DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND (PROV)
2050 WORTH ROAD
FORT SAM HOUSTON, TEXAS 78234-6000

5 FEB 1994

REPLY TO ATTENTION OF

HSMC-GCI (70)

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Policy on the Use of Animals for Medical Purposes in U.S. Army Medical Command Programs (Non-Army Medical Materiel Command [Non-AMMC])

1. Purpose: This memorandum provides guidance for the use of animals in the Army Medical Command (MEDCOM) programs (non-AMMC). The MEDCOM will continue to use animals for clinical investigations, research, medical training, diagnostic procedures and toxicity testing. The local Institutional Animal Care and Use Committee (IACUC) will continue to review animal use for compliance with existing laws, regulations, directives, and standards. The Army Medical Department Center and School (AMEDDC&S) Clinical Investigation Regulatory Office (CIRO) will provide oversight for all aspects of animal use and will monitor care and use programs for assurance of compliance with federal law and U.S. Army regulations. This guidance is provided to assist commanders in developing procedures consistent with federal law, Army regulations and MEDCOM policy on the humane care and use of animals in medical programs.

2. Technical assistance: The AMEDDC&S CIRO has a Veterinary Corps officer assigned who is board-certified by the American College of Laboratory Animal Medicine (ACLAM). Commanders and users of laboratory animals are encouraged to make use of this asset in determining appropriate mechanisms of suitable animal use for DOD military personnel and programs.

3. Operational impact: These guidelines may require further development of animal care and use policies and procedures at Army facilities. This document is in accordance with published laws and regulations. It is not the intent of this document to restrict valid and appropriate use of animal resources, nor to limit the ability of veterinary officers to use professional judgment in procuring or caring for those resources. It is the intent of this document to provide assurance, from procurement to final disposition, of: quality animal care, continuity with existing animal use programs, and appropriate concern for the welfare and well-being of animals utilized in MEDCOM programs. The AMEDDC&S CIRO shall serve as an assurance monitor and will provide guidance as required to accommodate federal law, Army regulation, and outside inquiry.

4. References: This guidance--and all Army animal facilities and programs utilizing animals for Army programs and/or by Army personnel for research, training, and testing purposes--will comply with provisions of the following laws, regulations and policies. In cases of conflict between this guidance and existing standards, the stricter standard will apply.

a. Public Laws 89-544, 91-579, 94-279, and 99-198. The Animal Welfare Act and amendments.

b. Code of Federal Regulations 9, subchapter A (Animal Welfare) Parts 1-4. (Implementing regulations for the public laws.

c. Army Regulation ~~(AR)~~ 70-18 (Tri-service). The Use of Animals in DOD Programs.

d. National Institutes of Health Publication 86-23. The Guide for the Care and Use of Laboratory Animals.

e. Consortium for developing a Guide for the Care and use of Agricultural Animals, March 1988. Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching.

f. American Association for Accreditation of Laboratory Animal Care. Program Description Portfolio.

g. American Association for Laboratory Animal Science, Animal Technician Certification Board. Policies and Procedures for the Animal Technician Certification Program. Revised 1988.

h. Academy of Surgical Research. Guidelines for Training in Surgical Research Using Animals. Revised 1990.

5. Accreditation: Accreditation of animal care and use programs and facilities by the American Association for Accreditation of Laboratory Animal Care (AAALAC), a nonmilitary peer review organization, provides to the public a sense of confidence in high quality animal care and use. Favorable public perception and assurances of quality animal care are vital to the continued advancement of biomedical investigation and animal-facilitated training efforts within the military medical community. The AAALAC is to the animal-facilitated research and training facility the equivalent of hospital accreditation by the Joint Commission on the Accreditation of Healthcare Organization (JCAHO). As directed by AR 70-18, commanders will seek accreditation by AAALAC for their animal use programs.

Commanders will support efforts required to maintain or bring facilities into compliance with AAALAC standards, using available local resources whenever possible. Additional resource requirements will be identified and reported to the AMEDDC&S CIRO, ATTN: HSMC-GCI. The CIRO will assist facilities in resolving needs for accreditation.

6. Protocol requirement:

a. The use of animals for any medical investigation or training purpose without a written approved protocol is prohibited by federal law. Clinical veterinary medical or veterinary diagnostic efforts are exempt from the requirement for an animal use protocol.

b. Principal investigators should submit proposals to the local IACUC.

c. Protocols should be developed according to Appendices A, B and C, and must be reviewed by the local IACUC and approved by the Institutional Official (IO) prior to implementation. Minutes of the IACUC meeting shall be prepared for approval or disapproval of the IO.

(1) The IO is defined by 9 Code of Federal Regulations (CFR) as "the individual at the research facility (MEDCEN, MEDDAC, installation, etc.) who is authorized to legally commit, on behalf of the facility, that the requirements of 9 CFR will be met."

