



**United States Army Medical Component
Armed Forces Research Institute of Medical Sciences
APO, AP 96546
315/6 Rajvithi Road, Bangkok 10400, Thailand**

REPLY TO
ATTENTION OF

Sly 12 Sep 2011
MCMR-UWQ-J (100)

12 September 2011

MEMORANDUM FOR SEE DISTRIBUTION

**SUBJECT: Institutional Animal Care and Use Committee and Animal Protocol Review,
Policy Statement No. 11-04**

- 1. GENERAL INFORMATION:** In the conduct of biomedical research, the judicious use of laboratory animals is essential. The Animal Welfare Act (7 U.S. Code Section 2131 et. seq.) and Animal Welfare Regulations (9 CFR Chapter 1A, parts 1-4), DoD Instruction Number 3216.01, Army Regulation 40-33/SECNAVINST 3900.38C, the United States Public Health Service *Policy on the Humane Care and Use of Laboratory Animals*, and the National Research Council's *Guide for the Care and Use of Laboratory Animals* mandate standards for the humane care and use of laboratory animals. Institutions conducting research, education or testing using animals must establish an institutional animal care and use committee (IACUC) that is functionally active.
- 2. PURPOSE:** This Policy Statement supersedes USAMC-AFRIMS Policy Statement 09-04. This Policy Statement describes the responsibilities, functions and composition of the United States Army Medical Component-Armed Forces Research Institute of Medical Sciences (USAMC-AFRIMS) IACUC, the components of an animal use protocol, the responsibilities of the Principal Investigator (PI), and it outlines USAMC-AFRIMS policies on animal care and use issues. The goal of this policy is to ensure that Research Development Testing and Evaluation (RDT&E), clinical investigations, diagnostic procedures, and instructional programs at USAMC-AFRIMS are conducted in compliance with applicable standards, regulations, guidelines and laws.

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4. REFERENCES:

a. AR 40-33/SECNAVINST 3900.38C, "The Care and Use of Laboratory Animals in DOD Programs," February 2005

b. DoD Directive Number 3216.1, 17 April 1995, re-issued as DoD Instruction 3216.01, 13 September 2010, "Use of Animals in DoD Programs."

c. *Guide for the Care and Use of Laboratory Animals*, 8th Edition. (Institute of Laboratory Animal Resources, National Research Council, National Academies Press), revised 2011. The Thai translated version is also available.

d. *United States Public Health Service Policy on the Care and Use of Laboratory Animals*, August 2002. Office of Laboratory Animal Welfare (OLAW), National Institutes of Health, Bethesda, MD 20892

e. Health Research Extension Act of 1985, PL 99-158, "Animals in Research", November 1985

f. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. 1985. Office of Laboratory Animal Welfare (OLAW), National Institutes of Health, Bethesda, MD 20892

g. American Veterinary Medical Association (AVMA) Guidelines on Euthanasia (formerly the 2000 Report of the AVMA Panel on Euthanasia), June 2007

h. 7 USC 2131-2156, Animal Welfare Act, as amended

i. 9 CFR, Chapter 1A, Parts 1-4, Animal Welfare Regulations, promulgated by the United States Department of Agriculture (USDA), as updated.

j. *Institutional Animal Care and Use Committee Guidebook*, Office of Laboratory Animal Welfare (OLAW) and Applied Research Ethics National Association (ARENA), 2nd Edition, 2002

k. *Institutional Administrator's Manual for Laboratory Animal Care and Use*. DHHS Publication 88-2959, 1988. Office of Laboratory Animal Welfare (OLAW), National Institutes of Health, Bethesda, MD 20205

l. *Occupational Health and Safety in the Care and Use of Research Animals* (Institute of Laboratory Animal Resources, National Research Council, National Academy Press),

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1997. The Thai translated version is also available.

m. *Ethical Principles and Guidelines for the Use of Animals for Scientific Purposes*
The National Research Council of Thailand, 2006

5. DEFINITIONS:

a. AAALAC – Association for Assessment and Accreditation of Laboratory Animal Care International, a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. DoD Instruction 3216.01 mandates that all DOD research institutes which use vertebrate animals in research shall be AAALAC accredited.

b. ALTERNATIVES – Activities that reduce, refine, or replace the use of animals in medical research as defined in DoD Instruction 3216.01.

c. ANIMAL – Any live or dead vertebrate animal used for research, development, testing and evaluation (RDT&E), clinical investigation, diagnostic procedures, instruction or exhibition.

d. ATTENDING VETERINARIAN – A veterinarian who has received training or has experience in the care, management and use of research animals being attended and who has direct program responsibility for activities involving animals at the Institute.

e. FIPR – Facility Inspection and Program Review. Federal law requires the IACUC to inspect all animal facilities and study areas at least once every six months and to insure the Institute's animal care and use program is in compliance with the regulations and standards promulgated under the Animal Welfare Act/Regulations and DOD regulations.

f. IACUC – Institutional Animal Care and Use Committee. The USAMC-AFRIMS institutional committee which is required by U.S. law and which reviews all proposed animal use protocols, all animal programs, and all USAMC-AFRIMS animal holding and animal use facilities. This Committee performs review of all proposed use of animals.

g. IO – Institutional Official. The individual at a research facility who is authorized to legally commit on behalf of the research facility that requirements of the Animal Welfare Regulations (9 CFR Parts 1, 2, and 3) and Public Health Service (PHS) Policy will be met. The Commander, USAMC-AFRIMS, is the IO.

h. OLAW – Office of Laboratory Animal Welfare, formerly OPRR, Office for Protection from Research Risks - the office that oversees compliance with the PHS Policy on Humane Care and Use of Laboratory Animals. The office is part of the National Institutes

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of Health, Bethesda, MD.

i. **PI – PRINCIPAL INVESTIGATOR.** The person responsible for conducting the research or teaching described in the proposed animal use protocol. There is only one USAMC-AFRIMS PI for each protocol and this person must be on-site. The PI signs the Assurance Statement and assumes responsibility for the use and care of animals in conformance with procedures set forth in the proposed protocol and in compliance with regulation and law.

j. **PROTOCOL –** A document prepared by the PI detailing the proposed use of animals. This protocol must contain specific information concerning the care and use of animals, the number and type of animals required, the training of the investigators, alternatives to the use of animals, justification for any unalleviated pain or distress caused to the animals and alternatives to the use of painful procedures, a written plan for euthanasia while on study or use of early endpoints (if applicable), information on biosafety/biohazard conditions, cited searches of appropriate databases to ensure that the research is not unnecessarily duplicative, a discussion of the need for this research, a review of the pertinent literature, a testable scientific hypothesis, detailed experimental design addressing the hypothesis and minimization of animal usage, data analysis plan and bibliography. Once approved by the IACUC, the protocol becomes a “contract” between the PI and the USAMC-AFRIMS IO. Note: Co-investigators shall have the duties of the PI in the absence of the PI or as directed by the PI.

