



Department of Defense

INSTRUCTION

NUMBER 3216.01
September 13, 2010

USD(AT&L)

SUBJECT: Use of Animals in DoD Programs

References: See Enclosure 1

1. **PURPOSE.** This Instruction reissues DoD Directive (DoDD) 3216.1 (Reference (a)) as a DoD Instruction (DoDI) in accordance with the authority in DoDD 5134.01 (Reference (b)) to establish policy and assign responsibilities for the use of animals in DoD programs. The Reference (a) designation of the Secretary of the Army as the DoD Executive Agent to develop and issue Service regulations to implement Reference (a) has been cancelled pursuant to Deputy Secretary of Defense Memorandum (Reference (c)).

2. APPLICABILITY

a. This Instruction 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 Department of Defense (hereafter referred to collectively 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. (See Glossary, Part II, for definitions.)

(3) Vertebrate animals, alive and dead, including birds, cold-blooded animals, and other designated mammalian species. (See Glossary, Part II, for definitions.)

b. This Instruction does not apply to:

(1) Animals used strictly for ceremonial and/or recreational purposes and working animals, such as military working dogs. However, if ceremonial, recreational, or military

working animals are also used to conduct RDT&E or training, as defined in the Glossary, this Instruction applies.

(2) Farm animals such as but not limited to livestock or poultry used or intended for use as food or fiber, or livestock or poultry used or intended for use improving animal nutrition, breeding, management, or production efficiency; or for improving the quality of food or fiber.

(3) Animals used in disease surveillance, as defined in the Glossary, unless the disease screening procedure harms the animal. If there is no Institutional Animal Care and Use Committee (IACUC) supporting the institution, a DoD veterinarian with demonstrated familiarity with this Instruction and not involved in the activity shall determine if the activity is disease surveillance or if it harms the animal.

(4) Animals involved in field studies, as defined in the Glossary. If there is no IACUC supporting the institution, a DoD veterinarian with demonstrated familiarity with this Instruction and not involved in the activity shall determine if the activity is a field study.

3. DEFINITIONS. See Glossary.

4. POLICY. It is DoD policy that:

a. RDT&E or training conducted or supported by the Department of Defense shall comply with sections 2131-2159 of title 7, United States Code (Reference (d)) and its implementation in parts 1-4 of title 9, Code of Federal Regulations (Reference (e)).

(1) RDT&E or training conducted or supported by the Department of Defense shall also comply with the DoD policy and guidance in DoDDs 6025.21E and 6400.4 (References (f) and (g)) and DoDI 3210.7 (Reference (h)), and shall adopt other Federal policies and guidance, as applicable, that provide national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals. This includes the policies and guidance in References (i) through (u). Federal policies for animal welfare shall be applied as directed in this Instruction.

(2) Activities subject to this Instruction shall also comply with all other applicable Federal, State, and local statutes and regulations, and requirements of non-U.S. entities when the work is conducted outside of the United States.

b. Methods other than animal use and alternatives to animal use (i.e., methods to refine, reduce, or replace the use of animals) shall be considered and used whenever possible to attain the objectives of RDT&E or training if such alternative methods produce scientifically or educationally valid or equivalent results.

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

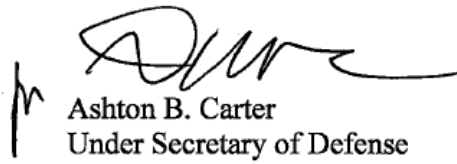
with section 8019 of Public Law 101-511 (Reference (i)). The purchase or use of nonhuman primates or marine mammals for inflicting wounds from any type of weapon(s) to conduct training in surgical or other medical treatment procedures is also prohibited.

5. RESPONSIBILITIES. See Enclosure 2.

6. PROCEDURES. See Enclosure 3.

7. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the Internet from the DoD Issuances Website at <http://www.dtic.mil/whs/directives>.

