# Ornithological Council

UPDATE AUGUST 2017

*The Ornithological Council and the American Society of Mammalogists developed this protocol form, designed specifically for wildlife research conducted either in the field or in captivity, in 2014. This August 2017 update incorporates important changes resulting from a Memorandum of Agreement between the National Science Foundation (NSF) and the Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health that calls for OLAW to oversee animal welfare compliance for NSF-funded research. To help IACUCs and researchers determine how the two animal welfare laws apply to wildlife research conducted in the U.S. (or outside the U.S. with funding from U.S. funding agencies), we have incorporated a comprehensive explanation that has been reviewed and approved by both OLAW and NSF. That statement, which was reviewed and approved by both OLAW and NSF, is found in Appendix B. Because the laws are overlapping but non-identical and become applicable subject to different criteria, most studies will be subject to parts of each law. For instance, institutional registration may be required under the Animal Welfare Act and/or an Animal Welfare Assurance may be required under PHS Policy, both laws require protocol review but the specifics as to covered taxa and procedures vary, and both require annual reporting but as to different taxa and different types of reports. We strongly encourage the researcher and the IACUC to review Appendix B before completing this form and reviewing the protocol.*

*We have also included an update on the status of the long-pending and now-defunct "rats, mice, and birds" regulation that had been in development at the USDA APHIS Animal Care program. That information appears in Appendix C.*

*All new material is denoted by the date, August 2017.*

PREAMBLE, AUGUST 2016

We recognized a need for this form as a result of feedback from the many IOs, IACUC members, and attending veterinarians who attended the conference we organized in Albuquerque (October 2011) to examine Animal Welfare Act compliance for studies of wildlife. It was our goal at that meeting to foster a robust conversation among researchers, IACUC members, and government officials that would lead to more meaningful and appropriate application of animal welfare laws in the context of wildlife research and, in turn, to improved care and use of wild animals in wildlife research. Nearly every participant suggested a need for a protocol form specific to wildlife because of the wide differences between biomedical and wildlife research, particularly when the latter is conducted in the field. Given that there are two overlapping laws, administered by two different agencies, one (APHIS) with a set of implementing regulations and the other (PHS) with a non-regulatory but mandatory policy, we took care to construct this form in a manner that will guide the IACUC and the researcher to the pertinent laws and standards.

A number of conference participants volunteered to help create this form and suggested key topics and specific questions as well as overall approach. After reviewing numerous forms that

were already in use, we were fortunate to be given a template created by John Martin of the U.S. Fish and Wildlife Service, later modified by John Bryan, DVM, a wildlife veterinarian with the National Park Service. After considerable review and revision, we are making this form available to IACUCs and researchers in what we are calling a beta version, though it is fully useable as is. It is our hope that you and your research staff will use this form, and that as you do so, you will take the time to suggest changes to us so that we can refine it to better meet the needs of both the researchers and the IACUCs. With this additional feedback from the field-testing, we hope to have a final version completed by the end of 2014.

For institutions without a protocol designed specifically for studies involving wildlife, this document can serve as a stand-alone form. Institutions that already have a protocol form designed for wildlife may incorporate any portions of the form to complement their existing document.

Of course, you may also modify the form as you see fit, but we encourage you to let us know what changes you have made and why, as this will help us to improve the final product. We suggest that it would be most efficient to use SmartForms or other electronic options that automatically bypass questions that do not require additional input when the initial question was answered with a "no" or "not applicable." Doing so will enable the researcher to move efficiently through the form.

We also encourage you to take full advantage of the additional resources available to you when assessing wildlife protocols. These peer-reviewed documents include the taxon specific guidelines published by the American Society of Ichthyologists and Herpetologists, the American Society of Mammalogists, and the Ornithological Council. These documents were formally recognized by NSF in December 2012 as appropriate standards for NSF funded research conducted on wild vertebrates and were also recognized by AAALAC International as Reference Resources.

We look forward to your feedback.

Sincerely,

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Development of this model protocol was supported, in part, by the National Science Foundation under Grant No. IOS 113273. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation.

**Suggestions for IACUCs**

- Critical review of protocols involving wildlife research requires the use of appropriate standards. Standards and protocol forms not developed for wild animals cover many topics not pertinent to wildlife studies and omit topics central to such work. In order to conduct a more biologically appropriate review and achieve a greater level of meaningful welfare for the study animals IACUCs should ensure that protocol forms, standards, and reference materials are appropriate for the type of study under consideration, be it biomedical, agricultural, or wildlife.
- Understanding the scope of applicability of an institution's Animal Welfare Assurance ("Assurance") is essential for compliance with PHS policy. All activities funded by the PHS must be conducted in a manner that is consistent with a single standard, the ILAR *Guide for the Care and Use of Laboratory Animals*. If the Assurance is written such that it covers activities regardless of funding source, then all activities with covered animals must be conducted in a manner consistent with the *Guide*. However, if the Assurance is written such that it is restricted to PHS-funded activities, then other standards, such as taxon-specific guidelines, are allowable for non-PHS funded activities.
- Institutions are encouraged to include one or more individuals with wildlife expertise on the IACUC. Where appropriate expertise is not locally available, IACUCs should consult outside sources familiar with the taxa and questions posed.
- The institution should ensure that a process is in place to determine whether or not an activity qualifies for exemption from the Animal Welfare Act as a field study. Institutions should also obtain clarification from their USDA Veterinary Medical Officer (VMO) as to whether wild birds used in research should be included on annual reports to the USDA.
- Review of wildlife protocols should include detailed evaluation of animal acquisition procedures. These evaluations should include consideration of potential impacts on target and non-target animals through animal capture.
- IACUCs should evaluate how any potential impact on local populations is assessed. In most cases, receipt of permits from applicable oversight agencies will assure that the impacts on local populations are minimal or are justified.
- The use of controlled substances or other hazardous materials to facilitate handling or for euthanasia of wild animals must be approached cautiously. Their use will require review of federal and state regulations to ensure compliance. Additionally, appropriate references must be consulted regarding their intended use in wild taxa. Particular attention must be given the potential for controlled or potentially hazardous substances entering the food chain or consumption of treated animals by humans.
- For PHS-covered projects, the IACUC should require justification for any method of euthanasia other than those designated as "acceptable" or "conditionally acceptable" "euthanasia" by the American Veterinary Medical Association in its 2013 *Guidelines for the Use of Euthanasia in Animals* and the decision to allow other forms of euthanasia or other methods of humane killing should be documented.
- For USDA covered species, the IACUC should document its classification of a

project with regard to the level of pain and distress for completion of required USDA annual reports.

- Review of proposed activities should include a risk assessment that takes into account location and timing of the study and species involved. A reasonable assessment must consider the likelihood of exposure to potential hazards. Investigators should be advised of the necessity to inform health care professionals of their exposure to wild animals and field conditions should they become ill.
- AAALAC-accredited institutions or institutions applying for AAALAC accreditation should note that AAALAC has recognized the guidelines published by the American Society of Mammalogists, the American Society of Ichthyologists and Herpetologists, and the Ornithological Council as resource references subject to clarifications and limitations delineated on the AAALAC website. It should also be noted that AAALAC's Council on Accreditation has voiced a clarification to the AVMA Guidelines on Euthanasia pertaining to ending the lives of healthy animals or scientific collection of animals and an exception with regard to euthanasia methods used in field conditions.

**Useful References**


- American Society of Mammalogists Animal Care and Use Guidelines
- Ornithological Council Guidelines to the Use of Wild Birds in Research
- American Fisheries Society, American Institute of Fishery Research Biologists, and American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research
- American Society of Ichthyologists and Herpetologists Guidelines to the Use of Amphibians and Reptiles in Research
- Sikes, R.S., E. Paul, and S. Beaupre. 2012. Standards for Wildlife Research: Taxon-Specific Guidelines Versus US Public Health Services Policy. BioScience 62(9):830-834.Sikes, R.S. and E. Paul. 2013.Fundamental differences between wildlife and biomedical research. ILAR Journal 54(1):5-13.
- Paul, E. and R.S. Sikes. 2013. Wildlife researchers running the permit maze. ILAR Journal 54(1):14-23.
- Nisbet, I.C.T. and E. Paul. 2000. Ethical issues concerning animal research outside the laboratory. ILAR Journal 45(3):375-377.

