



DoD INSTRUCTION 3216.01

USE OF ANIMALS IN DoD CONDUCTED AND SUPPORTED RESEARCH AND TRAINING

Originating Component: Office of the Under Secretary of Defense for Research and Engineering

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Approved by: Michael D. Griffin, Under Secretary of Defense for Research and Engineering

Purpose: In accordance with the authority in DoD Directive (DoDD) 5134.01 and the July 13, 2018 Deputy Secretary of Defense Memorandum, this issuance, establishes policy and assign responsibilities for the use of animals in DoD conducted and supported research and training.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

a. This issuance applies to:

(1) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the “DoD Components”).

(2) Research, development, test and evaluation (RDT&E), or training that is conducted or supported both within the continental United States and outside of the continental United States.

(3) Animals as defined in the Glossary.

b. This issuance does not apply to:

(1) Animals used strictly for ceremonial or recreational purposes and working animals, such as military working dogs. However, if ceremonial, recreational, or working animals are also used to conduct RDT&E or training this issuance applies.

(2) 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.

(3) Animals used in disease surveillance or in field studies, as defined in the Glossary.

(4) Activities performed as part of environment, safety, and occupational health programs in accordance with DoDD 4715.1E, or as part of pest management programs in accordance with DoD Instruction (DoDI) 4150.07. Animal use in these activities should comply with the relevant guidance in Armed Forces Pest Management Board Technical Guides 3, 38, and 41.

1.2. POLICY. It is DoD policy that:

a. RDT&E or training conducted or supported by the DoD will comply with applicable federal and DoD policies and guidance that provide national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, welfare, use, and final disposition of animals. This includes the statutes, policies, and guidance applicable to this issuance listed in the References and referred to collectively in this issuance as “Animal Use Authorities.” Where differences in standards exist, apply the standard that most stringently protects the health and welfare of the animals in question.

b. Activities subject to this issuance that are conducted by the DoD in foreign countries will comply with the requirements in Paragraph 1.2.a. and the requirements of the host nation.

c. Activities subject to this issuance that are supported by the DoD in foreign countries will comply with applicable DoD policies, adhere to host nation laws and regulations, and ensure animal welfare standards comparable to those in the United States.

d. Alternative methods to animal use will be considered and used whenever possible to attain the objectives of RDT&E or training if such methods produce scientifically or educationally valid or equivalent results.

e. Procedures will cause the least pain or distress to the minimum number of animals and be consistent with the scientific or training needs.

f. Animals used in RDT&E or training will have non-terminal disposition (e.g., adoption, retirement, inter-agency transfer) whenever possible.

g. The purchase or use of live dogs or cats for the purpose of training in surgical or other medical treatment of wounds produced by any type of weapon(s) is prohibited in accordance with Section 8019 of Public Law 101-511. The purchase or use of nonhuman primates or marine mammals for the purpose of training in surgical or other medical treatment of wounds produced by any type of weapon(s) is also prohibited.

h. In accordance with Section 718 of Public Law 115-232, medical simulation technology will be used to the maximum extent practicable, before the use of live tissue training to train medical professionals and combat medics of the DoD, except as provided by Paragraph 1.2.i.

i. The use of live tissue training within DoD may be used as determined necessary by the medical chain of command.

SECTION 2: RESPONSIBILITIES

2.1. UNDER SECRETARY OF DEFENSE FOR RESEARCH AND ENGINEERING (USD(R&E)). The USD(R&E):

a. Is the DoD point of contact for all matters related to DoD compliance with this issuance, and will act as the principal DoD liaison with agencies outside the DoD on matters pertaining to animal care and use for RDT&E and training.

b. Provides guidance and policy necessary to implement this issuance, after consulting with the Assistant Secretary of Defense for Health Affairs (ASD(HA)), for matters affecting medical training.

c. Provides guidance and policy necessary to implement this issuance, after consulting with the Director, Defense Health Agency, for matters affecting animal health and welfare in accordance with Paragraph 2.4.b.

d. Exercises the responsibilities and authorities of the Secretary of Defense identified in Section 2143(c) of Title 7, United States Code (U.S.C.) for:

(1) Ensuring corrective action is taken on significant deficiencies of DoD research facilities.