8. EFFECTIVE DATE. This Instruction is effective immediately.


Ashton B. Carter
Under Secretary of Defense
for Acquisition, Technology, and Logistics
ACTING USD(AT&L)

Enclosures

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ENCLOSURE 1

REFERENCES

- (a) DoD Directive 3216.1, "Use of Animals in DoD Programs," April 17, 1995 (hereby cancelled)
- (b) DoD Directive 5134.01, "Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L))," December 9, 2005
- (c) Deputy Secretary of Defense Memorandum, "Approval to Rescind the Designation of the DoD Executive (EA) for Use of Animals in DoD Programs," February 12, 2010
- (d) Sections 2131-2159 of title 7, United States Code
- (e) Parts 1-4 of title 9, Code of Federal Regulations
- (f) DoD Directive 6025.21E, "Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries," July 5, 2006
- (g) DoD Directive 6400.4, "DoD Veterinary Services Program," August 22, 2003
- (h) DoD Instruction 3210.7, "Research Integrity and Misconduct," May 14, 2004
- (i) Section 8019 of Public Law 101-511, "The Department of Defense Appropriations Act, 1991," November 5, 1990
- (j) Institute of Laboratory Animal Research, Commission on Life Sciences, and National Research Council, "Guide for the Care and Use of Laboratory Animals," January 2, 1996¹
- (k) Public Law 106-545, "ICCVAM Authorization Act of 2000," December 19, 2000
- (l) Title 21, Code of Federal Regulations
- (m) U.S. Department of Agriculture Policy Manual, Policy 23, "Criteria for Licensing Hoofstock Dealers," August 26, 2002
- (n) Sections 3109 and 3371-3376² of title 5, United States Code
- (o) National Institutes of Health, Office of Laboratory Animal Welfare, "Public Health Service Policy on Humane Care and Use of Laboratory Animals," August 7, 2002
- (p) Defense Federal Acquisition Regulations Supplement, clause 252.235-7002, "Animal Welfare," December 1991
- (q) U.S. Department of Agriculture, "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training," February 15, 2001
- (r) Sections 1361-1384 and 1531-1543 of title 16, United States Code
- (s) Section 42 of title 18, United States Code
- (t) Parts 10-14, 16, 23, and 216-226 of title 50, Code of Federal Regulations
- (u) Federation of Animal Science Societies, "Guide for the Care and Use of Agricultural Animals in Research and Teaching," January 2010
- (v) DoD Instruction 5025.01, "DoD Directives System," October 28, 2007

¹ Available on the Internet at http://www.nap.edu/openbook.php?record_id=5140&page=R1

² Also known as "The Intergovernmental Personnel Act of 1970, as amended"

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING (DDR&E). The DDR&E, under the authority, direction, and control of the Under Secretary of Defense for Acquisition, Technology, and Logistics, shall:

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

b. Provide guidance and policy necessary to implement this Instruction, after consulting with the Assistant Secretary of Defense for Health Affairs (ASD(HA)) for matters affecting medical training, and with the Director, DoD Veterinary Services Activity, for matters affecting animal health and welfare.

c. Exercise the responsibilities and authorities of the Secretary of Defense identified in section 2143(c) of Reference (d) for:

(1) Ensuring corrective action is taken on deficiencies of DoD research facilities (as defined in section 2132(e) of Reference (d)) reported by the DoD IACUC.

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

d. Establish a process to oversee DoD Component implementation of their respective Component animal use management plan and compliance with this Instruction.

e. Establish policies and procedures to facilitate efficient management, tracking, and reporting of the care and use of animals in DoD-conducted and -supported RDT&E and training.

f. Maintain the:

(1) DoD Standard Animal Use Protocol Format (available at http://www.dtic.mil/biosys/docs/au-DoD_Standard_Animal_Use_Protocol.pdf).