(2) The CEO (Chief Executive Officer) position is not specifically defined, but does have specific responsibilities, according to 9 CFR. For this policy letter, the CEO is considered to be the commander of the facility.

(3) Program authority may be delegated to a subordinate (i.e., MEDCEN Commander [CEO] delegating program authority to the Department of Clinical Investigation Chief [IO]) as long as the requirements of 9 CFR are met.

(4) Protocols, except expedited reviews which have been approved by the duly appointed subcommittee of the IACUC, may not be initiated without approval of the IACUC minutes by the Institutional Official.

d. All protocols should receive a review for scientific merit and medical significance and a review for humane and appropriate animal use and care. At all times, a review for humane and appropriate animal use and care must be expressly performed by the IACUC. The IACUC Chairperson may designate an individual to review the protocol for science in lieu of a separate scientific committee review. The committee may also request such a review by an outside professional. A secondary review for science and medical significance may also be performed by the IACUC.

e. No animal shall be used in more than one major operative procedure from which it is allowed to recover except in cases of medical or scientific necessity. Any such procedure shall have been approved by the IACUC unless prior knowledge was not available. A major operative procedure is defined as any procedure invading a body cavity or which may result in physiologic or locomotor alteration extending beyond a normal post-operative recovery period. The expedited review process may be used in emergencies.

f. All changes to an original protocol (e.g., requests for additional animals or modifications to procedures or techniques) require review and approval of the IACUC.

g. Veterinary clinical procedures performed for medical or diagnostic purposes are exempt from protocol requirements.

h. All protocols should receive preliminary review by the attending veterinarian. Prior to IACUC review, the attending veterinarian should consult with (advise/assist) the principal investigator on the following issues:

(1) Alternatives to the use of animals have been considered.

(2) Analgesic and anesthetic choices and doses are appropriate for the species under consideration.

(3) Measures have been addressed to provide for husbandry and care.

(4) Stress, anxiety and distress have been minimized by environmental and/or pharmaceutical management.

(5) Pain category recommended to the IACUC. (The IACUC may accept or modify the proposed pain category, since the IACUC has the responsibility to assign a pain designation.)

i. The attending veterinarian shall have direct responsibility for all government-owned laboratory animals at his/her institution, with express authority to suspend all animal procedures involved in research, training or testing if:

(1) Deviations from the stated protocol design occur.

(2) Deficiencies are noted in the care, handling, or treatment of the animals.

(3) The welfare of the animals is compromised.

j. The animal care staff (military or civilian) shall have express authority to suspend all animal procedures so described in paragraph 6i above until consultation with the attending veterinarian has been accomplished.

k. Suspension (paragraph 6i or 6j) shall remain in effect until the matter is discussed by the IACUC and a resolution effected.

l. Under unusual circumstances, protocols and modifications to existing protocols may be approved by Expedited Review (ER). An ER subcommittee of the IACUC should be established for this purpose. The ER subcommittee shall consist of a minimum of 3 voting members; the IACUC Chairperson, the Attending Veterinarian, and the nonaffiliated community representative (federal employee) member. If, in the opinion of this subcommittee, delay of consideration of the protocol is not in the best interest of the animals under study or would result in negative human patient care, the study may be initiated. However, all protocols and changes or additions approved by the expedited review process will receive full committee review at the next IACUC meeting.

7. Selection of appropriate animal species: Guidance for the selection of the appropriate animal species for specific purpose use is available through the MEDCEN Department of Clinical Investigation (DCI) attending veterinarian or the Clinical Investigation Regulatory Office veterinarian. Additional guidance includes:

a. Selection of cats and dogs for research use: Although the use of cats and dogs in DOD programs is discouraged, their use is justified when no suitable alternative exists. Requests for the use of cats or dogs for investigation must be approved by the local Institutional Animal Care and Use Committee (IACUC); the Institutional Official; and the Commander, U.S. Army Medical Department Center and School, ATTN: HSMC-GCI (Clinical Investigation Regulatory Office), Fort Sam Houston, TX 78234-6125.

b. Selection of cats and dogs for training use: The use of cats or dogs for Advanced Trauma Life Support (ATLS) training is discouraged. Their use for Wound Ballistics Training (WBT) is strictly prohibited. Commanders are discouraged from using cats for intubation training. The use of cats or dogs for veterinary surgical competence training is acceptable.

c. Selection of nonhuman primates for research or training use: Protocols involving the use of nonhuman primates require review and approval at four levels before work can be initiated.

(1) The protocol must be recommended for approval by the IACUC to the IO.

(2) The protocol (as defined in the IACUC minutes) must be approved by the IO.

