

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

Please review these guidelines when preparing a protocol for research, teaching, or pilot studies.

General Instructions

- The Institutional Animal Care and Use Committee (IACUC) consists of scientists from several disciplines as well as non-scientists, members of the University community, and persons who have no other affiliation with the University than as members of the Committee. **The protocol should therefore be described in terms understandable by an audience of educated non-specialists.**
- The Principal Investigator or Instructor must justify the ethical costs of using live vertebrate animals by demonstrating a reasonable expectation that such usage will contribute to the advancement of knowledge that may eventually benefit humankind and/or animals. The Principal Investigator or Instructor must further demonstrate that he or she has applied the concepts of "alternatives" in designing the protocol. The term "alternatives" includes three components: replacement (using non-vertebrate animals, cell cultures, tissues from slaughter or autopsy, or non-animal systems); reduction (in the number of animals used); and refinement (of design and methods to reduce pain and stress to animals used as well as ensuring that the number of animals used is optimal for the analysis proposed).
- **Please submit the completed protocol to the Institutional Animal Care and Use Committee via email to umric@maine.edu. The form is due TWO weeks prior to a scheduled IACUC meeting. NOTE:** 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.
- The [meeting dates](#) are posted on the IACUC website. **Protocols received late will be held until the next month's meeting. Please call Paula Portalatin (1-2657) if you have questions.**

Guidance on Specific Questions

This section will continue to be updated as needed. Currently, specific guidance is provided for:

Questions #1, #6a, #9b.1./9.c.1, #10.b.6., #12, and Risk Assessment

Question #1 – If Principal Investigator and Co-Investigators must be faculty or professional staff. List graduate and undergraduate students under question #11, personnel.

Question #6a – Veterinary Consultation: if the pain category classification is D or E (see the [USDA pain classification](#) and examples), you must have a veterinary consult with the attending veterinarian, Dr. James Weber. **This must take place before the protocol is submitted.** Email or call him (jaweber@maine.edu, 1-2774) with a description of the proposed procedures. Dr. Weber may ask to see a draft protocol, and he may advise you to make changes to your procedures. Be sure you incorporate all changes he requests into the protocol. Be sure to add the date of the consult in the place requested on the form.

Question #9b.1 and/or 9.c.1 – The question asks you to 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. Below is a sample table:

| Agent | Dose (mg/kg) Volume Route (e.g. ip, im, po etc.) | Frequency (e.g. sid, bid etc.) and duration | Pharmaceutical grade? (If no, a justification is needed) |
|--------------|--|--|--|
| Enrofloxacin | Dose: 5 mg/kg Volume: 0.03 ml Route: SQ | Frequency: BID for 5 days | Yes |
| XYZ | Dose: 25 mg/kg Volume: 0.5 ml Route: IV | Frequency: SID for 30 days | No; Pharmaceutical grade (USP) is not available |

Question #10.b.7 – State Permit for Native/Non-Native Wildlife and Freshwater Fish Species
(how to determine needed action for this section)

Native Wildlife and Freshwater Fish Species

Is the species/number included in your current annual year's wildlife and freshwater fish permits filed with the Bangor office of Maine Department of Inland Fisheries and Wildlife (MDIFW)?

If unsure, contact your department's chair to inquire about the process used in your department to secure the annual research permit.

If Yes, so indicate, and you are done with this question. Note that the species and number handled/captured must be reported annually to MDIFW in December in your permit end-of-year report. (Note: Some departments require that individual researchers submit this report. Contact your department chair for information about your department's process for meeting this permit requirement.) Contact IACUC for more information.

If No, PI must make a permit request to IF&W **following your department's procedures**. The request must indicate the requested **native** species, number of individuals, and project purpose. Please follow the approach outlined below.

- 1) Prepare email following format below (copy items below into email and complete):

SUBJECT: Request addition to UMaine wildlife or freshwater fisheries permit for calendar year____:

PI Name, university affiliation (department/school), contact information: _____

Species name(s) and numbers of each, by life stage: _____

Brief (5-6 sentences) explaining the proposed work to be done by PI named above. Indicate the start and end dates for collections, and if the collections will be conducted in multiple years, indicate the numbers per year for each life stage.

- 2) Send email request to Brenda Lord (Brenda.Lord@state.gov) at MDIFW and copy UMaine IACUC (umric@maine.edu). Make sure your email contains your contact information, so that MDIFW can contact you directly if they have questions about your request.
- 3) Answer question #12.a.6.i. by checking the "in process" line if the request is not approved at time of IACUC protocol submission. Also indicate the date that the e-mail request was sent to MDIFW.

Non-Native Species

(Please read a summary of [Maine's rules on fish and wildlife in captivity](#) and to find the form for requesting an importation permit)

If the proposed **non-native** species is on the “**unrestricted**” list, no permit is required.

If the proposed **non-native** species is on the **prohibited/restricted list**, and you are importing the species directly:

If the species is on the current UMaine non-native species permit agreement with MDIFW, no further action is required (contact the IACUC if you are unsure if the species is currently listed on the species permit).