# -- MODEL WILDLIFE PROTOCOL --

## Instructions

1. Answer every question. Do not leave any answer spaces blank. If a question is not applicable, answer the question by explaining briefly why the question is not applicable.

2. If you rely on the scientific literature or on any of the following reference standards to explain or justify an answer, identify the reference:

a) ILAR Guide to the Care and Use of Laboratory Animals
b) American Society of Mammalogists Animal Care and Use Guidelines
c) Ornithological Council Guidelines to the Use of Wild Birds in Research
d) American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research; Guidelines to the Use of Amphibians and Reptiles in Research

3. If you are working with collaborators and the protocol has already been reviewed by an IACUC at another institution, provide a copy of that protocol and the response by the IACUC, including questions or comments and your answers.

4. Audiovisual material (e.g., sound files, photographs, maps, and/or video footage) of your field work may help the IACUC to understand your proposed research methods and techniques. If you have created an audiovisual record, please consider submitting it to the IACUC. If you submit such material, include descriptive captions for all photographs; i.e. what action is taking place, how, and why.

*Audiovisual material is submitted in accompaniment to this form:*

☐ YES

☐ NO

NOTE: It is unlawful to begin work until all federal or state permits required for your research have been issued. An IACUC may choose to request that you provide copies of your permits for the administrative record.

Two different laws – the Animal Welfare Act [7 U.S.C. 2131 -2159] and the Health Research Extension Act of 1985 [42 U.S.C. §289 (d)] - implemented by two different federal agencies – the USDA APHIS Animal Care Program and the National Institutes of Health Office of Laboratory Animal Welfare, respectively - are applicable to wildlife research. Some of the differences are substantive and will determine which regulations or standards are applicable to a particular study. Most notable of these are the definition of covered species and the manner in which the life of an animal can be taken. These and other questions that entail differences between the applicable regulations and standards are noted in red.

UPDATE AUGUST 2017: To determine which regulations and standards apply to this study, read Appendix B and also determine if your institution has submitted an Animal Welfare Assurance ("Assurance") to the National Institutes of Health Office. If so, review the Assurance to determine whether it covers all vertebrate studies or only those funded by PHS or other agencies that have delegated animal welfare compliance to OLAW.

UPDATE AUGUST 2017*:* Certain other funding agencies, including NSF, also follow PHS Policy but the 2017 NSF Proposal & Award Policies and Procedure Guide also expressly states that "Taxon-specific guidelines may be used as supplemental references.[30] Departures from the Guide must be approved by the IACUC and based on scientific, veterinary, medical, or animal welfare issues (for more information, see Office of Laboratory Animal Welfare (OLAW) Departures from the Guide)." These would include the guidelines published by the American Society of Mammalogists, the Ornithological Council, the American Society of Ichthyologists and Herpetologists, and the American Fisheries Society. See Appendix B for further detail.

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**PRELIMINARY QUESTIONS**

**UPDATE AUGUST 2017: PLEASE REVIEW APPENDIX B TO DETERMINE IF THE PROPOSED STUDY IS SUBJECT TO PHS POLICY OR THE ANIMAL WELFARE ACT REGULATIONS**

**1. Does your research entail**

**a) the study of live vertebrates as defined by PHS Policy?**

> *Animal* - Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.
>
> A study that entails the eggs and embryos of vertebrates are not covered until those eggs hatch. However, the larval forms of fish and amphibians are covered.

**- OR -**

**b) the study of live animals as defined under the Animal Welfare Act regulations?**

> AWA: *Animal* means any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warmblooded 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.

**If no, stop here.**

UPDATE AUGUST 2017: The Animal Welfare Act regulations exempt "birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research" but the USDA APHIS Animal Care program has not promulgated standards for those rats, mice, and birds that are not covered by that exemption. As of July 2017, the U.S. government has discontinued work on this regulation. See Appendix C for more detail. However, an IACUC may nonetheless require a protocol for studies involving even the exempted taxa if the study is funded by PHS because the PHS Policy covers all vertebrates. In addition, some institutions have written the PHS-required Assurance to include all research involving vertebrates, not just studies funded by PHS. See Appendix B for more detail.

**2. If your research is to be conducted in the field**

**(a) will it alter or influence the activity of the animals (PHS Policy)?**

**- OR -**

**(b) does the research involve invasive procedures, or will it harm or materially alter the behavior of an animal under study (AWA regulations)?**

*Note: Any study that includes capture, handling, and marking is subject to initial review. The IACUC will determine whether or not the project meets the regulatory definition of a field study.*

**If no:**

a) provide your name, postal address, e-mail address, and phone number.

b) briefly describe the nature of the research procedures and what measures you will take to assure that these procedures will not alter or influence the activity of the animals. For instance, if you plan to take photos, will you use a blind or other camouflage? Will you use a long lens so as to increase your distance from the animal?

c) describe where the studies will be located, what procedures will be involved, and the nature of the habitat where you will be working.

The IACUC will determine if further review is needed. If so, you will be asked to supply the additional information requested on this form. If not, you will receive a letter from the IACUC stating that no further review is needed and you may proceed with your research, subject to these two provisions:

a) You must notify us if a significant change to the project occurs. With regard to the "field study exemption," a change will be considered significant if the changes include an invasive procedure, or that harm the animal or materially alters the behavior of an animal under study or that alter or influence the behavior or the animal.

b) It is unlawful to begin work until all federal or state permits required for your research have been issued. An IACUC may choose to request provide copies of your permits for the administrative record.

**If the answer to either Question 2(a) or 2(b) is YES, then complete the rest of this form.**

**Project title** _____

**Funding source** _____

**Approximate start date** _____

**Planned completion date** _____

**Ongoing project** _____

**Principal investigator** _____

**Postal address** _____

**Permanent phone number** _____

**Field site phone number (if available)** _____

**E-mail address** _____

*If the PI will not be on site during the entire project, identify the individual or individuals who will be responsible for supervising the on-site work. Give the name, a contact phone number and e-mail address where that individual can be reached when the research is actively underway. This person must be able to assume responsibility for decisions and/or actions necessary to ensure animal health and welfare and the health and safety of all field workers. If this alternate cannot be contacted, the IACUC will assume responsibility and take actions deemed necessary to ensure appropriate animal care.*

**Alternate contact name** _____

**Alternate phone number at field site** _____

**Alternate e-mail address** _____

**-- Personnel qualifications --**

List all personnel who will be involved with the animal component of this project, including biological technicians, graduate and undergraduate students, and volunteers. Identify the research procedures that each person will undertake and state their qualifications, including relevant educational background, training for each research procedure, and relevant experience. For the PI and co-PIs and anyone who will act in a supervisory role in the field, provide *Curriculum vitarum*.

Name _____

Role on the project _____

Degree(s) _____

Relevant education _____

Relevant experience _____

Procedures to be undertaken _____

Training for each procedure _____

Name _____

Role on the project _____

Degree(s) _____

Relevant education _____

Relevant experience _____

Procedures to be undertaken _____

Training for each procedure _____

## SECTION I: PROJECT DESCRIPTION, GENERALLY

### PURPOSE OF STUDY

a) Describe the specific objectives of your study. Try to use terms and language that could be understood by a non-scientist.

b) Explain how the study will benefit wildlife, humans, or society. Benefits can include basic scientific knowledge; conservation and/or management applications for wildlife; wildlife habitat; wildlife or human health.

c) Justify:

*Rationale for the study of live animals*: why must animals be studied rather than using computer models, habitat studies, etc.?)

*Appropriateness of species to be studied*

- Describe the biological characteristics of the animal species that make them suitable for this particular study. Cost should not be used as a justification, except as a means to choose among species that are equally suitable.
- Please explain how this work will benefit this particular species or other species that share its habitat or, if you are studying this species as a surrogate, how this species will serve as a model for the other species of interest.

*Number of animals to be studied*

- How did you determine the number of animals to be studied?
- When possible, include a statistical power justification of the sample size or yield of tissue per animal.
- For complex studies, providing a flow chart or table showing group size, time frame, study locations, and other information may be helpful in explaining how the total number of animals was determined.

| ANIMAL SPECIES (Scientific and Common Name) | Number to be studied (Year 1) | Number to be studied (Year 2) | Number to be studied (Year 3) |
|---|---|---|---|
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| | | | |
| *** NON-TARGET ANIMALS (Scientific and Common Name)** | **Potential Number Affected (Year 1)** | **Potential Number Affected (Year 2)** | **Potential Number Affected (Year 3)** |
| | | | |
| | | | |
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| | | | |

*** NON-TARGET ANIMALS** *include any non-study animals directly or indirectly affected by the research. Examples include the potential to live-capture or kill non-target individuals (e.g., loss of offspring due to taking of one or both parents) or disturb/harass other species during the research activity.*

***** NOTE: species lists might include general descriptors such as "all native mammals" rather than an extensive list of individual species.

