



Department of Defense DIRECTIVE

NUMBER 3216.1

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DDR&E

SUBJECT: Use of Laboratory Animals in DoD Programs

- References:
- (a) DoD Directive 3216.1, "Use of Animals in DoD Programs," February 1, 1982 (hereby canceled)
 - (b) Title 9, Code of Federal Regulations, "Animals and Animal Products," Chapter 1, Subchapter A, "Animal Welfare," Parts 1, 2, and 3
 - (c) Public Law 101-511, Department of Defense Appropriations Act for Fiscal Year 1991, Section 8019, and Section 2241 of title 10, United States Code
 - (d) Sections 2131 through 2156 of title 7, United States Code, "The Laboratory Animal Welfare Act of 1966," as amended
 - (e) through (f), see enclosure 1

1. REISSUANCE AND PURPOSE

1.1. Reissues reference (a) to update policy governing activities using animals within the Department of Defense.

1.2. Designates the Secretary of the Army as the DoD Executive Agent to develop and issue Service regulations to implement this Directive.

2. APPLICABILITY

This Directive applies to the Office of the Secretary of Defense, the Military Departments, the Uniformed Services University of the Health Sciences, and the Defense Agencies (hereafter referred to collectively as the "DoD Components") that perform or sponsor activities using animals.

3. DEFINITIONS

Terms used in this Directive are defined in enclosure 2.

4. DoD POLICY

4.1. Federal statutes, regulations, and publications that provide national standards and guidance for the acquisition, transportation, housing, control, maintenance, handling, protection, treatment, care, use, and disposal of animals shall be applicable to all activities using animals. A summary of the applicable documents cited as references is in enclosure 3.

4.2. Animals shall be legally obtained from suppliers licensed by the U.S. Department of Agriculture (USDA) in accordance with reference (b) unless specifically exempted from the licensing requirements stated in reference (b).

4.3. DoD organizations or facilities maintaining animals for use in research, testing or training shall apply for accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

4.4. Alternative methods to animal species shall be considered, whenever possible, if such alternatives produce scientifically valid or equivalent results to attain the research testing and training objectives.

4.5. The purchase or use of dogs, cats, or nonhuman primates in research conducted for developing biological, chemical, or nuclear weapons is prohibited.

4.6. The purchase or use of dogs, cats, or nonhuman primates for inflicting wounds from any type of weapon(s) to conduct training in surgical or other medical treatment procedures is prohibited (reference (c)).

4.7. DoD organizations or facilities wishing to hold training programs using animals, such as advanced trauma life support (ATLS) training programs, shall have the training protocol reviewed and approved by a duly constituted Institutional Animal Care and Use Committee (IACUC) in accordance with references (d) and (e) and paragraph 4.8. of this Directive to ensure the humane use of animals. DoD organizations or facilities conducting ATLS training that require housing of animals for short periods of time shall ensure adequate care and shall have the animal housing facilities inspected and approved by a veterinarian prior to receipt of the animals.

4.8. All proposals or protocols for animal experiments or demonstrations in RDT&E, clinical investigation, instructional, or training programs conducted or sponsored by a DoD organization or facility shall be reviewed and approved by a duly constituted IACUC composed of a minimum of five members. There shall be at least one non-scientific member on each IACUC. In addition, there also shall be a member who represents the general community interest and is non-affiliated with the facility sponsoring IACUC. The non-affiliated and the non-scientific membership can be filled by the same person. To ensure community representation at each meeting and inspection, an alternate to the non-affiliated member shall be designated for IACUCs having a single non-affiliated membership. Since the DoD IACUCs perform a Government function in an approval process and do not serve merely as an advisory body, the non-affiliated and the non-scientific member(s) to DoD IACUCs shall either be a Federal employee, with demonstrated commitment to the community or a consultant consistent with the requirements established by reference (f).

4.9. A headquarters-level administrative review shall be conducted for proposals involving the use of nonhuman primates conducted or sponsored by subordinate activities of the DoD Component for conformance with all applicable Federal regulations and policies. A DoD Component may delegate this responsibility to another DoD Component for purposes of efficiency and consolidation of functional offices.

4.10. The DoD Components shall coordinate and cooperate in the transfer of Government-owned nonhuman primates between facilities to maximize conservation and proper utilization.

4.11. Proposals intending to use chimpanzees must be further reviewed and approved by the Interagency Animal Model Committee, which coordinates national priorities for research utilization of this species.

4.12. The DoD Components that sponsor animal-based research, testing, and training under a DoD grant or contract shall ensure that:

4.12.1. All extramural research proposals using live animals shall be administratively reviewed by a DoD veterinarian trained or experienced in laboratory animal science and medicine before grant or contract award.

