

***DHA-MSR 6025.02
ARMY REGULATION 40-33
SECNAVINST 3900.38D
AIR FORCE MANUAL 40-401(I)
DARPAINST 18
USUHSINST 3203
SEPTEMBER 1, 2022***

***THE CARE AND USE OF ANIMALS IN DOD RESEARCH,
DEVELOPMENT, TEST, AND EVALUATION (RDT&E) OR
TRAINING PROGRAMS***

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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***THE DEFENSE HEALTH AGENCY AND THE DEPARTMENTS
OF THE ARMY, THE NAVY, AND THE AIR FORCE***

SEPTEMBER 1, 2022

UNCLASSIFIED

Defense Health Agency
Headquarters
Departments of the Army,
Navy, and Air Force
Falls Church, VA

DHA-MSR 6025.02
Army Regulation 40-33
SECNAVINST 3900.38D
Air Force Manual 40-401(I)
DARPAINST 18
USUHSINST 3203
September 1, 2022

DHA Veterinary Service Branch

SUBJECT: The Care and Use of Animals in DoD Research, Development, Test, and Evaluation (RDT&E) or Training Programs

References: See Enclosure 1.

1. PURPOSE. This Defense Health Agency-Multi-Service Regulation (DHA-MSR), based on the authority of References (a) through (ad), establishes the Defense Health Agency's (DHA) procedures to implement Reference (p). As such, it establishes the procedures to set forth the responsibilities and policies for the care and use of animals used in Research, Development, Test, and Evaluation (RDT&E) or training that is conducted or supported at any location by Department of Defense (DoD) programs. This publication covers any animal, as defined in the Glossary, being used or intended for use in RDT&E or training programs.

2. APPLICABILITY.

a. This DHA-MSR applies to the Defense Health Agency (DHA), DHA Components (activities under the authority, direction, and control of DHA), Office of the Secretary of Defense (OSD), the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Defense Agencies, and all other organizational entities within the DoD (referred to collectively in this publication as the "DoD Components").

b. This DHA-MSR does not apply to the following:

(1) Animals used strictly for ceremonial and/or recreational purposes and working animals, such as military working dogs and service dogs; however, if ceremonial, recreational, or military working animals are also used to conduct RDT&E or training, as defined in the Glossary, this publication 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 Reference (l), or as part of Reference (q). Animal use in these activities should comply with relevant Armed Forces Pest Management Board technical guidance (References (f) through (h)). Armed Forces Pest Management Board Technical Guides that are cited in DoD policy issuances carry the weight of DoD policy, and implementing component directives, instructions, and regulations.

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to Reference (n) and Reference (p), that the DHA, other DoD Components, and RDT&E and training institutions, will follow the procedures outlined within this MSR for the proper use and oversight of animals used in DoD-conducted and supported RDT&E and training. The Defense Health Agency (DHA) has been charged to work in consultation with the other DoD Components to develop, issue, and implement this publication.

4. CANCELLED DOCUMENTS. This publication cancels and replaces the Army Regulation 40-33/SECNAVINST 3900.38C/AFMAN 40-401(I)/DAPAINST 18/USUHSINST 3203, "The Care and Use of Laboratory Animals in DoD Programs," February 16, 2005.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. **Cleared for public release**. This publication is cleared for public release and is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx>.

8. EFFECTIVE DATE. This publication:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

9. FORMS. Forms referenced in this document can be retrieved from the following locations:

- a. DD Form 2856, DoD Semi Annual Program Review Facility Inspection Checklist is available at https://www.esd.whs.mil/Directives/forms/whs_forms/.

- b. OLAW Semiannual Program Review and Facility Inspection Checklist is available at <https://olaw.nih.gov/sites/default/files/Program%20Review%20checlist.pdf>

- c. APHIS Form 7023, Annual Report of Research is available at www.aphis.usda.gov/aphis/resources/forms.

