

**BY ORDER OF THE
SECRETARY OF THE AIR FORCE**

**DEPARTMENT OF THE AIR FORCE
POLICY DIRECTIVE 40-4**



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Medical Command

**PROTECTION OF ANIMAL AND
HUMAN SUBJECTS**

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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(Lt Gen Robert Miller)
Senior Coordinator, SAF/SQ
(Mr. Frank Calvelli)

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This publication implements Department of Defense Instruction (DoDI) 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*, and DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research*. This publication applies to all civilian employees and uniformed members of the Regular Air Force, the Air Force Reserve, the Air National Guard, the United States Space Force, the Civil Air Patrol when conducting missions as the official Air Force Auxiliary, and those with an obligation by agreement to abide by the terms of Department of the Air Force issuances. Ensure all records generated as a result of processes prescribed in this publication adhere to Air Force Instruction 33-322, *Records Management and Information Governance Program*, and are disposed in accordance with the Air Force Records Disposition Schedule, located in the Air Force Records Information Management System. Refer all recommended changes and questions about this publication to office of primary responsibility (usaf.pentagon.af-sg.mbx.afmsa-sge-c@health.mil) using DAF Form 847, *Recommendation for Change of Publication*; route DAF Forms 847 from the field through the appropriate functional chain of command. This publication may not be supplemented.

1. Overview. This publication establishes overarching DAF policy to ensure protection of animals used in research, development, test, and evaluation (RDT&E); animals used in training; and human subjects in research. A cornerstone in any research enterprise is ethical and compliant

conduct of RDT&E. The DAF is committed to protection of animals used in RDT&E, animals used in training, and human subjects in research.

2. Policy.

2.1. The DAF will ensure care and use of animals in DAF-conducted or -supported RDT&E and training in accordance with DoDI 3216.01 and its references.

2.2. The DAF will ensure protection of human subjects in DAF-conducted or -supported research in accordance with DoDI 3216.02 and its references.

2.3. DAF personnel will coordinate with appropriate officials identified in DoDI 3216.01 or DoDI 3216.02, as applicable, to ensure compliance with federal and DoD policies and guidance before conducting or supporting activities which are (or may include) RDT&E using animals, training using animals, or research involving human subjects. **Note:** Support includes provision of funds or other assistance to such activities.

3. Roles and Responsibilities.

3.1. The Air Force Surgeon General is responsible for policy and oversight of RDT&E using animals, training using animals, and research involving human subjects in accordance with Headquarters Department of the Air Force (HAF) Mission Directive 1-48, *The Air Force Surgeon General*. Additional responsibilities are identified in DoDI 3216.01, DoDI 3216.02, and their references.

3.2. The Assistant Secretary of the Air Force for Acquisition, Technology, and Logistics (SAF/AQ), and the Assistant Secretary of the Air Force for Space Acquisition and Integration (SAF/SQ), as the Service Acquisition Executives for the Air Force and Space Force, respectively, ensure acquisitions related to animals used in RDT&E, animals used in training, and human subjects in research comply with applicable acquisition requirements. This includes requirements to comply with DoDI 3216.01 and DoDI 3216.02, such as regarding use of animal use or human research protection clauses in acquisition agreements for such activities in accordance with the Defense Federal Acquisition Regulation Supplement Sections 252.235-7002 and 252.235-7004, or similar language, as required.

3.3. Each DAF Headquarters office, major command, field command, field operating agency, and direct reporting unit will:

3.3.1. Before conducting or supporting RDT&E or training using animals, ensure compliance with applicable requirements of DoDI 3216.01, as implemented by AF/SG in their operating publication for this policy directive.

3.3.2. Before conducting or supporting activities which are (or may include) research involving human subjects, ensure compliance with applicable requirements of DoDI 3216.02, as implemented by AF/SG in their operating publication for this policy directive.

FRANK KENDALL
Secretary of the Air Force

Attachment 1**GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

Defense Federal Acquisition Regulation Supplement, current edition

DoDI 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*, 20 March 2019

DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research*, 15 April 2020

HAF Mission Directive 1-48, *The Air Force Surgeon General*, 21 February 2023

AFI 33-322, *Records Management and Information Governance Program*, 23 March 2020

Abbreviations and Acronyms

DAF—Department of the Air Force

AFI—Air Force Instruction

DoDI—Department of Defense Instruction

HAF—Headquarters DAF (i.e., the Secretariat, Air Staff and Space Staff)

RDT&E—Research, Development, Test, and Evaluation

Prescribed Forms

None

Adopted Forms

DAF Form 847, *Recommendation for Change of Publication*

Office Symbols

AF/SG—Air Force Surgeon General

AFMRA/SGE-C—Air Force Medical Readiness Agency, DAF Component Office of Human Research Protections

SAF/AQ—Assistant Secretary of the Air Force for Acquisition, Technology and Logistics

SAF/SQ—Assistant Secretary of the Air Force for Space Acquisition and Integration

Terms

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. 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.

Research involving human subjects—Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens.

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

1. 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.

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

3. Test—A systematic analysis of the product to ensure that it meets its intended goals.

4. Evaluation—An analysis of the product's suitability and readiness to be produced and fielded.

5. 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.