**LOCATION OF STUDY AREA(S)**

a) Describe the location of your study area(s) as specifically as possible.

b) If it is public land, state the name of the government agency that owns the land. Ascertain if a permit or other form of authorization is required, and if so, note that information in the section on permits, below.

c) If the study will take place on private land, has the landowner's permission been obtained?

**PERMITS**: *Identify all required permits or other forms of written authorization including protected species permits at the national and state or provincial levels (in the U.S.: Migratory Bird Treaty Act, Endangered Species Act, CITES, Marine Mammal Protection Act, and Wild Bird Conservation Act; Lacey Act; state permits for state-listed species); national and state/provincial protected areas permits (in the U.S., National Wildlife Refuge System, National Parks, National Forest System, Bureau of Land Management; state permits for wildlife management areas, parks, or other protected areas)*.

| **Permit type or other form or written authorization** | **Permit number, if any** | **Expiration date (or if application or renewal application pending, date submitted)** |
|---|---|---|
| | | |
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| | | |

***If your research requires federal or state permits, it is unlawful to begin work until all permits have been obtained. You may not start the work for which permits are required until the permits are issued, even if your protocol has been approved.***

**VETERINARY INVOLVEMENT**

If your research entails a major procedure …

[As defined by the Guide to the Care and Use of Laboratory Animals: "As a general guideline, major survival surgery (e.g., laparotomy, thoracotomy, joint replacement, and limb amputation) penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection (Brown et al. 1993). Minor survival surgery does not expose a body cavity and causes little or no physical impairment; this category includes wound suturing, peripheral vessel cannulation, percutaneous biopsy, routine agricultural animal procedures such as castration, and most procedures routinely done on an "outpatient" basis in veterinary clinical practice."]

or the use of controlled substances, detail the involvement of a veterinarian in the planning of the procedure(s). Will the veterinarian collaborate with you in carrying out the procedure(s)? If so, provide details.

## SECTION II: MAINTAINING WILDLIFE IN CAPTIVITY

### TEMPORARY ANIMAL HOUSING

Will animals will be held in captivity temporarily but:

a) for more than 12 hours? (Animal Welfare Act)

YES NO

☐ ☐

b) for more than 24 hours? (Public Health Service Policy,)

YES NO

☐ ☐

c) overnight?

YES NO

☐ ☐

If you answered YES to any of the three questions, describe:

- *the planned duration of the captivity*
- *the temporary holding facilities you intend to use, specifying cage size/type:*
- *equipment that you intend to use;*
- *feeding strategies;*
- *plans for maintaining suitable environmental conditions, and*
- *release procedures.*
- *A photograph, drawing, or illustration of the holding facility may help to clarify your description.*

### PERMANENT ANIMAL HOUSING

If animals are to be held permanently, describe:

- *duration of quarantine and diagnostic testing;*
- *acclimatization to captivity and the presence of researchers and lab techs;*
- *housing facilities including cage size/type;*
- *sanitation procedures;*
- *social grouping or solitary housing and the reasons for such housing;*
- *health monitoring procedures.*

**DIET SUPPLEMENTATION OR ALTERATION**

If changing food quantities (supplementation or restriction) or food types (other than routine husbandry food items), describe

- *diet food items and quantity;*
- *duration of use;*
- *anticipated nutritional deficit/adverse effect;*
- *weight monitoring of animal(s);*
- *amount of weight loss or gain that will be allowed; and*
- *monitoring protocol/schedule for effects.*

## SECTION III: PROCEDURES OTHER THAN SURGERY

Check Yes or No and add details as applicable. Expected information is explained in italics. Some protocols may require information not specifically listed here. Please ensure that all information needed to evaluate your protocol is provided.

If an IACUC-approved Standard Operating Procedure(s) exists for the planned study, list the Standard Operating Procedure Protocol number, title, and review date. If you are planning activities not listed below, please describe all procedures under the section entitled **"OTHER."**

YES NO

☐ ☐ **WILDLIFE CAPTURE (LIVE CAPTURE OR KILL TRAPPING)**

*Describe*

- *equipment to be used;*
- *planned duration of trapping/restraint;*
- *monitoring protocol/schedule for traps;*
- *potential for trapping non-target species;*
- *disposition of trapped animals; and*
- *if anesthesia or immobilization is planned please complete those sections of this form.*
- *how injuries or conditions resulting from pursuit, capture, or manipulation will be addressed*

☐ ☐ **ANIMAL TRANSPORTATION**

YES NO

*Describe*

- *how animals will be transported from a capture location to a field camp or processing site or facility and returned; and*
- *if an animal (live or dead) is to be transported from the field, describe measures to be taken to avoid potential disease transmission to researchers and other animals.*

YES NO

☐ ☐ **PHYSICAL RESTRAINT FOLLOWING CAPTURE**

*Describe*

- *method(s) to be used;*
- *planned duration of restraint;*
- *equipment to be used, including dimensions of equipment if applicable;*
- *observation schedule during confinement;*
- *Provide detailed justification and protocol if animals are to be physically restrained for longer than 1 hour at a time.*

YES NO

☐ ☐ **DECONTAMINATION PROCEDURES**

*Describe*

- *where appropriate, the decontamination procedures for equipment that will be used to capture, transport, contain, etc. animals; and*
- *frequency of decontamination.*

YES NO

☐ ☐ **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

*Describe all PPE that will be used by personnel including, gloves, respirators, goggles or faceshields, etc. If no PPE is planned, explain the likelihood of exposure to potential hazards (pathogens – including mode of transmission; bites, scratches, and stings), the potential consequences, and any other methods you intend to use to avoid the hazards or the consequences, such as physical means, prophylactic medicines, post-exposure treatment.*

YES NO

☐ ☐ **MONITORING THE HEALTH OF CAPTURED ANIMALS**

*Describe*

- *observations planned for monitoring health of captured animals*
- *physiological parameters (e.g., temperature, pulse rate, respiration rate, capillary refill time) to be recorded;*
- *frequency of measurements;*
- *expected normal ranges for all physiological parameters monitored; and*
- *provide a protocol for addressing physiological parameters outside of normal ranges (e.g., how do you plan to treat hypothermia?).*

YES NO

☐ ☐ **MARKING OR TAGGING**

*Describe*

- *marker type and why that particular type is to be used;*
- *mass of the device as a proportion of body mass;*
- *recommended device mass proportionate to body mass;*
- *method and mass of attachment method;*
- *expected effect, if any, on behavior, health, or social status of an individual.*

YES NO

☐ ☐ **BLOOD SAMPLING**

*Describe*

- *needle gauge and length;*

- *collection site preparation;*
- *location of collection sites;*
- *sample volume;*
- *frequency of sampling(s);*
- *total samples per animal;*
- *how long an animal is retained for sampling; and*
- *indicate the percent blood loss per sample based on the animal's body mass, how fluid volume will be restored, and describe how animal(s) will be monitored for anemia.*

YES NO

☐ ☐ **URINE/FECES SAMPLING**

*If your method requires capture and holding of the animal, indicate the planned duration and method of holding.*

YES NO

☐ ☐ **OTHER BODY FLUIDS AND TISSUE SAMPLING**

*Indicate*

- *the type of substance, e.g. hair, feathers, scales, muscle tissue, abdominal fluid, swabs, bone marrow;*
- *method of collection;*
- *volumes per sample; frequency of sampling(s);*
- *length of time animal is held for sampling; and*
- *total samples per animal.*

YES NO

☐ ☐ **BEHAVIORAL OR OBSERVATIONAL STUDY (WITHOUT SIGNIFICANT RESTRAINT OR NOXIOUS STIMULI)**

*Describe*

- *procedure including frequency, duration of each observational session;*
- *number of observers;*
- *distance from animals; and*
- *type of equipment to be used.*

