BY ORDER OF THE COMMANDER
59TH MEDICAL WING

59TH MEDICAL WING INSTRUCTION
40-402

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Medical Command

ANIMAL CARE AND USE IN CLINICAL INVESTIGATIONS, TRAINING, RESEARCH AND DEVELOPMENT

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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This instruction implements DoDI 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*, and AFMAN 40-401(I), *The Care and Use of Animals in DoD Programs*. This instruction establishes policy, assigns responsibility, and describes procedures to assure the welfare and appropriate use of all animals required for graduate health sciences education, clinical research and training. It addresses facility and animal-related resource management at the 59th Medical Wing Clinical Investigations and Research Support (59 MDW/STC), and applies to all investigators and investigations or training using animals. This instruction does not apply to Air National Guard or Air Force Reserve. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) AFI 33-322, *Records Management and Information Governance Program*, and are disposed of in accordance with the Air Force Records Disposition Schedule which is located in the Air Force Records Information Management System.

SUMMARY OF CHANGES

This instruction has been revised throughout by removing duplicative requirements outlined in higher headquarters and other local policies and adding specific references to those policies.

1. General Overview. The 59th Medical Wing (MDW) requires the capability of using laboratory animals in education, training, and research. The use of laboratory animals must be IAW all applicable laws, regulations, publications and guidelines.

2. Institutional Compliance with Laws, Regulations, Policies and Guidelines.

2.1. The 59th Medical Wing (59 MDW) Animal Care and Use Program (ACUP) will comply with all pertinent laws, regulations, directives, publications, and guidelines intended to assure the welfare of animals required for clinical research, educational programs, and testing procedures.

2.2. The 59 MDW will maintain accreditation by AAALAC International (AAALACi).

2.3. Consistent with national guidelines and Department of Defense (DoD) policy, the 59 MDW will employ the internationally accepted approaches of replacement, refinement, and reduction when designing animal research studies and training protocols.

2.4. Central to joint medical training, the 59 MDW utilizes live tissue training (LTT) for medical and operational skill training, as determined necessary by the Military Health System chain of command. When possible, medical simulation technology or cadaveric training is used in lieu of LTT.

2.5. The 59 MDW ACUP does not conduct Research & Development or training protocols involving non-human primates, dogs, cats, or marine mammals.

2.6. The 59 MDW/CC will appoint the Director, Clinical Investigations & Research Support (CIRS) as the Institutional Official (IO), Animal Care and Use Program (ACUP). An alternate IO should also be appointed, typically the Deputy Director, CIRS.

2.7. Due to the size and complexity of the 59 MDW ACUP, the 59 MDW will employ and assign a full-time Attending Veterinarian (AV) to 59 MDW/STC.

2.8. An Institutional Animal Care and Use Committee (IACUC) shall be appointed to implement this policy by monitoring all aspects of the 59 MDW Animal Care and Use Program, including review of animal use protocols and inspection of animal procedures and facilities, the 59 MDW/CC may delegate this appointing authority to the 59 MDW ACUP IO.

2.9. Animal research and training supported, but not conducted, by the 59 MDW will comply with requirements outlined in **Attachment 2** of this instruction. Supported research and training will be reviewed by the USAF Office of Research Oversight and Compliance, Air Force Medical Research Agency (AFMRA/SGE-C) prior to funding and initiation of the protocol.

2.10. Public Health Service (PHS)-Funded Research: Researchers seeking funding from a PHS funding component for animal research conducted within the 59 MDW will notify the IO prior to applying for funding.

2.10.1. The PHS funding components include: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, Food and Drug Administration, and the Biomedical Advanced Research and Development Authority. Through memoranda of understanding, the NIH Office of Laboratory Animal Welfare additionally assures animal activities funded by the National Aeronautics and Space Administration, National Science Foundation, and the Department of Veterans Affairs.