(2) Granting exceptions to procedures or requirements in this issuance based upon an appropriate justification from an OSD or DoD Component head and consistent with law.

e. Establishes a process to oversee implementation of the respective DoD Component animal use management plans (CAUMPs) and compliance with this issuance.

f. Establishes policies and procedures to facilitate efficient management for the humane care and use of animals in DoD conducted and supported RDT&E and training.

g. Maintains and updates the:

(1) DoD Standard Animal Use Protocol Format available at https://www.acq.osd.mil/rd/hptb/programs/regulatory/doc_animal/references/au-DoD_Standard_Animal_Use_Protocol.pdf.

(2) DoD (DD) Form 2856, “DoD Semiannual Program Review/Facility Inspection Checklist” available at <https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2856.pdf>.

h. Designates a DoD representative to the Interagency Coordinating Committee on the Validation of Alternative Methods, pursuant to Public Law 106-545.

i. Establishes a working group on animal use in DoD programs to:

(1) Act as the central advisory committee for the DoD on all matters regarding the care and use of animals for RDT&E and training.

(2) Ensure the DoD has a continued focus on refining, reducing, and replacing animal use in RDT&E and training.

j. Maintains a list of vendors approved by OSD and each DoD Component for every training plan. Establish a process for communicating this throughout the components.

2.2. ASD(HA). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, the ASD(HA) advises the USD(R&E) on matters related to the necessity and appropriate educational use of animals to teach medical or surgical care for humans and the suitability of animal replacements.

2.3. CHIEF OF THE NATIONAL GUARD BUREAU. In addition to the responsibilities in Paragraph 2.5, the Chief of the National Guard Bureau serves as the:

a. Principal advisor to the Secretary of Defense, through the Chairman of the Joint Chiefs of Staff, on matters involving non-federalized National Guard and has the specific responsibility to address matters relating to the Army National Guard, the Army National Guard of the United States, and the Air National Guard of the United States.

b. Channel of communications between the other DoD Components and the Adjutants General of the States for matters pertaining to National Guard personnel, training, and resources, including when animals are used for RDT&E and training.

2.4. DIRECTOR, DEFENSE HEALTH AGENCY (DHA). Under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, and in addition to the responsibilities in Paragraph 2.5, the Director, DHA:

a. In consultation with DoD Components that have an animal use program, develops and issues supporting guidance for this issuance.

b. Designates a DoD veterinarian board certified in laboratory animal medicine to serve as a consultant to the ASD(HA) and to USD(R&E) for veterinary technical and professional matters related to this issuance.

2.5. OSD AND DOD COMPONENT HEADS. The OSD and DoD Component heads that use or directly support the use of animals covered by this issuance, excluding USD(R&E), will:

a. Oversee development of the CAUMP and obtain its approval from USD(R&E). The CAUMP:

(1) Designates an individual, referred to in this issuance as the component's "responsible official," to serve as the sole authority for implementing and overseeing the CAUMP. The

responsible official must be a single, senior official at the general officer/flag officer, Senior Executive Service, or equivalent level, or higher. Further delegations of authority and responsibility for the oversight of the use of animals for specific purposes (e.g., research versus training) will be designated in writing and detailed in the CAUMP.

(2) Contains implementing policies and procedures to ensure compliance with this issuance and any other supplementing or implementing issuances.

(3) Incorporates the procedures in Section 3.

(4) Integrates applicable federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, welfare, use, and final disposition of animals. This includes the Animal Use Authorities and other applicable federal policies and guidance.

b. Establish and oversee implementation of component policies and procedures for animal use. Component policies may be more restrictive than the requirements in this issuance, but they may not be less restrictive. They will include policies and procedures:

(1) For component oversight office administrative review of DoD conducted and supported RDT&E, training in accordance with Paragraphs 3.1. and 3.2., and allegations of noncompliance or misconduct in accordance with Paragraph 3.4.

(2) For component oversight office supervision of the inspections of the institutions' animal care and use program review, including the institutions' facility inspection. This should ensure that the program reviews are appropriately conducted and corrective action is taken in a timely manner in accordance with Paragraphs 3.1. and 3.2.

