IACUC Policy Number: 305
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Title: Field Studies

Purpose

To ensure that field studies involving animals are performed according to state, federal, and international laws and regulations and to ensure the proper care and use of animals in field research and teaching.

Regulatory Background

Princeton University is committed to ensuring that all of its researchers conducting field studies are following the requisite regulations. Field studies are subject to a wide body of regulations on the international, federal, and state levels. Where the Animal Welfare Act (AWA) and the Public Health Service (PHS) Policy apply, the Institutional Animal Care and Use Committee (IACUC) is required to review all protocols involving vertebrate animals, unless all of the following conditions are met:

- Experiments/observations do not involve invasive procedures or manipulation of animals.
- No harm is done to any animal.
- Experiments/observations do not involve material alteration of the behavior of any animal during field research activities. For example, any action that is designed to manipulate or alter the behavior of an animal (e.g., making noise to see behavior change) would not meet this condition.

For studies requiring invasive procedures or manipulation; studies that may potentially harm animals; or studies that involve the intentional material alteration of animal behavior, the Animal Welfare Act and Regulations (AWAR) §2.38 (f)1 apply and: “Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.” Such studies involving vertebrate animals require IACUC review and approval prior to onset of research.

The IACUC must also review risks to human health that are posed by research on wild animals and field studies. The Guide for the Care and Use of Laboratory Animals (Guide) states that field studies which may involve “Occupational health and safety issues, including zoonoses, should be reviewed by the institution’s health and safety committee or office, with assurances to the IACUC that the field study does not compromise the health and safety of animals or persons in the field. Additionally, the investigators conducting field studies with animals should assure the
IACUC that collection of specimens or invasive procedures will comply with state and federal regulations.”

Foreign countries may have specific regulation(s) or policies that impact international field studies involving methodology, personnel, transportation, shipment of specimens, and permitting. Additional timing may be required to obtain the necessary permits and licenses and the IACUC may request to review these documents prior to granting final protocol approval.

Scope

This policy applies to all Princeton University faculty, postdocs, research associates and students conducting field studies for the purposes of research and teaching.

Responsibility

Principal Investigator (PI) – Shall be knowledgeable about animal welfare, relevant zoonotic diseases, associated safety issues, and any laws and regulations that apply. Where international regulations and policies may apply, it is the responsibility of the PI to understand them, and to obtain any necessary permits/licenses prior to the onset of research. The PI must be appropriately qualified and experienced in conducting procedures on living animals and is ultimately responsible for his or her studies involving wild animals and field studies.

IACUC - In addition to review and approval of those field study protocols that are not exempt from the regulations, the IACUC must also review the likelihood of disease spread from the study animals (zoonoses), and occupational health and safety issues, so that the field studies do not compromise the health and safety of other animals or of persons working in the field.

Institutional Biosafety Committee (IBC) – IBC review and approval is required for field research with animals and animal tissues that pose zoonotic disease risk.

In general, field study sites are exempt from inspection by the IACUC. The Federal regulation AWAR §2.31(c) (2) states that “Animal areas containing free-living wild animals in their natural habitat need not be included in such (semiannual) inspection.” Neither the Guide nor PHS Policy addresses the issue of inspecting field studies. However, per OLAW guidance, the IACUC may, in its role to “consider risks to personnel, and impact on study subjects” request “written descriptions, photographs, or videos that document specified aspects of the study site.

Definitions

Animal – Any vertebrate animal used for research, teaching, testing, experimentation, or exhibition purposes.

Field Study – Any study conducted on free-living wild animals in their natural habitat or any study involving animals not housed in the University animal facilities. For example, studies involving domestic farm or companion animals in a coral, or studies at a University-owned farm
would be considered field studies because the animals are not housed in a University animal facility.

Exempt Field Study – A study which does not involve invasive procedures and does not cause harm or material alteration of the behavior of any animal. Generally, this type of study would involve behavioral observation, assessing population or impact to habitat, or collection of hair or feces from the environment (not the animal).

Non-Exempt Field Study – May involve invasive procedures, or when any animal is harmed, and/or the animal’s behavior is materially altered. Procedures classified as non-exempt may include, but are not limited to, surgery (transmitter implant); darting, anesthesia, tranquilization or sedation; trapping for placement of identification tags or sample collection (e.g., blood, hair, feces) from any animal; any confinement; transportation; euthanasia and/or anytime there may be a potential for zoonotic concerns.

AWA regulated species – Includes dogs, cats, nonhuman primates, rabbits, guinea pigs, hamsters, marine mammals and farm animals used for research as well as mice and rats not bred for research. The AWA requirements only apply to animals within the United States.

USDA Annual Report – Summary report of AWA regulated species held, bred and/or used for research purposes on an annual basis (October 1 through September 30). The AWAR §2.36(b) does not exclude animals used in field studies; however, collecting information on animals used in field studies is difficult since there may not be direct inspections and there is no ordering information. For PHS-funded studies, the IACUC will request an annual summary report from the investigator on the number of animals of each species used in non-exempt field research during the reporting period.

Policy

Field studies as defined above fall within two categories, exempt and non-exempt. When a field study is exempt, the principal investigator must complete an Observational Only Field Study Form and submit it to the IACUC office. In cases where invasive procedures, confinement or animal harm occurs, or the animal’s behavior is materially altered, the principal investigator must complete the regular Vertebrate Protocol Form for IACUC review and approval.