YES NO

☐ ☐ **BEHAVIORAL OR OBSERVATIONAL STUDY (WITH SIGNIFICANT RESTRAINT OR NOXIOUS STIMULI)**

*Describe*

- *restraint procedure;*
- *equipment;*
- *duration;*

- *frequency;*
- *type of noxious stimulus;*
- *methods used to monitor animals for pain or distress*
- *methods to minimize pain or distress, if any; and*
- *scientific justification for the degree of restraint and/or noxious stimuli.*

YES NO

☐ ☐ **DIET SUPPLEMENTATION OR ALTERATION**

*If food items or quantities other than the animal's natural diets will be used, describe*

- *diet items and quantities;*
- *purpose for dietary change;*
- *planned duration;*
- *anticipated nutritional deficit/adverse effect;*
- *weight monitoring of animal(s);*
- *amount of weight gain or loss that will be allowed; and*
- *monitoring protocol/schedule for effects;*
- *planned diet for animal's whose natural diet is live prey. For these cases. How will the adequacy of diets other than live prey be assessed?.*

YES NO

☐ ☐ **FOOD AND/OR WATER DEPRIVATION**

*If food or water will be restricted or withheld, describe*

- *duration of restriction or deprivation;*
- *frequency of deprivation;*
- *reason(s) for deprivation;*
- *monitoring protocol of animal(s);*
- *amount of weight loss that will be allowed;*
- *anticipated deficit/adverse effect; and*
- *monitoring protocol/schedule for effects*

YES NO

☐ ☐ **INDWELLING CATHETERS OR IMPLANTS**

*Describe*

- *type;*
- *size;*
- *duration of use;*
- *maintenance and monitoring protocol/schedule; and*
- *if implantation requires a surgical protocol please complete the section on Animal Surgery Information*

YES NO

☐ ☐ **ADMINISTRATION OF PARALYTICS (OTHER THAN IN THE COURSE OF SURGERY)**

*Describe*

- *agent;*
- *dose (mg/kg);*
- *route of administration;*
- *frequency of administration;*
- *duration of paralysis; and*
- *if used in conjunction with a procedure(s) involving potential pain, how will the presence of pain, depth of anesthesia, degree of analgesia be assessed?*

YES NO

☐ ☐ **ADMINISTRATION OF ANESTHETICS (OTHER THAN IN THE COURSE OF SURGERY)**

*Describe*

- *agent;*
- *dose (mg/kg);*
- *route of administration (manufacturer & model of equipment);*
- *duration of anesthesia;*
- *method of monitoring anesthesia;*
- *maintenance/monitoring procedures to ensure normal body temperature is maintained in the animal;*
- *procedures to be used in case of anesthetic emergency over-dose;*
- *monitoring protocol to ensure animal's complete recovery from anesthesia; and*
- *if by inhalation, the method of scavenging waste anesthetic gas/fumes; or*
- *if injectable agent(s) are not commercially prepared and sterility guaranteed please describe method used to assure the agent's sterility when injected.*

YES NO

☐ ☐ **ADMINISTRATION OF ANALGESICS (FOR OTHER THAN POST-SURGICAL PAIN RELIEF)**

*Describe*

- *agent;*
- *dose (in mg/kg);*
- *route of administration; and*
- *frequency, and duration of use.*

☐ ☐ **USE OF CONTROLLED AND/OR PRESCRIPTION SUBSTANCES**

*Irrespective of source, describe*

- *source of substances;*
- *record keeping;*
- *storage; and*
- *precautions taken to avoid unauthorized access.*

YES NO

☐ ☐ **ADMINISTRATION OF DRUGS, TOXINS, REAGENTS, CELLS, ETC. (OTHER THAN ANALGESICS, ANESTHETICS, OR PARALYTICS)**

*Describe*

- *agent;*
- *dose (mg/kg);*
- *diluent;*
- *route of administration;*
- *equipment to be used for administration;*
- *frequency of administration;*
- *length of time animal maintained under influence;*
- *anticipated deficit/adverse effect, if any;*
- *monitoring protocol/schedule for effects;*
- *monitoring procedures to ensure cell lines have been screened for rodent pathogens; and*
- *if injectable agent(s) or silastic implant(s) are not commercially prepared and sterility guaranteed, describe method used to assure the agent's sterility when injected.*

YES NO

☐ ☐ **SURVIVAL SURGERY (MINOR)**

*If YES, complete Animal Surgery Information.*

YES NO

☐ ☐ **SURVIVAL SURGERY (MAJOR, SINGLE)**

*If YES, complete Animal Surgery Information. A major operative procedure is one that enters a body cavity. For example, implanting a telemetry device into the body cavity constitutes a major operative procedure).*

YES NO

☐ ☐ **SURVIVAL SURGERIES (MAJOR, MULTIPLE)**

*If YES, complete Animal Surgery Information. You must provide additional justification to perform multiple major operative procedures on one animal. Removal of telemetry devices is an acceptable reason.*

YES NO

☐ ☐ **NON-SURVIVAL SURGERY** *[If YES, complete Animal Surgery Information]*

YES NO

☐ ☐ **DEATH AS AN ENDPOINT**

- *If the protocol involves observing or studying the animal until death occurs you must provide scientific justification as to why an earlier endpoint is not acceptable.*
- *If collecting the animal by shooting, lethal trapping or other means, describe the method of euthanasia or humane killing to be used.*

YES NO

☐ ☐ **OTHER**

*Describe any other procedure to be administered not previously addressed.*

## SECTION IV: ALTERNATIVES TO PROCEDURES THAT CAUSE PAIN OR DISTRESS

The Animal Welfare Act and its implementing regulations, the Public Health Service Policy, and the Interagency Research Animal Committee (the last applies only to federal agencies) ALL require that the principal investigator consider alternatives to procedures that may cause more than a momentary or slight pain or distress to the animal. The term "distress" is not defined under the Animal Welfare Act or its implementing regulations, under PHS Policy. Although not defined by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, those Principles state that, "Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals."

In the ILAR Guide to the Care and Use of Laboratory Animals (2011), the term distress is defined as "…an aversive state in which an animal fails to cope or adjust to various stressors with which it is presented….[although it] …may not induce an immediate and observable pathologic or behavioral alteration …" For the purpose of completing this table, please use this definition. You may also refer to Attachment A for category descriptions and examples.

Complete this table based on anticipated levels of pain and distress for your procedures.

| | **APHIS CATEGORY C**<br>NO PAIN, DISTRESS, OR THE USE OF PAIN-RELIEVING DRUGS | **APHIS CATEGORY D**<br>TEACHING, RESEARCH, SURGERY, OR TESTS INVOLVING PAIN OR DISTRESS FOR WHICH APPROPRIATE ANESTHETIC, ANALGESIC, OR TRANQULIZING DRUGS WILL BE USED | **APHIS CATEGORY E**<br>TEACHING, EXPERIMENTS, RESEARCH, SURGERY, OR TESTS INVOLVING PAIN OR DISTRESS FOR WHICH THE USE OF APPROPRIATE ANESTHETIC, ANALGESIC, OR TRANQUILIZING DRUGS WOULD ADVERSELY AFFECT THE PROCEDURES, RESULTS, OR INTERPRETATION OF THE TEACHING, RESEARCH, EXPERIMENTS, SURGERY, OR TESTS. |
|---|---|---|---|
| EXPECTED PRIOR TO PROCEDURE | ☐ | ☐ | ☐ |
| EXPECTED DURING PROCEDURE | ☐ | ☐ | ☐ |
| EXPECTED POST PROCEDURE | ☐ | ☐ | ☐ |

## FOR ALL PROCEDURES IN CATEGORIES D AND E, DESCRIBE ANY MEASURES YOU WILL TAKE TO ALLEVIATE PAIN/DISTRESS.

Provide a detailed description of the methods to be used. For any method that may cause more than momentary or slight pain or distress to the animals, provide a written narrative description of the effort made to identify and evaluate alternatives to these methods. This narrative must provide details on the methods used and sources consulted to determine that alternative procedures are either not available or not acceptable. If no published literature or sources are available, the researcher may describe discussions with other researchers with relevant experience and/or your own, unpublished observations. If the answer relies in whole or in part on discussions with other researchers, consider providing contact information for these individuals as the IACUC may wish to consult with one or more of them.