(3) That support the assignment of responsibilities when performing RDT&E and training in collaboration with another DoD Component, to include establishing written agreements for tasks such as single Institutional Animal Care and Use Committee (IACUC) approval, single component oversight office administrative reviews and inspections in accordance with Paragraph 3.1., or single oversight of extramural RDT&E and training in accordance with Paragraph 3.2.

(4) To evaluate and approve, or withhold approval of, animal care and use programs for component supported training in order to establish an approved list of vendors to provide component supported training, if applicable.

(5) To provide education and training for implementation, management, and oversight of this issuance in accordance with Paragraph 3.3.

c. Coordinate and cooperate in the transfer of government owned nonhuman primates within the DoD and with other governmental agencies to maximize conservation and proper utilization.

d. Provide members to intra- and interagency committees when requested by the USD(R&E).

e. Notify the USD(R&E) within 5 business days of any of the following:

(1) Significant deficiencies.

(2) Noncompliance with this issuance that results in animal pain, distress, or death for any reason.

(3) Change in an institution's Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) accreditation status.

(4) Reports of adverse events to outside agencies.

(5) Socially sensitive matters.

f. Maintain all component waivers, exemptions, exceptions, or other deviations from requirements granted in accordance with this issuance.

g. Maintain all records identified in this issuance or required by the Animal Use Authorities for at least 3 years beyond the expiration or closure date of the approved RDT&E or training activity in accordance with Paragraph 3.5.

SECTION 3: PROCEDURES

3.1. DOD-CONDUCTED RDT&E AND TRAINING.

a. Acquisition of Animals.

(1) When purchasing animals covered by this issuance within the United States, the DoD Components will ensure that the animals are obtained legally from suppliers licensed by the United States Department of Agriculture (USDA) in accordance with:

- (a) Sections 2133-2134 of Title 7, U.S.C.
- (b) Parts 1-4 of Title 9, Code of Federal Regulations (CFR).
- (c) Policy 8 in the USDA Animal Care Policy Manual.

(2) When a United States supplier claims it meets an exemption criterion in Title 7, U.S.C.; Parts 1-4 of Title 9, CFR; or Policy 8 in the USDA Animal Care Policy Manual:

(a) A DoD veterinarian designated by the DoD Component will conduct a program review that includes a facility inspection to confirm that the supplier cares for the animals according to accepted U.S. industry standards or practices and meets the exemption criterion.

(b) If the supplier is accredited by AAALAC International, the component may waive the requirement for on-site inspection. This waiver does not preclude the component from conducting an inspection at any time.

(3) When conducting RDT&E or training outside of the United States and using foreign suppliers, the DoD Component will:

(a) Require a program review that includes a facility inspection, as well as a DoD veterinarian who will conduct the review to confirm the animals are provided humane care and treatment and that the supplier is in compliance with their host nation laws and regulations.

(b) At its discretion, waive the requirement for on-site inspection if the supplier is accredited by AAALAC International. This waiver does not preclude the component from conducting an inspection at any time.

(4) When capturing animals from the wild for the purposes of RDT&E or training, DoD institutions will ensure they have all required capture and use permits before acquisition.

b. Accreditation by AAALAC International. All DoD institutions maintaining animals for RDT&E or training will attain and maintain AAALAC International accreditation. Exemptions to this requirement will be requested by the component's responsible official and granted as the USD(R&E) determines appropriate.

c. IACUC Membership. The IACUCs of DoD institutions will:

(1) Consist of committee members who are appointed by the most senior leader (commander, president, chief executive officer) of the institute or the institutional official he or she delegates this responsibility to.

(2) Consist of committee members who are federal employees or individuals covered by Sections 3371-3376 of Title 5, U.S.C. In accordance with Section 3109 of Title 5, U.S.C., IACUCs may consult with subject matter experts who are not members of the committee. These subject matter experts may not vote.

(3) Have at least five members with various backgrounds to promote complete and accurate review of RDT&E or training activities commonly conducted by the institution. An individual member may fulfill more than one role on the IACUC.

(4) Have one member serve as the Chair of the committee.

(5) Have at least one member who is a doctor of veterinary medicine with training or experience in laboratory animal science and medicine and who has direct or delegated authority and responsibility for RDT&E or training activities involving animals at the institution.

(6) Have at least one member who represents the general community interest and is not a present or former laboratory animal user, is not affiliated with the institution, and is not an immediate family member of a person who is affiliated with the institution. DoD IACUCs should designate an alternate member(s) for the nonaffiliated member to facilitate community representation in the IACUC's activities.