2.10.2. If PHS funding is approved for animal research within the 59 MDW, the funding component will notify Office of Laboratory Animal Welfare (OLAW) that the 59 MDW

does not have an Assurance, and OLAW will negotiate an Assurance directly with the 59 MDW before funds can be received.

2.10.3. If a secondary performing institution on a grant, the 59 MDW must be named as a performance site by the prime awardee institution. It is the 59 MDW submitting investigator's responsibility to inform the IO of this intent, and to ensure that the primary institution includes the 59 MDW in its grant application. As in section 2.10.3., the OLAW will negotiate an Assurance with the 59 MDW after approval as a performing site.

2.10.4. If receiving PHS funds to conduct animal research, the 59 MDW will apply for and maintain a Public Health Service (PHS) Assurance and comply with standards outlined in National Institutes of Health, Office of Laboratory Animal Welfare, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

3. Institutional Roles, Responsibilities and Authorities.

3.1. Institutional Official (IO): In accordance with DoDI 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*, the IO can legally commit the institution to comply with federal requirements for animal care and use. The IO is responsible for ACUP compliance, resource planning and ensuring the alignment of program goals of quality animal care and use with the institution's mission. The IO shall:

3.1.1. Ensure that the 59 MDW ACUP and facilities conform to applicable standards, guidelines and policies.

3.1.2. Ensure that all research, education, and training using animals is documented in an IACUC-approved protocol.

3.1.3. When delegated by the 59 MDW/CC, appoints a duly constituted IACUC to monitor and ensure humane care and use of animals.

3.1.4. Ensure that all deficiencies noted by the IACUC during semiannual reviews of Animal Care and Use Programs and facilities are documented and corrected. Ensure that significant deficiencies are corrected in accordance with a defined plan and timeline.

3.1.5. Ensure that AAALACi accreditation is maintained and that animal care is adequately resourced.

3.1.6. Review and approve proposals, projects, applications, and IACUC-approved protocols involving the use of laboratory animals.

3.1.7. In accordance with IACUC Policy 27, Suspension of Protocols, review the reasons for suspension of any activity involving laboratory animals and direct either necessary corrective action or termination of an activity, whichever is deemed appropriate.

3.2. IACUC: The IACUC is responsible for continuous and comprehensive monitoring of all aspects of the 59 MDW ACUP and associated facilities. The IACUC establishes administrative and program requirements through the use of IACUC-approved policies. IACUC policies may be accessed on-line at: **https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/IACUC-Policies.aspx** (CAC enabled), or requested by contacting IACUC administrative support staff at 210-292-1927/4210.

3.2.1. The IACUC shall be appointed and function in accordance with 59 MDW IACUC policies.

3.2.2. The IACUC will make recommendations to the 59 MDW ACUP IO regarding any aspect of the ACUP, including improvements to facilities, enhancement of personnel training, etc.

3.2.3. A duly constituted IACUC must approve all research and training protocols utilizing animals before the activity can begin. Refer to 59 MDW IACUC policies for further details regarding conduct of the IACUC and protocol approval, modification, and completion.

3.2.4. Semi-Annual Program Review: The IACUC will conduct program reviews every six months for all aspects of the Animal Care and Use Program, to include a facility inspection of all animal use areas. The program review is conducted and documented in accordance with IACUC policy and reported per section 6.1. of this instruction.

3.2.5. Animal Welfare Concerns: The IACUC will review and, if warranted, investigate any concerns or complaints that involve issues of humane care and use of animals or noncompliance with applicable laws, regulations, directives or guidelines. Personnel may report such concerns or violations to the IACUC Chairperson, any IACUC member, Attending Veterinarian, ACUP IO, 59 MDW/CC or 59 MDW Inspector General.

3.3. Attending Veterinarian (AV): The AV has direct authority and responsibility for the health and welfare of animals used in 59 MDW research and training activities, and access to all animals and resources to manage the program of veterinary care. The AV shall:

3.3.1. Provide a soundly managed Animal Care and Use Program in accordance with applicable references and applicable state and local laws and regulations.