**Literature search**

To satisfy the alternatives requirement, a literature search is required. The Animal Welfare Act regulations suggest the use of the USDA National Agricultural Library's Animal Welfare Information Center, which has a compilation of databases [http://awic.nal.usda.gov/literature-searching-and-databases/databases]. However, these dozens of databases include many that are not useful for searching for alternatives and most are useful only for biomedical research. Do not feel constrained to use this particular resource; any relevant source is acceptable. The taxon-specific guidelines, for instance, include hundreds of species-specific references.

- American Society of Mammalogists Animal Care and Use Guidelines
- Ornithological Council Guidelines to the Use of Wild Birds in Research
- American Fisheries Society, American Institute of Fishery Research Biologists, and American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research
- American Society of Ichthyologists and Herpetologists Guidelines to the Use of Amphibians and Reptiles in Research

Describe your search strategy by:

- Identifying the sources of information or databases used
- The date or dates of your search
- Your key words
- Summarize the search results

## SECTION V: TYPE, FREQUENCY, AND TREATMENT OF INJURIES

Describe the most likely forms of injuries to research animals, how frequent an injury (ies) is (are) expected to occur, and planned procedures to treat injuries. **Even if you do not intend or expect to injure an animal, you must describe potential injuries and expected methods of treatment(s).**

## SECTION VI. WHAT WILL HAPPEN TO THE ANIMALS AT THE END OF THE RESEARCH?

a) If you plan to release animals, describe the pre-release conditioning, the site and time (date and time of day) of release, and any permits required for such release. NOTE: the release of captive animals that is not a planned part of a manipulative study requires justification. PIs are directed to consult taxon-specific guidelines regarding precautions for the release of captive individuals.

- American Society of Mammalogists Animal Care and Use Guidelines
- Ornithological Council Guidelines to the Use of Wild Birds in Research
- American Fisheries Society, American Institute of Fishery Research Biologists, and American Society of Ichthyologists and Herpetologists Guidelines to the Use of Fishes in Research
- American Society of Ichthyologists and Herpetologists Guidelines to the Use of Amphibians and Reptiles in Research

b) If you plan to retain the animals for future research, when will you submit a protocol for the next research activity? Briefly describe that planned research activity.
c) If you plan to donate the animals to a zoo, captive-breeding program, or other arrangement entailing continued captivity, please describe the place where the animals to which the animals will be donated. Has this institution or organization agreed to accept the animals?
d) If you plan to euthanize the animals, describe the method of euthanasia to be used in the section on euthanasia, below.

Note: In some instances, the landowner or federal agency (such as the National Park Service) may retain ownership of animals, specimens, or samples. In such cases, consult with the landowner or agency as to disposition.

## SECTION VII: EUTHANASIA and HUMANE KILLING

The American Veterinary Medical Association published its revised *Guidelines for the Euthanasia of Animals* in 2013.

STUDIES SUBJECT TO PHS POLICY: The NIH Office of Laboratory Animal Welfare recognizes the AVMA document as the sole reference standard for euthanasia. As of 1 September 2013, OLAW required full implementation of the AVMA guidelines. Previously approved projects undergoing continuing review according to PHS Policy, IV.C.5., which requires a complete de novo review at least once every 3 years, must be reviewed using the 2013 Guidelines after September 1, 2013.

Because OLAW recognizes the AVMA document as the sole reference standard for euthanasia, methods of euthanasia must comply with the AVMA guidelines for all activities funded by the PHS unless the IACUC has approved a deviation. Deviations must be scientifically justified and included on the semiannual IACUC report to the Institutional Official. Acceptable methods of euthanasia for studies not funded by the PHS depend on the scope of applicability of the institution's PHS Assurance (see note in instructions) and the species under consideration. If the PHS Assurance applies to ALL work with vertebrate animals regardless of funding source, then all activities must be in compliance with the requirements for research funded by the PHS. Other funding agencies, including the NSF, have voluntarily elected to follow PHS Policy, but the NSF also expressly recognizes the guidelines published by the American Society of Mammalogists, the Ornithological Council, the American Society of Ichthyologists and Herpetologists, and the American Fisheries Society.

If the circumstances of field settings or study requirements preclude the use of methods deemed acceptable by the AVMA for euthanasia, investigators may request approval of alternative methods to humanely end the lives of wild animals. Such a request is consistent with the AVMA guidelines which recognize that ending the life of wild animals in field settings might more appropriately be considered humane killing than euthanasia (AVMA pg. 81). Although the AVMA guidelines expressly do not apply to humane killing, methods considered acceptable therein are also acceptable and preferred for humane killing where possible. Under PHS Policy (section C.1.g), the IACUC has the authority to approve killing techniques not recognized as forms of euthanasia by the AVMA. Examples of other methods used for euthanasia or humane killing include those approved by the American Society of Mammalogists, the Ornithological Council, and the American Society of Ichthyologists and Herpetologists.

UPDATE AUGUST 2017: STUDIES SUBJECT TO APHIS ANIMAL CARE OVERSIGHT: Until recently, the APHIS Animal Care program's Animal Care Policy Manual, Policy #3, recognized the AVMA guidelines, the American Association of Zoo Veterinarians (AAZV) Guidelines for Euthanasia of Nondomestic Animals, and the European Commission Working Party documents (APHIS Animal Care Policy #3). This text does not appear in the 23 May 2016 edition of the Animal Care Policy Manual. Instead, the text now reads, "The method of euthanasia should be consistent with the current AVMA Guidelines for the Euthanasia of Animals." The Animal Welfare Inspection Guide also states, "Establish and maintain the method(s) of euthanasia for the animals, which should be consistent with the current AVMA Guidelines on Euthanasia" and refers to Policy 3. Unfortunately, both documents overlook the fact that the Animal Welfare Act regulations do not mandate the use of the AVMA Guidelines.

The regulations state that "Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, § 1.1 of this subchapter" and the given definition is "*Euthanasia* means the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." Oddly, the definition of euthanasia in the Animal Welfare Inspection Guide is consistent with the regulation, "the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death."

Further, both the Animal Care Policy Manual and the Animal Welfare Inspection Guide overlook the fact that the regulation also provides that the investigator may submit for IACUC approval a written justification a deviation for scientific reasons. Under the two guidance documents, the researcher and the institution would nonetheless be considered noncompliant. However, the regulation is the official, enforceable law.

This matter has been brought to the attention of Animal Care officials. In the meantime, institutions that have been determined to be noncompliant or subjected to a "teachable moment" on the basis of the method of euthanasia should follow the inspection appeals process. The inspection appeals process is described in a fact sheet on AC's website: https://www.aphis.usda.gov/publications/ animal_welfare/2017/AC-Tech-Note-Inspection-Report-Appeals-Process.pdf. Please also consider notifying the Ornithological Council.

***Whether euthanasia or humane killing, it is expected that investigators will use the most humane technique(s) feasible that is also consistent with study objectives.***

Even if you do not intend to end animals' lives at any point in your project, a method of euthanasia or humane killing must be listed in cases of emergency except in instances where permits or statutes prohibit the killing of individuals of the species involved. If euthanasia or humane killing is prohibited by law or by permit conditions, provide supporting documentation.

YES NO

☐ ☐ Does the project involve planned euthanasia?

If yes, which reference guidelines are used?

☐ AVMA (specify revision year) _____

☐ Other (Specify) _____

YES NO

☐ ☐ Does the project involve humane killing?

If yes, which reference guidelines are used?

Describe the planned method of humane killing.

Describe the method used to ensure the animal will not revive and method of disposal of remains.

## SECTION VIII: ANIMAL SURGERY INFORMATION

The term "surgery" is not defined in PHS Policy or the Animal Welfare Act regulations. The latter defines the term "major operative procedure" as any surgical intervention that penetrates and exposes a body cavity or any procedure which produces permanent impairment of physical or physiological functions. There is no definition of minor operative procedure; presumably, it is any procedure that does not penetrate or expose a body cavity or that does not produce permanent impairment of physical or physiological functions.

In the context of discussing laparotomies, OLAW states:

Surgical procedures can be categorized as major or minor. (See *Guide* page 117.) Major survival surgery penetrates and exposes a body cavity, produces substantial impairment of physical or physiologic functions, or involves extensive tissue dissection or transection (e.g., laparotomy, thoracotomy, joint replacement, and limb amputation). Minor survival surgery does not expose a body cavity and causes little or no physical impairment (e.g., wound suturing, peripheral vessel cannulation, percutaneous biopsy, and most procedures routinely done on an outpatient basis in veterinary clinical practice). Animals undergoing a minor survival surgical procedure typically do not show significant signs of postoperative pain, have minimal complications, and quickly return to normal function.