(7) Have at least one member whose interests, training, and education are in a nonscientific area.

(8) Have no more than three primary voting members from the same administrative unit of the institution. If an institution's administrative units are unclear, a final determination will be made by the DoD Component oversight office.

(9) Have a quorum when official business requiring full committee is conducted.

d. IACUC Approval and Oversight.

(1) An IACUC constituted in accordance with Paragraph 3.1.c. must approve all RDT&E and training before the activity in question can begin.

(2) DoD Components will submit all proposed RDT&E and training to the IACUC using the DoD Standard Animal Use Protocol Format or in a pre-approved alternative format with comparable detail approved by the USD(R&E). When the DoD Standard Animal Use Protocol Format is used, additions to, but not subtractions from, the DoD Standard Animal Use Protocol Format do not require pre-approval.

(3) A veterinarian, with direct or delegated authority and responsibility for the animals, will oversee the animals being used during the RDT&E or training as described either in the protocol approved by the IACUC or as described in IACUC policy.

(4) The IACUC must review and approve all modifications to an IACUC-approved protocol before modification implementation.

(5) The IACUC must review all its approved RDT&E and training at least annually.

(6) The IACUC will perform a *de novo* review at least every 3 years on all RDT&E and training approved by the IACUC.

e. Program Review and Facility Inspection. All DoD institutions using or housing animals for RDT&E or training will conduct a program review, including a facility inspection, at least once every 6 months. The program review and facility inspection must be documented using DD Form 2856 or in an alternative format with comparable detail pre-approved by the USD(R&E). A majority of the institution's IACUC members will sign the report to the institutional official, and the report will include a statement indicating the presence or absence of minority opinions.

f. Component Oversight Office Approval and Oversight.

(1) The component oversight office must conduct an administrative review of all RDT&E requiring the use of nonhuman primates, dogs, cats, or marine mammals, and all training using animals to teach human medical or surgical care.

(a) This review must be approved by a DoD veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with all applicable regulations, policies, and standards of veterinary care before any such use of animals can begin.

(b) To facilitate the review and approval process and preclude redundancy of effort, the components may establish a process for administrative reciprocity in their CAUMPs.

(c) Component oversight offices without an appropriately trained DoD veterinarian can use another component's DoD veterinarian to perform this function, provided an organizational agreement is in place that establishes compliant processes and procedures.

(2) When an IACUC approves a major modification to an approved protocol that was administratively reviewed by the component oversight office as required in Paragraph 3.1.f.(1), the component oversight office must review and approve the changes to the IACUC approved protocol before they can be implemented unless the component oversight office has reviewed and approved IACUC policies and procedures for exceptions.

(3) The component oversight office will regularly review reports of the institutional program review conducted by the IACUC required by Paragraph 3.1.e. to ensure that corrective actions are completed in a timely manner.

g. USDA Inspection Reports. The DoD research facility will submit Animal and Plant Health Inspection Service Form 7023 (Annual Report of Research Facility) to the USDA as required and in accordance with Parts 1-4 of Title 9, CFR.

h. Site Visit. The component oversight office should conduct a compliance inspection at each DoD facility every 3 years or prior to the facility's AAALAC international site visit.

i. Notifications to the DoD Component. Institutions will notify their DoD Component oversight office of any significant deficiencies, noncompliance with this issuance, change in AAALAC international accreditation status, reports of adverse events, and socially sensitive matters in a manner that is consistent with the CAUMP and current policies. The component oversight office will notify the USD(R&E) within 5 business days of any of the following:

- (a) Significant deficiencies.
- (b) Noncompliance with this issuance that results in animal pain, distress, or death for any reason.
- (c) Change in an institution's AAALAC international accreditation status.
- (d) Reports of adverse events to outside agencies.
- (e) Socially sensitive matters.

