

SMITHSONIAN DIRECTIVE 605, August 11, 2014

ANIMAL CARE AND USE

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1. BACKGROUND

The Smithsonian Institution (SI) conducts research, laboratory, collection, and exhibition programs, which involve the use of live vertebrate animals. The Smithsonian acknowledges and accepts responsibility for the care and use of animals, and seeks to conduct animal activities with the highest respect for animal well-being.

2. APPLICABILITY

This Smithsonian directive applies to all SI employees and affiliated persons, as defined in Section 5 below, conducting research, research training, experimentation, biological testing, collection, exhibition, and related activities involving all species of vertebrate animals, also as defined in Section 5.

In addition, this policy applies to the above activities, whether carried out solely with Smithsonian resources or with the assistance of outside funds, conducted at facilities or field sites anywhere in the world, or at another institution (domestic or international), that is under the responsibility of the Smithsonian.

When Smithsonian researchers conduct activities using another institution's facilities or field sites, the Smithsonian's Animal Care and Use Committees (ACUCs) may review and accept another organization's established and approved policy for animal care and use.

3. PURPOSE

This directive establishes policies to ensure the humane care and use of all vertebrate animals involved in research, laboratory, collection, and exhibition activities at SI facilities and field locations, and to support SI compliance with applicable animal welfare laws and regulations.

4. POLICY

The Smithsonian Institution acknowledges and accepts responsibility for the care and use of vertebrate animals involved in activities covered by federal laws and policies protecting animals against risk. The Institution makes a reasonable effort to ensure that all SI employees and affiliated persons who are involved in the care and use of vertebrate animals in laboratories, hospitals, museums, exhibitions, or in captivity or in the field, understand their individual and collective responsibilities for compliance with this policy as well as all other applicable laws and policies pertaining to animal care and use.

The Smithsonian Institution is subject to the Animal Welfare Act, 7 *United States Code* (U.S.C.) §2131 et. seq., and the regulations promulgated thereunder by the U.S. Department of Agriculture (USDA).

The Smithsonian Institution also adheres to the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, developed by the Interagency Research Animal Committee and adopted in 1985 by the Office of Science and Technology Policy. This directive implements and supplements those principles.

In addition, the Smithsonian Institution complies with the Public Health Service (PHS) Policy on Humane Care and the Use of Laboratory Animals, which was revised in August 2002, for all of its PHS-supported activities involving vertebrate animals. The Institution is committed to complying with this and subsequent editions of this policy, when other sponsors require PHS compliance as a term of grant agreements that support activities involving vertebrate animals.

Furthermore, SI employees and affiliated persons are encouraged to follow animal care and use guidelines and policies provided by professional associations and societies. Examples of specific guidelines and policies can be found in Guidelines to the Use of Wild Birds in Research by The Ornithological Council; The Care and Use of Amphibians, Reptiles and Fish in Research by the Scientists' Center for Animal Welfare; and the Code of Ethics and Animal Welfare by the World Association of Zoos and Aquaria.

The Smithsonian conducts research, laboratory, collection, and exhibition programs, which involve the use of live vertebrate animals, in accordance with the *Guide for the Care and Use of*

4. POLICY (continued)

Laboratory Animals (hereafter, the *Guide*) revised in 2011 by the Institute of Laboratory Animal Resources, Commission on Life Sciences, for the National Research Council, and subsequent revised editions. This *Guide* serves as the standard by which animal care and use programs are developed and assessed. Because the *Guide* is written in general terms, the Smithsonian's ACUCs have a key role in the interpretation, oversight, and evaluation of these animal care and use programs.

SI employees and affiliated persons who submit proposals to granting agencies that require additional animal care and use guidelines must also comply with the granting agencies' guidelines.

All SI employees' and affiliated persons' proposals to use vertebrate animals at a non-Smithsonian facility (domestic or international) must be evaluated by their unit's ACUC. However, Smithsonian ACUCs may accept written certification from another institution's established Institutional Animal Care and Use Committee (IACUC), provided that the institution has filed a PHS Assurance of Compliance and that the compliance policy of the approving institution does not conflict with the Smithsonian's compliance policy.

In these cases, the approving institution's assurance number and a signed copy of its most recent protocol approval must be provided. ACUCs are responsible for ensuring that research performed under the approval of another institution's IACUC is documented in committee files.

Without exception, SI employees and affiliated persons may not collect animals, as defined below, or begin their proposed animal use without written authorization from their unit's ACUC, stipulating that the proposed animal care and use complies with the requirements outlined in this directive.

SI employees and affiliated persons who conduct activities with domestic or international partners that do not have in place a policy or mechanism to ensure the humane use and treatment of vertebrate animals must certify in writing to their ACUC that they will manage the animals proposed for use in accordance with the *Guide for the Care and Use of Laboratory Animals*, regardless of where the research or exhibition is conducted. In these cases, SI employees and affiliated persons may also provide their ACUC with the partners' certifications before proceeding.