For the purposes of wildlife research, it is important to recall that the field studies exemption (from protocol review) does not pertain to studies that involve "an invasive procedure, harms, or materially alters the behavior of an animal under study." The term "invasive procedure" is not defined in the Animal Welfare Act regulations. It is not clear if a minor operative procedure is considered invasive. However, OLAW recognizes the authority of the IACUC to determine whether specific manipulations used in research are major operative procedures and, given that neither OLAW nor APHIS has defined invasive procedure, it is reasonable to conclude that both agencies extend the authority to IACUCs to define invasiveness. The IACUC's determination must be based on a detailed description of the procedure and the anticipated or actual consequences, as characterized by the investigator. In some cases, the classification by the IACUC of a procedure as major or minor may be readjusted post-procedurally depending on clinical outcome. If the IACUC, after thorough review, determines that the surgical procedure only penetrates but does not expose a body cavity and that the procedure does not produce substantial impairment, the IACUC may conclude that it is not a major operative procedure. Any laparoscopic surgery that produces substantial impairment of physical or physiological function must be considered a major operative procedure. Whether the laparoscopic procedure is classified as major or minor, the IACUC must ensure that the appropriate analgesia, sterile technique, and perioperative monitoring is employed.

FAQ 13: http://grants.nih.gov/grants/olaw/faqs.htm

☐ Check here if no surgery is planned.

| ANIMAL SPECIES (Scientific and Common Name) | Number that will be subjected to surgical procedure | S = Survival N = Non-survival | Surgery Location (Anatomic) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**PRE-OPERATIVE PROCEDURES AND CARE**

a) Have obviously unhealthy or compromised animals been exempted from surgery?

Yes ☐ No ☐

If no, explain the rationale for performing surgery on obviously unhealthy or compromised animals.

b) Identify the individual responsible for evaluating pre-operative health status of animals.

c) Provide a brief description of all pre-operative procedures and care.

*Include*

- *withholding of food and water;*
- *pre-operative antibiotic/therapeutic drug/fluid administration (agent, dose in mg/kg);*
- *route of administration, frequency, duration of treatment; and*
- *preparation of surgical site (e.g., clipping, use of antiseptic scrub/solution, etc.).*

d) Describe the facility or the area where the surgery will be performed:

*Include*

- *how it is prepared before each surgery;*
- *how surgical instruments are prepared; and*
- *how individuals responsible for surgery prepare themselves.*

## SURGICAL PROCEDURES

a) Provide a brief description of all surgical procedures to be performed.

*Include*

- *incision site;*
- *procedures to be performed;*
- *anticipated duration of procedure; and*
- *method of wound closure including type and size of suture/staples.*

b) Describe procedure(s) employed to ensure aseptic technique is maintained throughout surgical procedure.

*Include*

- *sterilization method used for instruments, equipment and supplies;*
- *sterilization methods such as the use of sterile gloves, gowns, drapes, mask, cap, sterile implants, and sterile suture/closure material; and*
- *if same surgical instruments are used for multiple animals (i.e. birds), describe how the instruments are managed to assure continued sterility.*

c) Identify all individuals performing surgery and describe their training and experience with regard to surgery involving the study species.

## ANESTHESIA

a) Provide a brief description of anesthetic procedures.

*Describe*

- *agent;*
- *dose (i.e., mg/kg or % if by inhalation);*
- *route of administration;*
- *expected duration of anesthesia;*
- *monitoring procedure to evaluate depth of anesthesia;*
- *maintenance and monitoring procedures to ensure normal body temperature is maintained in the animal;*
- *procedures to be employed in case of anesthetic emergency such as over-dose; and*
- *monitoring protocol to ensure animal's complete recovery from anesthesia; if by inhalation describe the equipment used and state the method of scavenging waste anesthetic gas/fumes; if injectable agent(s) are not commercially prepared and sterility guaranteed, please describe method used to assure the agent's sterility when injected;*
- *safety mechanisms to prevent personnel exposure to volatile anesthetics..*

b) Identify the individual(s) performing and monitoring anesthesia. Describe that person's training and experience with regard to the administration of anesthesia for the study species.

## POST-OPERATIVE PROCEDURES AND CARE

a) Provide a brief description of all post-operative procedures and care.

*Include*

- *criteria to assess animal pain and the need for analgesics;*
- *type of post-operative analgesics (describe agent, dose, route of administration, frequency, duration of treatment);*
- *techniques used to ensure maintenance of normal body temperature in the animal;*
- *incision care, monitoring and time of suture removal;*
- *catheter or long term care of any chronically instrumented/implanted animals, monitoring and time of removal; and*
- *bandage/dressing monitoring and changing schedule.*

b) If post-operative analgesics will not be used, provide scientific justification.

c) Describe arrangements for post-operative monitoring of animals, the individual(s) responsible for performance of monitoring, including after-hour, weekend and holiday care.

d) Describe the use of any antibiotics or other therapeutic drugs.

*Include*

- *agent;*
- *dose (i.e. mg/kg, IU/kg);*
- *route of administration; and*
- *frequency, duration of treatment.*

e) If this surgical procedure induces a disease or other functional alteration, describe any anticipated adverse effects and deficiencies, monitoring protocol/schedule for animals, animals' degree of tolerance to disease/functional deficit.

## MULTIPLE SURGERIES

Will animals be subjected to more than one (1) survival surgery? Yes ☐ No ☐

If yes, provide scientific justification and explain how surgeries are related.

## SECTION IX: OTHER CONSIDERATIONS

YES NO

☐ ☐ Does the project involve recombinant DNA or the intentional introduction of biohazards into animals?

If yes, has approval from the Institutional Biosafety Committee (IBC) approval been obtained? Provide date of approval and IBC protocol number. (NOTE – IBC approval must be obtained prior to IACUC review).

If the project involves introduction of one or more biohazards, specify the hazard(s) and risk group.

YES NO

☐ ☐ Does the project involve ionizing radiation?

If yes, has approval been obtained from the Radiation Safety Committee?

Provide date of approval and RSC protocol number_____

# LITERATURE CITED

PLEASE PROVIDE COMPLETE CITATIONS OF ALL LITERATURE CITED TO SUPPORT THIS PROTOCOL.

# DECLARATION

THE INFORMATION PROVIDED HEREIN IS AN ACCURATE DESCRIPTION OF MY ANIMAL CARE AND USE PROTOCOL(S). ALL PEOPLE STUDYING ANIMALS UNDER THIS PROTOCOL HAVE BEEN OR WILL BE PROPERLY TRAINED TO USE APPROPRIATE METHODS AND HAVE READ AND AGREED TO COMPLY WITH THIS PROTOCOL. ALL INDIVIDUALS WORKING UNDER THIS PROTOCOL WILL COMPLY WITH THE PROCEDURES AND METHODS OUTLINED IN THE ANIMAL WELFARE ACT, ITS IMPLEMENTING REGULATIONS, THE PUBLIC HEALTH SERVICE POLICY (AS APPLICABLE) AND THE GUIDE TO THE CARE AND USE OF LABORATORY ANIMALS (AS APPLICABLE) AND THE U.S. GOVERNMENT PRINCIPLES FOR THE UTILIZATION AND CARE OF VERTEBRATE ANIMALS USED IN TESTING, RESEARCH, AND TRAINING (IF APPLICABLE) EXCEPT AS OTHERWISE AUTHORIZED BY THE APPROVAL OF THIS PROTOCOL.

ALL WORK PROPOSED HEREIN IS DESIGNED TO AVOID DISCOMFORT, DISTRESS, AND PAIN TO ANIMALS TO THE EXTENT POSSIBLE; DOES NOT UNNECESSARILY DUPLICATE PREVIOUS EXPERIMENTATION; AND NON-ANIMAL ALTERNATIVES HAVE BEEN CONSIDERED.

