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Institutional Animal Care and Use Committee Protocol Review Form for Research, Teaching, or Pilot Studies

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Version September 2020

PROTOCOL NUMBER:
PI/INSTRUCTOR NAME:
PROTOCOL TITLE:

OFFICE OF RESEARCH COMPLIANCE
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
PROTOCOL REVIEW FORM FOR
RESEARCH, TEACHING, OR PILOT STUDIES

This protocol form is for research, teaching, or pilot studies using vertebrate animals. Husbandry (breeding and production) of vertebrates solely for the purpose of supplying animals for research, teaching or pilot studies requires a different documentation form (found on the IACUC website). This form is for a new protocol. To amend a currently approved protocol, use the protocol amendment form (found on the IACUC website).

Things to remember when completing the protocol:

- The protocol must be written so that it is understood by an audience of educated nonspecialists.
- For assistance, read the guidance for completing the protocol.
- Call Paula Portalatin (1-2657) if you have questions (or email umric@maine.edu)
- Submit the completed protocol to the Institutional Animal Care and Use Committee via email to umric@maine.edu.
- All personnel named in the protocol must complete the web-based training in animal welfare (Note: protocol approval will not be granted until all personnel have completed the training.)
- Remember: activities may not begin until you have received IACUC approval from the Office of Research Compliance.

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1. Principal Investigator/Instructor and Co-Investigator(s) (NOTE: faculty or professional staff **only**):

   PI/Instructor Name:
   Department:
   Phone:
   Email:

   Co-PI/Co-Instructor Name:
   Department:
   Phone:
   Email:

Include same information if more than one Co-PI/Co-Instructor

Will any non-UMaine personnel handle or have responsibilities for the animals (i.e., collaborations)? ☐ No ☐ Yes. If yes, please name personnel below with his/her affiliation. An Inter-Institutional Agreement may be required.

2. Title and number of course/Title of project:

3. Funding agency for project, if applicable:
Please attach the vertebrate animal (VA) section/methods section from the proposal. If multiple agencies are involved, please send only the VA sections that specifically relate to this protocol.

4. Briefly describe the (check appropriate category) ☐ research, ☐ teaching, or ☐ pilot study objectives **(not procedures)** that involve use of animals. Describe these objectives in non-technical language. Do not paste in sections of grant proposals.

5. Describe how this use of animals contributes to the advancement of knowledge that may eventually benefit humankind and/or animals.

6. Total Animals and Pain Classification: Tabulate the total number of animals per species, life stage (e.g., larval, adult, all) and USDA pain classification. **Do not list animals in combined categories (e.g., C/D)**. Indicate if these individuals are genetically modified (e.g., knock-out or transgenic). Individuals should be accounted for only once, under the highest pain classification planned for their use (see USDA pain classification for classification definitions and examples). Breeding and maintenance colonies used to produce or hold study subjects are generally not included in these numbers, unless this protocol requires significant deviations from approved husbandry practices (see husbandry protocol for associated colony). Any future increases to these numbers require an approved amendment. (NOTE: to add rows, right-click within table, click on "insert" and choose "insert rows above" or "insert rows below")

Species (Scientific Name/Common Name)	Stage(s)	USDA Class (B, C, D or E)	GMO (Y/N)	3 Year Total
			PROJECT TOTAL:	

Mandatory Requirements for Classification D or E:

a. Veterinary Consultation: A consultation is required **before the protocol is submitted**. Please email or phone Dr. James Weber (1-2774, jaweber@maine.edu) with a description of the proposed procedures.

   Date of veterinary consult:

b. Search for Alternatives: Federal law requires that the PI conduct a documented search for alternatives to these procedures. This includes a written narrative describing the written and electronic sources surveyed to identify potential alternatives to painful procedures. Complete the required form for this search found at the end of this document.