6. APPLICABILITY:

a. This policy letter applies to all investigators using or receiving USAMC-AFRIMS laboratory animals, USAMC-AFRIMS veterinary support, USAMC-AFRIMS funding, or USAMC-AFRIMS animal facilities.

b. USAMC-AFRIMS personnel conducting animal research in facilities or locations outside of USAMC-AFRIMS, including contractors who receive funding to conduct research outside of USAMC-AFRIMS, must comply with this policy statement. Animal research conducted by staff members in collaboration with other laboratories may be reviewed and approved by that laboratory's IACUC if all of the following conditions are met:

(1) All of the animals will be procured, maintained, and all procedures performed at the other laboratory.

(2) The animal care and use procedures of the other laboratory meet the spirit of all US Federal and DOD requirements. If the Institute does not hold an OLAW Assurance or is not accredited by AAALAC, the Attending Veterinarian will visit the Institution to determine if the local IACUC can review, approve, and provide oversight for the proposed study.

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(3) A copy of the approved protocol will be submitted to the Chair, USAMC-
AFRIMS IACUC.

c. Studies involving animal by-products (tissue, blood, cells, antibodies, biochemicals, etc.) obtained entirely from commercial sources (e.g. selected from a company's product catalog) may be conducted at USAMC-AFRIMS without USAMC-AFRIMS IACUC approval. However, transport of animal by-products that have the potential to carry animal pathogens and/or biohazards into the USAMC-AFRIMS colony (frozen serum and tissue, infected blood products etc.) must be brought to the attention of the USAMC-AFRIMS Attending Veterinarian and the Safety Officer. In addition, any biological product that is to be used in an experimental animal (including any tissue culture-derived products) must be listed in the protocol and must be certified free of pathogens and adventitious agents prior to its use. Source information for animal by-product screening can be obtained from the Department of Veterinary Medicine. A copy of the certificate must be provided to the IACUC and will be filed with the protocol.

7. AUTHORITY: The IACUC has the authority, mandated by U.S. Federal law, to act on behalf of the Institutional Official to:

a. Investigate any concerns relating to laboratory animal care and use practices (see paragraph 10.h.).

b. Suspend any activity which violates Federal laws, regulations and guidelines, DOD Regulation, and/or IACUC policy.

c. Terminate immediately any use of animals that deviates from the approved protocol.

d. Humanely euthanize an animal that is suffering from pain or distress that cannot be alleviated. Certain exceptions may apply when thorough justification is provided in approved, specific protocols.

8. RESPONSIBILITIES:

a. The Commander, USAMC-AFRIMS, as IO, will:

(1) Ensure that Research Development Testing and Evaluation (RDT&E), clinical investigations, diagnostic procedures, and instructional programs are conducted in compliance with applicable laws, regulations, guidelines and standards. Contract and grant programs, and collaborative research facilities must meet the spirit of all U.S. Federal and DOD requirements. If there is a conflict or difference between the regulations with respect

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to standards of humane care and use, then the stricter of the standards will apply.

(2) Ensure that local animal care, use, procurement, and transportation policies comply with applicable laws, regulations, guidelines and standards.

(3) Ensure that animals will experience no unnecessary pain, suffering, or distress and that their use meets valid DOD requirements.

(4) Ensure that efforts will be made to seek and utilize procedures, which minimize pain and distress.

(5) Ensure that Alternatives must be used if they produce scientifically satisfactory results.

(6) Ensure every effort is made to reduce the number of animals used in research, that appropriate controls will be in place, and that unnecessarily duplicative research does not occur.

(7) Ensure that an Occupational Health and Safety Program constitutes part of the overall Animal Care and Use Program.

(8) Establish and appoint members to the IACUC, and appoint the chairperson.

(9) Ensure that the IACUC Chair and the Attending Veterinarian have direct access to, and report directly to, the IO.

(10) Review and approve the minutes, reports and protocols recommended for approval by the IACUC.

(11) Render reports on animal care and use programs as required by DOD requirements, USPHS Policy, AAALAC or the Animal Welfare Act.

(12) Ensure that all USAMC-AFRIMS scientists, research technicians, animal technicians, and other personnel involved in animal care are qualified to perform their duties.

b. Department Chiefs will:

(1) Ensure that all Department animal research is performed under approved protocols.

(2) Review all protocols submitted by Department PIs for mission relevance,

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scientific merit, and program need.

(a) The primary responsibility for scientific review belongs to the Department Chief. His/her signature on the protocol title page certifies that the protocol is scientifically meritorious and relevant to the Department's mission. The Department Chief may choose to delegate scientific review but retains primary responsibility for this process.

(b) There must be no conflict of interest in the scientific review process (i.e. a co-investigator may not perform the scientific review).

(c) In the event that the Department Chief is also a primary investigator on the protocol, the Commander, USAMC-AFRIMS or a person designated by the Commander, must review and sign the protocol cover sheet for scientific merit prior to submission of the protocol to the IACUC.

(3) Ensure that all studies are conducted under current occupational health and safety, as well as biosafety and biosurety, guidelines.

(4) Nominate member(s) of the Department to serve on the IACUC when requested by the IO.

(a) The Department IACUC member(s) provide guidance to investigators on correct format and composition of protocols.

(b) The member(s) serve as a liaison between the investigator, their respective departments and the IACUC.

c. The IACUC will:

(1) Review all proposed animal use protocols or proposed changes to ongoing activities to be conducted by PIs for compliance with applicable laws, regulations, guidelines and standards.

(2) Ensure that an annual report is submitted for each protocol.

(3) Semiannually review, inspect and approve:

(a) The animal care and use program for compliance with all applicable laws, regulations, guidelines and standards as well as IACUC policies and SOPs

(b) All animal facilities, including laboratories where animal work is performed and/or where animals are housed including laboratories, support and surgical facilities and

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field sites.

(4) Prepare a report of deficiencies found, a plan for correction of the deficiencies found, and the facility's adherence to Federal law. The Facility Inspection and Program Review (FIPR) Report will be prepared IAW DoD Instruction 3216.01.

