

**Eastern Washington University
Institutional Animal Care and Use Committee (IACUC)**

INSTRUCTIONS FOR COMPLETING THE IACUC “PROTOCOL REVIEW FORM”

- By federal regulations, before any experimental procedures involving vertebrate animals at EWU can be done, an approved IACUC Protocol Review Form is required.
- The Protocol Review Form (PRF) is available on the EWU IACUC Website (<https://inside.ewu.edu/ogrd/compliance/animal-care-use/>) and Canvas site (<https://canvas.ewu.edu/courses/1347572>).
- The PRF should be written so it is understandable to a nonscientists.
- Questions should be addressed to Dr. David Daberkow, Chair of IACUC Committee (ddaberkow@ewu.edu or 509-359-2780).
- Email the completed PRF to Dr. David Daberkow and Charlene Alspach (ddaberkow@ewu.edu; calspach@ewu.edu).

Title:

- Provide a title that is clear, concise, and encompasses all aspects of the project.

Faculty Supervisor/Principle Investigator:

- Each IACUC protocol requires a designated faculty member to serve as the Faculty Supervisor (or Principle Instigator).

Contact person:

- Each IACUC protocol requires a designated contact person for more information and/or to address IACUC reviewer’s concerns.
- The contact person can be the Faculty Supervisor or another person involved in the project (i.e., other faculty, graduate student, or primary undergraduate research assistant). However, the Faculty Supervisor must be aware of (and approve) all revisions and protocol versions.

Project type:

- Identify (with an “X”) the project type.
- For class projects, identify the department code and course number (e.g., Biol 490).

Project dates:

- Identify the projected/anticipated project start and ending dates.
- Note: Once approved, most protocols are good for three years. If the project dates change while the protocol is still active, submit a protocol amendment (see page 6).
 - Non-USDA covered species protocols are valid for three years from the date of approval. It is a violation of the Office of Laboratory Animal Welfare (OLAW) and the Public Health Policy to work on an expired protocol. Any non-compliance must be reported.
 - Protocols involving USDA covered species need to be renewed yearly.

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- USDA covered species include all warm-blooded animals except laboratory rats, mice, and birds.

Grant funding:

- If the project is supported by grant funding please indicate the source of the funding, grant number, and if the grant proposal includes funds for the mammal or aquatics facilities at EWU.

Permits:

- If the project requires any permits, identify the specific permit type and date of acquisition (or anticipated acquisition date). Also, include the permit number, if possible).

USDA covered species:

- Amphibians, fish, and laboratory rats, mice and birds are not USDA covered species.
- The USDA defines ‘covered species’ as any live 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, testing, experimentation, or teaching. This term *excludes birds, rats of the genus *Rattus*, and mice of the genus *Mus** bred for use in research.
- Protocols involving USDA covered species need to be renewed yearly.
- Protocols not involving USDA covered species are good (active) for three years; however, if changes occur within the three years (including changes in personnel) a protocol amendment must be filled out and approved (see page 6 of these instructions).

I. Purpose of the project:

- Start this section by briefly (in 1 or 2 sentences) stating the project’s overall purpose (or research/teaching objective).
- After the “purpose statement”, provide the most relevant general information justifying the scientific merit of the project and/or educational intent.
- Also, include any additional information (paragraphs) needed for IACUC reviewers to understand the background related to the purpose of the project.
- Cite scientific references, whenever appropriate.
- Research projects should also include a hypothesis(es) statement(s).
- If the purpose and hypothesis(es) are not clearly stated for research projects, the protocol may be returned to the authors for revisions to clarify and clearly state the purpose and hypothesis(es) of the research project.

II. Animal information and justification:

- State specific animal species (and/or strain).
- Explain (justify) why these specific animals (choice of species) are required/requested.
- State animal gender(s).
- If appropriate, state animal ages (or age range).

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- If appropriate, state the average size/weight of the animals.
- State the total number of animals required/requested. If applicable, the number of animals per group should also be identified (e.g., n=10, rats per group).
- Justify how the number of animals (total and group) was determined (e.g., by statistical rationale and/or referencing similar studies from the scientific literature).

III. Animal housing, general care and comfort:

- Location – The specific building and room number the animals will be housed.
- Light/dark cycle – The light/dark cycle the animals will be kept on and how the cycle will be controlled. State “natural light/dark cycle”, if appropriate.
- Feeding – How and what the animals will be fed and provided access to water. State “*ad libitum*”, if appropriate.
- Temperature – The specific temperature range the animals will be kept at and how the appropriate temperature will be maintained.
- pH – For aquatic organisms, state the pH range of the water and how it will be monitored and maintained.
- Cite references, when appropriate (e.g., suitable temperature and pH for aquatic organisms).
- Contact Dr. Mike Satterwhite (email: msatterwhite@ewu.edu) for questions related to the housing of animals in the EWU Department of Biology vivarium.