/S/
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Director

By Order of the Army, Navy, Air Force, Defense Advanced Research Projects Agency, and
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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” August 24, 2018
- (d) American Veterinary Medical Association Guidelines for the Euthanasia of Animals: 2020 Edition¹
- (e) American Veterinary Medical Association Guidelines for the Humane Slaughter of Animals: 2016 Edition²
- (f) Armed Forces Pest Management Board Technical Guide No. 3, “Feral Animal Risk Mitigation in Operational Areas,” August 2020³
- (g) Armed Forces Pest Management Board Technical Guide No. 38, “Protecting Meal, Ready-to-Eat Rations (MREs) and Other Subsistence During Storage,” December 2016⁴
- (h) Armed Forces Pest Management Board Technical Guide No. 41, “Rodent-Borne Diseases, with Special Emphasis on Protection of Hantavirus” December 2020⁵
- (i) Code of Federal Regulations, Title 9, Parts 1-4, 160-162, and 313
- (j) Code of Federal Regulations, Title 50, Parts 10–14, 16, 23, and 216–226
- (k) Defense Federal Acquisition Regulation Supplement, clause 252.235-7002, “Animal Welfare,” current edition
- (l) DoD Directive 4715.1E, “Environment, Safety, and Occupational Health (ESOH),” March 19, 2005, as amended
- (m) DoD Directive 6025.21E, “Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries,” July 5, 2006, as amended
- (n) DoD Directive 6400.04E, “DoD Veterinary Public and Animal Health Services,” June 27, 2013, as amended
- (o) DoD Instruction 3210.07, “Research Integrity and Misconduct,” May 14, 2004, as amended
- (p) DoD Instruction 3216.01, “Use of Animals in DoD Conducted and Supported Research and Training,” March 20, 2019, as amended
- (q) DoD Instruction 4150.07, “DoD Pest Management Program,” December 26, 2019
- (r) Federation of Animal Science Societies, “Guide for the Care and Use of Agricultural Animals in Research and Teaching,” 2020

¹ This reference can be found at: <https://www.avma.org/sites/default/files/2020-02/Guidelines-on-Euthanasia-2020.pdf>

² This reference can be found at: <https://www.avma.org/sites/default/files/resources/Humane-Slaughter-Guidelines.pdf>

³ This reference can be found at: <https://extranet.acq.osd.mil/eie/afpmb/cac/techguides/tg3.pdf>

⁴ This reference can be found at: <https://www.acq.osd.mil/eie/afpmb/docs/techguides/tg38.pdf>

⁵ This reference can be found at: <https://www.acq.osd.mil/eie/afpmb/docs/techguides/tg41.pdf>

- (s) National Research Council, National Academies Press, “Guide for the Care and Use of Laboratory Animals,” Eighth Edition, 2011
- (t) National Institutes of Health, Office of Laboratory Animal Welfare, “Public Health Service Policy on Humane Care and Use of Laboratory Animals,” Revised 2015
- (u) Public Law 101-511, Section 8019 “The Department of Defense Appropriations Act, 1991,” November 5, 1990
- (v) Public Law 106-545, “ICCVAM Authorization Act of 2000,” December 19, 2000
- (w) United States Code, Title 5, Sections 3109 and 3371-3376
- (x) United States Code, Title 7, Chapter 48, Sections 1901-1907(y), United States Code, Title 7, Sections 2131-2159
- (z) United States Code, Title 10, Chapter 55, Section 1073c
- (aa) United States Code, Title 16, Sections 1361-1423 and 1531-1544
- (ab) United States Code, Title 18, Section 42
- (ac) Department of the Air Force Instruction 33-360, “Publications and Forms Management,” July 21, 2021, as amended
- (ad) Air Force Instruction 33-322, “Records Management and Information Governance Program,” March 23, 2020, as amended
- (ae) Deputy Secretary of Defense Action Memorandum, “Transition of Executive Agent Responsibilities to the Defense Health Agency,” July 9, 2014⁶

⁶ This reference can be found at: <https://info.health.mil/hco/phealth/OCBC/Documents1/Forms/AllItems.aspx>.

ENCLOSURE 2
RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will designate a veterinarian board certified in Laboratory Animal Medicine to serve as a consultant to the Under Secretary of Defense for Research and Engineering (USD(R&E)) and the Assistant Secretary of Defense for Health Affairs for veterinary technical and professional matters related to this publication.

2. OSD AND DOD COMPONENT HEADS. The OSD and DoD Component heads will:

a. Develop, issue, and monitor a Component Animal Use Management Plan (CAUMP) as defined in Reference (p) that contains implementing policies and procedures to ensure compliance with Reference (p), and any other supplementing or implementing regulations.

(1) The CAUMP will:

(a) Incorporate the procedures set forth in Enclosure 3 of this Regulation.

(b) Identify the responsible Component office or authority for each action.

(c) Integrate statutes, policies, and guidance applicable to this publication (References (d) through (aa)), for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, welfare, use, and final disposition of animals.

(2) The sole authority and responsibility for implementing and overseeing the CAUMP will be delegated to a single, senior official at the general or flag officer, Senior Executive Service, equivalent level, or higher herein identified as the Component's "responsible official." 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.

b. Establish and oversee Component policies and procedures for animal use. Component policies may be more restrictive than the requirements in Reference (p), but they may not be less restrictive; they will include policies and procedures:

(1) For Component oversight office (as defined in Glossary), administrative review and approval of DoD conducted or supported RDT&E and training as well as allegations of noncompliance or misconduct as required by Reference (o).

(2) For Component oversight of the reports of the Institutional Animal Care and Use Committee (IACUC) conduct of semiannual facility inspection and program review. Oversight should ensure that the program evaluations are appropriately conducted, and corrective actions are taken in accordance with deadlines established by the IACUC.