(2) DoD (DD) Form 2856, "DoD Semiannual Program Review/Facility Inspection Checklist" (available at <http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2856.pdf>).

g. Maintain a list of foreign and international standards that are at least equivalent to those in the "Guide for the Care and Use of Laboratory Animals" (Reference (j)) or the United States Department of Agriculture (USDA) and Department of Defense.

h. Designate a DoD representative to the Interagency Coordinating Committee on the Validation of Alternative Methods established under the management of Department of Health and Human Services (DHHS) pursuant to Public Law 106-545 (Reference (k)).

i. Designate a DoD representative to the Interagency Research Animal Committee established by DHHS who is a veterinarian of appropriate rank or grade and experience and a diplomate of the American College of Laboratory Animal Medicine.

j. Establish the Joint Technical Working Group (JTWG) on Animal Use in DoD Programs to act as the central advisory committee to the Armed Services Biomedical Research Evaluation and Management (ASBREM) Committee on all matters regarding the care and use of animals for RDT&E or training pursuant to Reference (f). Membership shall be as described in section 4 of Enclosure 3.

2. ASD(HA). The ASD(HA), under the authority, direction, and control of the Under Secretary of Defense for Personnel and Readiness, shall advise the DDR&E on matters related to the necessity to use animals in medical education and training and the appropriate use of alternatives.

3. HEADS OF THE OSD AND DoD COMPONENTS. The Heads of the OSD and DoD Components that use or support the use of animals covered by this Instruction shall:

a. Develop, issue, and monitor the Component animal use management plan that contains the Component implementing policies and procedures to ensure compliance with this Instruction and any other supplementing or implementing issuances.

(1) The Component animal use management plan shall:

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

(b) For each action, identify the responsible Component office.

(c) Integrate applicable Federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals. This includes References (d) through (u) and other applicable Federal policy and guidance.

(2) The authority and responsibility for implementing and overseeing the Component animal use management plan shall only be delegated to a single, senior official at the general or flag officer, Senior Executive Service, or equivalent level, or higher.

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

(1) For Component headquarters administrative review of DoD-conducted and -supported RDT&E and training (sections 1 and 2 of Enclosure 3) and allegations of noncompliance or misconduct (section 5 of Enclosure 3).

(2) For Component headquarters oversight of the inspections of the institutions' animal care and use program review, including the institutions' facility inspection. Oversight should ensure that the program reviews are appropriately conducted and corrective action is taken in a timely manner (sections 1 and 2 of Enclosure 3).

(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 IACUC approval, single Component headquarters administrative reviews and inspections (section 1 of Enclosure 3), and/or single oversight of extramural RDT&E and training (section 2 of Enclosure 3).

(4) To maintain a list of providers approved by the Component for each training plan and establishing a process to communicate this list with the other DoD Components to allow a Component to rely on the review and inspection of another Component (section 2 of Enclosure 3).

(5) To provide education and training for implementation, management, and oversight of this Instruction (section 3 of Enclosure 3).

c. Coordinate and cooperate in the transfer of Government-owned nonhuman primates within the Department of Defense and with other Governmental agencies to maximize conservation and proper utilization.

d. Ensure prior approval for proposals intending to use chimpanzees by the DHHS Interagency Animal Model Committee, which coordinates national priorities for research utilization of this species.

e. Provide members to intra- and interagency committees and to the JTWG when requested by the DDR&E (section 4 of Enclosure 3).

f. Report in a timely manner to the DDR&E any research misconduct or serious noncompliance issues related to animal use for RDT&E or training (section 5 of Enclosure 3). Report at a minimum annually to the DDR&E any waivers, exemptions, exceptions, or other deviations from requirements granted in accordance with this Instruction.

g. Maintain all records identified in this Instruction or required by References (d) through (u) for at least 3 years beyond the end of the RDT&E or training or the effective date of the record (section 6 of Enclosure 3).

4. SECRETARY OF THE ARMY. The Secretary of the Army, in addition to the responsibilities in section 3 of this enclosure, and as the DoD Executive Agent for the DoD Veterinary Services Program pursuant to Reference (g), shall:

a. Develop and issue, in consultation with the other DoD Components that have an animal use program, a joint Component regulation to implement this Instruction.

b. Designate the Director, DoD Veterinary Services Activity, a Field Operating Agency of the Army under the authority, direction, and control of the Army Surgeon General, to serve as:

(1) A consultant to the ASD(HA) and the DDR&E for technical and professional matters related to this Instruction.