4.12.2. The most recent USDA inspection reports are provided or obtained for the facility under consideration for a research contract or grant using animals, and that during the term of the award, the most recent USDA inspection reports be reviewed on an annual basis.

4.12.3. A DoD veterinarian trained or experienced in laboratory animal science and medicine shall conduct an initial site visit to evaluate animal care and use programs at contracted facilities conducting DoD-sponsored research using nonhuman primates, marine mammals, dogs, cats, or proposals deemed to warrant review. The initial site visit shall occur within 6 months of when the facility has taken delivery of the animals under DoD contract or grant award. Any facility receiving a DoD-funded grant or contract for animal-based research shall notify the DoD Component sponsor and shall have a site inspection within 30 days of notification of loss of AAALAC accreditation for cause, or notification that the facility is under USDA investigation. Site inspections for cause shall evaluate and ensure the adequacy of animal care and use in DoD-sponsored programs, and provide recommendations to the sponsoring DoD Component about continued funding support of the research.

4.13. In the case of differences between the standards of care and use of animals as cited in enclosure 3, the most stringent standard shall apply.

4.14. Activities covered by this Directive that are performed or sponsored in foreign countries shall be conducted in accordance with applicable U.S. statutory requirements, and regulations and standards of the host country. If differences exist between U.S. and host country regulations or standards, unless prohibited by the host country, the more stringent standard shall apply.

4.15. While not specifically addressed in this Directive, ceremonial, recreational, and working animals, such as military working dogs, shall be treated in a humane manner.

4.16. Personnel with complaints of violation of this Directive shall report such violations to either of the following members of the organization or facility: The IACUC chairperson, the attending veterinarian, the facility Commander, or the Inspector General. The IACUC shall review and, if warranted, investigate all reports of complaints of animal use or noncompliance with 7 U.S.C. 2131-2 of reference (d), applicable Directives, and Regulations.

5. RESPONSIBILITIES

5.1. The Director, Defense Research and Engineering under the Under Secretary of Defense for Acquisition and Technology or designee shall:

5.1.1. Issue policy and procedural guidance concerning animal use consistent with all applicable Federal regulations and policies.

5.1.2. Designate a DoD representative to the Interagency Research Animal Committee who is a veterinarian of appropriate rank or grade and experience, and preferably also a diplomate of the American College of Laboratory Animal Medicine.

5.1.3. Establish the Joint Technical Working Group (JTWG) to act as the central advisory committee to the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee on all matters on the care and use of animals for research, testing, clinical investigation, or training within the Department of Defense. The co-chairpersons of the ASBREM Committee shall designate the chairperson of JTWG.

5.2. The Heads of the DoD Components shall:

5.2.1. Establish appropriate mechanisms to monitor compliance with this Directive and applicable Federal statutes and regulations.

5.2.2. Establish offices or facilities that shall serve as reviewing or approving authorities of animal use proposals from subordinate activities and extramural facilities proposing research under contract or grant.

5.2.3. Provide members to JTWG, as required.

5.2.4. Designate the appropriate office(s) within the DoD Component that shall perform the headquarters-level administrative review of proposals requiring the use of nonhuman primates and shall serve as the office where exemptions under paragraph 4.2., above, may be approved.

5.2.5. Support, and as necessary, ensure the development of animal care and use training programs for researchers and members of the IACUC, and certification programs for all personnel involved in the care, use, and treatment of animals.

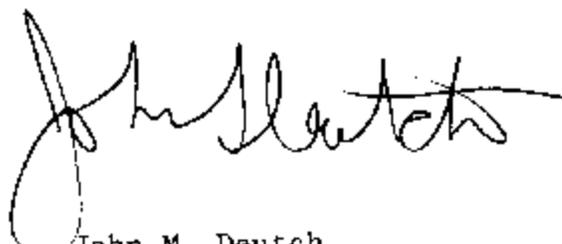
5.3. The Secretary of the Army shall:

5.3.1. As Executive Agent, develop and issue, in consultation with the other DoD Components, joint Service regulations to implement this Directive.

5.3.2. Designate the Commander, U.S. Army Veterinary Command/Director, DoD Veterinary Services Activity, a Field Operating Agency of the Army, Office of the Surgeon General, who shall serve as a consultant to the Assistant Secretary of Defense for Health Affairs and the Director, Defense Research and Engineering for technical and professional matters related to this Directive.

6. EFFECTIVE DATE

This Directive is effective immediately.