(3) To ensure a compliance inspection is conducted at each DoD facility at least every three years by the Component oversight office.

(4) To support the assignment of responsibilities when performing or supporting RDT&E or training in collaboration with another DoD Component, to include establishing written agreements for tasks such as single IACUC approval, single Component oversight office administrative reviews and inspections, and/or single oversight of extramural RDT&E and training.

(5) 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.

(6) To provide education and training for implementation, management, and oversight of this publication.

(7) To ensure continuity of operations during government shutdowns, deployments, and the like in order to ensure the requirements of this publication are satisfied.

c. Coordinate and cooperate in the transfer of Government-owned nonhuman primates (NHPs) within the DoD and with other Federal agencies to maximize conservation and proper utilization.

d. Provide members to intra-agency and interagency committees when requested by the USD(R&E), Assistant Secretary of Defense for Health Affairs, or Director, DHA.

e. Notify the USD(R&E) within five business days of being notified of any of the following: significant deficiencies; noncompliance with this publication that results in animal pain, distress, or death for any reason; change in an institution's AAALAC accreditation status; reports of adverse events to outside agencies; and socially sensitive matters.

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

g. Maintain all applicable records identified in this publication required by statutory and regulatory guidance applicable to this publication, and References (d) through (aa), for at least three years beyond the expiration or closure date of the approved RDT&E or training activity(ies).

3. INSTITUTIONAL OFFICIAL. The Institutional Official will:

- a. Ensure that DoD animal care and use programs and facilities conform to applicable standards, guidelines, and policies (References (d) through (ab)). If there is a conflict between this publication and References (d) through (aa), the more stringent reference will apply.
- b. Ensure that all RDT&E or training using animals is documented in an IACUC-approved protocol.
- c. Ensure an IACUC is duly appointed to monitor and ensure humane care and use of animals.
- d. Ensure that all significant deficiencies noted by the IACUC during semiannual reviews of animal care and use programs and facility inspections are documented, to include a defined plan and timeline for correction, and ultimately, that deficiencies are corrected.
- e. Ensure that local animal care, use, treatment, procurement, and transportation policies and procedures comply with this publication.
- f. Ensure that DoD organizations or facilities maintaining animals for use in RDT&E or training will attain and maintain accreditation with AAALAC International and that the animal care unit is adequately resourced.
- g. Support and, as necessary, ensure the development of animal care and use training programs for staff; encourage and resource appropriate certification for all personnel involved in the care, use and treatment of animals in RDT&E or training.
- h. Perform other duties as listed in accordance with Chapter 1, subchapter A, part 2 of Reference (i).

4. IACUCs WITHIN THE DOD. The IACUCs within the DoD will:

- a. Review protocols for all RDT&E or training conducted by their institutions, organizations, or facilities.
- b. Ensure that intramural protocols are submitted in the DoD animal use protocol format available at: <https://rt.cto.mil/wp-content/uploads/DoD-Standard-Protocol-Format-final.pdf?csrt=13573136120626586819> or in an alternative format with comparable detail approved by USD(R&E).
- c. Review and approve all modifications to IACUC-approved protocols before implementation and, if applicable, have written policies to address modifications by veterinarians.

e. Ensure all RDT&E and training activities approved by an IACUC undergo *de novo* review at least every three years upon renewal of the protocol.

f. Submit all protocols and major modifications for projects involving NHPs, dogs, cats, or marine mammals and training activities that use animals to teach human medical or surgical care to appropriate Component oversight office for administrative review and approval prior to initiation.

g. Perform semiannual reviews of animal care and use programs and facilities. The IACUC is responsible for reviewing the institute's program for humane care and use of animals and inspecting all animal facilities, including animal study areas, at least once every six months using Chapter 1, subchapter A, parts 1-4 of Reference (i), and Reference (s), as a basis for review. The IACUC may determine the best means for conducting the review. No committee member wishing to participate in any review may be excluded. The IACUC may use subcommittees composed of at least two committee members and may invite ad hoc consultants to assist in conducting the reviews; however, the IACUC remains responsible for the reviews and reports. Submit semiannual reviews to appropriate Component oversight office, if requested.

h. Consider non-terminal means of final disposition (e.g., adoption, retirement, inter-agency transfer), of animals used in RDT&E or training.

i. Have a quorum when official business requiring full committee is conducted.

j. Perform other duties as listed in Chapter 1, subchapter A, part 2 of Reference (i), and Reference (s).

k. Maintain all applicable records identified in this publication required by statutory and regulatory guidance applicable to this publication, and References (d) through (aa), for at least three years beyond the expiration or closure date of the approved RDT&E or training activity(ies).