(2) The DoD representative on animal care and use matters for implementing Food and Drug Administration regulatory requirements in accordance with title 21, Code of Federal Regulations (Reference (1)).

ENCLOSURE 3

PROCEDURES

1. DoD-CONDUCTED RDT&E AND TRAINING

a. Acquisition of Animals

(1) When purchasing animals covered by this Instruction, the DoD Components shall ensure that the animals are legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of Reference (d), unless specifically exempted from the licensing requirements in References (d), (e), and Department of Agriculture policy manual (Reference (m)). When a U.S. supplier claims it meets an exemption criterion in References (d), (e), or (m), the Component shall 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. A DoD veterinarian with training or experience in laboratory animal science and medicine shall conduct the review. If the supplier is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (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.

(2) When conducting RDT&E or training outside of the United States and using foreign suppliers, the DoD Component shall require 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. A DoD veterinarian with training or experience in laboratory animal science and medicine shall conduct the review. If the supplier is accredited by AAALAC, or meets the equivalent standards established as directed in paragraph 1.g of Enclosure 2, the Component may waive the requirement for on-site inspection. This waiver does not preclude the Component from conducting an inspection at any time. Foreign suppliers shall also be in compliance with their national policies.

(3) When capturing animals from the wild, institutions shall ensure they have all required capture and use permits approved prior to acquisition.

b. AAALAC Accreditation. ALL DoD institutions housing animals for RDT&E or training shall attain and maintain AAALAC accreditation, with these exceptions:

(1) DoD institutions using or housing animals for RDT&E or training for less than 8 continuous calendar days. However, they shall have the animal facilities inspected and approved by a DoD veterinarian trained or experienced in laboratory animal medicine prior to initiation of any research protocol or training plans involving animals. The inspection shall ensure that the institution has met the requirements in this Instruction. The DoD Component may waive this requirement for an inspection when they have determined a compelling reason exists.

(2) Additional exemptions as the DDR&E determines appropriate.

c. IACUC Membership

(1) The IACUCs of the DoD institutions established in accordance with section 2143 of Reference (d) shall:

(a) Consist of committee members who are Federal employees; individuals covered by sections 3371-3376 of title 5, United States Code (also known as “The Intergovernmental Personnel Act of 1970, as amended” (Reference (n))); or individuals considered as experts or consultants in accordance with section 3109 of Reference (n). IACUCs may consult with subject matter experts who are not members of the committee; these consultants may not vote.

(b) Have at least five members with various backgrounds to promote complete and accurate review of RDT&E and training activities commonly conducted by the institution, in accordance with National Institutes of Health policy (Reference (o)). No more than three members shall be from the same administrative unit of the institution.

(c) Have at least one member who is a doctor of veterinary medicine with training or experience in laboratory animal science and medicine.

(d) Have at least one member who represents the general community interest and is not affiliated with the institution sponsoring the IACUC. The IACUCs must designate an alternate member(s) for the non-affiliated member to ensure community representation at convened IACUC meetings.

(e) Have at least one member who does not have a scientific background. When appropriate, the non-affiliated and the non-scientific member may be the same person.

(2) To have a quorum, at least one veterinarian and one non-affiliated member (or his or her alternate) must be present. When a compelling reason exists, the IACUC may request approval from the Head of the OSD or DoD Component to waive this requirement in order to meet without the non-affiliated member.

d. IACUC Approval and Oversight

(1) All RDT&E and training shall be approved and provided oversight by a duly constituted IACUC in accordance with Reference (d) before the activity can begin.

(2) All proposed RDT&E shall be submitted to the IACUC using the DoD Standard Animal Use Protocol Format. All proposed training plans submitted to the IACUC shall contain the relevant information outlined in the DoD Standard Animal Use Protocol Format.