(5) Review and investigate concerns or complaints involving the use of animals. No person shall be discriminated against or suffer reprisals for reporting violations and complaints may be made anonymously (see paragraph 10.h).

(6) Suspend any activity, which violates applicable laws, regulations, or Institute policies, or any use of animals that is conducted without an approved protocol or approved modification to a protocol.

(7) Make recommendations to the IO regarding the animal care and use program.

(8) Ensure that all scientists, technicians and other personnel involved in the animal care and use program are qualified to perform their duties.

(9) Ensure that scientists, technicians and other personnel are provided with training opportunities to enhance their knowledge of principles of humane animal care and use.

(10) Ensure AAALAC accreditation of the Institute and the Institutional Animal Care and Use Program.

(11) File annual reports required by AAALAC, OLAW, USDA and DOD.

(12) The IACUC will establish and publicize procedures for reporting conditions or procedures which any observer perceives to violate humane care and use of animals, or violate guidelines established by the Institutional Animal Care and Use Program.

d. The Chair, IACUC will:

(1) Call and conduct meetings of the IACUC at least every six (6) months.

(2) Ensure that all animal use protocols are reviewed and approved by the IACUC in accordance with applicable laws, regulations, guidelines and standards before any procedures are begun involving animals.

(3) Ensure that the composition of the IACUC meets the requirements of all applicable Thai and U.S. laws and DoD regulations.

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(4) Call and conduct semi-annual (every six months) reviews of the animal care and use program.

(a) Prepare a report to include the facility's adherence to U.S. Federal law, major and minor deficiencies found, a plan for correction of deficiencies and a schedule with dates for correction of each deficiency.

(b) Any failure to adhere to the plan and schedule that results in a significant deficiency (one that is or may be a threat to the health or safety of the animals) remaining uncorrected shall be reported in writing within 10 business days to the Commander, USAMC-AFRIMS. This failure shall be reported in writing within 15 business days through the Commander, USAMC-AFRIMS to the Commander, USAMRMC and OLAW.

(5) Keep a current list of facility deficiencies and update it semi-annually. Prepare a plan and time schedule for correction of facility deficiencies.

(6) Direct recording, preparation and maintenance of the minutes of IACUC meetings and submit them to the Institutional Official.

(7) Direct maintenance of files of approved protocols, inspections, training and correspondence pertaining to the activities of the IACUC.

(8) Request that the PI, or knowledgeable representative, attend the IACUC meeting where his/her protocol, or a related animal care and use issue, is to be discussed.

(9) Notify the PI in writing when the protocol is approved and when the PI may commence use of animals as described in the approved protocol.

(10) Investigate, or appoint a subcommittee to investigate any reports of inhumane or inappropriate use of research animals (see paragraph 10.h).

(11) Notify the PI in writing at least 60 days before the annual review is required. Provide the PI with an annual checklist to describe the protocol and the anticipated use of animals for the upcoming year.

(12) Ensure that all correspondences to and from the IACUC are reviewed at each IACUC meeting.

(13) Approve minor modifications to protocols.

(14) Delegate administrative functions as appropriate to the IACUC Administrator.

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e. The Principal Investigator (PI) will:

(1) Prepare, submit and have an approved protocol for the use of animals before any research using animals is performed. The specifics of how to prepare an animal protocol are described in this policy letter (see section 10) and in the standard DOD Protocol Format with instructions, which can be found on the USAMC-AFRIMS Intranet.

(2) Protocols submitted on behalf of other institutions must identify a USAMC-AFRIMS Principal Investigator.

(3) Obtain approval and signatures from Department Chief, Attending Veterinarian, biostatistician, the USAMC-AFRIMS Safety Officer, and any supporting Departments **prior** to submission of protocols to the IACUC. Review and signature by Department Chiefs serves to validate scientific mission relevance.

(4) Sign Assurance Statement and assume responsibility for the performance of the research conducted under the protocol. Also, assure the continued humane care and use of animals used in the research for which he/she is PI. Furthermore:

(a) The research must be performed in accordance with the description provided in the IACUC-approved protocol, and all approved major and minor modifications.

(b) Adherence to approved protocols, attention to animal health and to unexpected changes in animal facilities, safety procedures, and strict oversight of technicians working on the protocol are the responsibility of each PI.

(c) The PI must ensure that he/she and all personnel working on the protocol will be properly trained in basic animal care and use principles, and have received occupational health clearance to work with animals. The PI will ensure all training for relevant personnel is documented fully.

(d) Each PI is charged to keep current of new techniques that could reduce the number of animals needed, could reduce pain or distress, or could replace animals with non-animal systems.

(e) The PI must use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds may only be used in animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone is not an adequate justification for using non-pharmaceutical-grade compounds.

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(5) Obtain approval, in writing, for modifications to an approved protocol before modifications are implemented.

(6) Ensure that all individuals and all activities associated with any protocol involving biohazards are in compliance with current CDC/NIH, DOD, USAMC-AFRIMS guidelines and regulations, as well as local SOPs.

(7) Assume responsibility for the disposition of animals following their use on the protocol by coordinating with the Department of Veterinary Medicine to determine whether euthanasia, transfer of animals to the Issue Pool or to another protocol is the best course of action.

(8) Submit annual Protocol Reports to the IACUC as requested, describing progress, conclusions and publications, as well as any developments in the field that might alter the number of animals needed or the procedures to be used in the future. Protocols are generally reviewed and approved for a 3-year period, but annual reports to the IACUC by the PI are reviewed to determine whether each protocol should continue. Modifications made in the protocol during the year should be detailed in the annual report.

(9) Submit, if required, information requested by the IACUC as a result of their Facility Inspection and Program Review, and address any deficiencies in the PI's area of responsibility cited by the FIPR.

(10) Wait until official written approval is received from the Chair, IACUC authorizing that the protocol may be initiated before beginning research.

(11) Submit an official memorandum to the Chair, IACUC, when the protocol work has been completed and no additional animal support is planned. Request closure of the protocol and include a brief summary of the findings and disposition of the animals. Note: protocol closure indicates that the relevant animal use is complete; it does not preclude further analysis of resulting biosamples or further data analysis.

f. The Attending Veterinarian (AV) will:

(1) Procure, maintain, and provide health care to animals housed in Institute facilities and maintain required records of those activities. Provision of animal husbandry and health care, animal facility maintenance and other Department of Veterinary Medicine responsibilities shall be conducted in accordance with applicable Thai and U.S. laws and DoD regulations, including all Department of Veterinary Medicine Standard Operating Procedures. Any procurement of animals other than under an approved protocol and by the direction of the AV is strictly prohibited.