3.2. DOD-SUPPORTED, BUT NOT CONDUCTED, RDT&E AND TRAINING.

a. Clause in Contracts and Agreements. All contracts for DoD supported RDT&E or training must contain Defense Federal Acquisition Regulations Supplement (DFARS) clause 252.235-7002. Agreements not subject to the DFARS (e.g., grants, cooperative research, and development agreements) must contain language equivalent to that in DFARS 252.235-7002.

b. USDA Registration. Non-federal institutions conducting DoD supported RDT&E or training in the United States must be registered with the USDA, unless otherwise exempt from this requirement by meeting the conditions in Title 7, U.S.C., and Title 9, CFR for the duration of the activity.

c. Accreditation by AAALAC International. For all training to teach human medical or surgical care using live animals, institutions will attain and maintain AAALAC international accreditation.

d. IACUC Approval and Oversight.

(1) The performing institution's IACUC must approve DoD-supported RDT&E and training involving animals in accordance with Title 7, U.S.C., before the activity begins.

(2) A veterinarian with direct or delegated authority and responsibility from the performing institution for the animals will oversee the animals being used during the RDT&E or

training as described either in the protocol approved by the IACUC or as described in IACUC policy.

(3) The IACUC must review and approve all modifications to an IACUC-approved protocol before that protocol can be implemented.

(4) The IACUC must review, at least annually, all RDT&E and training that it approved in accordance with Parts 1-4 of Title 9, CFR.

e. Component Oversight Office Approval and Oversight.

(1) The component oversight office must conduct an administrative review of all DoD supported RDT&E involving animals and training to teach human medical or surgical care involving animals.

(a) This review must be approved by a DoD veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with all applicable regulations, policies, and standards of veterinary care before animal work can begin.

(b) To facilitate the review and approval process and preclude redundancy of effort, the components may establish a process for administrative reciprocity in their CAUMPs.

(c) Component oversight offices without an appropriately trained veterinarian can request that another component's veterinarian perform this function, provided an organizational agreement is in place that establishes compliant processes and procedures.

(d) Although non-DoD institutions are not required to use the DoD Standard Animal Use Protocol Format, documents submitted to the component oversight office will provide all pertinent information and level of detail regarding animal care contained in the DoD Standard Animal Use Protocol Format.

(2) When an IACUC approves a major modification to an approved protocol that was administratively reviewed by the component oversight office as required in Paragraph 3.2.e.(1), the component oversight office must review and approve the changes to the IACUC approved protocol before they can be implemented, unless the component oversight office has reviewed and approved IACUC policies and procedures for exceptions.

f. Acquisition of Animals.

(1) **Extramural RDT&E and Training Conducted in the United States.** The performing institution will include in the documents submitted to the DoD Component for review a statement that the animals are legally obtained from suppliers licensed by the USDA in accordance with Sections 2133-2134 of Title 7, U.S.C., unless the supplier claims to meet the exemption criteria in Title 7, U.S.C.; Parts 1-4 of Title 9, CFR; or Policy 8 in the USDA Animal Care Policy Manual. When a supplier claims to meet the exemption criteria, the institution performing the work will convey the claim of exemption to the DoD component that is supporting the performing institution's RDT&E or training involved.

(2) **Extramural RDT&E and Training Outside of the United States.** The performing institution will include in the documents submitted to the DoD Component for review a statement that the animals are legally obtained from suppliers in accordance with national policy.

(3) **Wild Animals.** When capturing animals from the wild for the purpose of the DoD supported RDT&E or training, the performing institution will include in the documents submitted to the DoD Component for review all required capture and use permits.

g. USDA Inspection Reports. As part of the DoD approval process, the DoD Component will also review the most recent USDA inspection reports, unless the institution is exempt from inspection by meeting the criteria in Title 7, U.S.C., and Title 9, CFR. The inspection reports must be reviewed annually for the duration of the activity.

h. Site Visit.

(1) For all RDT&E using dogs, cats, nonhuman primates, or marine mammals, and for all training using live animals, the DoD supported institution must pass an onsite compliance inspection conducted by a DoD veterinarian to ensure that the animal care program meets the standards in Title 7, U.S.C.; Parts 1-4 of Title 9, CFR; and the National Research Council's Guide for the Care and Use of Laboratory Animals. These inspections may be extended to include DoD-supported RDT&E involving any species. At its discretion, the component may also conduct site inspections for DoD-supported RDT&E regardless of animal species. The initial and any subsequent onsite inspections will be performed at the discretion of the component as long as animals are being used. For efficiency, a component may rely on the inspection of another component provided there are established policies or agreements between the components.