(3) A veterinarian, working under the authority of the IACUC, shall oversee the animals being used during the RDT&E or training as described either in the protocol approved by the IACUC or in the IACUC policy, which is referenced in the protocol.

(4) When an investigator proposes significant changes to an IACUC-approved protocol, the IACUC must review and approve the changes before they can be implemented.

(5) All RDT&E and training approved by an IACUC must be reviewed by the IACUC at least annually.

e. Program Review. All DoD institutions using or housing animals for RDT&E or training for more than 12 hours shall conduct a program review, including a facility inspection, at least semiannually using DD Form 2856. A majority of the institution's IACUC members shall sign the report to the institutional official, and the report shall include a statement indicating the presence or absence of minority opinions. This review shall also be submitted to the DoD Component headquarters oversight office.

f. DoD Component Headquarters Approval and Oversight

(1) At a minimum, the DoD Component headquarters oversight office must conduct an administrative review and approve all RDT&E and training requiring the use of nonhuman primates, dogs, cats, or marine mammals, and all medical training involving live animals. The review must be conducted to ensure conformance with all applicable regulations and policies.

(2) When an IACUC approves significant changes to an approved protocol that was administratively reviewed by the Component headquarters oversight office as required in subparagraph 1.f.(1) of this enclosure, the Component headquarters oversight office must review and approve the changes to the IACUC-approved protocol before they can be implemented.

(3) The institutional program review conducted by the IACUC (required by paragraph 1.e. of this enclosure) shall be reviewed by the Component headquarters oversight office. Any issues needing corrective action shall be overseen by the Component headquarters oversight office to ensure that actions are completed in a timely manner.

g. Institution Notifications to the DoD Component

(1) When an institution is notified by the USDA that it is under investigation, the institution shall notify their Component headquarters oversight office within 5 business days.

(2) When an institution is notified by AAALAC that it has lost its accreditation status, the institution shall notify their Component headquarters oversight office within 5 business days.

(3) When an institution has experienced any adverse events regarding the RDT&E or training, the institution shall notify their Component headquarters oversight office within 5 business days.

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 (Reference (p)). Agreements not subject to Reference (p) (e.g., grants and cooperative research and development agreements) must contain language equivalent to that in Reference (p).

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 Reference (d) for the duration of the activity.

c. IACUC Approval and Oversight

(1) DoD-supported RDT&E and training involving animals must be approved by the performing institution's IACUC in accordance with Reference (d) before the activity begins.

(2) A veterinarian, working under the authority of the IACUC, shall oversee the animals being used during the RDT&E or training as described in either the protocol approved by the IACUC or in the IACUC policy, which is referenced in the protocol.

(3) When an investigator proposes significant changes to an IACUC-approved protocol, the IACUC must review and approve the changes before they can be implemented.

(4) All RDT&E and training approved by an IACUC must be reviewed by the IACUC at least annually.

d. DoD Component Headquarters Approval and Oversight

(1) Protocol or Training Plan Approval. At a minimum, the DoD Component headquarters oversight office must conduct an administrative review and approve all DoD-supported RDT&E and training. The review must be conducted to ensure conformance with all applicable regulations and policies. The review shall be conducted by a DoD veterinarian trained or experienced in laboratory animal science and medicine to ensure the activity meets the requirements in this Instruction. This Component review and approval must occur before the performing institution is allowed to begin animal work. Although non-DoD institutions are not required to use the DoD Standard Animal Use Protocol Format, the documents submitted to the Component shall provide all pertinent information contained in the DoD Standard Animal Use Protocol Format. When an IACUC approves significant changes to an approved protocol that has been reviewed by the Component supporting the RDT&E or training, the Component must review and approve the changes before they can be implemented. The Component must ensure the IACUC conducts an appropriate continuing review at least annually.

(2) Veterinary Care Plan. The DoD Component must review and approve the veterinary care plan required by subparagraph 2.c.(2) of this enclosure before the performing institution is allowed to begin animal work.