If the species is not on the current UMaine non-native species permit agreement with MDIFW, you must acquire a permit issued directly to you or show evidence of a permit that had been issued by MDIFW to the person from whom you are receiving the species. If you do not have a current importation permit from MDIFW for importing the species, follow these steps:

- 1) Go to the MDIF&W website, [Fish and Wildlife in Captivity](#).
- 2) Download either the Wildlife Importation Permit or the Fish Importation Permit, available on the [Fish and Wildlife in Captivity webpage](#).
- 3) Complete and e-mail the form to Mr. James Connolly, Wildlife Division Director, Maine Department of Inland Fisheries and Wildlife at this e-mail address: James.Connolly@maine.gov. **Add a note that the request is part of the University of Maine's non-native species permit. Copy IACUC (umric@maine.edu) on the e-mail to Mr. Connolly so that IACUC can assist with questions about the permit request.**
NOTE: payment is not required for research conducted by UMaine personnel.
- 4) Answer question #12.a.6.ii. with “in process” if request isn’t approved at time of IACUC protocol submission. Also indicate the date that the e-mail was sent to MDIFW.

(NOTE: *Marine fish species* require a [state permit](#) issued directly to the PI. Contact Amanda Ellis, Department of Marine Resources, amanda.ellis@maine.gov.)

NOTE: The above permit guidance applies only to species involved in research or teaching activities that require a UMaine IACUC protocol. Permits issued to the *individual* and not to the University of Maine are required for *personal use or display* of all native vertebrate fish and wildlife species and non-native species not on the State's unrestricted list.

Question #12: Personnel: examples of how responses should be given; the examples cover various types of projects (we don't expect to have a protocol with lab mice, songbirds, and fish!)

| Personnel Name | Procedures performed | Years of experience and specific skills | Training plan (if no experience) |
|--------------------------------|--------------------------|---|---|
| Jane Doe, PI | Blood Draws | 3 yrs with over 500 mice | n/a |
| John Student, Graduate Student | Bird collection | < 1 yr mist netting birds | Further training will be provided by PI. PI will directly supervise student, and he will not work independently until PI is confident skills are mastered. |
| Sally Undergrad, Undergraduate | Fish collection/handling | None | A training plan* will be implemented to ensure that she is proficient in collection/handling techniques prior to the study. She will not work independently; PI will always be present. |

*Training plan – briefly describe

Risk Assessment Guidance (Sample)

RISK ASSESSMENT EXAMPLE FOR FIELD STUDY WITH SMALL MAMMALS

(For each numbered task, provide a description of the hazard and the planned approach for managing the hazard)

List tasks required:

- 1) Setting and baiting traps
- 2) Anesthetizing/euthanizing small mammals
- 3) Handling small mammals
- 4) Walking through tick and mosquito habitat
- 5) Travel to and from study site

For each task described above, list associated hazards

- 1) Potential for cuts/abrasions from metal traps.
Exposure to infectious agents left from animals (urine, feces etc.)
- 2) Direct contact with [list anesthetic] and/or inhalation of [list anesthetic]
Transport and disposal of anesthetic
- 3) Biting and scratching from animals.
Exposure to zoonotic pathogens.
- 4) Exposure to tick and/or mosquito pathogens
- 5) Unable to get prompt emergency services at field study location, limited road access, nearest medical facilities over 1 hour away.

For each of the hazards described above list how the hazards will be managed.

1) Cuts/abrasions from traps: Traps will be maintained to minimize risk of injury. A first aid kit will be available in the vehicle. Soap and water will be available in the vehicle to clean wounds. In the event of a wound, the area will be washed thoroughly with soap/water and proper first aid measures will be applied.

Exposure to infectious agents left from animals in the trap: After capturing and processing animal all materials will be removed from the trap. The trap will be wiped down with a bleach solution to disinfect. Nitrile gloves and masks will be worn at all times.

2) Direct contact with / inhalation of isoflurane: Isoflurane will be kept in a sealed container in a locked box in the trunk/truck-bed of the vehicle. Use of isoflurane will be done outside to minimize risk of inhalation. A second person will be on-hand in the event of spill/contact. Nitrile gloves, goggles, and a mask will be worn while handling isoflurane. In the event of direct contact with isoflurane, skin/eyes will be immediately flushed with water and medical attention will be sought.

3) Biting scratching from animals: Nitrile gloves will be worn while handling the animals. Kevlar gloves will be available to personnel. We will encourage the use of Kevlar gloves whenever possible. [If Kevlar gloves cannot be used you need to explain why]. In the event of an animal bite/scratch, the animal will be placed back into the trap, the bite/scratch site will be scrubbed with soap/water for 5 minutes and assessed. For minor wounds an antibiotic cream will be applied and the bite will be bandaged. For deeper punctures with bleeding, pressure will be applied and medical attention will be sought.

Exposure to zoonotic pathogens: Nitrile gloves will be worn while handling animals/traps. Equipment (forceps, scissors, etc.) will be wiped down with ethanol or a bleach solution between traps. All personnel involved in this project will be up to date on tetanus vaccines.

4) Exposure to mosquito and tick-borne pathogens: Participants will be instructed to wear long pants tucked into their socks and check daily for ticks and tick bites. Insect spray will also be made available for use on the face and exposed skin. Participants will be encouraged to wear permethrin-infused clothing. Participants will be given a brief training on the risks of mosquito and tick-borne diseases and the typical signs of the diseases. Participants will also be directed to the [Maine CDC Website](#) to obtain additional information.

5) Establish communication plan with xxxxx using radio/cell phone/satellite phone. Training in first aid/CPR for all members of team. First Aid kit and/or Wilderness First Aid kit included in equipment inventory.