every six months at least two (2) members of the IACUC will visit all of the Institution's facilities where animals are housed or used (e.g., holding areas, animal care support areas, storage areas, animal surgical areas, procedure areas, and laboratories where animal manipulations are conducted). The Beaver Island facilities are inspected only when that satellite location is open and actively housing animals (approximately May - August). Equipment used for transporting animals will also be inspected.

A. The Committee uses *The Guide* and other pertinent resources (e.g., the PHS Policy and the Code of Federal Regulations - Animal Welfare Act) as a basis for the review.

B. To facilitate the evaluation, the Committee will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

C. If deficiencies are noted during the inspection, they will be categorized as significant or minor. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

D. The Committee will develop a reasonable and specific plan for remediation or review the remediation plan and status from the responsible parties. As needed, an anticipated schedule for correction of deficiency will be included.

E. No member will be involuntarily excluded from participating in any portion of the inspections.

II. SEMIANNUAL PROGRAM REVIEWS

Twice annually the IACUC will review the Institutional Program for Humane Care and Use of Animals, this includes details regarding the full inspections of all facilities, policies, and procedures. A full report is generated and provided to the Institutional Official (IO) (see Reporting Functions below).

A. The Committee uses *The Guide* and other pertinent resources (e.g., the PHS Policy, the Animal Welfare Act) as a basis for the review.

B. To facilitate the evaluation, the Committee will complete this review utilizing the checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.

C. The evaluation will include, but not necessarily be limited to, a review of the following:
   1. IACUC Membership and Functions
   2. IACUC Records and Reporting Requirements

3. Husbandry and Veterinary Care (all aspects)
4. Personnel Qualifications (Experience and Training)
5. Occupational Health and Safety
6. Emergency and Disaster Plans

D. In addition, the evaluation may include a review of the Institution's PHS Assurance.

E. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan for remediation and schedule specific timeframe for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

F. Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.

III. POST APPROVAL MONITORING

Continuing IACUC oversight of animal activities is required per PHS Policy, and post approval monitoring (PAM) is defined by The Guide as "All types of protocol monitoring after the IACUC's initial protocol approval." (p.33)

A. Examples of PAM may include, but are not limited to:
   1. Continuing reviews are evaluated by the IACUC Coordinator or Committee review process
   2. In the course of their routine duties, the Animal Facility Managers and Veterinary team conduct monitoring activities.
   3. Mortality reports are reviewed by the Veterinary team to evaluate any trends of concern
   4. Quarterly animal use numbers
   5. Review of adverse events
   6. Concerns regarding potential non-compliance are reported to the Chair and/or ORC for further review and potential investigation
   7. Semi-annual facility inspections
   8. For-cause and not-for-cause audits conducted by the ORC and/or IACUC
   9. Review of training records

B. As protocols are only approved for a maximum of 36 months, the IACUC will review progress and intent to continue protocol activities with submission of a new protocol as detailed previously in this document.

IV. REVIEWING ANIMAL RESEARCH or WELFARE CONCERNS

All concerns regarding research activities reported in good faith are investigated cooperatively by the IACUC and ORC and are referred to the IACUC and IO as appropriate.

A. Reporting Concerns
   1. Anonymous and confidential mechanisms for reporting concerns are posted on the Office of Research Compliance and IACUC websites.

   a. Concerns may be reported directly to the Office of Research Compliance (ORC) using the "Report a Concern" online anonymous and confidential reporting tool, email or phone. These concerns will subsequently be reported to the IACUC Chair. The ORC may conduct a preliminary investigation and forward findings to the Chair.
2. Signs describing the procedure for reporting concerns are placed in animal care and use areas.
3. Reporting animal welfare concerns is also addressed as part of the training provided by the animal care personnel.
4. Central Michigan University also has selected EthicsPoint to provide a simple, accessible, confidential, and anonymous way for employees to confidentially report activities that may involve unethical or otherwise inappropriate behavior in violation of CMU policies. To file a report, there is a toll-free number or a hotline link on the CMU Ethics Hotline webpage. The hotline is managed by an outside firm, EthicsPoint.

B. No individuals, who in good faith report concerns or file a complaint, shall be discriminated against or be subject to any reprisal. This statement is supported by the President's Letter of Endorsement (February 9, 2021), the Research Integrity and Misconduct policy, and the Office of Research and Graduate Studies program for Enhancement of Employee Whistleblower Protection for Federal Grants and Contracts. The institutional policies are compliant with applicable whistleblower policies.

