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CARE AND USE OF ANIMALS IN RESEARCH

I. Purpose

This Management Directive (MD) establishes the Department of Homeland Security (DHS) practices for the care and use of animals in DHS research programs. In particular, this MD 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 Care Extension Act, and the other related federal principles and guidelines as they represent the ethical foundation for the care and use of animals in research.

II. Scope

This MD applies to all DHS personnel. It applies only to research activities involving animals conducted by DHS or that are sponsored or funded by DHS through a contract, grant, cooperative agreement, other transaction, or other arrangement.

III. Authorities

- A. Title 6, U.S.C., Section 182, "Responsibilities and authorities of the Under Secretary for Science and Technology"
- B. Title 7, U.S.C., 2131, et seq., "Transportation, Sale, and Handling of Certain Animals" (Animal Welfare Act)
- C. Title 42, U.S.C., 289d, "Animals in Research"
- D. Title 9, CFR, Chapter 1, Subchapter A, Parts 1, "Definition of terms," 2, "Regulations," and 3, "Standards" (USDA Regulations)
- E. Guide for the Care and Use of Laboratory Animals, National Research Council, 1996
- F. Public Health Service Policy on Humane Care and Use of Laboratory Animals, Office of Laboratory Animal Welfare, 2002

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, 50 Federal Register 20864 (May 20, 1985)

H. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, Federation of Animal Science Societies, 1999

IV. Definitions

All definitions of words and phrases in the USDA Regulations and Public Health Service Policy on Humane Care and Use of Laboratory Animals apply to this MD, except as otherwise defined:

A. **Activity**: Those elements of research, testing, teaching procedures, exhibition, or other related purposes that involve the care and use of animals.

B. **Animal**: Any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded 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.

C. **Animal Welfare Assurance or Assurance**: The documentation from an organization or institution assuring organizational or institutional compliance with this MD.

D. **Component**: Shall have the meaning given to the term in DHS MD 0010.2, Management Directives System.

E. **Department**: DHS.

F. **Institutional Animal Care and Use Committee (IACUC)**: A committee appointed by the head of the Component or chief executive of the institution with the experience and expertise to oversee the organization's or institution's program for the care and use of animals, facilities, and procedures.

G. **Secretary**: The Secretary of Homeland Security.

V. Responsibilities

A. **The Under Secretary for Science and Technology** is the DHS Animal Welfare Official (AWO) and is responsible for the implementation of and compliance with this MD and the other related regulations, guidelines, and principles to provide the appropriate care and use of animals in research activities conducted or supported by DHS. To this end, the AWO may delegate within Science and Technology the specific authority to train for, monitor, and oversee animal welfare compliance within DHS for research activities.

1. To establish executive oversight the AWO will:
 - a. Ensure that the heads of DHS Components incorporate the provisions of this MD into their policies, procedures, and programs that involve the care and use of animals in research activities as defined herein.
 - b. Approve any further DHS-wide practice, procedure, or guidance to ensure the proper care and use of animals in DHS research activities.
 - c. Take action as deemed appropriate in regard to reported issues of serious noncompliance with this MD.
 - d. Designate a DHS representative to the National Institutes of Health (NIH) Interagency Research Animal Committee (IRAC) who is an individual of appropriate technical qualifications, grade and experience.
 - e. Support budget requests to meet the requirements of this MD.
2. In addition, to ensure operational compliance the AWO will:
 - a. Develop training and training guidance, as needed, to enable the consistent and effective application of animal care and use in research practices DHS-wide.
 - b. Monitor DHS compliance with the provisions of this MD, as appropriate.
 - c. Conduct reviews and site visits of DHS conducted or sponsored research activities which use animals, when deemed necessary to assess the adequacy or accuracy of compliance with this MD.

- d. Prior to implementation approve any practice, procedure, or guidance concerning the care and use of animals in DHS research activities.
- e. Monitor remedial activity, as appropriate, with regard to reported issues of serious noncompliance with this MD.
- f. Act as the DHS approval authority for all Assurances submitted to DHS for approval and maintain a database of DHS-approved Assurances.
- g. Review and approve all proposals requiring the use of nonhuman primates in research activities conducted or sponsored by DHS.
- h. Act as the DHS point of contact for the coordination and response to inquiries from public and private entities not involved in the DHS program concerning the conduct and support of animal research by DHS.

B. **The Associate General Counsel for Science and Technology** will coordinate on all policies and procedures concerning the use of animals in research.

C. **The DHS Chief Veterinarian (CV)** has general technical responsibility to support the AWO in the effort to ensure that the Department fully understands and implements this MD and the other related regulations, guidelines, and principles to provide the appropriate care and use of animals in research activities conducted or supported by DHS. Specifically, prior to implementation the CV will review any practice, procedure, or guidance concerning the care and use of animals in DHS research activities and review any use of nonhuman primates in research activities conducted or sponsored by DHS.