7. State the rationale for use of this/these species and life stages. Address the issue of replacement by explaining why educational or research objectives cannot be met by the use of nonvertebrate animals, cell or tissue cultures, or non-animal systems. (Please note: the IACUC does not consider "hands-on experience" to be in and of itself an adequate educational objective, unless the course serves students whose anticipated educational and professional futures will require the skills imparted through such hands-on experience. If that is true in this instance, please describe the student population that typically enrolls in the course.)

8. Justify the number of animals with respect to your overall project design:

   a. Study Groups (e.g., treatments and replicates): Briefly outline the specific groups or treatment types that comprise your project. Describe the role each of these groups performs with respect to your specific project objectives/hypotheses (e.g., control or

comparison to another treatment). Indicate whether and how these groups would be replicated.

b. Sample Sizes: Provide a rationale for the number of individuals (per study group or replicate) based on the specific inferential methods to be used. Address the issue of reduction by explaining why the proposed number individuals is sufficient, but not excessive. A simple statement that the number proposed is required for statistical significance is not an adequate response. Formal power analyses often provide the most direct and informative rationale, and are useful in assessing sample sufficiency even when numbers are logistically limited by captures, space etc. See How to do a Power Analysis regarding doing a power analysis. If a rationale is based on comparison to prior studies, or specific recommendations for a field, provide relevant citations and justify how the current design compares to those contexts. In the case of pilot studies, meaning investigations conducted for the express purpose of determining suitable approaches and sample sizes for future research, justify your numbers in terms of those objectives.

c. Summary: Provide summary formula(s) that clearly depict how the numbers of individuals listed in #6 above are obtained as a product of the number of study groups, replicates and sample sizes presented in 10a and 10b. (Example: 500 adult zebrafish = 5 exposure groups (including control) * 2 time points * 50 individuals per group). Consider providing a table or figure to indicate numbers per treatment and experiment.

9. Procedures

The Committee does not wish to receive copies of research proposals or laboratory manuals. The Principal Investigator or Instructor is asked to address succinctly the following questions, as applicable. Special care should be taken to justify any procedures generally discouraged by the University's code of ethics and policy.

a. Major categories of procedures. Please check the appropriate box for **EACH category**.

Any "yes" responses must be described in sections b. (nonsurgical procedures), c. (surgical procedures) or d. (euthanasia) that follow.

Yes	No		Categories
☐	☐	1.	collection or capture (provide details under section 12)
☐	☐	2.	nonsurgical marking, tagging, or device attachment
☐	☐	3.	antibody production: describe antigen, adjuvant and route of immunization
☐	☐	4.	noninvasive physical or physiological measurements
☐	☐	5.	dietary manipulations

☐ ☐ 6. pharmacology/toxicology: material used, route of administration, etc.
☐ ☐ 7. blood draw, biopsy or other nonsurgical tissue collection
☐ ☐ 8. behavior studies
☐ ☐ 9. environmental stress, e.g., temperature, restraint, forced exercise
☐ ☐ 10. irradiation: type, facility to be used
☐ ☐ 11. hazardous materials, e.g., carcinogens, radioactive materials, immunogens and teratogens
☐ ☐ 12. biohazardous or infectious agents (use of Class 2 or higher agents requires the approval of the University's Biosafety Committee). Description must include precautions to restrict the spread of biohazardous or infectious agents to non-target animals or humans.
☐ ☐ 13. experimental trauma, e.g., planned injury, significant behavioral stress
☐ ☐ 14. anesthesia/sedation/immobilization (describe in sections 11 b or 11 c)
☐ ☐ 15. nonsurvival surgical procedure
☐ ☐ 16. survival surgical procedure (animal is allowed to recover for any length of time)
☐ ☐ 17. multiple major operative procedures from which animal is allowed to recover
☐ ☐ 18. planned euthanasia (describe method in section 11 d, e.g., harvest tissue, necropsy, etc.)
☐ ☐ 19. other, **specify**:

b. Nonsurgical Procedures (**Categories 2-14 and potentially 19**):

1. **USING THE ABOVE NONSURGICAL CATEGORIES MARKED "YES" AS HEADINGS**, provide a succinct description of the procedures to be conducted on live vertebrate animals. Specify any drug(s), including adjuvants, doses (including frequency) and routes of administration (if you are using several substances, create a table with the required information – see guidance for completing the protocol for example). Specify duration of procedures. Include any monitoring procedures used to ensure effective anesthesia/sedation or recovery from other nonsurgical procedures.