Exempt Field Study
Generally, field studies defined as exempt research will follow an abbreviated review cycle which will be processed by the Research Integrity and Assurance (RIA) staff and reviewed by a representative of the IACUC, unless the study is funded by the National Science Foundation (NSF) or potential hazards exist. When either of these situations exists, the Observational Only Field Study Form will be routed to the IACUC and/or the Institutional Biosafety Committee (IBC) for the appropriate review and approval.

Non-Exempt Field Study
Field studies classified as non-exempt research go through the normal route of IACUC review and approval. Non-exempt field study protocols should be submitted to the IACUC office at least 2 months prior to the requested study start date. The PI will submit the IACUC Vertebrate Protocol Form to the IACUC office for veterinary and compliance pre-reviews. The reviewers’ comments will be returned to the PI for requested revisions. The PI will return the revised protocol to the IACUC office in preparation for the review at the monthly IACUC meeting, if necessary. In cases where potential biological hazards exist, the PI must submit an IBC Registration form which will undergo a concurrent review by the IBC. The IACUC Vertebrate Protocol Form will not receive full approval until the IBC Registration has been approved.

For the IACUC Vertebrate Protocol Form, the information listed below should be considered and included in the protocol. Deviations from the protocol must be documented immediately and reported to the IACUC within 5 days of reaching a location where communication can occur.

1. **Species Selection:** the investigator should provide information on the species and population(s) to be studied, rationale for such choice(s), and risk to those animals. The IACUC reserves the right to consult with subject matter experts with relevant expertise.

2. **Site Selection:** The investigator should explain how the chosen study location will maximize the opportunity for data collection and minimize disruption to the animals and their environment caused by the investigator. Information on supervision at the site should be included as well.

3. **Methodology Employed:** The potential short- and long-term effects of procedures on individual animals should be described. Provide species-specific information as appropriate.
   
   a. If animals are to be captured or trapped, describe the method used, how long they will be kept in a contained environment, and what will be done to make sure that the animals are not in distress and properly taken care of in terms of food, water, etc.
   
   b. If animals are to be monitored individually, describe whether they will be identified by natural markings or artificially marked. If they are artificially marked, the protocol must describe the procedures associated with the marking.
   
   c. Describe the possible impact of capture on subsequent behavior and survival of animals.
   
   d. Describe sampling methods to be used following capture (e.g., blood collection, euthanasia). Describe the degree of invasiveness of the procedure and, where relevant, potential problems associated with the animals’ return to the field (e.g. avoiding predators, seeking shelter, surviving inclement weather).
e. Describe measures taken to prevent injuries and alleviate pain and distress during capture, trapping, marking or sampling, and a contingency plan for adverse events that may occur in the process.

f. Describe whether individual animals are treated experimentally by surgery or drugs to alter their behavior or physiology. Any invasive surgery, such as organ removal or implanting of transmitters, should be done using aseptic technique.

g. Describe and justify any use and choice of anesthesia, including whether field conditions render certain agents too difficult to transport or use. Consideration should be given to drug availability at the field location and if there are potential barriers to import, transport or storage. Describe and justify any euthanasia.

h. Describe and justify procedures involving site manipulation such as the addition of a predator in well-justified cases. If fences are erected to limit movement of individuals or populations, the impact on other species should be considered.

i. If animals are to be transported during the study, describe the precautions that will be taken to secure the animals, prevent hypo- or hyperthermia, and reduce stress during transport. Another consideration is to employ practices to decrease the likelihood of capture myopathy. Capture myopathy is a disease complex associated with the capture or handling of any wild animal.

j. Describe the precautions taken by the researchers working with animals to protect themselves from possible zoonotic diseases or injury.

k. Describe any experiment that may cause potential distress, what outcomes are likely and whether the impact (or outcome) is within the range of ‘normal’. For example, a robotic stimulus used to simulate an actual lion for the measurement of normal responses of vigilance and flight, animals are minimally disturbed but the range of the outcomes is normal. In other words, are the behavioral responses likely to be extraordinary (troubling) or not?

l. Describe potential alternative methods that may result in the reduction, replacement or refinement of those activities that may cause pain or distress. Describe why those alternatives are not appropriate for your research.

4. The investigator must certify to the IACUC whether physiological or behavioral data collection methods are minimally invasive. When possible, minimally invasive procedures must be used.

5. Euthanasia of wildlife in the field can raise unique and challenging issues that must be addressed by the investigator. The investigator should consult the 2013 Edition of the AVMA Guidelines for the Euthanasia on Animals, which includes considerations and techniques for euthanasia of wildlife.
6. The investigator must assure the IACUC that all necessary federal and state permits have been or will be obtained before the research begins. In addition, if the research is being conducted in a foreign country, the investigator must assure the IACUC that all necessary local permits have been or will be obtained before the research begins. See Appendix A.

7. The investigator must assure that all personnel working in the field will be properly trained and knowledgeable of the procedures as they are detailed in the protocol.

References


OLAW FAQ #4 Program Review and Inspection of Facilities: Is the IACUC required to inspect field study sites?


Mpala Research Center: http://www.mpala.org/

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