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(2) Provide protocol support as needed to research personnel to ensure that all animal use procedures are performed in accordance with applicable Thai and U.S. laws and DoD regulations.

(3) Provide training to investigators and technicians with regard to animal care and use, and maintain training records. The qualifications and training of personnel shall be reviewed on an annual basis to fulfill the requirements of the 9 CFR.

(4) Provide veterinary consultation to PIs during the draft stages of each protocol.

(5) Maintain the Institute's AAALAC Accreditation standard of quality animal care and related documentation.

(6) Serve as a voting member on the IACUC.

g. IACUC Administrator will provide administrative support for the IACUC:

(1) Schedule, coordinate, record and document Committee meetings and inspections.

(2) Prepare correspondence.

(3) Maintain protocol files and other Committee records.

(4) Prepare reports as required by the DOD, USDA, OLAW, AAALAC and the Institute.

9. IACUC MEMBERSHIP:

a. The IACUC membership may vary with the needs of the Institute but will be in accordance with the 1985 amendments to the Animal Welfare Act, USPHS Policy, DoD Instruction 3216.01, and AR 40-33/SECNAVINST3900.38C. The voting membership will include, but may not be limited to:

(1) A senior scientist experienced in animal research.

(2) A veterinarian trained in laboratory animal science, preferably with experience in research animal care and use, that has direct program responsibility for activities involving animals at the Institute (Attending Veterinarian).

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(3) At least one person representing community interests (Non-Affiliated). This individual cannot have any liaison with the Institute other than as a member of the IACUC and shall not be a member of the immediate family of a person affiliated with the Institute*.

(4) At least one person whose primary background is outside of biomedical science (Non-scientist)*.

(5) Whenever possible, at least one (1) representative from each USAMC-AFRIMS scientific department as either a primary or alternate member.

(6) There shall be no more than three (3) voting members from the same Department.

(7) The recorder of the minutes, a non-voting member.

(8) The Chair, IACUC, to be appointed by the Institutional Official.

*these two positions may be fulfilled by a single member

b. Whenever possible, each member shall have an alternate member who will be trained in IACUC procedures and responsibilities, will receive the same general information as IACUC members to stay abreast of current issues, and who may serve on various IACUC subcommittees.

c. Nonvoting or Ad Hoc members may include the IACUC Administrator, consulting veterinarians, animal care personnel, technicians, subject matter experts and other consultants.

d. Should expertise not be available in-house, a subject matter expert may be called to advise the Committee.

e. All members must obtain an initial eight hours of training in laboratory animal care issues and ethics, as directed by AR 40-33.

10. GENERAL IACUC PROCEDURES

a. Institutional Animal Care and Use Committee Meetings:

(1) The IACUC will meet at least every six (6) months, or more frequently as necessary, to review and discuss protocols, reports, the results of program and facility reviews, and other animal care and use issues brought before the Committee.

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(a) A tentative monthly IACUC meeting schedule with a suspense date for protocol submission will be made available to PIs and IACUC members.

(b) IACUC meetings will be held on the day scheduled IF:

- There is new or pending IACUC business, or
- It has been six (6) months since the last meeting

(2) A quorum consisting of a majority of the IACUC voting membership is required for each official meeting. No member may vote on a protocol for which that member has a conflict of interest (i.e. is a PI or co-investigator or a subordinate of the PI or co-investigator) and that member may not be counted toward a quorum for that vote. (Note: An alternate may only vote in place of the primary member specified in the appointment memorandum.) If a quorum cannot be attained on the scheduled date, a new date, which is to be as close to the scheduled date as possible, will be selected by the Chair, IACUC.

(3) At least five (5) working days prior to the IACUC meeting, primary and alternate members receive packets containing the upcoming meeting agenda and supporting documentation. The packets may include copies of protocols to be reviewed, minutes of previous meetings, a list of protocols approved by the IACUC during the interim since the last meeting, inspection reports, and general information pertaining to facilities and the general health and welfare of research animals. Packets may be sent electronically.

(4) IACUC members may contact the Chair or the IACUC Administrator seven (7) days prior to a regularly scheduled meeting to place issues on the agenda, or to request that a consultant, investigator, or other personnel be invited to the meeting.

b. A review and inspection of the Animal Care and Use Program and facilities [Facility Inspection and Program Review (FIPR)] will be conducted by the IACUC every six months. Reports of the IACUC on evaluations and inspections will be reviewed and signed by a majority of IACUC members. Minority views, if expressed, must be included.

c. Determining Protocol Types

(1) **Standard protocols** require full IACUC approval and include but are not limited to the following:

- Use of any animals other than rodents or insectivores;
- Any protocols that contain pain category E;
- Use of death as an endpoint.

(2) **Rodent/insectivore (R/I) protocols** do not require full committee approval as



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long as they meet the following criteria:

- No animals in pain category E;
- Death is not used as an endpoint.

(3) Final decision on whether the protocol meets the criteria as a rodent/insectivore protocol is made by the Chair in consultation with the Attending Veterinarian.

d. Protocol Review Process for Standard Protocols

(1) PIs will submit animal use protocols using the standard DOD protocol format (USAMC-AFRIMS Intranet) to the IACUC Administrator for IACUC review after the protocol has received review and signature from the Attending Veterinarian, biostatistician, the Department Chief, the Safety Officer, and any additional support personnel as indicated.

(2) All new standard protocols will receive full committee review at the next appropriate IACUC meeting. All protocols received prior to 7 working days before the scheduled monthly IACUC meeting will be discussed at that month's IACUC meeting. Any protocol received within 7 working days of the meeting may be held for review until the next month's meeting.

(3) Each protocol to be reviewed will be submitted to all IACUC members. The members will have up to five (5) working days to review the protocol prior to the IACUC meeting

(4) If prior to the meeting an IACUC member notes questions, comments or suggestions they want the PI to address at the upcoming IACUC meeting, the member should:

(a) Indicate his/her remarks in writing.

(b) Forward these remarks to the IACUC administrator at least 2 working days before the scheduled IACUC meeting.

(c) The IACUC Chair or Administrator will compile these comments and communicate them to the PI one (1) working day before the meeting, so that the PI may be prepared to discuss these issues. No written response is required of the PI at this time.

(d) New issues regarding the protocol may also be brought up to the PI during the meeting without prior notification.

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(e) At any time, each member of the IACUC may also contact the PI directly, or ask the IACUC Administrator to do so, to ask any questions about the proposed protocol.