(2) If an institution is accredited by AAALAC international or meets comparable standards for the duration of the RDT&E or training agreement, the DoD Component may waive the requirement for onsite inspection. This waiver does not preclude the component from conducting an inspection at any time.

i. Notifications to the DoD Component.

(1) When a DoD supported institution is notified by the USDA that it is under investigation, the institution will notify the supporting DoD Component within 5 business days. An institution with AAALAC international accreditation will notify the component within 5 business days of a change in status of AAALAC international accreditation. Upon either of these notifications and when the issues are relevant to a DoD supported activity, a DoD veterinarian will perform a site inspection for cause as soon as practicable, ideally within 30 days of the notification.

(2) Site inspections for cause will evaluate and ensure the adequacy of animal care and use in DoD supported programs, and provide recommendations to the component about:

- (a) Allowing continued DoD support of the RDT&E or training.
- (b) Suspending the RDT&E or training until necessary changes have been made.

(c) Terminating the RDT&E or training.

(3) The DoD supported institution must notify the component oversight office in accordance with Paragraph 3.2.e.(2) when the IACUC approves a major modification to the protocol or approves IACUC policies that affect major modifications to protocols, and when the IACUC conducts its continuing review.

(4) The component will require the DoD supported institution to inform the component oversight office, in a timely manner, of any significant deficiencies, noncompliance with this issuance, and reports of adverse events regarding DoD-supported RDT&E or training. The component oversight office will notify the USD(R&E) within 5 business days of any of the following:

(a) Significant deficiencies.

(b) Noncompliance with this issuance that results in animal pain, distress, or death for any reason.

(c) Change in an institution's AAALAC international accreditation status.

(d) Reports of adverse events to outside agencies.

(e) Socially-sensitive matters.

3.3. EDUCATION AND TRAINING. The DoD Components will ensure that all DoD personnel involved in the conduct, review, or approval of RDT&E and training involving animals, including the non-affiliated members of the DoD IACUCs, receive initial and ongoing education and training.

a. Training and education will integrate federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, welfare, use, and final disposition of animals.

b. Both initial and ongoing education and training will be commensurate with the duties and responsibilities of the DoD personnel.

c. All training and education of DoD personnel will be documented.

d. Certification by professional organizations is encouraged for all personnel involved in the care and use of animals in RDT&E or training.

3.4. RESEARCH MISCONDUCT. The DoD Components will comply with the requirements for reviewing allegations of misconduct in accordance with DoDI 3210.7.

3.5. RECORD KEEPING.

a. Records of approved RDT&E and training activity will be retained if they are:

(1) Records from DoD conducted or supported RDT&E and training that are created by the government and institution conducting the work.

(2) All records regarding component waivers, exemptions, and extensions, and all component requests for exceptions, waivers, exemptions, and extensions submitted to the USD(R&E) for action.

b. For complete recordkeeping guidance and instruction, the DoD Components will consult their respective records disposition schedules.

c. Records that document extramural compliance or noncompliance with this issuance will be made accessible for inspection and copying by authorized representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

GLOSSARY

G.1. ACRONYMS.

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ASD(HA)	Assistant Secretary of Defense for Health Affairs
CAUMP	component animal use management plan
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DoDD	DoD directive
DoDI	DoD instruction
IACUC	Institutional Animal Care and Use Committee
RDT&E	research, development, test, and evaluation
U.S.C.	United States Code
USDA	United States Department of Agriculture
USD(R&E)	Under Secretary of Defense for Research and Engineering

G.2. DEFINITIONS. Unless otherwise noted, these terms and their definitions are for the purpose of this issuance.

administrative review of an RDT&E or training protocol. A review of documents related to animal use for RDT&E or training by a component oversight office that is overseen by a component-level veterinarian. This review is not intended to be another IACUC review. The purpose of this review is to ensure that the institution performing the RDT&E or training has met the requirements in all applicable regulations and policies and meets acceptable standards of animal care and welfare.

adverse event. An incident that leads to unintended and substantial injury or illness, unrelieved pain or distress, or death of an animal.

alternatives. Alternatives to animal use are characterized by “the three R’s”: replacement, reduction, and refinement. Investigators may replace animals with less complex (sentient) models or use non-animal methods. Reduction refers to the use of fewer animals. Existing procedures may be refined so that animals are subjected to less pain and distress.

animal. Any living or dead vertebrate animal, including birds, cold blooded animals, rats of the genus *rattus* and mice of the genus *mus*. With respect to avians and other egg laying vertebrate species, their offspring are considered animals only after hatching. With respect to fish and

amphibians, their larval offspring are considered animals. Title 7, U.S.C., governs most species of vertebrate animals; this issuance governs all species of vertebrate animals.