IV. Describe and justify all methods and procedures to be done with the animals:

- Be complete:
 - e.g., Explain why the methods are necessary to achieve the goals of the project.
 - e.g., If blood samples will be taken, include technique, volume, and frequency.
 - e.g., If drugs will be administered, include dose or dose range (i.e., in mg/kg), route of administration, and frequency.
 - Cite the scientific literature, whenever appropriate (e.g., drug dose and regimen).
 - Unique feeding procedures that deviate from general/standard care (e.g., food and/or water restrictions or socialized diets, duration of treatment, and how the animals will be monitored to ensure proper health and nutrition).

V. Pain and/or discomfort management:

- Explain any circumstance when animals will experience discomfort, distress, pain or injury.
- Explain procedures to alleviate discomfort, distress, pain or injury.
- Explain any use of tranquilizers, analgesics and/or anesthetics (identify drugs by name/class).
- Explain any provisions for special care or housing.
- Explain plans for post-surgical care, if applicable.
- Explain any use of restraint devices/methods, if relevant.

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- Note: Student projects involving more than momentary pain should be discouraged. If proposed, these projects need to be strongly justified and supported by the scientific literature.

VI. Euthanasia or final animal destination:

- If animals will not be euthanized, describe what will be done with the animals at the conclusion of the project.
- If animals will be euthanized, describe the specific euthanasia method and who will perform the euthanasia procedure.
- All euthanasia procedures need to be performed by someone well trained in the technique or assisted by someone who is an experienced expert.
- In all cases a secondary method of euthanasia should be administered, if possible.
- For more information on procedures for animal euthanasia at EWU contact Dr. Mike Satterwhite (email: msatterwhite@ewu.edu)

VII. Irregular EWU vivarium working hours:

- Class student projects should be done within regular vivarium operating hours (M-F, 8am - 5pm).
- If work needs to be conducted outside of normal hours, a supervisor (i.e., class instructor, TA, or other authorized personnel) is required to be present.
- Describe why this work needs to be done outside of normal operating hours.
- State who will perform the procedures after hours.
- State who will supervise procedures after hours.
- Faculty and/or graduate student research done outside do not require additional supervision (as long as the person performing the procedures is qualified and experienced); however, work outside of normal vivarium hours should still be explained and justified.

VIII. Experimenter health and safety:

- Explain any human safety hazards that are involved in the project and detail how experimenter safety will be ensured.
- If any hazardous chemicals (or materials) are required for the project, explain specifically what the hazards are and how experimenter health and safety will be safeguarded.
- If hazardous or toxic chemicals are going to be used, explain how they will be safely used and properly discarded (according to EWU Environmental Health and Safety standards).
- Before using and/or discarding any hazardous chemicals, John Shields needs to be consulted (EWU Dept. of Biology Safety Officer, email: jshields@ewu.edu).
- If appropriate (determined by John Shields), an S.O.P. (standard operating procedures, approved by John Shields) form for all hazardous chemicals should be included with the submission of the protocol.

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IX. Students:

- For research projects (class or faculty/grad student research), list each individual directly involved and include their full name, EWU ID number, email, and phone number.

X. Training and experience:

- Describe the training and/or experience the individuals implementing the project have for the procedures described in this protocol (e.g., IACUC training modules posted on the EWU IACUC Canvas site; <https://canvas.ewu.edu/enroll/W6JDKH>).
- There are five IACUC training modules on the EWU IACUC Canvas site: (1) Introduction to Animal Care and Use, (2) EWU Vivarium, (3) Field Studies for Mammals and Birds, (4) Car and Use of Ectothermic Vertebrates, (5) Aquatics Facilities. Everyone should review module 1 and additional modules should be reviewed if applicable.
- If future training on any of the described procedures will be needed, explain the training and who will perform the training.

XII. Literature cited:

- Use a typical scientific format for in-text citations (e.g., Daberkow et al., 2013) and reference list/bibliography (i.e., for journal articles include: authors, publication date, title, journal, volume, and page numbers).

e.g., Daberkow DP, Brown HD, Bunner KD, Kraniotis SA, Doellman MA, Ragozzino ME, Garris PA, Roitman MF (2013) Amphetamine paradoxically augments exocytotic dopamine release and phasic dopamine signals. *J Neurosci* 33:452-463.