(3) Acquisition of Animals

(a) Extramural RDT&E and Training Conducted in the United States. The performing institution shall include in the documents submitted to the DoD Component for review a statement that the animals shall be or have been legally obtained from suppliers licensed by the USDA in accordance with sections 2133-2134 of Reference (d), unless the supplier claims to meet the exemption criteria in References (d), (e), or (m). When a supplier claims to meet the exemption criteria, the institution performing the work shall convey the claim of exemption to the supporting Component.

(b) Extramural RDT&E and Training Outside of the United States. The performing institution shall include in the documents submitted to the DoD Component for review a statement that the animals shall be or have been legally obtained from suppliers in accordance with national policy.

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

(4) USDA Inspection Reports. As part of the DoD approval process, the DoD veterinarian shall also review the most recent USDA inspection reports, unless the institution is exempt from inspection by meeting the criteria in References (d) and (e). The inspection reports must be reviewed annually for the duration of the activity.

(5) On-Site Inspection

(a) For all RDT&E using dogs, cats, nonhuman primates, or marine mammals, and for all medical training using live animals, the contractor must pass an on-site evaluation conducted by a DoD veterinarian trained or experienced in laboratory animal medicine to ensure that the animal care program meets the standards in References (d), (e), and (j). The site visit shall be conducted within 30 days of the signed agreement with the Department of Defense (e.g., contract award) if the animals are already at the institution or training site, or within 30 days of delivery of the animals if they are not. The DoD Component may allow this inspection to occur at a later date if the Component determines that it is in the best interest of the animals. The on-site evaluation shall be repeated annually for the duration of the training agreement, as long as animals are being used. For efficiency, a Component may rely on the evaluation of another Component.

(b) If the institution is accredited by AAALAC or meets equivalent standards referenced in paragraph 1.g. of Enclosure 2 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) For institutions outside of the United States, if the facility can provide evidence to the DoD Component that it meets either their national standards or standards from an

internationally recognized organization, the Component may waive the requirement for an on-site inspection. In either case, the standards must be determined by the DDR&E to be at least equivalent to the standards referenced in paragraph 1.g. of Enclosure 2. This waiver does not preclude the Component from conducting an inspection at any time.

e. Notifications to the DoD Component

(1) When an institution is notified by the USDA that it is under investigation, the institution shall notify the supporting DoD Component within 5 business days. An institution with AAALAC accreditation shall notify the Component within 5 business days of loss of AAALAC accreditation. Upon either of these notifications and when the issues are relevant to a DoD-supported activity, a DoD veterinarian trained or experienced in laboratory animal medicine shall perform a site inspection within 30 days of the notification. The Component may allow more time for this inspection to occur on a case-by-case basis.

(2) Site inspections for cause shall evaluate and ensure the adequacy of animal care and use in DoD-supported programs, and provide recommendations to the Component about allowing continued DoD support of the research, suspending the research until necessary changes have been made, or terminating the research.

(3) The IACUC must notify the Component in accordance with subparagraph 2.d.(1) of this enclosure when the IACUC approves significant changes to the protocol, and when the IACUC conducts its continuing review.

(4) The Component shall require the contractor to inform the Component of any adverse events regarding the RDT&E or training that might impact DoD continued support of the activity.

3. EDUCATION AND TRAINING. The DoD Components shall 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 continuing education and training.

a. Training and education shall integrate Federal policy and guidance that provides national standards for the acquisition, transportation, housing, control, maintenance, handling, treatment, care, use, and disposal of animals.

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

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

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

4. JTWG MEMBERSHIP. The ASBREM Committee Co-Chairs shall designate the JTWG Chair. At a minimum, the JTWG shall be composed of representatives of the DDR&E, each of the DoD Components with an animal use management plan, and the DoD Veterinary Services Activity.

5. RESEARCH MISCONDUCT AND NONCOMPLIANCE. The DoD Components shall comply with the requirements for reviewing allegations of misconduct as required by Reference (h). DoD Component implementing policies and procedures for addressing allegations of noncompliance with animal care and use standards by their Component, or by an institution supported by their Component, shall refer the matter to the next higher management echelon to take deliberate action to resolve. All findings of serious noncompliance shall be reported to the DDR&E.