5. DEFINITIONS

Animal — Any live vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing, exhibition, collection and related activities, excluding

5. DEFINITIONS (continued)

livestock or poultry solely used or intended for use as food or fiber or in routine husbandry. The above definition applies to wildlife and aquatic studies in natural settings. It does not apply to the Smithsonian's national collections of "dead" preserved animals or cryopreserved living tissue.

Animal Facilities — All SI facilities for animal activities, field sites, and facilities at other institutions (domestic or international), whether or not under the sub-granting or subcontracting of an activity supported by this Institution. This includes buildings, rooms, areas, enclosures, or vehicles or satellite facilities used for animal confinement, transport, maintenance, breeding, or experimentation inclusive of surgical manipulation.

Animal Study Proposal/Protocol — Proposed activities (protocols) related to animal care and use, as well as proposals for significant changes in previously approved ongoing activities, which the SI employee or affiliated person submits to his or her ACUC for review and approval prior to initiation of the project involving live animals.

Animal Welfare Regulations — Regulations promulgated by the USDA, Animal and Plant Health Inspection Service, pursuant to the authority in the Animal Welfare Act, 7 U.S.C. §2131 et. seq., and contained in 9 *Code of Federal Regulations* (CFR), Parts 1, 2, and 3.

Assurance — Documentation from the Smithsonian that must be filed with and approved by the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW), certifying that the Institution's four ACUCs are in compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Field Site — The location where a field study is performed. A field site is defined as an animal facility only when an animal is housed there for more than 12 hours.

Field Study — A study conducted on free-living wild animals in their natural habitat, as defined by the Animal Welfare Act Regulations (AWAR).

Guide — The *Guide for the Care and Use of Laboratory Animals*, which serves as the national standard by which animal care and use programs are developed and assessed. The *Guide* is published by the Institute of Laboratory Animal Resources, Commission on Life Sciences, for the National Research Council (2011, 8th edition or supplemental revised editions).

Institutional Animal Care and Use Committee (IACUC) — Referred to as ACUC for unitspecific committees — the Smithsonian IACUC is made up of ACUCs appointed by the directors of units that use animals in their research, collection, exhibition, educational programs, or related activities. Each committee oversees its unit's animal program, facilities, and procedures to ensure the humane care and use of animals, and compliance with pertinent

5. DEFINITIONS (continued)

guidelines and regulations, and is responsible for reviewing and approving requests for animal use in research.

The Smithsonian's four ACUCs are established within the National Museum of Natural History (NMNH), the National Zoological Park (NZP), encompassing both the Rock Creek (NZP-RC) Park and the National Zoological Park — Smithsonian Conservation and Biology Institute (SCBI) campuses, the Smithsonian Environmental Research Center (SERC), and the Smithsonian Tropical Research Institute (STRI).

Investigator or **Exhibitor** — An SI employee or affiliated person who is responsible for proposing and directing a project that includes research, training, experimentation, biological testing, collection, or exhibition. The terms "Principal Investigator," "Responsible Investigator," "Project Director," "Program Director," "Researcher," and "Curator" are interchangeable with the terms "Investigator" or "Exhibitor."

PHS Policy — The Public Health Service (PHS) Policy on Humane Care and use of Laboratory Animals, revised as of August 2002 (or in subsequent editions). PHS policy requires that all investigators receive ACUC approval for all PHS-funded projects using animals. The approval needs to be renewed every three years. PHS policy also requires ACUCs to review all active protocols on an annual basis. A number of sponsors (e.g., the National Science Foundation [NSF] and Morris Animal Foundation) also require Smithsonian compliance with this PHS policy.

Principles — The U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, as outlined in the PHS policy.

Smithsonian Institution Employees and Affiliated Persons — SI employees may be either federal or trust employees. Affiliated persons refers to the following categories of individuals who are not Smithsonian employees but who operate on Smithsonian property:

- Contractors embedded with Smithsonian employees;
- Volunteers, including Regents and advisory board members;
- Interns and Fellows;
- Friends of the National Zoo (FONZ) employees and Smithsonian Early Enrichment Center (SEEC) employees;
- Visiting researchers, scientists, scholars, and students;

5. DEFINITIONS (continued)

- Research associates, regardless of working title, with respect to their SI-related activities;
 and
- Federal agency or non-profit employees located at a Smithsonian facility with respect to
 their SI-related activities. Federal agency employees subject to animal care regulations of
 their home agency will be governed both by the regulations of the home agency and this
 directive. Smithsonian ACUCs will require protocol review, and the IACUC of the home
 agency may also require protocol review.