   Example (remove example before submitting to IACUC):
   4. Noninvasive physical or physiological measurements: fish will be weighed and measured and then immediately released; procedure should take 2-3 minutes.

c. Surgical Procedures (**Items 14-17; and potentially 19**):

1. **USING THE ABOVE SURGICAL CATEGORIES MARKED "YES" AS HEADINGS**, provide a succinct description of the surgical procedures to be conducted on live vertebrate animals. Specify any drug(s), including adjuvants, doses (including frequency) and routes of administration (if you are using several substances, create a table with the

required information – see guidance for completing the protocol for example). Specify duration of procedures. Be sure to include any monitoring procedures use to ensure safe and effective anesthesia/sedation.

Example (remove example before submitting to IACUC):
16. Survival surgical procedure: Following anesthesia, a 2cm incision will be made anterior to the pelvic fins…

2. Is animal allowed to regain consciousness after surgery? Yes/No

3. Describe the postsurgical monitoring and care procedures, including what response(s) you will look for to indicate recovery or deterioration and the frequency of observations. Indicate dosage or frequency of any analgesics, other drugs, or pain relieving measures that will be used post-operatively.

d. Euthanasia (**Both questions must be answered**):

1. Will the animals be killed as part of the study design or at the conclusion of the study?

   Yes/No.

   If yes, how will this be accomplished (include dosages/duration if applicable) and verified?

2. If euthanasia becomes necessary due to unplanned injury or illness to the animal(s), how will it be accomplished (include dosages/duration if applicable) and verified? *

*See the 2020 Report of the AVMA Panel on Euthanasia for assistance. NOTE: When possible, euthanasia should be conducted in a place or fashion that minimizes the potential for cues that could cause distress in other animals (e.g., outside housing room or in an isolated chamber or container).

10. Animal Sources: Please indicate source of animals. Note: The IACUC will approve animal purchases from a licensed pet store provided the researcher/instructor informs the pet store (in writing) that the purchased animals will be used for research/teaching.

a) ☐ Purchased/conveyed from a company/other institution (please answer the following)

1. What are the specific planned commercial or institutional sources?

2. Are Federal permits required? If so, does source hold permit or is PI securing permit? Please provide brief explanation. **NOTE: Permit documents must be made available if requested by the IACUC.**

3. If the purchase/conveyed species is **non-native** to Maine, please complete section 6.ii., below.

b) ☐ Captured from the wild (please answer the following)

1. Where and when will the animals be captured?

2. What specific capture gear will be employed (nets, traps, electrofishing etc.) and how will it be operated (e.g., frequency of net or trap checks). Include information how often traps checked, how long animal(s) will be in trap, how non-target species will be avoided or handled if captured (e.g., immediately released, euthanize, weigh/measure).

3. What steps will be taken to protect animals from exposure or other danger during collection?

4. Please include your plans for removal of traps, barriers or other gear from the field site.

5. If your field study protocol includes trapping, please indicate at least two people who can be contacted to respond to a reported animal care emergency at your trapping location:

Primary person to contact in case of an emergency =
Office phone =
Home phone =
Cell phone =

Secondary person to contact =
Office phone =
Home phone =
Cell phone =

Tertiary person to contact =
Office phone =
Home phone =
Cell phone =

6. Indicate if Federal permits are required and whether they have been obtained. **NOTE: Permit documents must be made available if requested by the IACUC.**

7. State Permit for Native/Non-Native Wildlife and Freshwater Fish Species (please review the guidance for completing the protocol prior to answering the questions below):

   NOTE: Marine fish require a state permit from the Maine Department of Marine Resources (MDMR) issued to the individual researcher. Contact Amanda Ellis amanda.ellis@maine.gov for more information about the marine fish permit.

   i) For use of **native species**:

   _____The species/number/purpose for wildlife or fish collection is included in my current annual year's permit filed with the Bangor office of Maine Department of Inland Fisheries and Wildlife (MDIFW). Note: Your department may submit one permit request for all researchers in the department. Other departments require individual researchers to submit their permit requests to MDIFW individually. Contact your department chair if you are uncertain about your department's process for obtaining an annual MDIFW research permit.