For the purposes of this definition, “dead” is defined as animals killed for the direct purpose of conducting RDT&E or training. However, it does not include dead animals or parts of dead animals purchased at grocery stores or slaughterhouses.

component oversight office. The office(s) identified in the CAUMP as having the responsibility to conduct the headquarters-level administrative review of RDT&E and training.

de novo review. A complete review of each previously IACUC approved, ongoing activity at least every 3 years, performed by the IACUC. The same assessment criteria that IACUCs use to conduct a new protocol submission must be adhered to because it is very likely that the science has evolved, that the current protocol may include multiple amendments that have been approved over the 3-year period, and that the IACUC may have new policies or a revised protocol application form that asks new questions that need to be addressed.

disease surveillance. A systematic collection, analysis, and interpretation of health data of an animal or animals for the purpose of monitoring the presence of a condition in an individual animal or an animal population. Disease surveillance in animals is not governed by Title 7, U.S.C., or this issuance unless the animal is harmed for the purpose of collecting data.

DoD-conducted RDT&E or training. RDT&E or training conducted by DoD personnel. DoD-conducted RDT&E or training is also referred to as “intramural” RDT&E or training. The intramural RDT&E or training may be performed in collaboration with a non-DoD institution or supported by a non-DoD institution (also referred to as an “extramural institution”).

DoD-supported RDT&E or training. The provision of DoD funding, animals, facilities, equipment, or any other resources to an institution other than the DoD that are needed to conduct the RDT&E or training. DoD-supported RDT&E or training is also referred to as “extramural” RDT&E or training.

extramural RDT&E or training. RDT&E or training that is conducted by an institution that is not part of the DoD.

field study. An investigation conducted on free-living wild animals in their natural habitat. A field study excludes any investigation that involves an invasive procedure, harms, or materially alters the behavior of the animal under study. A field study is not governed by Title 7, U.S.C., or this issuance.

harm. Any procedure that causes lasting physical, behavioral, psychological deficits or damage, or exposes an animal to potentially perilous situations (e.g., releasing a nocturnal animal during daylight hours).

IACUC. A board that is charged with evaluating an institution’s care, treatment, housing, and use of animals, and with assuring compliance with Title 7, U.S.C., and this issuance.

institution. An entity that may be a DoD Component or a non DoD public or private entity that is engaged in RDT&E or training involving the use of animals.

institutional official. The institutional official is, or is appointed by, the institution's most senior leader (commander, president, chief executive officer) and can legally commit the institution to comply with federal requirements for animal care and use. The institution involved may be a DoD Component or a non DoD public or private entity.

major modification. A major amendment or significant change to an approved protocol as determined by the IACUC performing the review.

marine mammal. Animals belonging to the class *mammalia* and whose primary habitat is the sea or ocean (e.g., cetaceans and pinnipeds).

minority opinion. A belief or judgment that represents the view of less than one-half of the whole group.

non-affiliated IACUC member. An individual who represents general community interests in the proper care and use of animals, is not a current or former laboratory animal user, is not affiliated with the institution, and is not an immediate family member of a person who is affiliated with the institution.

noncompliance. An activity not in accordance with this issuance and its references.

nonhuman primate. Any nonhuman member of the order *primata*, including prosimians, monkeys, and apes.

quorum. A quorum is obtained when a majority of the voting members of the IACUC are present.

