

CARE, USE, AND TRANSPORTATION OF ANIMALS IN RESEARCH

I. Purpose

This Directive and the accompanying Instruction establish the authorities, responsibilities, requirements, and procedures for the care, use and transportation of animals in all activities conducted or sponsored by the Department of Homeland Security (DHS). This Directive adopts the principles of the U.S. Department of Agriculture (USDA) implementation of the Animal Welfare Act, the Public Health Service (PHS) implementation of the Health Research Extension Act, and other related regulations and guidelines listed in Part III.

II. Scope

This Directive applies to all activities conducted, sponsored, or funded by DHS through a contract, grant, cooperative agreement, or other transaction or arrangement. Its scope includes all activities involving the care, use, and transportation of animals, as defined in the accompanying Instruction hereto. This includes all such activities conducted at DHS-owned facilities and non-DHS facilities, including subcontractors and sub-awardees.

III. Authorities

- A. Title 6, United States Code (U.S.C.), Chapter I, Subchapter III, Section 182, "Responsibilities and Authorities of the Under Secretary for Science and Technology"
- B. Title 7, U.S.C., Chapter 54 (Sections 2131-2159), "Transportation, Sale, and Handling of Certain Animals" (Animal Welfare Act)
- C. Title 42, U.S.C., Chapter 6A, Subchapter III, Part H, Section 289d, "Animals in Research"
- D. Title 9, Code of Federal Regulations, Chapter 1, Subchapter A, Part 1, "Definition of Terms," Part 2, "Regulations," and Part 3, "Standards" (Animal Welfare Regulations)
- E. Guide for the Care and Use of Laboratory Animals, National Research Council, 2011 (8th Edition)
- F. PHS Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, National Institutes of Health (NIH), 2015
- G. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, U.S. Interagency Research Animal Committee (IRAC), Federal Register, May 20, 1985, Vol. 50, No. 97
- H. Guide for the Care and Use of Agricultural Animals in Research and Teaching, Federation of Animal Science Societies, 2010 (3rd edition)

I. DHS Delegation 10001, "Delegation to the Under Secretary for Science and Technology"

IV. Responsibilities

A. The **Under Secretary for Science and Technology** is the DHS Animal Welfare Official (AWO). The AWO ensures full implementation of and compliance with this Directive and relevant regulations, guidelines, and policies to ensure the proper care, use, and transportation of animals in DHS conducted or supported activities. The AWO:

1. Ensures all DHS Components incorporate the provisions of this Directive into their policies, procedures, and programs;
2. Approves any further DHS-wide practice, procedure, or guidance to ensure proper care, use, and transportation of animals in DHS-conducted, funded, or sponsored activities;
3. Monitors any incidents of noncompliance with this Directive, and takes appropriate action in response to such incidents;
4. Designates a DHS representative to the NIH Interagency Research Animal Committee (IRAC) or subsequent committees or bodies convened for similar purposes, who is an individual with the necessary technical qualifications, grade, and experience; and
5. Supports budget requests to meet Directive requirements.

B. The **Compliance Assurance Program Manager (CAPM)** acts as the focal point for oversight and compliance with this Directive. The CAPM operates the Compliance Assurance Program Office (CAPO) and supports the AWO in ensuring operational compliance. The CAPM:

1. Supports the AWO in the effort to ensure all DHS Components fully implement and comply with this Directive and relevant laws, regulations, guidelines, and principles to ensure proper care, use, and transportation of animals in activities conducted or sponsored by DHS;
2. Provides guidance and assistance to DHS Components and entities to ensure and maintain compliance with this Directive and relevant laws, regulations, guidelines, and principles;
3. Monitors DHS compliance with the provisions of this Directive;
4. Reviews and approves proposals involving the care, use, or transportation of animals prior to the initiation of work for DHS-sponsored and funded activities at non-DHS facilities;
5. Conducts inspections, site visits, and project and documentation reviews of activities conducted or sponsored by DHS that involve the care, use, or transportation of animals to ensure compliance with this Directive and the Authorities in Part III; and

6. Monitors corrective actions taken in response to reported incidents of noncompliance with this Directive and its authorities.

C. The **Veterinary Medical Officer (VMO) of the Office of Health Affairs** coordinates with CAPO in the review and approval of all protocols involving the care, use, or transportation of nonhuman primates in activities conducted or sponsored by DHS.