(5) At the IACUC meeting:

(a) The PI, or the PI's representative, will give a brief overview of the protocol and answer all IACUC questions. The PI will be excused from the room once all questions have been answered to the best of his/her ability.

(b) After the PI leaves the room the Committee will discuss the protocol and vote.

(c) By a majority vote the IACUC may decide to:

- Approve the protocol as submitted.
- Request modifications or clarifications to secure approval. When this occurs, the Committee generally authorizes one member of the Committee to approve the revised protocol on behalf of the IACUC when resubmitted. However the IACUC reserves the right to require that the revised protocol be submitted to the next convened meeting for full committee review or be distributed via e-mail for Committee review. When distributed by e-mail, members have 5 working days to comment or request that the resubmitted protocol be reviewed at the next full meeting
- Disapprove the protocol. The PI will be made aware of the reasons for this decision.
- Table or defer review.

(6) The IACUC Chair communicates the IACUC's decision, comments and requests to the PI and designates a Communicating Member. It is the responsibility of the PI to assure that all revisions requested by IACUC members are addressed and incorporated into the protocol before the protocol is forwarded, via the Communicating Member, to the IACUC Chair for approval. The PI must respond to this communication in writing within 3 months of the initial review.

(7) In reviewing the protocol, the IACUC will:

(a) Consider whether the protocol contains all required management and regulatory elements as defined by this Policy Letter and the Standard DOD Protocol Template (AR 40-33), and whether the body of the protocol is understandable and complete. The IACUC will determine if the proposal meets the current standards and practices for pain management, adjuvant use, end-point determination, etc., as defined in applicable laws, regulations, guidelines and standards.

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(b) The IACUC will evaluate whether proposed protocols involving cats, dogs, or nonhuman primates can only be performed in those species or whether some other species or test system could produce comparable data. The IACUC will evaluate whether the species of nonhuman primate proposed for use is the most suitable.

(8) Protocols involving non-human primates, cats or dogs are forwarded to the Animal Care and Use Resource Office (ACURO), USAMRMC, for central review in accordance with DoD Instruction 3216.01.

e. Protocol Review Process for Rodent/Insectivore (R/I) Protocols

(1) PIs will submit animal use protocols using the standard DOD protocol format (USAMC-AFRIMS Intranet) to the IACUC Administrator for IACUC review after the protocol has received review and signature from the Attending Veterinarian, biostatistician, the Department Chief, the Safety Officer, and any additional support personnel as indicated.

(2) Upon receipt and administrative acceptance by the IACUC administrator, the R/I protocol is sent to all Committee members via e-mail. Members are given 5 working days to review the protocol, make comments and to request a full Committee review, if desired. Comments may be made without requesting full Committee review.

(3) If any member (primary or alternate) requests full committee review, then the protocol is held until the next IACUC meeting and reviewed in the same manner as a standard protocol.

(4) If no member requests a full Committee review, the chair assigns a subcommittee consisting of the Chair or Alternate Chair, Attending Veterinarian or Alternate Attending Veterinarian, and two IACUC members or alternate members. The subcommittee acts on behalf of the IACUC and communicates any IACUC comments and concerns to the PI and judges whether responses are adequate. The sub-committee may meet at a schedule that is convenient for them and the PI. This process should be completed within 1 month of receipt of the original submission. Once all concerns are adequately addressed the protocol is recommended for approval and forwarded to the Commander, USAMC-AFRIMS, for final approval. NOTE: the subcommittee may not withhold approval but may refer the protocol for full committee review.

f. Protocol Approval (Standard and R/I)

(1) After recommended approval by the IACUC (and central review when indicated), the protocol is forwarded to the Commander, USAMC-AFRIMS, for final approval and signature. The Commander may not approve an animal protocol if it has not been recommended for approval by the IACUC.

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(2) The protocol is officially approved and research can begin when the PI receives official notification from the Chair, IACUC.

(3) Approved protocols are assigned a protocol number by the IACUC Administrator.

(4) Protocols are approved for a three-year period.

(5) Annual review and approval is required for the protocol to remain active. Annual reviews are due in November of each year and cover the previous fiscal year.

g. Protocol Modifications

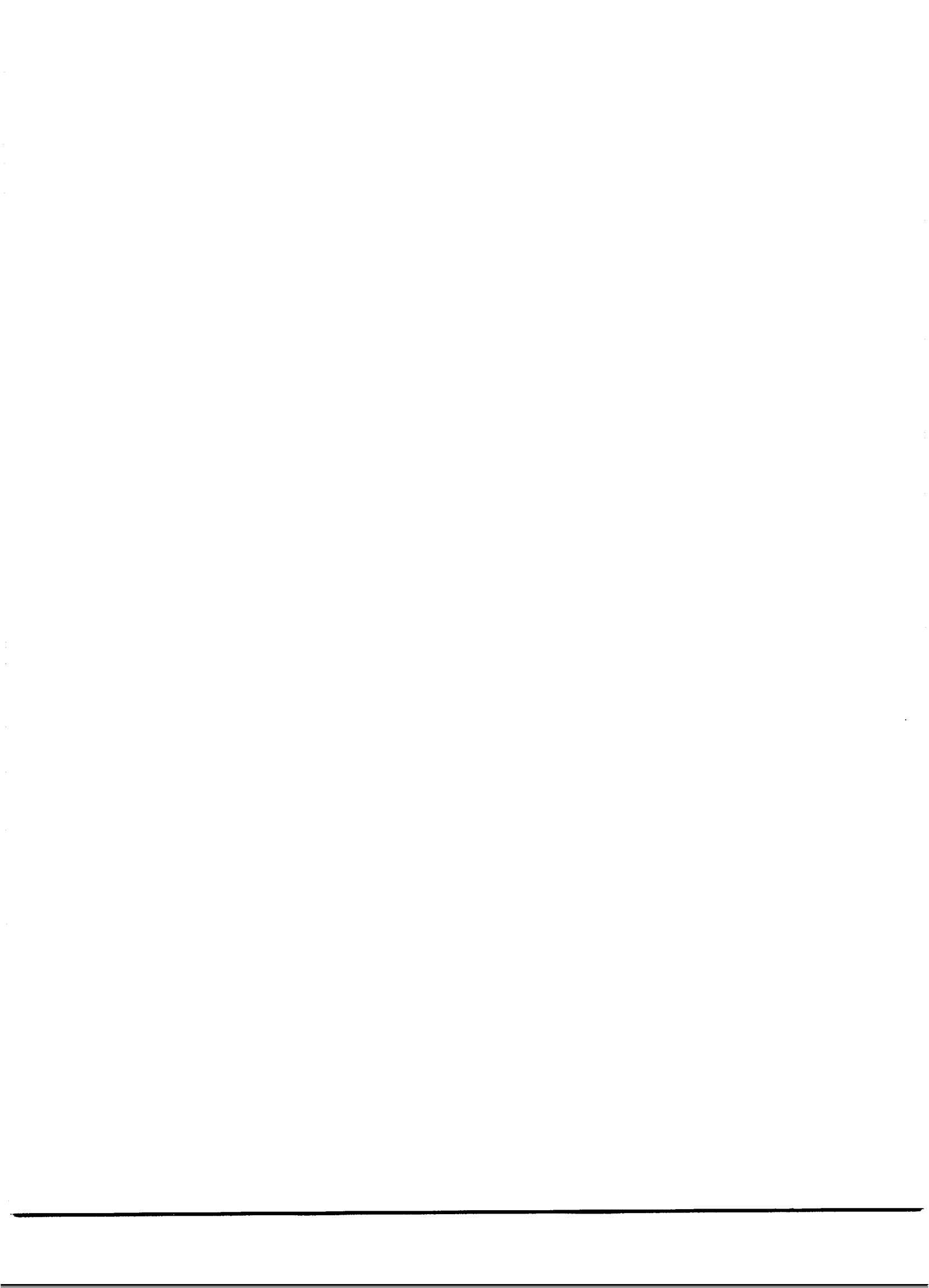
(1) There are two categories of modifications:

(a) **Major modifications** require full IACUC approval and include, but are not limited to, the following:

- Changing the scientific direction of a protocol;
- Increasing the number of non-human primates, dogs or cats, or increasing the number of other animals by more than 10%;
- Change in the species of the animals approved on the original protocol;
- Change in the USDA-APHIS Form 7023 pain column (C, D, or E) of the protocol to a more severe rating;
- Adding surgery to the protocol;
- Changing the Principal Investigator. The new PI must submit a training statement with his/her request, and a signed assurance statement.

(b) **Minor modifications** to the original protocol do not require full IACUC approval. Typical minor modifications might include the following:

- Changing doses or routes of administration of a drug, to include requesting approval for use of a non-pharmaceutical-grade medication;
- Recording or measuring additional variables (e.g. locomotor activity, heart rate) in the whole animal that are no more invasive than procedures currently approved under the protocol and that do not increase the Pain Category of the protocol;
- Adding additional investigative compounds or veterinary health drugs that are functionally similar to one another;
- Changing personnel supporting the protocol. All new personnel must submit a statement outlining training credentials with their request.



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- Changing small animal numbers by 10% or less of the original number (this excludes dogs, cats or nonhuman primates). [Note: The maximum number of animals that can be approved by a minor amendment is 10% of the original number of approved animals. This can be accomplished by 1 minor amendment for a 10% increase, or multiple minor amendments whose total number of requested animals does not exceed the 10% of original approved animal number. All requests exceeding the 10% will be considered a major amendment.]

- The IACUC may direct a PI to provide additional information for individual experiments (for example drugs to be tested in a drug screening model) in a minor modification prior to the start of each experiment.

(c) Guidance from IACUC members or the Attending Veterinarian should be sought when the PI is unsure whether proposed changes constitute a major or minor modification.

(d) The final decision on modification classification will be made by the Chair in consultation with the Attending Veterinarian.

(2) All modifications must be documented in a memo and staffed through the Department Chief (or the Deputy Commander for Science, if the Department Chief is PI of the protocol) and the protocol's consulting veterinarian to the Chair, IACUC, for filing with the protocol record. All modifications should be noted in the annual report of the protocol.

(3) Major modification submission and review:

(a) Major modifications are submitted and approved as a protocol amendment. The protocol amendment template is available on the intranet and from the IACUC Administrator.

(b) The amendment is reviewed and initialed by the Attending Veterinarian, Department Chief, safety officer (if applicable) and any other coordinating personnel before it is submitted to the IACUC. The PI should contact the IACUC administrator if unsure which signatures are required.

(c) Upon receipt and administrative acceptance by the IACUC Administrator, the major amendment is sent to all Committee members via e-mail. Members are given 5 working days to review the amendment, make comments and to request a full Committee review if desired. Comments may be made without requesting full Committee review.

(d) If any member (primary or alternate) requests full Committee review, then the amendment is held until the next IACUC meeting and reviewed in the same manner as a new protocol.

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(e) If no member requests a full Committee review, the chair assigns an IACUC member as primary designated-reviewer. The primary reviewer acts on behalf of the IACUC and communicates any IACUC comments and concerns to the PI and judges whether responses are adequate. This process should be completed within 3 months of receipt of the original modification. Once all concerns are adequately addressed, amendment is recommended for approval and forwarded to ACURO (MRMC) (in the case of non-human primate, dog and cat protocols) and the Commander, USAMC-AFRIMS for final approval. NOTE: a designated-reviewer may not withhold approval but may refer the amendment for full committee review.

(f) The amendment is officially approved when the PI receives official notification from the Chair, IACUC.

(4) Memorandums for both major and minor modifications must be completed as per the protocol amendment template (available on the USAMC-AFRIMS Intranet) which requires the PI state the proposed modification, justify the modification, provide personnel training documentation (when applicable), and sign an assurance statement that the changes are in compliance with all animal welfare regulations and guidelines. The current protocol amendment template can be found at the USAMC-AFRIMS Intranet site.

h. Investigating Animal Use Related Concerns

(1) All allegations of inappropriate animal use reported to the IACUC will be evaluated by the IACUC Chair, Attending Veterinarian and the IACUC Administrator. This subcommittee will make a determination if there is any basis for the allegation. If there is imminent danger to an animal, corrective action will be taken immediately. All written allegations and allegations determined to have basis will be investigated fully.

(2) The IACUC Chair will bring the issue to the IACUC. If additional information is required, the Chair will designate a sub-committee of at least 2 members to investigate the complaint. The results of all completed investigations will be reviewed by the IACUC. At any time, the IACUC Chair or subcommittee can request the full IACUC be convened to discuss the complaint.

(3) All persons involved will be informed of the purpose of the investigation and the manner in which it will be conducted.

(4) Those against whom the complaint is addressed will have an opportunity to explain their side of the issue.

(5) The results of the IACUC investigation will be available to all involved.