5. PRINCIPAL INVESTIGATOR CONDUCTING RDT&E OR TRAINING AT A DOD INSTITUTION. The Principal Investigator conducting RDT&E or training at a DoD institution will:

a. Submit protocols in the DoD animal use protocol format, or in an alternate format approved by USD(R&E).

b. Ensure that protocols are executed as approved by the IACUC and report adverse events and noncompliance to the IACUC.

c. Submit proposed modifications to ongoing protocols for IACUC approval prior to implementation.

d. Maintain accurate records for all animals held or used on an approved protocol and provide an audit trail delineating each animal using the appropriate United States Department of Agriculture (USDA) pain category.

6. ATTENDING VETERINARIAN. The Attending Veterinarian (AV) will:

a. Serve as a voting member of the IACUC.

b. Have direct or delegated authority for activities of animal care and use and be able to ensure the provision of adequate veterinary care.

c. Provide, if employed on a part-time or consulting basis, a written program of veterinary care, to the facility, with a written list of regularly scheduled visits and description of provision of emergency veterinary care, to include contingency plans for when the veterinarian is not on site.

d. Oversee the animals used in RDT&E or training as described either in the protocol approved by the IACUC or as described in IACUC policy.

e. Report to the USDA Area Veterinarian-in-Charge and the State Animal Health Official all diagnosed or suspected cases of a communicable animal disease (not induced as part of an animal use protocol) for which USDA's Animal and Plant Health Inspection Service (APHIS) has a control or eradication program in Reference (i), and all diagnosed or suspected cases of any animal disease not known to exist in the United States. The AV shall comply with applicable federal and state regulations governing the movement of animals and on procedures applicable to disease control and eradication programs, including emergency programs. If the AV or their designee must issue health certificates for animal movements, they must be accredited by the USDA for the relevant species.

ENCLOSURE 3

PROCEDURES

1. DECISION TO USE ANIMALS. The inclusion of animals in DoD programs is the responsibility of DoD Component and sub-level directors or commanders and should be documented along with appropriate justification.

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

3. EXTRAMURAL RDT&E OR TRAINING

a. DoD Components. The DoD Components that sponsor RDT&E or training under a grant, cooperative agreement, contract, or other transaction agreement will ensure that:

(1) Extramural protocols using all animal species for RDT&E or training are administratively reviewed and approved by a DoD veterinarian at the appropriate Component oversight office prior to release of funding for animal use and initiation of animal use activities. The following documentation must be provided to the Component oversight office for review:

(a) Final IACUC-approved protocol written in the DoD standard animal use protocol format or local format with all pertinent information contained in the DoD protocol format and with additional information as requested by the appropriate Component oversight office.

(b) IACUC approval documentation (for example, a memorandum signed by IACUC Chair/Administrator or Institutional Official).

(c) Verification of AAALAC International accreditation, if applicable.

(d) Verification of Public Health Service Office of Laboratory Animal Welfare assurance, if applicable.

(e) A brief description of veterinary care and oversight provided in either the local format or a format requested by the appropriate Component oversight office.

(f) A statement that all animals are obtained legally from suppliers licensed by the USDA (or exempted) according to Chapter 1, subchapter A, part 2 of Reference (i), provided either in local format or in a format requested by the appropriate Component oversight office. When animals are procured outside of the United States, a statement that all animals are obtained legally from suppliers in accordance with host nation laws and regulations, provided either in local format or in a format requested by the appropriate Component oversight office.

(g) Copies of wildlife capture and use permits, if applicable.

(h) IACUC-approved major modifications to DoD-supported protocols.

(i) Verification of de novo reviews in accordance with Chapter 1, subchapter A, part 2 of Reference (i), for submitted protocols.

(2) All contract or grant facilities subject to inspection by the USDA provide the most recent USDA APHIS Animal Care Inspection Report to the respective overseeing Component oversight office in accordance with section 3.2.g of Reference (p).

(3) A DoD veterinarian conducts site visits in accordance with section 3.2.h of Reference (p).

(a) For all RDT&E using dogs, cats, NHPs, or marine mammals, and for all training activities that use animals to teach human medical or surgical care, the DoD-supported institution must pass an on-site inspection conducted by a DoD veterinarian to ensure that the animal care program meets the standards in accordance with Chapter 1, subchapter A, parts 1-4 of Reference (i), Reference (s), and sections 2131-2159 of Reference (y). 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 on-site inspections will be performed at the discretion of the Component as long as animals are being used. If an institution does not pass the on-site inspection, the Component oversight office will provide recommendations to the agency/institution/command funding the activity about allowing or continuing DoD support of the RDT&E or training. For efficiency, a Component may rely on the inspection of another Component provided there are established policies or agreements between the Components.

(b) 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 on-site inspection. This waiver does not preclude the Component from conducting an inspection at any time.