PRINCIPAL INVESTIGATOR

_____

DATE

_____

## APPENDIX A: CATEGORIES OF IMPACTS IN ANIMAL EXPERIMENTS

APHIS Category C: Procedures with no pain or distress, no use of pain-relieving drugs

Capture is an essential element of most wildlife studies. For the purpose of determining the appropriate categorization of capture, the American Society of Mammalogists and the Ornithological Council analyzed existing guidance used by APHIS and the NIH Office of Animal Care and Use to determine that most methods of capture in properly functioning devices with appropriate monitoring by field staff would constitute Category C. Free-ranging mammals captured in live traps and subsequently euthanized as part of the research study or that are taken in properly functioning kill-traps meet the standards for either USDA category C or D; the distinction between these reporting categories depends upon how the animal dies. Animals taken in live traps that show no obvious signs of pain or distress and subsequently euthanized using accepted methods that avoid inducing pain or distress and those taken in properly functioning kill traps fit the definition for reporting under USDA category C. This conclusion is consistent with example #4 in the USDA APHIS Research Facility Inspection Guide (section 14.1.10) except that death is intentional rather than unexpected. The Research Facility Inspection Guide pertains to laboratory animals rather than free-ranging wildlife, but euthanasia following a live capture that does not result in pain or distress is analogous to this example.

Mammal capture devices are designed either to hold the animal unharmed (live-traps) or to kill the animal outright upon capture. The guidelines of the American Society of Mammalogists for the use of wild mammals in research discuss appropriate methods and trap types for capturing or collecting free-ranging mammals (Gannon et al. 2007). Birds can be captured with a variety of devices, all designed to capture and hold a bird unharmed until released. Although scientific collecting of birds may sometimes entail capture of a live bird followed by euthanasia, the capture methods themselves are not intended to be lethal and in fact do not kill birds. The 2010 revision of the Guidelines to the Use of Wild Birds in Research discusses capture methods and the practices needed to assure that capture does not result in harm to birds (Fair et al. 2010).

Barring mechanical malfunctions and with appropriate placement and trap-checking frequency, animals captured in live-traps or nets are simply held without injury until removal. Appropriate training is essential for setting capture devices and for removing animals from those devices. Pain or distress, as described in the APHIS Animal Care Resource Guide, is unlikely to result from the simple capture of free-ranging mammals or birds using most live traps or capture techniques covered in the American Society Mammalogists or Ornithological Council Guidelines, so animal usage in these instances is consistent with USDA category C.

*Other example of Category C procedures in wildlife research*:

- *individual or small numbers of animals being confined and maintained in natural habitat that affords an appropriate quantity and quality of food, cover, and water*
- *The short-term and skillful restraint of animals for purposes of observation or physical examination*
- *injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac*

- *acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness*
- *approved methods of euthanasia or humane killing*
- *short periods of food and/or water deprivation equivalent to periods of abstinence in nature.*
- *collection of feathers, small skin punches, urine, feces, tracheal swabs, cloacal swabs*
- *application of tagging or marking devices, except implantations into body cavities*
- *most blood collection procedures.*
- *administration of an anesthetic, analgesic or tranquilizing drug to an animal for restraint purposes to perform a procedure that involves no pain or distress.*

Most tissue sampling and marking techniques in the field also are consistent with USDA pain category C provided that procedures are not more invasive than peripheral blood sampling. Support for this classification is provided in the Guidelines for Preparing USDA Annual Reports and Assigning USDA Pain and Distress Categories. This document is distributed by the NIH Office of Animal Care and Use, which is the oversight office for intramural research. This guidance expressly states that Category C includes most blood and tissue collection procedures that involve no or only momentary or slight pain.

Free-ranging mammals captured in live traps and subsequently euthanized as part of the research study or that are taken in properly functioning kill-traps meet the standards for either USDA category C or D; the distinction between these reporting categories depends upon how the animal dies. Animals taken in live traps that show no obvious signs of pain or distress and that are subsequently euthanized using accepted methods that avoid inducing pain or distress and those taken in properly functioning kill traps fit the definition for reporting under USDA category C. This conclusion is consistent with example #4 in the USDA APHIS Research Facility Inspection Guide (section 14.1.10) except that death is intentional rather than unexpected. The Research Facility Inspection Guide pertains to laboratory animals rather than free-ranging wildlife, but euthanasia following a live capture that does not result in pain or distress is analogous to this example.

APHIS Category D: Procedures involving pain or distress for which appropriate anesthetic, analgesic, or tranquilizing drugs were used

*Examples*:

- *Surgical implantation of telemetry devices or identification devices that require anesthesia or analgesia*
- *Invasive tissue sampling, such as intracardial blood draws or invasive biopsies*

APHIS Category E: Procedures that involve pain or distress for which the use of anesthetics, analgesics, or tranquilizers would have adversely affected the procedure, results, or interpretation of the results.

*Examples:*

- *Experimental increase of litter or clutch size that results in a statistically significant depression in growth rates, excessive loss of parental mass, or death of young or adults.*
- *Diets that cause a statistically significant reduction in growth or cause excessive loss of body mass.*

**The U.S.D.A. Annual Report requires the IACUC to report the number of studied animals in each of the several categories (APHIS Form 7023). Please assist the IACUC in this determination by assigning the animal procedures in your project to one of the categories below.**

**(B)** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

**(C)** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.

**(D)** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.

**(E)** Number of animals upon which teaching experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report.

You must report the number of animals planned to be studied in each category. The IACUC will record that information on the approval letter sent to the principal investigator of each project.

Retrospectively, list only those animals that were used and experienced pain or distress during the reporting year, rather than listing the number of animals that were approved in the protocol. All animals approved for use in painful or distressful procedures without appropriate and adequate anesthetics, analgesics or tranquilizers may not have been determined to have experienced pain or distress. Animals not actually used in Column E conditions should then be listed in the appropriate column (Column C or D)

**APPENDIX B: Which federal animal welfare policies govern ornithological research?**

Two overlapping but non-identical laws govern the implementation and oversight of federal animal welfare requirements for research. The older of the two is the Animal Welfare Act (AWA), initially enacted in 1966. This law regulates the transportation, sale, housing, handling, and treatment of animals in research and exhibition, as implemented through regulations issued by USDA through the public-notice-and-comment process mandated by the Administrative Procedure Act. The standards and procedural requirements are found in those regulations.

*The Animal Welfare Act (AWA) applies to research facilities, which are defined under that law as "any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that:*

1.Purchases or transports animals "in commerce" – a legal term of art meaning "across state or federal borders" or affecting such commerce, even if entirely within a state; or
2. Receives funding under a grant, award, loan, or contract from any federal agency for the purpose of conducting that research.

The AWA is implemented by the Animal and Plant Health Inspection Service, Animal Care Program. Specific requirements include the review of research protocols by the Institutional Animal Care and Use Committee (IACUC), annual technical reporting, and inspections.

Another federal law that protects animals studied in research is implemented by the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW). Known as the "Health Research Extension Act of 1985," its requirements are similar but not identical to those imposed by the AWA.

*The specific requirements, which are detailed in the Public Health Service Policy on Humane Care and Use of Laboratory Animals, apply to live vertebrates if the research is funded in whole or in part by the Public Health Service (National Institutes of Health, Centers for Disease Control, Food and Drug Administration, and in certain other situations as described below).*

Compliance with PHS Policy is implemented through grant conditions in agency funding awards. By law, grant conditions are not regulatory and are thus not subject to the public-notice-and-comment process. However, as a matter of practice, NIH often publishes proposed policies and solicits public comment.

Other federal funding agencies that fund research involving live vertebrates have signed Memoranda of Agreement with OLAW that delegate oversight of animal welfare funded by those agencies to OLAW. These agencies are:

- National Air and Space Administration
- National Science Foundation
- Veterans Health Administration

Finally, some federal research agencies receive PHS funding and are therefore subject to the PHS Policy. If there is no current funding, the Assurances are inactivated but can be reactivated once NIH issues new grants**.** These may include:

- U.S. Geological Survey, National Wildlife Health Center
- Some USDA facilities
- Some Department of Defense facilities
- Other federal agencies that receive PHS funding for research involving live vertebrates.

How can you know if your university, institution, or organization is covered by PHS Policy?

First, check this list to see if your organization has an approved PHS Assurance. However, even if your institution has an approved PHS assurance, if your research is not federally funded, it may not be subject to the PHS Policy. It depends on the terms of the Assurance. If the Assurance states that it covers all research, regardless of funding source, then your research is covered even if it is not federally funded. Ask your IACUC chair or institutional official to provide a copy of the Assurance to see if it is covers only federally funded research or all research that involves live vertebrates.