6. RESPONSIBILITIES

Institutional Official

The Smithsonian Under Secretary for Science (USS) is the Institutional Official (IO) responsible for ensuring that activities using research, laboratory, and exhibition animals, or other animals in captivity at the Smithsonian Institution, and the use or collection of animals under field conditions, are humane and in compliance with all applicable laws, outside policies, and Smithsonian policy. To that end, the IO is responsible for:

- establishing and enforcing relevant policies for the Institution, and procedures for mandatory annual federal reporting
- providing OLAW with a full explanation of the circumstances and actions taken with respect to:
 - a. any suspension of an activity by the ACUCs
 - b. any substantive deviations from the *Guide* (unless previously approved by the ACUC)
 - c. any serious or continuing noncompliance with the PHS policy

Directors of Units Caring for or Using Animals

Each director of a unit that uses or cares for animals on site or with off-site programs that involve animal care, collection, or research conducted by SI employees or affiliated persons is required by the USS to have an ACUC.

6. RESPONSIBILITIES (continued)

The director is responsible for appointing the committee members and the chairperson, and for ensuring that SI personnel are properly trained in the humane care and use of animals, and that they are qualified to perform their duties.

This includes making sure that staff members understand their obligation to comply with all relevant regulations and the specifics of the approved animal use and care protocols.

In addition, the director of the National Zoological Park is responsible for preparing the *Annual Report* to the USDA for approval by the IO, and for submitting the report to the USDA.

Animal Care and Use Committees (ACUCs)

The responsibilities of the ACUCs are listed in OLAW's *Institutional Animal Care and Use Committee Guidebook*, 2nd Edition, 2002), and the SI's internal ACUC Procedures (issued by the Office of the Under Secretary for Science). The Smithsonian ACUCs must follow the SI's internal ACUC procedures, using OLAW forms available at http://prism.si.edu/osp/index.htm on the Institution's intranet.

The ACUC will ensure that persons listed as animal handlers or researchers on protocols have completed required training in animal care and use, as outlined in SI's Internal ACUC Procedures (issued by the Office of the Under Secretary for Science), to include refresher training on a regular basis.

In addition, the ACUC Chairs are responsible for promptly informing the IO, through the Office of Sponsored Projects (OSP), of any suspension of an activity by the ACUC, substantive deviations from the *Guide* (unless previously approved by the ACUC), or any serious or continuing noncompliance with the PHS policy.

Director of the Office of Sponsored Projects (OSP)

The director of the OSP is responsible for collecting information from all ACUCs and reporting to OLAW, as needed. The specific responsibilities of OSP are to:

- inform the IO and ACUCs of changes made to applicable animal welfare laws and policies
- ensure that ACUC approval has been obtained prior to acceptance of a grant or contract

6. RESPONSIBILITIES (continued)

- write, negotiate, and maintain the Institutional Assurance of Compliance (#A3655-01) with OLAW
- collect and maintain the semiannual reports from each ACUC
- prepare the consolidated Annual Report to OLAW for approval by the USS, and submit the report to OLAW
- provide the SI internal ACUC procedures and OLAW forms to be used by the ACUCs

Investigator or Exhibitor

The investigator or exhibitor is responsible, either directly or by working with animal/laboratory managers or veterinarians, for supervising activities related to the care and use of animals in his or her projects. This person is responsible for conducting the animal study, project, or exhibit in compliance with this directive, the *Guide*, the PHS policy (when using PHS or NSF funds, or other sponsored funds when required by the sponsor), the Animal Welfare Act, and other applicable animal welfare laws and policies.

SI Employees and Affiliated Persons

Every SI employee and affiliated person has a responsibility to report incidents involving the improper treatment of animals to a member of the unit's ACUC, the ACUC chairperson or designee, or the USS as the Institutional Officer for animal welfare matters. Such individuals are protected from retribution by the SI's whistleblower policy (available on Prism).

7. ENFORCEMENT AND SANCTIONS

Smithsonian employees can be subject to the disciplinary process of the Institution if they fail to fully comply with this policy.

8. REFERENCES

References in support of this directive can be found in the following sources:

OSP Guide to Sponsored Projects

8. REFERENCES (continued)

- Smithsonian Institution Assurance of Compliance with PHS Policy on Humane Care and Use of Laboratory Animals (available from OSP's webpage)
- SD 604, Misconduct in Research (available on Prism)
- SD 321, Review and Submission of Proposals for Sponsored Projects (available on Prism)
- USDA Animal Welfare Act, as amended (7 U.S.C., §§ 2131–2156). See
 http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf
- PHS *Policy on Humane Care and Use of Laboratory Animals* (1986), amended August 2002. See http://grants2.nih.gov/grants/olaw/references/phspol.htm
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985), Office of Science and Technology Policy. See http://www.grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples
- Guide for the Care and Use of Laboratory Animals (8th ed., 2011), National Research Council. See http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-Laboratory-animals.pdf

CANCELLATION: SD 605, March 4, 2006

INQUIRIES: Office of Sponsored Projects (OSP)

RETENTION: Indefinite. Subject to review for currency 24 months from date of issue.