(c) A site inspection for cause is required if an extramural institution is notified by USDA that it is under investigation or there is a change in AAALAC accreditation status and when issues are relevant to a DoD-supported activity. A DoD veterinarian will perform a site inspection for cause as soon as it is practicable, ideally within 30 calendar days of notification.

The DoD veterinarian will evaluate and ensure the adequacy of animal care and use in DoD-supported programs. The Component oversight office will provide recommendations to the agency/institution/command funding the activity about allowing continued DoD support of the RDT&E or training, suspending the RDT&E or training until necessary changes have been made, or terminating the RDT&E or training.

(4) As applicable, a headquarters-level review of the program of instruction for all DoD-supported organizations using animals for the provision of training to teach human medical or surgical care is conducted by a medical authority designated to approve training for the appropriate DoD Component.

(5) All applicable contracts contain the most current version of Reference (k), on animal welfare.

(6) Applicable agreements not subject to DFARS clause (Reference (k)), (e.g., DoD grants and cooperative research and development agreements) should contain appropriate animal welfare terms and conditions.

(7) Component oversight offices require notification from extramural institutions within five business days of either of the following:

- (a) Notification from USDA that it is under investigation.
- (b) Change in AAALAC International accreditation status, if applicable.

(8) Component oversight offices require notification from extramural institutions within five business days of any of the following events that affect DoD funded animal use:

- (a) Significant deficiencies.
- (b) Noncompliance with this publication.
- (c) Reports of adverse events to outside agencies.
- (d) Socially sensitive matters.
- (e) Failure to adhere to the plan and schedule to correct a significant deficiency.

(9) Component oversight office require prompt notification from extramural institutions of research misconduct as required in section 3.4 of Reference (p), Freedom of Information Act (FOIA) requests, media inquiries, or Congressional requests for information concerning or potentially impacting DoD-supported protocols.

(10) Component oversight office send any information requests about animal use programs to extramural institutions and require they provide the information in the format specified by the requesting federal or DoD agency.

(11) Component oversight offices report to USD(R&E) as described in Enclosure 2, paragraph 2.e.

4. REVIEW AND OVERSIGHT OF INTRAMURAL RDT&E OR TRAINING INVOLVING LIVE ANIMALS

a. An administrative review of all NHP, dog, cat, or marine mammal protocols, and training protocols involving any species used to teach human medical or surgical care will be conducted by a veterinarian at the appropriate Component oversight office to ensure conformance with all applicable federal regulations and policies. A Component oversight office may delegate this responsibility to another Component oversight office for purposes of efficiency and consolidation of functional offices (see Appendix 2). Component oversight offices without an appropriately trained veterinarian can use another Component's veterinarian to perform this function, provided an organizational agreement is in place that establishes compliant processes and procedures.

b. DoD programs will encourage coordination and cooperation in the transfer of Government-owned NHPs between facilities to maximize conservation and proper utilization.

c. The component oversight office will conduct a compliance inspection at each DoD facility in accordance with Reference (p). If the component oversight office determines that major deficiencies identified during the inspection require mandatory corrective action, the component oversight office will notify the institution in writing. This notification will describe the deficiencies identified, clearly state the required corrective actions and provide a suspense for a corrective action plan. A copy of the notification will be forwarded to the appropriate component responsible official. Major deficiencies requiring mandatory corrective action include noncompliance with the requirements or standards in the references listed in Enclosure 1 that, as determined by the Component Oversight Office, present a substantial risk to animal welfare or personnel safety. Major deficiencies that remain unaddressed or uncorrected will be reported through the Component Oversight Office to USD(R&E). In cases where the command/directorate and the component oversight office cannot come to a consensus, the command/directorate can appeal to USD(R&E) for guidance.

5. ACCREDITATION BY AAALAC INTERNATIONAL. The DoD organizations or DoD facilities maintaining animals for use in RDT&E or training and DoD-supported organizations using animals for the provision of training will:

a. Attain and maintain accreditation with AAALAC International.

b. Provide the Component oversight office with documentation of any change in AAALAC International accreditation status.

c. Explain the absence or loss of accreditation and submit a plan of action and milestones to the Component oversight office, to obtain or regain accreditation.

6. COMPOSITION AND TRAINING OF THE IACUC

a. The IACUCs of DoD institutions established in accordance with sections 2131-2159, Reference (y) and Chapter 1, subchapter A, part 2 of Reference (i) will:

(1) Consist of committee members who are federal employees or individuals covered by sections 3371-3376 of Reference (w). IACUCs may consult with individual subject matter experts who are not members of the committee. These subject matter experts may not vote.

(2) 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.

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

(4) 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.