**Why does this matter to ornithologists?**

The two laws differ in key ways as well as minor procedural variations.

For instance:

» The AWA covers live warm-blooded animals but the PHS Policy pertains to live vertebrates.

» Although the PHS Policy requires compliance with the AWA, it also establishes as a key standard the ILAR *Guide for the Care and Use of Laboratory Animals* (the "*Guide*"). The AWA regulations make no mention of this document.

» PHS Policy requires that euthanasia methods be consistent with the AVMA Guidelines for the Euthanasia of Animals: 2013 Edition.. The Animal Welfare Act regulations make no mention of the AVMA Guidelines. Instead, the regulation defines euthanasia as "… the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death." This difference is significant in that the AVMA Guidelines are of limited scientific and practical value for field research; methods that meet the Animal Welfare Act regulatory definition are not considered acceptable by the AVMA. Note that APHIS Animal Care Policy Manual and the Animal Care Inspection Guide both mandate compliance with the AVMA Guidelines. Unfortunately, neither document acknowledges that the IACUC may approve the use of a method not approved by the AVMA. Therefore, under the APHIS guidance, a researcher would be in violation of the law even if the IACUC had approved the method of euthanasia. The Ornithological Council is engaged in discussion with APHIS leadership about this situation. Moreover, as APHIS is a regulatory agency, it can't regulate via internal guidance. It must comply with the requirements of the Administrative Procedure Act. Therefore, the OC has asked that this standard be removed from these internal guidance documents.

» As of August 2017, there are no AWA regulations pertaining to birds. APHIS Animal Care in 2004 published a Notice of Intent to publish regulations but as of [date published] no regulations

have been published. See Appendix C for more detail. The PHS Policy requires that facilities and the program for the humane care and use of animals (which includes birds) be consistent with the standards of the ILAR *Guide.*

» The AWA regulations exempt field studies, defined as a study conducted on free-living wild animals in their natural habitat unless the study involves an invasive procedure, harms, or materially alters the behavior of an animal under study. The PHS Policy makes few exceptions for field studies. OLAW FAQ A6 (https://grants.nih.gov/grants/olaw/faqs.htm#591) states:

> "If the activities are PHS-supported and involve vertebrate animals, the IACUC is responsible for oversight in accord with PHS Policy. IACUCs must know where field studies will be located, what procedures will be involved, and be sufficiently familiar with the nature of the habitat to assess the potential impact on the animal subjects. If the activity alters or influences the activities of the animal(s) that are being studied, the activity must be reviewed and approved by the IACUC (e.g., capture and release, banding). If the activity does not alter or influence the activity of the animal(s), IACUC review and approval is not required (observational, photographs, collection of feces).
>
> Investigators are encouraged to consult relevant professional societies, available guidelines, wildlife biologists, and veterinarians, as applicable, in the design of the field studies (*Guide* page 32, Appendix A). Studies with the potential to impact the health or safety of personnel (*Guide* page 18) or the animal's environment may need IACUC oversight, even if described as purely observational or behavioral. When capture, handling, confinement, transportation, anesthesia, euthanasia, or invasive procedures are involved, the IACUC must ensure that proposed studies are in accord with the *Guide*. The IACUC must also ensure compliance with the regulations and permit requirements of pertinent local, state, national, and international wildlife regulations. A study on free-living wild USDA-covered species that involves invasive procedures, harms or materially alters the behavior of an animal under study is covered by USDA animal welfare regulations and requires IACUC review and approval."

» Effective 14 January 2013, the NSF Proposal and Award Policies and Procedures Guide (PAPPG) expressly recognized the taxon-specific guidelines:

"In the case of research involving the study of wildlife in the field or in the laboratory, for the provision in the PHS Assurance for Institutional Commitment (Section II) that requires the organization to establish and maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide), the organization has established and will maintain a program for activities involving animals according to the Guide. The organization will follow recommendations specified in the Guide for details involving laboratory animals, and taxon-specific guidelines approved by the American Society of Ichthyologists and Herpetologists, the American Society of Mammalogists, and the Ornithological Council, as is appropriate for the taxon to be studied."

A memorandum of agreement between NSF and NIH went into effect on 1 October 2015, calling for OLAW to provide general and comprehensive administration and coordination of the PHS

Policy for NSF-funded research. The MOA resulted in changes to the NSF PAPPG, effective 30 January 2017, which resulted in a clarification effective 30 January 2017:

» "Any project proposing use of vertebrate animals for research or education must comply with the provision in the PHS Assurance for Institutional Commitment (Section II) that requires the submitting organization to establish and maintain a program for activities involving animals in accordance with the *Guide for the Care and Use of Laboratory Animals* (Guide). Taxon-specific guidelines may be used as supplemental references.[30] Departures from the Guide must be approved by the IACUC and based on scientific, veterinary, medical, or animal welfare issues (for more information, see Office of Laboratory Animal Welfare (OLAW) Departures from the Guide)" (NSF PAPPG, Chapter II.D.4.).

The PHS Policy does not mention the taxon-specific guidelines except by reference to the *Guide,* which mentions the taxon-specific guidelines in an appendix. The OLAW FAQs, which supplement the PHS Policy, mention the taxon-specific guidelines as permissible sources of information: OLAW FAQ D17 (https://grants.nih.gov/grants/olaw/faqs.htm#633) states: "PHS Policy is intentionally broad in scope and does not prescribe specifics about the care and use of any species, assigning that task to the IACUC and allowing for professional judgment. Many of the principles embodied in the *Guide* can generally be adapted to the care and use of various kinds of nontraditional research animals. IACUCs may seek the advice of experts when necessary, and refer to scientific-based publications prepared by professional organizations with interest in various species. Appendix A of the *Guide* references many such publications.

**USDA grants**

The USDA National Institute of Food and Agriculture Federal Assistance Policy Guide (at page 135) states: "Grantees must have an approved Animal Welfare Assurance be on file with the Office of Laboratory Animal Welfare (OLAW) at NIH at the time of award for all grantee organizations receiving Federal support for research or related activities using live vertebrate animals. At USDA, APHIS will oversee the organization and operation of IACUCs. (9 CFR 321). Additional requirements applicable to lab animals must also be followed." It also alludes to the *Guide* as an additional resource: "PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) and the Guide for the Care and Use of Agricultural Animals in Research and Teaching, Third Ed. (January 2010)…

However, no memorandum of understanding between OLAW and USDA NIFA is currently in place. OLAW will not consider Animal Welfare Assurances from institutions in the absence of funding from a PHS agency, NASA, NSF, or the VA. Many institutions receiving funds from USDA NIFA already have an Assurance with OLAW. In any case, the USDA guide treats PHS Policy as a recommended resource.

**Conforming the Model Wildlife Protocol**

The Model Wildlife Protocol published by the Ornithological Council delineated between standards applicable to research subject to both the Animal Welfare Act and PHS Policy and research subject only to the Animal Welfare Act. This document has been modified as of August 2017 to make clear which ornithological research is subject to the Animal Welfare Act, the Public Health Service Policy, both or neither.

## APPENDIX C: STATUS OF THE APHIS "RATS, MICE, AND BIRDS RULE"

At the USDA, a major policy change took place in 2004 when the agency decided, as a result of litigation, that it would begin to regulate rats, mice, and birds used in research. The new law exempted "*purpose-bred* rats, mice, and birds" so the agency rule, if and when promulgated, would have affected other birds bred in captivity but not for the purpose of research, wild birds brought into captivity, and wild birds studied in the field. The agency then began the process of developing regulatory standards by way of an advanced notice of public rulemaking, asking the stakeholders and the public for input as to what and how to regulate. Nothing more was heard until December 2011, when the agency announced that the proposed regulation was on hold pending an assessment of the agency's resources for implementing the rule. Nothing more had been heard since then.

In July 2017, the Administration published the Current Unified Agenda of Regulatory and Deregulatory Actions. This semi-annual list covers all new regulations and regulatory changes in some stage of preparation. The list now has three components: new regulations and regulatory changes that are in preparation, long-term actions (under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda), and Inactive Actions. The "rats, mice, and birds" rule appears on none of the three lists. Therefore, it appears that the rule is defunct.

For all practical purposes, this regulation would have had little impact on those studying wild birds because it was unlikely that the agency would have attempted to oversee such research. However, it would have impacted those studying wild birds in captivity.