   OR

   _____The PI holds a current permit issued by MDMR for the species and proposed research. Date permit issued: _____

   OR

_____The PI is in process of making an individual request to MDIFW for a wildlife or freshwater fish permit or to MDMR for a marine fish permit issued to the individual researcher. The request must include the requested native species, number of individuals, and project purpose. (See guidance for completing the protocol for instructions on this process.)

Date request sent to MDIFW: _____

OR

Date request sent to MDMR: _____

ii. For use of **non-native species** (Read the information from the MDIFW website (unrestricted, prohibited, and restricted species), as well as see the guidance for completing the protocol for an explanation of the process for obtaining a non-native species permit and the list of unrestricted, restricted, and prohibited species:

_____Proposed species is on the "unrestricted" list; no permit from MDIFW is required.

OR

_____Species is on the Prohibited/Restricted List:

If PI is importing the species directly (not receiving it from another person who holds a current, valid importation permit):

____The species is already on the UMaine non-native species permit agreement with MDIFW. Inquire with IACUC (umric@maine.edu) to confirm.

OR

____The species is NOT on the current UMaine non-native species permit held by IACUC, but PI has obtained a current importation permit from MDIFW (**NOTE: the IACUC needs to see this permit; please attach a copy to the protocol).**

OR

_____The species is NOT on the UMaine non-native species permit. PI is in process of making an individual request to MDIFW. (See guidance for completing the protocol for instructions on this process.)

Date request sent to MDIFW: _____

_____If PI is receiving the species from another person, the contact information must be provided for the person who holds a valid importation permit from MDIFW.

Name:
Phone:
e-mail:

8. What precautions will be taken in the field to restrict the spread of pathogens among study animals or between study animals and humans?

11. Animal Care/Housing:

IMPORTANT NOTE: Investigators are expected to follow care and housing guidelines outlined in the *Guide for the Care and Use of Lab Animals* or the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching* unless special exceptions are requested and approved. If specific requirements for your animals are not listed in the Guides (e.g. some wildlife), you are expected to adhere to recommended practices of the field (e.g., as outlined by professional societies) and known biological needs of the species. All investigators working with housed animals are expected to keep records of daily care/feeding, as well as records of other periodic care (e.g., grooming, water quality, medical care) for inspection by the IACUC. Please note that it is the responsibility of the PI to be aware of drugs that require prescription and to work with the attending veterinarian (Dr. James Weber) to obtain a prescription for drugs that require one.

Will animals be housed or maintained for more than 12 hours?

☐ Yes
☐ No

If yes – answer the following. If no, skip to question #12.

a. Where will the animals be housed and maintained?

b. Does your housing deviate from the requirements of the Guides or recommended practices? If so, include a justification for an exception to the Guides for taxa covered therein. For taxa not covered by the guides, specify any other guidelines you intend to

follow, or provide a detailed description of housing and care based on your study organism's known requirements.

c. For genetically modified animals (GMAs – produced via targeted or random genetic manipulations), the Guide requires enhanced monitoring and reporting to the IACUC. If this protocol involves GMAs, describe any special care and monitoring (including frequency) that will be used to minimize known or unknown adverse effects in the genetically altered line.

d. Identify the room or facility in which the procedures will be conducted.

e. What precautions will be taken to restrict the inadvertent spread of pathogens among study animals or between study animals and humans?