C. Assessment of Reported Concerns
   1. The Chair or designee reviews each concern to determine if further investigation is necessary.
   2. If a concern is found to be valid, the IACUC Chair will determine whether there is noncompliance that is minor, serious, or continuing. The Chair or designee will contact the parties involved and communicate appropriate steps for remediation.
   3. The Committee and the IO are notified of all concerns determined to be noncompliant or a risk to the Animal Care and Use Program.
   4. Where appropriate, animal care and use by the party or parties involved will be monitored to ensure compliance with university procedures.
   5. If a violation is not corrected within a specified time or the problem is too complex for immediate remedy as determined by a majority of the IACUC, then the Committee may:
      a. Immediately suspend animal care and use by the accused
      b. Notify the IO, the Department Chairperson, and the College Dean of the suspension
      c. Notify OLAW when the activity is supported by PHS funding
   6. Reported concerns and all associated IACUC actions will be recorded in the minutes of a convened meeting.
   7. The Committee will report such actions, in writing, to the IO and, as warranted, to OLAW. If necessary, initial reports to both the IO and OLAW may be made verbally.

V. REPORTING FUNCTIONS

The IACUC has responsibility and requirements to report activities and status to institutional and regulatory agencies.

A. Semi-Annual Report to the IO

1. The IACUC Chair, IACUC Coordinator, or designee, drafts the report using the sample OLAW Semi-Annual Report to the IO format from the OLAW website
2. The reports will contain a description of the nature and extent of the institution's adherence to The Guide and the PHS Policy.
3. The reports will specifically identify any departures from the provisions of *The Guide* and the PHS Policy, if any exist, and state the reasons for each departure. If there are no departures the reports will so state.
    a. Approved departures must be approved as part of a protocol, protocol amendment, or other document.
        i. For protocol-related departures, they are reviewed using either Full Committee Review (FCR) or Designated Member Review (DMR)
        ii. Program or facility-wide departures will be reviewed by the full committee.
    b. Departures from the provisions of *The Guide* that are not IACUC approved are considered deficiencies and will be addressed as such.
        i. The IACUC will develop a reasonable plan for remediation and schedule a specific timeframe for discontinuing the departure or for having the departure properly reviewed and approved.
        ii. Any departures determined to be noncompliant with PHS policy will also be reported to OLAW.
4. The reports will distinguish significant deficiencies from minor deficiencies.
    a. A significant deficiency is one that is or may be a threat to the health or safety of the animals or personnel.
    b. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan for remediation and timeframe for correcting each deficiency.
    c. The IACUC Coordinator may acts as liaison between the Committee and the Animal Facility Managers for a building in which a deficiency has been noted. In addition, progress or resolution of a deficiency may be reported at monthly IACUC meetings until the problem is resolved.
5. If some, or all, of the institution's facilities are accredited by AAALAC International or another accrediting body recognized by PHS, the report will identify those facilities as such.
6. Copies of the draft reports will be reviewed and revised as appropriate by the Committee.
7. The final report will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
8. Following each evaluation, the reports will be completed and submitted to the IO in a timely manner.
9. The IACUC Coordinator acts as liaison between the Committee and the Animal Facility Managers for the building in which the deficiency has been noted. In addition, progress or resolution of a deficiency may be reported at monthly IACUC meetings until the problem is resolved.

B. The procedure for providing the IO with recommendations regarding any aspect of the Institution's Animal Care and Use Program or animal facilities is via Committee meeting minutes, Semi- Annual Reports, or separate letters or emails.
    1. Recommendations are developed and approved by the Committee prior to being sent to the IO.
    2. In addition, specific recommendations from the Chair of the IACUC and/or the Attending Veterinarian that need immediate attention can be given at any time. Such

recommendations or actions will be reported to the IACUC at the next scheduled meeting or sooner as warranted.

C. Annual Reports to OLAW and USDA
   1. The PHS Policy require that at least once every 12 months the IACUC, through the Institutional Official (IO), must report to OLAW. The report is due by December 1st. Information to be reported includes:
      a. Any change in the institution's accreditation status
      b. Any change in the institution's program of animal care and use or facilities
      c. Any change in the IO
      d. Any changes in the IACUC membership
      e. The dates that the IACUC conducted its semiannual evaluations of the program and facilities
      f. Any minority views filed by members of the IACUC
   2. The USDA requires annual animal usage reporting every 12 months. The report is due by December 1st.
      a. Animal's covered by the Animal Welfare Regulations
      b. Animal numbers for animals covered by the Animal Welfare Regulations with separation by humane use category

References

1. Animal Welfare Act Regulations. (2018) https://www.aphis.usda.gov/animal_welfare/downloads/bluebook-ac-awa.pdf.
2. PHS Policy on Humane Care and Use of Laboratory Animals. (2015) https://olaw.nih.gov/policieslaws/phs-policy.htm.
3. The Guide for the Care and Use of Laboratory Animals, 8th ed. 2011. National Research Council of the National Academies. Washington, D.C.: The National Academies Press.

Appendix A: IACUC Copy for Amend User Guidance Document

Using the new "Copy For Amend" feature:

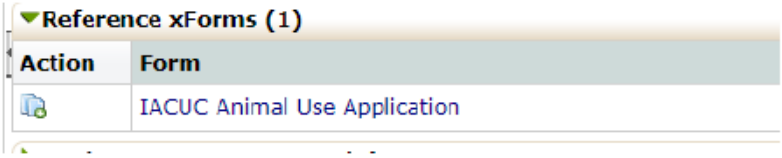
Note: this functionality will only work for new IACUC Full Applications that includes Copy for Amend (CFA).