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(6) The IACUC may suspend a previously approved protocol according to section 2.31, paragraph d.6. of the Animal Welfare Act. In brief, the IACUC may suspend a protocol only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote by a majority of the quorum present.

i. IACUC Guidance Documents (GDs)

(1) The intent of an IACUC GD is to provide investigators with detailed guidance on IACUC issues and may take the form of an SOP.

(2) An IACUC GD is generated by the IACUC and approved by the Institutional Official.

(3) Any member of the IACUC may propose a topic for a new IACUC GD at the monthly IACUC meeting or by e-mailing the IACUC Chair.

(4) The final version of an IACUC GD is reviewed at an IACUC meeting before being forwarded to the IO for final approval.

(5) The IACUC Administrator maintains a list of all active IACUC GDs and keeps the original IACUC GDs on file.

11. PROTOCOLS COMPOSITION, KEY POINTS

a. Protocol format and content

(1) Protocols must use the DOD Standard Protocol Template (AR 40-33). The current template can be found on the USAMC-AFRIMS Intranet or obtained from the IACUC Administrator.

(2) Protocols by law, by regulation and by the mandate of the IACUC must include much specific information. The data required are detailed in the protocol template. In general, the IACUC is primarily interested in issues of animal care and use, while the Department Chiefs are primarily responsible for scientific merit and mission relevance. However, since the approval of animal use is tied to the value of the information gained, the IACUC may decide on the basis of scientific merit whether the use of the animals is justified. The IACUC may also require additional scientific review. Conversely, Department Chiefs should consider whether the proposed use of the animals is justified by the scientific merit and mission relevance.

(3) Protocols involving potential pain or distress.

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(a) A painful procedure is any procedure which would be reasonably expected to cause more than slight or momentary pain or distress in a human being, (i.e., pain in excess of that caused by injections or other minor procedures).

(b) USDA-APHIS Form 7023 categorizes pain into Columns C (no, momentary, or slight pain), D (deferred or alleviated pain through use of appropriate anesthetics and/or analgesics) and E (non-alleviated pain or distress, usually used where analgesics would interfere with the variable to be measured). A protocol may contain more than one USDA-APHIS designation.

(c) The decision to withhold the use of drugs to relieve pain must be explicitly justified. Protocols with Column E designations must provide a detailed justification in the protocol section V.4.1.4. Additionally a literature search on alternatives to painful procedures (V.4.1.3. Literature Search for Alternatives to Painful or Distressful Procedures) must accompany the protocol.

(d) PIs must check with the Attending Veterinarian at the time their protocol is prepared with regard to classification of certain procedures and euthanasia methods.

(4) Protocols must contain a detailed description for monitoring the animals and include provisions for supportive care (e.g. placing food in the cage within easy access, supplemental fluids, extra bedding, etc.). Justification for not providing supportive care for clinically ill animals is essential.

(5) Protocols should be scientifically rigorous, yet be written in a clear and logical style. An intelligent reader should be able to understand, in general, why and how the PI is going to use the animals.

(6) The protocol must include a section on safety or hazards if infectious (human or animal), chemical or radioisotope hazards exist. This section should explain in detail how these elements will be managed by the PI.

(7) All protocols must be signed by the Safety Officer or a person designated by the Safety Officer.

(8) The protocol must include a section on training of the PI and associated personnel who will perform the procedures described in the protocol. Training includes educational background, experience, and knowledge with the procedures and animal species to be used. Specific formal training should be cited. IACUC members and/or Department of Veterinary Medicine staff may observe and document a technique performed by an investigator as part of their animal use and training oversight responsibilities.

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(9) The protocol must also include the verbatim Assurance Statement detailed in the DOD Protocol Template, followed by the typed name and signature of the PI.

b. Prolonged restraint (greater than 12 hours) should be avoided. Strong scientific justification must be given if prolonged restraint is necessary to achieve research objectives. Physical restraint is not considered a normal method of housing and should not be used simply as a convenience in handling or managing animals IAW *The Guide*. Conditioning is necessary to accustom nonhuman primates, dogs, cats and rabbits to restraint devices. Animals will not be placed in these devices while equipment is calibrated. Animals may be monitored by unannounced visits by veterinary personnel or IACUC members.

c. Procedures that require surgery must be fully and explicitly described in Section V.4.3. By law and regulation, very specific rules apply to all animal surgery, especially survival and multiple major surgeries.

(1) All survival surgery (that from which an animal recovers) must be performed in accordance with applicable laws, regulations, standards, and guidelines.

(2) All survival major operative procedures on non-rodents must be performed in a facility dedicated for that purpose (i.e., a surgery room). Major operative surgery is any surgical intervention that penetrates and exposes a body cavity or any procedure that produces permanent impairment of physical or physiological functions (9 CFR).

(3) Minor operative surgery, non-survival surgery and all surgery on rodents may be performed in a non-dedicated facility (e.g., a portion of the laboratory) but surgery must be performed away from pedestrian traffic and aseptic conditions must be used.

(4) No animal will be used in more than one major operative procedure from which it is allowed to recover unless the multiple procedures are explicitly justified by the PI in the protocol or the multiple procedures are required as veterinary procedures needed to protect the health of the animal as determined by the attending veterinarian. The animal must be allowed to recover fully from the effects of the previous surgical anesthesia and all physiologic parameters must be within normal limits unless variations are the result of an approved surgical manipulation before the next surgical procedure is performed.

(5) A plan for appropriate post-operative care and monitoring must be detailed in the protocol.

(6) According to the *Guide for the Care and Use of Laboratory Animals*, "The attending veterinarian must provide guidance or oversight to surgery programs and oversight of post-surgical care." Additionally, this document indicates that "the investigator and veterinarian share responsibility for ensuring that post-surgical care is adequate."

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d. The use of Freund's adjuvant must be completely described and explicitly justified, since this agent can cause pain and distress and alternative methods are sometimes suitable. Complete Freund's Adjuvant (CFA) is inappropriate as a priming agent for the ascites method of monoclonal antibody production and will not be used.

e. Collection of blood from the retroorbital venous sinus or plexus:

(1) Collection of blood from the retroorbital venous sinus or plexus is considered by the USAMC-AFRIMS IACUC to be a painful procedure. This procedure must be done under anesthesia unless scientifically justified and must be designated in the protocol under Column D (deferred or alleviated pain).