6. RECORD KEEPING

a. The requirement in paragraph 3.g. of Enclosure 2 for the DoD Components to retain records for at least 3 years beyond the end of the RDT&E and training activity or the effective date of the record applies to:

(1) Records from DoD-conducted or -supported RDT&E and training that are created by either the Government 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 DDR&E for action.

b. The DoD Components may be required to retain records for longer than specified in paragraph 6.a. of this enclosure. For complete recordkeeping guidance and instruction, the DoD Components shall consult their respective records disposition schedules.

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

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care, International
ASBREM	Armed Services Biomedical Research Evaluation and Management
ASD(HA)	Assistant Secretary of Defense for Health Affairs
DDR&E	Director of Defense Research and Engineering
DHHS	Department of Health and Human Services
DoDD	DoD Directive
DoDI	DoD Instruction
IACUC	Institutional Animal Care and Use Committee
ICCVAM	Interagency Coordinating Committee on the Validation of Alternative Methods
JTWG	Joint Technical Working Group
RDT&E	research, development, test, and evaluation
USDA	United States Department of Agriculture

PART II. DEFINITIONS

Unless otherwise noted, these terms and their definitions are for the purpose of this Instruction.

administrative review of an RDT&E protocol or training plan. A review of documents related to animal use for RDT&E and training by a Component headquarters-level veterinarian trained or experienced in laboratory animal medicine. 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.

alternatives. Alternatives to animal use are characterized by “the three R’s:” replacement, reduction, and refinement. Investigators may replace methods that use animals with those that do not. 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. Reference (d) governs most

species of vertebrate animals; this Instruction 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.

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 Reference (d) or this Instruction unless the disease screening procedures harm the animal. When the disease surveillance harms the animal, the activity is governed by this Instruction.

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 (which 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 Department of Defense 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 institution. An institution that is not part of the Department of Defense.

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

field research. An investigation conducted on free-living wild animals in their natural habitat that DOES involve an invasive procedure, harms the animal, or materially alters the behavior of the animal under study. Field research is governed by Reference (d) and this Instruction.

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 the animal under study. A field study is not governed by Reference (d) or this Instruction. A field study is distinct from field research.

harm. Any procedure that either causes lasting detrimental physical, behavioral, or psychological 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 Reference (d) and this Instruction. When full committee review of a project is requested, the IACUC shall have a quorum as defined in this Instruction. The board members are appointed by the institution’s commander or the institutional official. The DoD institutional official is, or is appointed by, the institution’s commander and can legally commit the institution to comply with Federal requirements for animal care and use.

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

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 involved in animal care and use, 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).

non-scientific IACUC member. A person whose interests, training, and education are not in a scientific discipline.

OSD Component. Defined in DoDI 5025.01 (Reference (v)).

quorum. A quorum is obtained when a majority of the members of the IACUC are present. At least one veterinarian and one non-affiliated member, or their alternates, must be part of the majority present.

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 four categories of RDT&E 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.

serious noncompliance. An activity that is not in accordance with this Instruction and its references and that is currently or has the likelihood to affect the health and well-being of an animal adversely.

training. An activity with the goal of imparting knowledge, skills, and competencies to a human student. Activities conducted solely for the purpose of training animals are covered by Reference (d) but are not covered by this Instruction. Training is covered by Reference (d) and this Instruction if the activity is conducted for the purpose of training personnel about animal care and handling, and when the animals will also be used in support of activities that are

covered by this Instruction. If the training is conducted to teach animal care for animals that will be used in RDT&E, the training is covered by this Instruction. If the training is conducted to teach medical care for humans, the training is covered by this Instruction. However, if the training is conducted to teach animal care and handling for routine veterinary procedures, or for handling of ceremonial, recreational, or working animals (e.g., military working dogs), the training is not covered by this Instruction.

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.