(5) Have at least one member who represents the general community interest and is not affiliated with the institution, is not an immediate family member of a person who is affiliated with the institution and should not use or have used animals for purposes of RDT&E or training. DoD IACUCs should designate an alternate member(s) for the non-affiliated member to facilitate community representation in the IACUC's activities.

(6) Have at least one member whose primary concerns are in a nonscientific area.

(7) 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 Component oversight office.

b. All DoD IACUC member(s) and alternate(s) will receive initial and ongoing education and training commensurate with the duties and responsibilities of the IACUC members. Training will at least include formal orientation to introduce new members to the institution's program; relevant legislation, regulations, guidelines, and policies; animal facilities and laboratories where animal use occurs; and the processes of animal protocol and program review. Training and education must be documented and consist of training in regulatory responsibilities

and proper techniques of the animal protocol review process, humane care and ethical issues dealing with animal use.

7. SUPPLIERS. Animals must be obtained from suppliers licensed by the USDA in accordance with Chapter 1, subchapter A, part 2 of Reference (i), unless specifically exempted from licensing requirements by such regulations. Procurement of animals outside of the United States must comply with host nation laws and regulations.

8. PROHIBITED USE. It is prohibited to use dogs, cats, NHPs, and marine mammals for inflicting wounds with any type of weapon(s) to conduct training in surgical or other medical treatment procedures.

9. TRAINING USES. The DoD intramural programs using animals in training programs will:

a. Consult with the appropriate Component oversight office to determine if the training activity is required to comply with Reference (p). All training activities involving live animals should receive veterinary review and consultation to ensure adequate care, even if IACUC approval is not required (e.g., animal use).

b. Ensure that required training protocols are submitted in the DoD standard animal use protocol format or in an alternate format approved by USD(R&E) and are reviewed and approved by a duly constituted IACUC. Organizations without an IACUC should contact the appropriate Component oversight office (see Appendix 2), for guidance and assistance.

c. Ensure animal housing facilities, enclosures, and equipment are inspected and approved by a DoD veterinarian before receiving animals.

d. Ensure reduction, refinement, and replacement considerations are addressed in training-specific contexts, which may differ from those used in RDT&E. Considerations should include items such as the trainee's requirement for training and the availability and efficacy of non-animal training models.

10. MANAGING COMPLAINTS

a. Personnel with complaints of violation(s) of this publication may report such violations to one or all of the following:

- (1) The IACUC chairperson or any IACUC member.
- (2) The Attending Veterinarian or their official alternates.

- (3) The institutional Commander, Director, or Institutional Official.
- (4) The Component oversight office.
- (5) The Inspector General.

b. The IACUC will review and, if warranted, investigate complaints involving animal use or noncompliance with applicable laws, regulations, directives, or guidelines. Institutions will notify their designated Component oversight office (see Appendix 2), within five business days of any significant deficiencies noncompliance with this publication, change in AAALAC International accreditation status, reports of adverse events to outside agencies, and socially-sensitive matters. Component oversight offices will report to USD(R&E) as described in Enclosure 2, paragraph 2.e.

11. REPORTS

a. At least once every six months, all IACUCs within DoD will submit a written evaluation of the animal care and use program to the Institutional Official. The report must contain a description of the nature and extent of the research facility's adherence to References (i) and (s), identify specifically any departure from those references, and state the reasons for each departure.

(1) The evaluation will be documented using DD Form 2856, DoD Semi Annual Program Review Facility Inspection Checklist, the OLAW Semiannual Program Review and Facility Inspection Checklist, or in an alternative format with comparable detail approved by USD(R&E).

(2) The DD Form 2856, the OLAW Inspection Checklist, or alternate format approved by USD(R&E) is used as the basis of the program review and facility inspection and must be included in the final report. The form is reviewed and signed by a majority of the IACUC members and describes any facility or program deficiencies, the corrective actions taken or planned, and timelines for expected completion of corrective actions. Reports must include minority opinions or a statement that there were no minority opinions.

(3) Any failure to adhere to the plan and schedule to correct a significant deficiency will be reported within five business days by the Institutional Official or designee for forwarding to the appropriate Component oversight office (see Appendix 2 for addresses).

(4) After the Institutional Official signs the report, it is returned to the IACUC and retained for a minimum of three years.

b. The DoD research facility will submit APHIS Form 7023, Annual Report of Research Facility, to the USDA as required and in accordance with Chapter 1, subchapter A, part 2 of Reference (i).

c. When information is requested about animal use programs, provide that information in the format specified by the requesting federal or DoD agency. Instructions for satisfying the requirement will be sent out by the Component oversight office upon initiation of the data request.