RDT&E. Refers to a series of four broad categories of activities beginning with the exploration of a concept and ending with the determination that a product is suitable for its intended use. RDT&E is not defined by appropriation type, budget activity, the DoD institution supporting or conducting the work, the type of extramural institution conducting the work, the program title, the security classification, or other limiting criteria when animals are used for one of these activities. The four categories of activity are:

research. A systematic investigation of a scientific question employing a hypothesis, structured methodology, and controlled study design (e.g., a manipulation of variables, an assessment of differences in outcome due to variables) for the purpose of contributing to the generalized body of knowledge.

development. A systematic investigation, structured methodology, or controlled study designed for the purpose of further refining the product and demonstrating its intended use.

test. A systematic analysis of the product to ensure that it meets its intended goals.

evaluation. An analysis of the product's suitability and readiness to be produced and fielded.

responsible official. The general officer/flag officer, Senior Executive Service, or equivalent level individual within a component who has sole authority and responsibility for implementing and overseeing the component's animal use management plan.

significant deficiency. A deficiency that, in the judgement of the IACUC and the institutional official, is or may be a threat to the health or safety of animals.

training. An activity with the goal of imparting knowledge, skills, and competencies to a human. Training is covered by this issuance when using animals:

To conduct training in support of RDT&E;

To teach medical or surgical care for humans;

To teach veterinary procedures when the training may cause pain or distress to the animal and is not part of a necessary medical procedure.

veterinarian. A person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has a certificate issued by the American Association of Veterinary State Boards Program for the Assessment of Veterinary Education Equivalence, is licensed, and has received training or experience in the species being used.

weapon. A device (e.g., a club, knife, gun, or directed energy) used to injure, defeat, or destroy.

wound. An injury or damage usually restricted to those caused by physical means with disruption of normal continuity of the body's structures.

REFERENCES

Animal Use Authorities

Use of the most current version of the following is appropriate.

- American Veterinary Medical Association, "Guidelines for the Euthanasia of Animals," 2013 Edition
- Code of Federal Regulations, Title 50, Parts 10-14, 16, 23, and 216-226
- Code of Federal Regulations, Title 9, Parts 1-4, and 313
- DoD Directive 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," July 5, 2006
- DoD Directive 6400.04E, "DoD Veterinary Public and Animal Health Services," June 27, 2013, as amended
- Federation of Animal Science Societies, "Guide for the Care and Use of Agricultural Animals in Research and Teaching," January 2010
- Interagency Research Animal Committee, "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," 1985
- National Institutes of Health, Office of Laboratory Animal Welfare, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," March 16, 2015
- National Research Council, "Guide for the Care and Use of Laboratory Animals, 8th edition" National Academies Press, 2011
- United States Code, Title 7, Chapter 48, Sections 1901-1907, and Sections 2131-2159
- United States Code, Title 16, Sections 1361-1423 and 1531-1544
- United States Code, Title 18, Section 42
- United States Department of Agriculture Animal Care Policy Manual

Other References

- Armed Forces Pest Management Board Technical Guide No. 3, "Feral Animal Risk Mitigation in Operational Areas," January 2017
- Armed Forces Pest Management Board Technical Guide No. 38, "Protecting Meal, Ready-to-Eat Rations (MREs) and Other Subsistence During Storage," December 2016
- Armed Forces Pest Management Board Technical Guide No. 41, "Protection From Rodent-Borne Diseases," December 2013
- Defense Federal Acquisition Regulation Supplement, Clause 252.235-7002, "Animal Welfare," and Clause 237.175, "Training that uses live vertebrate animals," current edition, December 2014
- Deputy Secretary of Defense Memorandum, "Establishment of the Office of the Under Secretary of Defense for Research and Engineering and the Office of the Under Secretary of Defense for Acquisition and sustainment," July 13, 2018

DoD 7000.14-R, DoD Financial Management Regulation, Volume 1-16, Under Secretary of Defense (Comptroller)

DoD Directive 4715.1E, “Environment, Safety, and Occupational Health (ESOH),” March 19, 2005

DoD Directive 5134.01, “Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)),” December 9, 2005, as amended

DoD Instruction 3210.7, “Research Integrity and Misconduct,” May 14, 2004

DoD Instruction 4150.07, “DoD Pest Management Program,” May 29, 2005, as amended

Public Law 101-511, Section 8019, “The Department of Defense Appropriations Act, 1991,” November 5, 1990

Public Law 106-545, “ICCVAM Authorization Act of 2000,” December 19, 2000

Public Law 115-232, section 718, “John S. McCain National Defense Authorization Act for Fiscal Year 2019,” August 8, 2018

United States Code, Title 5