(2) For mice, drawing blood from the mandibular vein is recommended as an alternative to retroorbital bleeding. Obtaining blood from the mandibular vein in mice is considered a nonpainful procedure and may be done without anesthesia.

f. The means of euthanasia must be stated and must adhere to the most current recommendations of the AVMA. If animals are given CO₂ or lethal drug injection, death must be assured by a method approved by the IACUC.

g. Tissue sharing: Investigator sharing of animal tissues is encouraged because it can help to decrease the overall numbers of animals needed in research. Tissues may be collected at the time of euthanasia.

(1) If an animal not on study is euthanized by Department of Veterinary Medicine personnel for medical reasons, or colony management purposes, tissues may be offered for scientific use.

(2) When an animal is euthanized by the original PI as part of the research procedure, another PI wishing to use tissue from the dead animal should provide the description to the protocol PI directly, who should then include it in his/her annual protocol update.

h. Investigators who need to collect animal tissues (including blood) regularly from live animals should prepare protocols for this purpose. Transfer of live animals among approved protocols, (with veterinary review, IACUC approval and proper documentation) is acceptable. The sharing of animals is one way of meeting the Alternatives concept of reduction of animal numbers, and is encouraged by the IACUC, provided such sharing does not violate the restriction against multiple, major survival surgeries on a single animal (see 11.c.4).

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i. Death-as-Endpoint procedures must be scientifically justified. A plan to provide enhanced care to moribund animals must be included. The plan may include a clinical score sheet developed specifically by the PI for the study.

j. Detailed descriptions of all capture, handling and chemical restraint procedures, and explanations of their appropriateness are essential with studies involving wildlife. The necessity for these procedures must be clearly established. Criteria used to assess suitability for release must be clearly stated. Provisions for recovery, treatment or euthanasia of injured animals and disposal of carcasses must be specified. If traps are used, the type of trap, its injury potential, and the monitoring frequency of the traps are important considerations. Protocols for field studies involving euthanasia must include justification for the method used.

12. RECORDS and REPORTS:

a. The IACUC Administrator will maintain:

(1) All records of IACUC activities required by law or regulation in accordance with the Animal Welfare Act, USPHS Policy, DoD Instruction 3216.01, and AR 40-33/SECNAVINST 3900.38C.

(2) Records of approved protocols, including approved amendments, for a minimum of three years after completion of the protocol.

(3) Records of the minutes of IACUC meetings. These minutes will include a record of attendance, the title and PI for each protocol voted upon, and a brief summary of all business discussed at the meetings. The IACUC Administrator will maintain the file of minutes.

(4) Records of the IACUC's semiannual Facility Inspection and Program Review (FIPR) and recommendations (including minority views). The inspection reports contain a description of the nature and extent of the facility's adherence to U.S. Federal law and must distinguish between significant versus minor deficiencies. A significant deficiency is one that, with reference to Subchapter A, Title 9, CFR, and in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a continued uncorrected significant deficiency shall be reported in writing by the IACUC to the Institutional Official within 10 days. The IO reports to OLAW and USAMRMC ACURO within 15 days.

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(5) Reports of suspension of animal care and use activity. The IACUC will report any suspended activity to the IO as soon as possible. The IO will report the suspension in a timely fashion to USAMRMC ACURO, OLAW (NIH) and any other applicable federal funding agency.

(6) IACUC training records on primary investigators and IACUC members.

b. The Department of Veterinary Medicine maintains:

(1) Records which fully and correctly disclose the following information concerning each live dog, cat, or nonhuman primate purchased or otherwise acquired, owned, held, or otherwise in their possession or under Institute control, transported, euthanized, sold, or otherwise disposed of by the Institute:

(a) A list of any offspring born of any animal while in the Institute's possession or under its control;

(b) The name and address of the person from whom the dog, cat, or nonhuman primate was purchased or otherwise acquired, whether or not the person is required to be licensed or registered under the Animal Welfare Act;

(c) The USDA license or registration number of the person if he/she is licensed or registered under the Animal Welfare Act;

(d) The vehicle license number and state, and the driver's license number and state of the person, if he/she is not licensed or registered under the Animal Welfare Act;

(e) The date of acquisition of each nonhuman primate;

(f) A description of each nonhuman primate, which shall include:

- Species and breed or type of animal;
- Gender;
- Date of birth or approximate age;
- Color and any distinctive markings;
- Any identification number or mark assigned to each nonhuman primate by the

Institute.

c. Prior to transferring ownership of any live non-human primate to another facility or individual, the Department of Veterinary Medicine will make and maintain records, which fully and correctly disclose the following information:

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(1) The name and address of the person to whom a live non-human primate is transported, sold, or otherwise disposed;

(2) The date of transportation, sale, euthanasia, or other disposition of the animal;

(3) The method of transportation including the name of the initial carrier or intermediate handler, or if a privately owned vehicle is used to transport the animal, the name of the owner of the privately owned vehicle.

(4) Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) permits.

d. All IACUC records and reports are maintained for at least three years.

e. Annual reports

(1) The Institute, through the IO, submits annual reports to the following:

(a) Fiscal year report on or around 15 December of the current calendar year. AAALAC will send a memorandum requesting the Annual report covering animal and facility use for the previous fiscal year.

(b) Updated assurances with OLAW on or before 15 January of the following calendar year;

(c) The online Department of Defense Data Call on or before 31 October for the fiscal year ending in the previous calendar year (e.g., for an October 31, 2012 data call, all data from Oct 2010-Sep 2011 are submitted);

(d) The USDA-APHIS Form 7023 Animal Census report to MRMC on or before 1 December of the current calendar year, covering animal use and Column E justifications (for USDA covered species only) for the previous fiscal year. Overseas labs are not required to submit this report directly to USDA, since animal use falls outside CONUS, but MRMC maintains the census for record-keeping and oversight purposes.

(2) The reports assure:

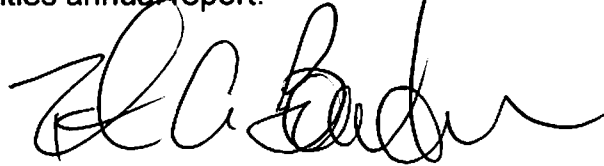
(a) That professionally acceptable standards governing the care, treatment and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by the institute;

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(b) That each PI has considered alternatives to painful procedures;

(c) That the facility is adhering to standards and regulations under the Animal Welfare Act and that it has required that exceptions to the standards and regulations be specified and explained by the PI and approved by the IACUC. A summary of all such exceptions must be attached to the facilities annual report.

A handwritten signature in black ink, appearing to read 'R. A. Bowden', written in a cursive style.

ROBERT A. BOWDEN
COL, MS
Commanding