D. **The Office of the Secretary and all DHS Components** will ensure that all research activities involving animals that they conduct or sponsor comply with this MD and the other related federal, state, and local laws, regulations, guidelines, and principles. The Office of the Secretary and all DHS Components will:

- 1. Ensure that all personnel involved in the conduct or sponsorship of research activities including the use of animals are fully trained, commensurate with their duties; to ensure the proper care of said animals in accordance with the provisions of this MD.

2. Develop any needed practices, procedures, or guidance to ensure the proper care and use of animals in DHS research activities and submit the practices, procedures or guidance through the CV to the AWO for approval.
3. Monitor compliance with the provisions of this MD within the DHS Component.
4. Prepare and submit Assurance documentation for approval in accordance with the provisions of this MD when conducting research activities involving the use of animals.
5. Ensure that all institutions conducting DHS sponsored research involving animals have Assurances that are approved as required by this MD.
6. Ensure that all DHS conducted or sponsored research activities involving the use of animals are reviewed and approved by a duly constituted IACUC.
7. Forward all proposals requiring the use of nonhuman primates in research activities conducted or sponsored by the Component to the CV for review and the AWO for approval prior to execution.
8. Coordinate with the Science and Technology Office of Technology Assurance prior to entering into any contracts, grants, cooperative agreements, or like arrangements which pertain to animal research.
9. Ensure that any issues of noncompliance with this MD within the Component are reported through the CV and CS&T to the AWO; and that serious issues are also forwarded to the Inspector General in accordance with MD 0810.1. Report any injuries to personnel resulting from animal research activities in the same fashion as a biological mishap (see MD 10101, Biosafety).
10. Forward all inquiries from public and private entities not involved in the DHS program concerning the conduct and support of research activities involving the use of animals through the CV to the AWO for coordination and response.

VI. Policy & Procedures

A. Policy.

1. The proper care and use of animals in research activities conducted or sponsored by DHS are primary goals that will be achieved through the establishment and maintenance of appropriate measures implementing the applicable federal statutes, practices, principles, and guidelines that are endorsed and adopted by the Department, as well as measures addressing applicable state and local regulations.
2. All proposals or protocols for the use of animals in research activities conducted or sponsored by DHS will be reviewed and approved by a duly constituted IACUC before any research activities involving animals are initiated.
3. All research involving the use of animals conducted or supported by DHS will be accomplished under an Assurance of compliance acceptable to and approved by the AWO for DHS or the Office of Laboratory Animal Welfare (OLAW), NIH.
4. Assurances acceptable to DHS must be in accordance with the basic requirements of the Public Health Service on Humane Care and Use of Laboratory Animals (PHS Policy), and any affiliated IACUCs must be established under the same requirements as set forth in that PHS Policy.
5. Alternative methods to the use of animals shall be considered, whenever possible, if such alternative methods produce scientifically valid and equivalent results to attain the research or activity objectives.
6. Animals used in research activities conducted or sponsored by DHS will be legally obtained from suppliers licensed by the USDA in accordance with the USDA Regulations, unless specifically exempted.
7. When DHS maintains animals for use in research, it will develop a plan for, and work towards accrediting its programs of animal care and use by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), provided that any information it is required to submit to AAALAC will not compromise DHS security concerns and mandates. Such documents must be reviewed and approved by DHS security personnel as appropriate before submission to AAALAC.

8. All DHS personnel involved in the conduct, review, or approval of the use of animals in research activities will receive appropriate, annual training in animal care and use which is commensurate with their duties.

9. All proposals requiring the use of nonhuman primates in research activities conducted or sponsored by DHS must be reviewed by the CV and approved by the AWO prior to execution.

10. Proposals intending to use chimpanzees must be reviewed and approved by the Interagency Animal Model Committee.

11. Research activities involving animals that are conducted outside the United States, including those that are performed or jointly sponsored by a foreign government, will comply with U.S. regulatory and legal standards and requirements, unless the standards of the host country are more stringent. Such animal use research will be cleared in advance by the AWO and the CS&T.

12. Issues related to noncompliance with this MD will be referred within 10 days to the next higher management level, and through the CV and CS&T to the AWO to resolve. All serious noncompliance issues must also be reported to the Office of Inspector General in accordance with MD 0810.1. No action, administrative or disciplinary, will be taken against a person for the act of reporting any such noncompliance.

B. **Procedures:**

All officials and employees shall conduct themselves in accordance with the responsibilities set forth in Section V as well as with any subsequently developed and properly approved policy, procedure, or guidance to ensure the proper care and use of animals in DHS research activities.

VII. Questions

Any questions or concerns regarding this MD should be addressed to the Under Secretary for S&T.