3.3.2. Oversee the animals being used during research or training, as described either in the IACUC-approved protocol or as described in IACUC policy.

3.3.3. Procure and maintain animals for investigations, training, demonstration and testing procedures.

3.3.4. Consult with investigators, project directors, and the IACUC on the selection and use of animal models, the appropriate use of anesthetic, analgesic and tranquilizing drugs, and methods of euthanasia. On issues involving the appropriate use of these types of drugs, methods of euthanasia, as well as issues of animal health in general, the AV's professional judgment will prevail.

3.3.5. Serve as a technical advisor to the Contracting Officer and coordinate all aspects of animal procurement. The AV shall also provide technical specifications as needed for each animal species requested for use by investigators and project managers. The AV is the local authority to approve sources of animal procurement.

3.3.6. Conduct pre-acceptance examination of all animals to ensure contract compliance (primarily health status).

3.3.7. Prevent outbreak of disease in the animal colonies by applying appropriate quarantine, immunization and management measures.

3.3.8. Procure routine drug and support items such as cages, bedding, and feed, as well as equipment unique to laboratory animal medicine.

3.3.9. Provide general veterinary medical support to investigators and project managers.

3.3.10. Advise the 59 MDW/CC, the ACUP Institutional Official, and the IACUC on matters pertaining to laboratory animal science.

3.3.11. Serve as a core member of the IACUC and "chair" the IACUC meetings when the chairperson is absent, unless another individual has been specifically appointed to act in the IACUC Chairperson's absence.

3.4. Principal Investigators shall:

3.4.1. Coordinate pre-proposals, proposals, and grant applications involving use of animals in research or training with 59 MDW/CIRS.

3.4.2. Submit the final draft of their proposed investigation to the IACUC for review, using the prescribed protocol format in accordance with AFMAN 40-401(I), *The Care and Use of Animals in DoD Programs*. Protocol-related templates are available at: **https://kx.health.mil/kj/kx8/ClinicalResearchJBSALackland/Documents/Forms/HideFolders.aspx?FilterField1=Classification&FilterValue1=crfwhmcanimalresearchtemplates** (CAC enabled), or can be requested by contacting IACUC administrative support staff at 210-292-1927/4210.

3.4.3. Provide written assurance that the activities do not unnecessarily duplicate previous experiments.

3.4.4. If seeking approval by the 59 MDW IACUC, use animals only at 59 MDW/CIRS, unless this is specifically waived in an approved protocol or the IACUC grants specific approval to use other facilities.

3.4.5. Coordinate with the AV all support concerning the routine (non-surgical) care of animals.

3.4.6. Coordinate with personnel of the 59 CIRS Operations Branch to assure adequate surgical support, care of animals following recovery from anesthesia, and immediate post-operative care is given to all surgical subjects.

3.4.7. Discuss with the AV the final disposition of all animals assigned to the project, and coordinate proper disposition of all animals and/or carcasses with the 59 CIRS Operation Branch. Required necropsies, as stipulated in protocols, testing, and training projects shall be coordinated with 59 CIRS Pathobiology personnel.

3.4.8. Notify the IACUC in writing of intended protocol changes affecting animal use matters, in accordance with IACUC Policy 15 (Protocol Amendment Review) and 33 (Veterinarian Verification and Consultation (VVC) Process and Administrative Changes).

3.4.9. Refrain from initiating any protocol or modification involving animal use prior to appropriate IACUC review and approval. Work can begin only after the principal investigator is notified of all approvals.

3.4.10. Obtain Radioisotope/Radiation Safety Committee, Institutional Biosafety Committee, and other specialized committee review and approval of protocols, as appropriate. AFMRA/SGE-C will provide a second-level review and approval for all training protocols. Other committees may not approve those sections of proposals, projects,

or applications related to the care and use of animals until they have first been approved by the IACUC.