John M. Deutch
Deputy Secretary of Defense

Enclosures - 3

- E1. References, continued
- E2. Definitions
- E3. Guidance Documents

E1. ENCLOSURE 1

REFERENCES, continued

- (e) National Institutes of Health (NIH) Publication No. 86-23, "Guide for the Care and Use of Laboratory Animals," United States Department of Health and Human Services, National Institutes of Health, Revised 1985
- (f) Section 3109 of title 5, United States Code

E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Animal. Any dog, cat, non-human primate, guinea pig, hamster, rabbit or any other live vertebrate animal, which is being used or is intended for use for research, training, testing, or experimentation purposes. For this Directive, it includes birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, training, testing or experimentation purposes. The term excludes animals used for ceremonial or recreational purposes, military working animals, and animals intended for use as livestock and poultry 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.

E2.1.2. Clinical Investigation. All activities directed towards clinical research conducted principally within medical treatment facilities. The Clinical Investigations program is part of the Defense Health Program of the Assistant Secretary of Defense (Health Affairs) and is supported by Major Force Program 8 (MFP-8) funds.

E2.1.3. Instructional Program. All educational and training activities, except training of ceremonial and recreational animals and training associated with military working animals or survival skills training.

E2.1.4. Research, Development, Test, and Evaluation. All activities that form the RDT&E program of the Director, Defense Research and Engineering (DDR&E) and are supported by Major Force Program 6 (MFP-6) funds.

E2.1.5. Alternatives. Any system or method that covers one or more of the following: replacing or reducing the number of laboratory animals required for an investigation by computer simulation, cell culture techniques, etc.; or, refining an existing procedure or technique to minimize the level of stress endured by the animal.

E2.1.6. DoD Sponsored Programs. All proposals or designs for animal experiments or demonstration in RDT&E, clinical investigation, or instructional programs conducted or funded by grant, award, loan, contract, or cooperative research and development agreement (CRADA).

E3. ENCLOSURE 3

ADDITIONAL FEDERAL STATUTES, REGULATIONS, AND GUIDELINES ON THE USE OF ANIMALS

E3.1.1. The following documents provide national standards and guidance for the protection, treatment and use of animals:

E3.1.1.1. Animal Welfare Act (Sections 2131-2158 of title 7, United States Code, as amended, and Title 9, Code of Federal Regulations, Parts 1-4, implementing rules and regulations). Administered by Regulatory Enforcement and Animal Care (REAC), Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture. Requires licensing of dealers, identification of animals, maintenance of records, submission of reports, establishment of an Institutional Animal Care and Use Committee (IACUC), and compliance with standards for the humane handling, care, treatment, and transportation of animals by dealers and research facilities.

E3.1.1.2. Endangered Species Act of 1973 (Sections 1531-1543 of title 16, United States Code, as amended, and Title 50, Code of Federal Regulations, Parts 10-14 and 217-227, implementing rules and regulations). Provides a program under the U.S. Fish and Wildlife Service, Department of Interior, for conserving threatened and endangered species. Requires import/export permits, maintenance of records, and submission of reports on the care and handling of endangered, threatened, and conserved species.

E3.1.1.3. Marine Mammal Protection Act (Sections 1361-1384 of title 16, United States Code, as amended, and Title 50, Code of Federal Regulations, Parts 10-14 and 216-227, implementing rules and regulations). Provides a program under the Departments of Commerce (National Marine Fisheries Service) and Interior (U.S. Fish and Wildlife Service) for the protection of marine mammals and marine mammal products. Requires acquisition permits, maintenance of records, submission of reports, and inspections on the care and handling of marine mammals.

E3.1.1.4. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (TIAS 8249, as amended, and Title 50, Code of Federal Regulations, Part 23, implementing rules and regulations). CITES is a treaty involving 106 signatory nations administered in the United States by the Fish and Wildlife Service of the Department of the Interior. CITES regulates the import and export of imperiled species covered by the treaty but imposes no restrictions or control on interstate shipments.

E3.1.1.5. Lacey Act (Section 42 of title 18, United States Code, as amended, and Title 50, Code of Federal Regulations, Part 16 and Subpart B, implementing rules and regulations). A program under the U.S. Fish and Wildlife Service, Department of the Interior. Prohibits the importation of certain wild animals or their eggs if the Secretary of the Interior determines that they are injurious to humans, the interest of agriculture, or other specified national interests.

E3.1.1.6. Guide for the Care and Use of Laboratory Animals. Public Health Service, National Institutes of Health, NIH Publication No. 86-23, Revised. Provides guidelines for institutional policies, husbandry, requirements, veterinary care, and physical plant requirements for programs involving the care and use of laboratory animals.

E3.1.1.7. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. Published by the Consortium for Developing a Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching, 309 West Clark Street, Champaign, IL 61820, March 1988. Provides guidelines for the care and use of the major agricultural animal species in the United States in research and teaching.