The new version of the IACUC Full Application allows you to make changes directly to your original application, rather than having to submit a separate form (i.e. amendment xForm).

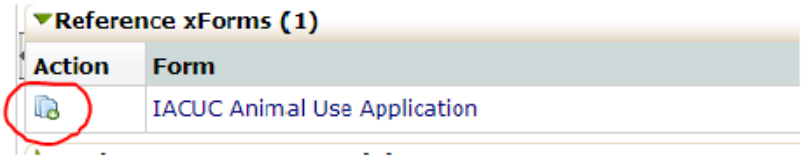
This guidance will allow you to determine whether this feature is available for your current application, and, if so, how to use it.

1. Go to "My projects" on your dashboard and select the project that you want to amend.

If your application includes the CFA functionality you will see a "Reference xForms" section in the center of your project page. This is your initial application.



2. To use the CFA feature, select the button under "Action" in the "Reference xForms" section. This will make a copy of your application for you to make revisions to.



You will be asked to update each section of the application that will be impacted by the requested changes. Make the appropriate changes where necessary.

Once you have provided a general summary of the revisions made and revised the appropriate sections of the application, you may then submit the application as normal, for review. Those sections of the application that you have changed will now be highlighted in yellow.

If you do not see any of the options mentioned above, then you are more than likely working with an old version of the application/form.

This will still require you to submit a separate xForm form by following the same steps as you have done previously.

If you encounter any issues with this form, immediately reported these issues via email to IACUC_Admin@cmich.edu or by calling 989-774-7313.

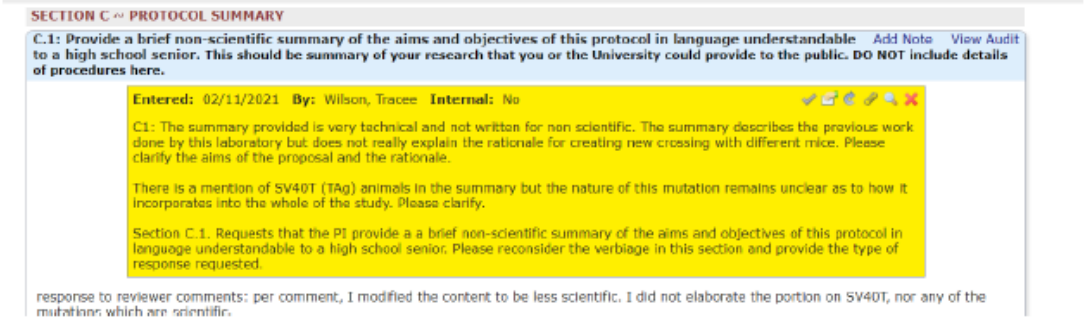
Appendix B: Guidance for Using the View Audit Feature in IRBManager

Guidance for Using the View Audit Feature in IRBManager

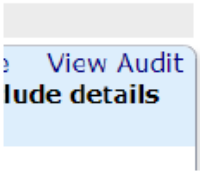
Note this feature will work for all xForms in IRBManger

This guidance will help you use the View Audit feature in IRBManger, which will show changes made within any xForm section.

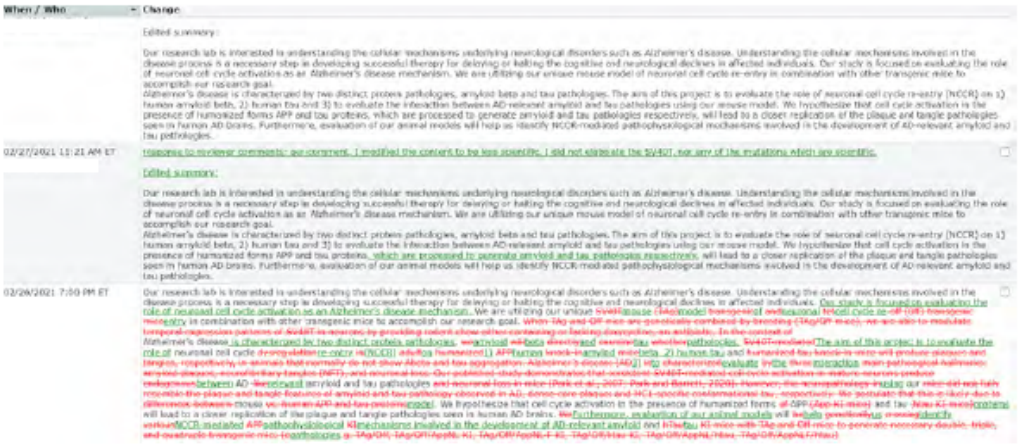
1. After opening an xForm in IRBManager, go to the form section in which you want to review changes.



2. In the top right-hand corner of the selected section, select "View Audit".



3. The audit will provide a complete list of all changes made to that section. Removed items will be listed in red and will be crossed out, and added items will be listed in green and underlined. The most current information for this audit will be at the top of the list.



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