3.4.11. Ensure protocols are executed as approved by the IACUC. Report adverse events and non-compliance to the IACUC.

3.4.12. Maintain accurate animal use records, to include United States Department of Agriculture (USDA) pain and distress categories.

4. Education and Training.

4.1. The ACUP IO will provide appropriate training resources to ensure on-going, documented, education and training for all personnel involved in the conduct, review, or approval of research and training involving animals.

4.2. The IACUC is responsible for establishing through policy the training requirements for the IO, IACUC members, CIRS Operations Branch staff, Principal Investigators, and Associate Investigators. Requirements are outlined in 59 MDW IACUC Policy 23, Training of Personnel.

4.3. Training and education will be commensurate with the duties and responsibilities of the personnel, and will be documented.

5. DoD-Supported, But Not Conducted, Research & Development.

5.1. The 59 MDW Science & Technology (ST) Program Director or Program Manager overseeing protocol management and support is responsible for ensuring that all regulatory and policy requirements regarding 59 MDW-supported Research and Development (R&D) are met. **Attachment 2** outlines pre-funding and oversight requirements regarding 59 MDW-supported animal protocols.

6. Program Reports and Required Notifications.

6.1. Semi-Annual Program Review: At least once every six months, the IACUC will submit a written evaluation of the Animal Care and Use Program to the IO, in accordance with applicable references and IACUC Policy 1, Institutional Animal Care and Use Committee (IACUC) Administrative Policies.

6.2. USDA Annual Report*:* Annually, the AV will submit a completed Animal and Plant Health Inspection Service (APHIS) Form 7023, *Annual Report of Research Facility* to the USDA, no later than 1 December. A copy of the APHIS Form 7023 and analogous information for non-regulated species will be forwarded to AFMRA/SGE-C.

6.3. AAALACi Annual Report: Annually, the IO will submit a completed annual report to AAALACi, no later than 1 February.

6.4. Component Notifications: The IO will notify AFMRA/SGE-C of any significant deficiencies, noncompliance with this issuance, change in AAALAC International accreditation status, reports of adverse events, and socially sensitive matters.

7. Publication of Animal Research. All abstracts, presentations, manuscripts, graduate level defense presentations at civilian institutions, and related publications describing the use of animals in the 59 MDW will be submitted for security review and public affairs clearance, in accordance with 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*. Animal-

related products will undergo a legal review, per requirement by Secretary of the Air Force/Public Affairs.

8. Release of Information.

8.1. All animal-based protocol final reports will be submitted to the Defense Technical Information Center for public release, once cleared by Public Affairs and the Judge Advocate.

8.2. The IO and/or ACUP Clinical Research Administrator will notify AFMRA/SGE-C promptly upon receipt of a Freedom of Information Act (FOIA) request. Documentation compiled in response to FOIA requests will be submitted to 502 ABW/JA, AFMRA/SGE-C, and Office of the Under Secretary of Defense for Research & Evaluation for legal and policy review.

9. Animal Mistreatment, Protocol Non-Compliance, and Research Misconduct.

9.1. Individuals witnessing or having knowledge of improper care and/or use of animals within the 59 MDW should report the program immediately to the IO, AV, or IACUC Chair, per the IACUC Whistleblower policy. If unavailable or unable to solve the program, reports may be elevated to the 59 MDW/CC or 59 MDW/IG. Reports may also be made to AFMRA/SGE-C, at email: **usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil**.

9.2. The IO or AV have the authority to immediately halt non-compliant animal activities, and will report the action to the IACUC Chair.

9.3. The IACUC will review, and if warranted, investigate complaints involving animal or non-compliance.

9.4. Protocol Suspensions: The IACUC will suspend any activity involving animal care and use if it is determined that the activity is not being conducted in accordance with applicable provisions, or other relevant policy or pertinent regulation. Administrative processes for protocol suspension will be accomplished in accordance with 59 MDW IACUC Policy 27, Suspension of Protocols.