12. RECORD KEEPING

a. The requirement in Enclosure 2, paragraph 2.g, for the DoD Components to retain records for at least three years beyond the expiration or closure date of the approved RDT&E or training activity(ies) applies to:

(1) Approval records for DoD-conducted or-supported RDT&E and training programs and protocols that are created by the Government and/or the 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. Records that document extramural compliance or noncompliance with this publication 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.

c. The requirement in Enclosure 2, paragraph 5.k, for DoD IACUCs to retain records for at least three years beyond the expiration or closure date of the approved RDT&E or training activities includes but is not limited to:

(1) All records for DoD-conducted or supported RDT&E and training that are created by the Government.

(2) All records regarding IACUC waivers, exemptions, and exceptions.

(3) All approved animal use protocols and amendments.

d. DoD Components and IACUCs may be required to retain records for longer than specified in this section. For complete recordkeeping guidance and instruction, the DoD Components will consult their respective records disposition schedules.

13. USE OF DOD FACILITIES. The use of animals in a collaborative effort with or on behalf of other government or nongovernment organizations in DoD facilities will comply fully with this publication.

14. ANIMAL PROGRAMS OUTSIDE THE UNITED STATES. Activities subject to this publication conducted by the DoD outside the United States will comply with References (d) through (aa), as well as, the host nation requirements for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, welfare, use, and final disposition of animals. Where differences in standards exist, the more stringent standard will apply. Activities subject to this publication that are supported by the DoD outside the United States will comply with applicable DoD policies, adhere to host nation laws and regulations, and assure animal welfare standards comparable to those in the United States.

15. FOIA REQUESTS AND OTHER MATTERS. Institutions will promptly notify the appropriate Component oversight office of FOIA requests, media inquiries, and Congressional requests for information.

APPENDIX 1

AIR FORCE-RECORDS MANAGEMENT

1. RECORDS MANAGEMENT. Ensure that all Air Force records created as a result of processes prescribed in this publication are maintained in accordance with Air Force Instruction Reference (ac) and disposed of in accordance with Air Force Records Disposition Schedule located in the Air Force Records Information Management System Publications and Forms Management, Table 1.1 for a description of the authorities associated with Tier 0. Submit requests for waivers through the chain of command to the Air Force Publication Office of Primary Responsibility for consideration. Supplementation of this publication and establishment of command and local forms are prohibited without prior approval from The Air Force Surgeon General, 7700 Arlington Boulevard, Falls Church, VA 22041-5143.

2. WAIVER AUTHORITY. All compliance items in this publication are determined by respective non-Air Force authority (for example, Media Interaction), to be Tier 0 compliance items. See Reference (ab), for a description of the authorities associated with the Tier 0. Submit requests for waivers through the chain of command to the appropriate Tier waiver approval authority, or alternately, to the Publication Office of Primary Responsibility for non-tiered compliance items.

APPENDIX 2

DoD COMPONENT OVERSIGHT OFFICES

The following DoD Component agencies have been designated as oversight offices:

(Army)

Commander
U.S. Army Medical Research and Development Command
MCMR-RPA
810 Schreider Street—Fort Detrick
Frederick, MD 21702-5012

(Air Force)

Air Force Medical Readiness Agency
Office of the Surgeon General
7700 Arlington Blvd Ste 5151
Falls Church, VA 22042-5151

(Navy)

Special Assistant
Department of the Navy Research Protections
1564 Freedman Drive
Fort Detrick, MD 21702

(United States Special Operations Command)

Commander
U.S. Special Operations Command
Attention: Office of the Command Surgeon (SOCS-SG)
7701 Tampa Point Blvd
MacDill AFB, FL 33621

(Defense Advanced Research Projects Agency)

Director, Defense Advanced Research Projects Agency
Attention: Administrative Office
675 North Randolph Street
Arlington, VA 22203-2114

(Defense Threat Reduction Agency)
Director, Defense Threat Reduction Agency
8725 John J Kingman Road, Stop 6201
Fort Belvoir, VA 22060-6201

(Defense Health Agency)
Deputy Assistant Director
Research and Development
Defense Health Agency
7700 Arlington Blvd
Falls Church, VA 22042

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

APHIS	Animal and Plant Health Inspection Service
AV	Attending Veterinarian
CAUMP	Component Animal Use Management Plan
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DoD	Department of Defense
FOIA	Freedom of Information Act
IACUC	Institutional Animal Care and Use Committee
OLAW	Office of Laboratory Animal Welfare
OSD	Office of the Secretary of Defense
NHP	nonhuman primate
RDT&E	Research, Development, Test, and Evaluation
USDA	United States Department of Agriculture
USD(R&E)	Under Secretary of Defense for Research and Engineering

PART II. DEFINITIONS

The terms and their definitions are for the purposes of this DHA-MSR.

administrative review of an RDT&E or training protocol. A review of documents related to animal use for RDT&E and 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, and/or death of an animal.

alternatives. Alternatives to animal use are characterized by “the three Rs” 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. Sections 2131-2159, Reference (y) and Chapter 1, subchapter A, parts 1-4 of Reference (i), govern most species of vertebrate animals; this DHA-MSR governs all species of vertebrate animals. For the purposes of this definition, “dead” is defined as any living animal that is killed for the direct purpose of RDT&E or training; however, it does not include dead animals or parts of dead animals purchased at grocery stores or slaughterhouses.