f. list the name, phone number, and email of the person who should be contacted to accompany the IACUC during facility inspections:

g. Disaster Planning and Emergency Preparedness. The Guide requires that facilities have disaster plans to "define the actions necessary to prevent animal pain, distress, and deaths due to loss of systems such as those that control ventilation, cooling, heating, or provision of potable water." Safety Management, in conjunction with the IACUC and researchers, are putting disaster plans in place that meet University and individual investigator needs, include provisions for triage and euthanasia, and provide for training and contact of essential personnel. Please provide the following information:

   1. Triage: Some animals may require priority care (or euthanasia) under a facility-wide or campus-wide disaster. For example, they may have greater potential to experience severe pain or distress under disruption of services (e.g., post-operative individuals) or they may be irreplaceable in a replicate study (e.g., novel genetic lines). Do any animals used in this study require special priority for triage? If so, please describe the basis for this special priority and indicate how such animals will be made identifiable within the facility (e.g., special marks, lists).

   2. Special euthanasia: Would a different method of euthanasia than that listed in section 9.d. be used in the event of a disaster that disrupts normal services required for humane care and treatment of these animals? If yes, please describe the special method (include dosing information for pharmaceutical approaches).

3. Satellite Facility: If the facility listed under section 11.a. is not a "core" facility (Aquaculture Research Center, Center for Cooperative Aquaculture Research, Small Animal Research Facility, or the Witter Center), the facility must have an approved Satellite Facility Designation and Disaster Plan (contact the IACUC Office for the form).

   ☐ The facility under section 11.a. is designated as a 'core' facility.

   ☐ A Satellite Facility Designation and Disaster Plan is has been approved for this facility.

   ☐ I have attached a completed Satellite Facility Designation and Disaster Plan for approval.

4. Emergency Contact for the Care of Animals: (at least two people must be listed):

   Primary person to contact in case of an emergency =
   Office phone =
   Home phone =
   Cell phone =

   Secondary person to contact =
   Office phone =
   Home phone =
   Cell phone =

   Tertiary person to contact =
   Office phone =
   Home phone =
   Cell phone =

12. List all person(s) (including PI) who will handle animals (e.g., carry out the procedure(s), animal care, etc.) or provide training of personnel. For each person named below, describe what proposed procedures he/she will carry out, his/her individual experience in performing those proposed procedures (e.g., years of experience and specific skills); if none, explain how training will be obtained. (NOTE: to add rows, right-click within table, click on "insert" and choose "insert rows above" or "insert rows below") See guidance for completing the protocol for a sample.

Personnel Name	**Procedures performed**	**Years of experience and specific skills**	**Training plan (if no experience)**

13. **If this is a teaching protocol** where students will handle animals as part of course participation, please see Required Training for Students in Class on the IACUC website.

    Indicate which option you will require your class to follow to meet the training requirement:

    ☐ Students will complete the web-based tutorial (referenced above).
    ☐ Students will read the document, "Use of Animals in a Courses: What You Need to Know" (found on the IACUC website under "Training Requirement for Students…" as referenced above).
    ☐ Students will be trained by the instructor; attached is a written description of the training for IACUC review.

Risk Assessment
(Risks to researchers)

In compliance with our Public Health Service Animal Welfare Assurance, we have implemented an Occupational Health/Medical Surveillance Program. The first step will be for investigators to identify potential hazards with tasks involved with the study, so the IACUC veterinarian and Safety Management (SM) can assess the risks to determine if further information will be required from everyone named in the protocol (i.e., a health questionnaire). **NOTE:** In evaluating this risk assessment statement, we will be looking for animal care tasks that increase the risk of illness (such as a zoonotic disease), physical injury (such as animal bites), and/or allergic reactions to those handling the animals. Also consider hazards of animal excrement/hazards to workers handling the animals' bedding that may be important to an accurate risk assessment. The investigator is also responsible for sharing guidance regarding special health concerns when working with animals with all personnel listed on the protocol.

Please complete the following for your proposed protocol. See guidance for completing the protocol for a sample.