9.5. Allegations of research misconduct may follow the general procedures outlined in 59 MDWI 44-111, *Research Misconduct.*

10. Records Retention: All records pertaining to 59 MDW-conducted or–supported R&D and/or training will be retained IAW AFRIMS RDS.

JEANNINE M. RYDER, Brig Gen, USAF, NC
Commander, 59th Medical Wing

Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

The Animal Welfare Act of 1966 (P.L. 89-544) and subsequent amendments, as promulgated in USDA regulations 9 CFR Chapter 1, Subchapter A, Animal Welfare Parts 1, 2, and 3, 1 January 2018

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

AFMAN 40-401(I), *The Care and Use of Animals in DoD Programs,* 16 February 2005

National Research Council, National Academies Press, "Guide for the Care and Use of Laboratory Animals," Eighth Edition, 2011

National Institutes of Health, Office of Laboratory Animal Welfare, Public Health Service Policy on Humane Care and Use of Laboratory Animals, 16 March 2015

59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers,* 26 April 2022

59 MDWI 44-111, *Research Misconduct,* 6 November 2020

Adopted Forms

AF Form 847, *Recommendation for Change of Publication*

APHIS Form 7023, *Annual Report of Research Facility*

Acronyms and Abbreviations

AAALACi—Formerly "Association for the Assessment and Accreditation of Laboratory Animal Care, International"; currently AAALAC International.

ACUP—Animal Care and Use Program

AFMRA/SGE-C—Air Force Medical Research Agency/ Research Oversight and Compliance Office

AFRIMS—Air Force Record Information Management System

APHIS—Animal and Plant Health Inspection Service

AV—Attending Veterinarian

CIRS—Clinical Investigation & Research Support

DoD—Department of Defense

FOIA—Freedom of Information Act

IACUC—Institutional Animal Care and Use Committee

IAW—In Accordance With

IO—Institutional Official

LTT—Live Tissue Training

MDW—Medical Wing

NIH—National Institute of Health

OLAW—Office of Laboratory Animal Welfare

PHS—Public Health Service

R&D—Research and Development; Research, Development, Test and Evaluation

RDS—Records Disposition Schedule

ST—Science & Technology

USDA—United States Department of Agriculture

Attachment 2

PRE-FUNDING AND OVERSIGHT REQUIREMENTS FOR 59 MDW-SUPPORTED ANIMAL RESEARCH

A2.1. Component Oversight and Approval. All 59 MDW-supported R&D conducted outside the 59 MDW/STC facility and involving animals will undergo an administrative review by AFMRA/SGE-C, the regulatory oversight Component for the 59 MDW.

A2.1.1. The review must be approved, before funds are released and work can begin, by a DoD veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with applicable regulations, policies, and standards. Document submission requirements include the following:

A2.1.1.1. The performing institution's IACUC-approved protocol. If the standard DoD protocol format is not used by the conducting institution, documents submitted to AFMRA/SGE-C will include all pertinent information and detail regarding animal care contained in the DoD Standard Animal Use Protocol Format. Science & Technology Program Directors and/or PIs should consult with the 59 MDW/STC protocol office for assistance.

A2.1.1.2. IACUC approval documentation (e.g., Notice of Action or a memorandum signed by the IACUC Chair or Institutional Official).

A2.1.1.3. The performing institution's statement that the animals are legally obtained from suppliers licensed by the USDA in accordance with Sections 2133-2134 of Title 7, U.S.C., unless the supplier claims to meet the exemption criteria in Federal law, regulation or policies. When a supplier claims to meet the exemption criteria, the performing institution performing the work will convey the claim of exemption to AFMRA/SGE-C.

A2.1.1.4. The most recent USDA inspection report, unless the institution is exempt from inspection by meeting the criteria in Title 7, U.S.C., and Title 9, CFR. The performing institution must also provide inspection reports annually to AFMRA/SGE-C for the duration of the activity, if applicable.