Attending Veterinarian. A person who is a veterinarian, has direct or delegated authority for activities of animal care and use, and is able to provide adequate veterinary care.

Commander. Laboratory or unit Commander or other official having equivalent authority.

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.

Director. A person who is in charge of a department, institute, or agency.

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 sections 2131-2159 of Reference (y); Chapter 1, subchapter A, parts 1-4 of Reference (i); or this DHA-MSR unless the animal is harmed for the purpose of collecting data.

euthanasia. A method of killing that minimizes pain, distress, and anxiety experienced by the animal prior to loss of consciousness and causes rapid loss of consciousness followed by cardiac or respiratory arrest and death.

extramural institution. An institution that is not part of the DoD.

extramural RDT&E or training. RDT&E or training that is conducted by an institution that is not part of the DoD. Extramural RDT&E or training is also referred to as “DoD-supported” RDT&E or training.

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 the animal, or materially alters the behavior of an animal under study. A field study is not governed by sections 2131-2159 of Reference (y); Chapter 1, subchapter A, parts 1-4 of Reference (i); or this DHA-MSR.

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 sections 2131-2159 of Reference (y); Chapter 1, subchapter A, parts 1 - 4 of Reference (i); and this DHA-MSR. The institution’s equivalent of the Chief Executive Officer (commander, director, president, most senior leader) will appoint the IACUC or delegate this responsibility specifically and in writing.

Institutional Official. The Institutional Official is, or is appointed by, the institution’s Chief Executive Officer (commander, director, president, most senior leader) and can legally commit the institution to comply with federal requirements for animal use.

intramural RDT&E or training. RDT&E or training conducted by DoD personnel. Intramural RDT&E or training is also referred to as “DoD-conducted” 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 (which is also referred to as an “extramural institution”).

marine mammal. Animals belonging to the class Mammalia and whose primary habitat is the sea or ocean (for example, cetaceans and pinnipeds).

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

NHP. Any nonhuman member of the order Primates, including prosimians, monkeys, and apes.

non-affiliated IACUC member. A member of the public who represents the interests of the general community in the proper care and use of animals. A public IACUC member should not be affiliated with the institution(s) supporting or relying on the IACUC or be an immediate family member of a person who is affiliated with the institution(s) and should not use or have used animals for the purposes of RDT&E and training at a research facility.

noncompliance. An activity not in accordance with this DHA-MSR and its references.

non-scientific IACUC member. A person whose primary concerns are in a nonscientific area.

principal investigator. An employee of a research facility, or other person associated with a research facility, responsible for a protocol to conduct research or training and for the design and implementation of RDT&E or training involving animals.

quorum. A quorum is obtained when a majority of the voting members of the IACUC are present. Any member recused due to potential conflict of interest cannot count toward quorum for any action related to the activity for which they are recused.

RDT&E. 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 budget activity, the DoD institution supporting or conducting the work, the type of extramural institution conducting the work, the program title, or the security classification. The 4 categories of RDT&E are:

research. A systematic investigation of a scientific question employing a hypothesis, structured methodology, and controlled study design (for example, 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 a product or biproduct to ensure that it meets its intended goals or detect potential unwanted impacts.

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

research facility. Any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in RDT&E or training.

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

State animal health official. The State animal health official who is responsible for the livestock and poultry disease control and eradication programs of a state.

threatened species. A species or subspecies of animal listed as “threatened” in accordance with sections 1361-1423 and 1531-1544 of Reference (z).

training. An activity with the goal of imparting knowledge, skills, and competencies to a human. Training is covered by this regulation when using animals: 1) to conduct training in support of RDT&E; 2) to teach human medical or surgical care; and 3) to teach veterinary procedures when the training may cause pain (experienced or alleviated pain) or distress to the animal and is not part of a necessary medical procedure.

veterinarian. Veterinarians in institutions within the United States: A person who has graduated from a veterinary school accredited by the American Veterinary Medical Association’s Council on Education, or 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 and/or experience in the species being used. Veterinarians in institutions outside the United States: A person who has comparable qualifications to U.S. veterinarians and has training and/or experience in the species being used.

Veterinarian-in-charge. The veterinary official of APHIS who is assigned by the Administrator to supervise and perform the official work of APHIS in a state or group of states.

weapon. A device intended (for example, a club, knife, gun, or laser gun) to injure, defeat, or destroy people.

wound. Injury or damage usually restricted to that caused by physical means with disruption of normal continuity of the body’s structures.