XI. Figures and tables (optional):

- Include any figure(s) and/or table(s) that are relevant to the project and would help the IACUC reviewers understand the project's purpose and procedures.

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TO MAKE A CHANGE (AMEND) AN ALREADY APPROVED IACUC PROTOCOL

- Once approved, most protocols are good for three years (protocols involving USDA covered species need to be renewed yearly).
- If a change to an already approved (“active”) protocol is needed (e.g., personnel, treatments, procedures), a protocol amendment needs to be submitted and approved.
- As of spring quarter 2016, approved protocols will have an amendment section at the end (orange box at the end of protocol review form). If you have a previously approved protocol (within the last 3 years) that does not have this amendment section, contact Charlene Alspach (calspach@ewu.edu).
- Complete this amendment section at the end of the active protocol, make any necessary revisions to the protocol (via Microsoft Word track changes), and email it to David Daberkow and Charlene Alspach (ddaberkow@ewu.edu; calspach@ewu.edu).
- You should receive a response within a week of submitting an amendment.
- The U.S. Department of Agriculture requires that *significant changes to protocols involving animals be reviewed and approved by the IACUC Chair prior to implementation.
- Examples of changes considered to be *significant include:
 - changes in personnel
 - increase in animal numbers
 - change in animal housing (method and/or location)
 - change in method of animal identification
 - changes in experimental substances, anesthesia, analgesia, or sedation
 - changes in duration, frequency, type or number of procedures performed
 - addition of noninvasive techniques or sampling/analysis
 - change in blood collection technique
- Once the amendment is approved, the Faculty Supervisor will be notified via email and the project amendment can be implemented.
- *General rule:* if an amendment to an active protocol involves changing the overall purpose of the project, a new/separate protocol should be submitted for full review.

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IACUC PROTOCOL REVIEW PROCEDURE

Note: please allow 2-4 weeks for the review of IACUC protocols.

1. Faculty (or individual) planning a class or research project involving vertebrate animals need to complete an IACUC Protocol Review Form (PRF) in its entirety.
2. Once completed, the PRF should be emailed to the IACUC Chair, David Daberkow (ddaberkow@ewu.edu) and Charlene Alspach (calspach@ewu.edu, Executive Director, Grant and Research Development).
3. IACUC reviewers will be designated and a timeline for review planned.
4. The protocol ("version 1") will then be emailed to the IACUC reviewers and the protocol's Faculty Supervisor will be included in the email list.
5. The reviewers will read the protocol and incorporate any edits (via Microsoft Word track changes), comments or questions (via Microsoft Word, under Review tab > new comment) that they deem appropriate.
6. Process for posting reviewer's edits/comments and responding to edits/comments:
 - a. After reviewers have reviewed the protocol and approved it or added edits/comments to the protocol (Word document), **SAVE it as the next version in the sequence** (i.e., version 2, version 3, etc.) followed the persons initials.
 - b. Reviewers will send all edits/comments back via **Reply All** so that everyone has a chance to view the revisions and comment as necessary.
 - c. The protocol's Faculty Supervisor will look over all edits and comments and provide any necessary responses to reviewer comments (via Microsoft Word, under Review tab > new comment) and make any necessary changes to the protocol (via Microsoft Word track changes). The Faculty Supervisor will then save the protocol as the next version in the sequence (followed by their initials) and send (email) the modified document via **Reply All**.
 - d. IACUC reviewers may approve a protocol at any time in the process; indicate 1 in the in the APPROVAL section of the form and add the date, SAVE as the next version (as outlined above).
 - e. Note: If students are involved in the research project, the students may (and in some cases should) be involved in the IACUC protocol review process but only under the direction of the Faculty Supervisor. Importantly, the Faculty Supervisor is required to approve all responses to reviewer's comments and protocol modifications. Additionally, it is the responsibility of the Faculty Supervisor to make the protocol (and each revised version of the protocol) available to the students and will be in charge of email correspondence with the IACUC reviewers (as outlined above).
7. Once all comments are satisfied and the protocol is approved by all reviewers, the Grants Office Staff will provide official notification that the protocol has been approved so the investigators can begin research. Note: Research can begin on the date that the protocol is approved by all assigned IACUC reviewers.

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8. All protocols will be entered onto a quarterly tracking sheet to guarantee that status will be monitored and to ensure timeliness of reviews.
9. The Grants Office will maintain the tracking sheet recording the status of all protocols and maintain all records and Animal Care documents to ensure federal compliance.