A2.1.1.5. Documentation of AAALACi accreditation and/or the performing institution's Public Health Service Office of Laboratory Animal Welfare assurance, if applicable.

A2.1.1.6. A brief description of veterinary care and oversight (local format or that requested by AFMRA/SGE-C).

A2.1.2. Major modifications to an AFMRA/SGE-C reviewed protocol must be approved both by the performing institution's IACUC and by AFMRA/SGE-C prior to implementation.

A2.1.3. Continuing annual review documentation for approved, supported (sponsored) protocols will be submitted to AFMRA/SGE-C.

A2.2. On-Site Inspections.

A2.2.1. For all 59 MDW-supported R&D using dogs, cats, non-human primates, or marine mammals, the supported institution must pass an on-site compliance inspection conducted by a DoD veterinarian. These site inspections may be extended to include 59 MDW-supported

R&D involving any species. AFMRA/SGE-C may coordinate with another component (Army or Navy) to conduct such inspections.

A2.2.2. AFMRA/SGE-C may also conduct on-site inspections at its discretion as long as animals are being used.

A2.2.3. If a performing institution is AAALACi-accredited, AFMRA/SGE-C may waive the on-site inspection requirement, though the waiver does not preclude future conduct of an inspection at any time.

A2.3. Contracts and Agreements.

A2.3.1. In accordance with DoDi 3216.01, all 59 MDW contracts for DoD supported R&D or training involving animals must contain the current version of Defense Federal Acquisition Regulations Supplement (DFARS) clause 252.235-7002.

A2.3.2. Agreements not subject to the DFARS (e.g., grants, cooperative research, and development agreements) must contain language equivalent to that in DFARS 252.235-7002.

A2.3.3. Extramural contractors proposing to provide R&D or training as DoD-supported animal use programs must be approved by AFMRA/SGE-C prior to initiation of animal use activities.

A2.4. USDA Registration. In accordance with DoDi 3216.01, non-federal institutions conducting 59 MDW-supported R&D must be registered with the USDA, unless otherwise exempt from this requirement by meeting the conditions in Title 7, U.S.C., and Title 9, CFR for the duration of the activity.

A2.5. Performing Institution's IACUC Oversight. The performing institution's IACUC must approve 59 MDW-supported R&D before activity begins. The institution's IACUC and AV will provide protocol oversight as outlined in DoDi 3216.01, section 3.2.d.

A2.6. Notifications by the DoD-supported institution (extramural contractor).

A2.6.1. The supported institution will notify the 59 MDW and AFMRA/SGE-C that it is under USDA investigation within 5 business days of being notified.

A2.6.2. A supported institution with AAALACi accreditation will notify the 59 MDW and AFMRA/SGE-C within 5 business days of change of accreditation status.

A2.6.3. Upon either of these notifications, and when the issues are relevant to a DoD-supported activity, AFMRA/SGE-C will require a DoD veterinarian to perform a site inspection for cause, ideally within 30 days of the notification. The site inspection will evaluate the adequacy of animal care and use in DoD-supported programs and will result in recommendations regarding continuance, suspension, or termination.

A2.6.4. The supported institution will notify the 59 MDW and AFMRA/SGE-C when the IACUC:

A2.6.4.1. Approves a major modification.

A2.6.4.2. Approves IACUC policies that affect major modifications.

A2.6.4.3. Conducts its continuing review.

A2.6.5. The supported institution will inform the 59 MDW and AFMRA/SGE-C, in a timely manner, of any significant deficiencies, non-compliance with DoDI 3216.01 and DHA-MSR 6025.02, and reports of adverse events regarding DoD-supported R&D.

A2.6.6. The supported institution will promptly inform the 59 MDW and AFMRA/SGE-C of research misconduct or Freedom of Information Act (FOIA) requests concerning or potentially impacting DoD-supported protocols.

A2.6.7. When requested by AFMRA/SGE-C, the supported institution will provide information about animal use programs, in the format requested.