D. **DHS Component Heads** are responsible for supporting Department-wide implementation of and compliance with this Directive, the accompanying Instruction, and relevant regulations, guidelines, policies, and principles. In exercising this authority, DHS Components and Subcomponents:

1. Monitor compliance, in coordination with CAPO, with the provisions of this Directive for activities conducted or sponsored by DHS involving the care, use, or transportation of animals;
2. Ensure timely submission of documentation and CAPO review and approval for all relevant activities prior to the initiation of work involving the care, use, or transportation of animals;
3. Consult with CAPO on the development of any further Component-wide practice, procedure, or guidance, as needed, to ensure the proper care, use, and transportation of animals in activities conducted, funded, or sponsored by DHS; and
4. Report to CAPO and appropriate DHS Program Office instances of any serious or continuing incidents of noncompliance with this Directive that occur in association with DHS-conducted, funded, or sponsored activities no more than 10 calendar days after occurrence.

E. **All DHS personnel** conduct themselves in accordance with the responsibilities set forth above, as well as with any subsequently developed and approved policy, procedure, or guidance to ensure the proper care, use, and transportation of animals in DHS activities.

V. Policy and Requirements

A. **Policy:**

1. The proper care, use, and transportation of animals in activities conducted or sponsored by DHS are primary goals achieved through the establishment and maintenance of appropriate measures implementing applicable federal, state, and local regulations, statutes, practices, principles, and guidelines that are endorsed and adopted by DHS.

2. Entities performing DHS-conducted, funded, or sponsored activities establish and maintain proper measures to ensure appropriate care, use, and transportation of animals. Each entity conducting DHS-funded or sponsored activities involving the care, use, and transportation of animals is responsible for ensuring compliance with the Authorities in Part III of this Directive, but this Directive does not supersede those Authorities.

3. A duly constituted Institutional Animal Care and Use Committee (IACUC) reviews and approves all DHS-conducted, funded, or sponsored activities and proposed significant changes to ongoing activities involving the care, use, or transportation of animals prior to the initiation of work. IACUCs are established in accordance with the requirements set forth in the PHS Policy and Animal Welfare Regulations;
4. DHS-conducted or sponsored activities involving animal care, use, or transportation are accomplished by entities under a written Assurance approved by DHS or the NIH Office of Laboratory Animal Welfare that are in accordance with PHS Policy requirements.
5. Entities performing DHS-conducted, funded, or sponsored activities consider alternative methods to the use of animals, whenever possible, if such methods produce scientifically valid and equivalent results to attain the research or activity objectives.
6. Entities performing DHS-conducted, funded, or sponsored activities obtain animals used in activities conducted or sponsored by DHS from USDA-licensed suppliers in accordance with all applicable regulations, unless specifically exempted.
7. DHS-owned or operated laboratories that maintain animals for use in research are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) or are actively implementing a documented plan for and progressing towards successful AAALAC accreditation.
8. All personnel involved in the conduct, review, or approval of DHS-conducted, funded, or sponsored activities involving animal care, use, or transportation have received appropriate training, and are provided annual refresher training, in proper animal handling, care, and use.
9. Protocols and significant protocol changes, involving the care, use, or transportation of nonhuman primates are submitted to CAPO by entities performing DHS-conducted, funded, or sponsored activities for review and approval, in coordination with the VMO, prior to initiation of work.
10. Entities conducting DHS-funded or sponsored activities involving the care, use, or transportation of animals outside the U.S., including those performed or jointly sponsored by a foreign government, provide written assurances, and additional documentation as determined by CAPO, prior to the initiation of work, that the entity is compliant with all applicable laws, regulations, standards, and guidelines of the country where the work is being performed.
11. Instances of any serious or continuing incidents of noncompliance with this Directive are reported within 10 calendar days after identification of occurrence to CAPO and the sponsoring DHS Program Office. Any consequences of reporting outside the deadline are determined on a case-by-case basis.

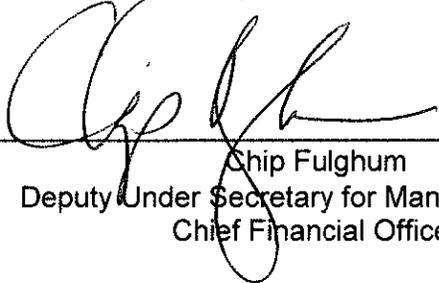
B. **Requirements:**

1. All personnel involved in the conduct, review, or approval of DHS-conducted, funded, or sponsored activities involving animal care, use, or transportation conduct themselves in accordance with the responsibilities set forth in Section IV as well as with any subsequently developed and approved policy, procedure, or guidance to ensure the proper care, use, and transportation of animals in DHS activities.

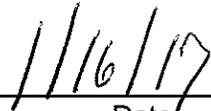
2. All definitions in the USDA Animal Welfare Regulations and the PHS Policy apply to this Directive, except as otherwise defined.

VI. Questions

Any questions or concerns regarding this Directive should be addressed to the CAPM.



Chip Fulghum
Deputy Under Secretary for Management and
Chief Financial Officer



Date