NOTE: For field studies, the Field Research Hazard Assessment/Safety Plan will be helpful in identifying possible risks)

a) Provide a brief description of the protocol (cut and paste response from question 6 of the protocol). (NOTE: Only this page, not the whole protocol, goes to SEM and the Occupational Health Physician, thus the request for duplication of the answer to question 6.)

b) List the tasks required. Add additional numbers as needed. (Examples: handling animals, administering drugs, euthanasia; field work could include driving, operating watercraft.)

1.
2.
3.

c) For each of the tasks described in b) above, list the associated hazards. (Examples; exposure to allergens, needle stick.)

1.
2.
3.

d) For each of the hazards described in c) above list how the hazards will be managed. (Examples: use of gloves and goggles, field work training.)

1.
2.
3.

After this risk assessment is reviewed, everyone named in the protocol may be required to complete a health questionnaire. The health questionnaire may require review by the Occupational Health Physician. If so, there is a charge for this review (~$45). Researchers are asked to budget for these costs in proposals for outside funding. For unfunded studies, the cost will be covered by the Office of the Vice President for Research and Dean of the Graduate School. If you have any questions regarding the completion of this page, please contact, Safety Management (SM), 1-4055, SEM@maine.edu.

SEARCH FOR ALTERNATIVES TO PAINFUL/DISTRESSFUL PROCEDURES

This form must be completed if the pain classification from Question #6 was D or E

Please read the background information on the USDA policy for painful and distressful procedures before completing this form.

The written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods.

The following information is required:

1) The names(s) of the database(s) searched (due to the variation in subject coverage and sources used, one database is seldom adequate);

2) The date the search was performed.

3) The time period covered by the search.

4) The search strategy (including scientifically relevant terminology) used and number of citations resulting from the search terms.

5) Did your database search (or other source) identify a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposed)? Yes/No.

   If yes, please explain why the alternative found was not proposed. (NOTE: The IACUC will consider this explanation, but may determine it is not adequate to justify not using the bona fide alternative.

   If no, the IACUC would like a description of the results of the database search (or other source) to document the lack of relevant alternatives.

ASSURANCES FOR THE HUMANE CARE AND USE OF ANIMALS

As the Principal Investigator on this protocol, I assure that…

1) I have provided an accurate description of the animal care and use protocol to be followed in the proposed project/course.

2) the activities proposed do not unnecessarily duplicate previous experiments.

3) all individuals named in this application who are at risk will be registered in the Occupational Health and Safety Program.

4) all individuals performing animal procedures described in this application are technically competent and have been (or will be) properly trained in the procedures to ensure that no unnecessary pain or distress will be caused as a result of the procedures.

5) I will obtain approval from the IACUC before initiating any changes to this protocol.

6) I am familiar with and will comply with the *University of Maine's Policies and Procedures for the Humane Care and Use of Animals*, and I assume responsibility for compliance by all personnel involved with this protocol.

7) I have read and will follow the appropriate guidelines for the proposed species.

8) if using laboratory animals, all personnel handling the animals have had a tetanus shot within the past ten years.

9) all applicable rules and regulations regarding radiation protection, biosafety, recombinant issues, hazardous chemicals, etc., have been addressed in the preparation of this application and the appropriate reviews have been initiated.

10) animals will be purchased only from licensed, reputable vendors. If animals are purchased form a pet store, the pet store has been informed (in writing) that the animals will be used for research or teaching purposes.

11) I will maintain appropriate animal records (e.g., census, health, veterinary care, euthanasia, surgery, diagnostic, anesthesia, etc.)

12) **I will report at once to the IACUC any unanticipated harm to animals.**

13) I acknowledge that in the event of a disaster (natural or man-made) it may become necessary to triage, euthanize or otherwise modify the care and disposition of the study animals in order to avoid unacceptable pain or distress. I delegate overriding authority for emergency decisions of animal disposition to the Institutional Veterinarian or his/her designated representative.

Submission of the protocol indicates you have read and agree to the above Assurances

REMINDER: The Principal Investigator (PI) MUST submit the protocol. Another faculty member (no students) may submit the protocol on behalf of the PI with documentation of an email exchange that the PI has read and approves. We require this because the PI is ultimately responsible for the content of the protocol submission.