(3) The protocol must be approved by the Commander, U.S. AMEDDC&S, ATTN: HSMC-GCI (CIRO), 1608 Stanley Road, Fort Sam Houston, TX 78234-6125.

(4) Proposals involving the use of nonhuman primates will receive an additional centralized review by the Commander, U.S. Army Medical Research and Development Command, ATTN: SGRD-AR, Fort Detrick, MD 21701-5012, the DOD component office for Army.

8. Procurement of animals used in research or training:

a. The Animal Welfare Act defines an animal as any live or dead ... warm-blooded animal, which is being used ... for research, teaching, testing, experimentation, exhibition, or as a pet. Excluded from this definition are birds, rats and mice used in research and farm animals used, or intended for use, as food or fiber.

b. All animals used in research and training programs shall be procured from USDA Class A or Class B licensed dealers, if such dealers exist for that species. Class A dealers are defined in 9 CFR (U.S. Department of Agriculture Animal Welfare Regulations) as breeders whose business involving animals consists of sales of only those animals that are bred and reared on the premises in a closed or stable colony. Class B dealers are defined as those persons engaged in animal procurement and sales who may be breeders, but do not necessarily breed the animals they sell.

c. If Class A or Class B dealers are not available for the species required, exceptions to policy to purchase from a non-Class A or B source may be granted by the Commander, U.S. AMEDDC&S, ATTN: HSMC-GCI (CIRO), Fort Sam Houston, TX 78234-6125.

(1) Cats and dogs will only be purchased from USDA Class A or Class B dealers. Under no circumstances are cats and dogs to be procured from pounds, animal shelters, or pet stores.

(2) Nonhuman primates will only be procured from USDA Class A or Class B dealers, existing DOD facilities housing primates, or regional primate centers supported by National Institute of Health (NIH) funding.

d. Requests for exception will include, and are contingent upon, the following:

(1) The requirement to procure animals from Class A or Class B dealers may be waived if travel time of animals from distant vendors or cost of purchase or transport is of such significance that is not in the best interest of the animals under procurement, (temperature extremes, difficulty to house in transit, etc.) or if such distant procurement would impose a serious impact on clinically relevant data obtained from the study. The judgment of the attending veterinarian will be a major factor in the final determination of procurement source.

(2) Prior to purchasing animals from non-Class A or B dealers, a military veterinarian will perform an inspection of the dealer's business and provide a memorandum of assurance to the IACUC on the quality of that dealer's animal care program and animal facilities. The method for determining acceptability of a vendor shall incorporate the professional judgment of the attending veterinarian and the standards contained in the publications identified in paragraph 4 of this document.

e. Animal tissues or parts required for study or training (chicken breast or pigs' feet for suture training) may be purchased from the DeCA (Defense Commissary Agency) without an exception to policy.

f. Only after granting an exception to policy shall local slaughter house purchase for tissues be used.

9. The Institutional Animal Care and Use Committee (IACUC):

a. Each facility (installation) using animals shall constitute an IACUC. The IACUC is the responsible body for program oversight at the local level.

b. The IACUC shall consist of at least five (5) voting members. Membership of the IACUC shall include, as a minimum, one qualified veterinarian who is either board-certified by the American College of Laboratory Animal Medicine or trained and experienced in the use of laboratory animals; one senior physician, preferably with medical research or clinical investigation experience; one animal care staff member who is either a military 91T or a civilian technician or care provider; and one nonaffiliated community representative (federal employee) member, preferably civilian, and who is not in the supervisory chain of the DCI, animal users, animal care staff, or direct support personnel. Other members may be appointed as needed.

c. Committees should be comprised of an uneven number of members, with the chair acting as tiebreaker. The attending veterinarian shall not serve as chairman or IACUC recorder except in cases of true necessity. The recorder shall be a committee member but shall be non-voting.

d. Members shall be appointed by the commander annually in writing for the fiscal year 1 October through 30 September. One copy of appointing orders will be forwarded to this HQ, ATTN: HSMC-GCI (CIRO) prior to the initial IACUC meeting of the new fiscal year (not later than 1 December).

e. Except for the chair and the attending veterinarian, committee appointments shall be limited to 5 consecutive years. This mechanism should prevent committee member burn-out and foster fresh perspective from new committee members.

f. Members shall participate in IACUC training during the first quarter of each fiscal year, annually, for the duration of their appointment. Training may be local or imported, but as a minimum it shall address:

(1) IACUC authority.

(2) IACUC responsibility.

(3) Laws and regulations governing animal care and use.

(4) Local care and use program (SOPs, Lab Animal Handbook, command policies, accreditation status, facility capability).

(5) Animal rights versus animal welfare issues.

(6) Pain assessment in lab animals.

(7) Protocol review.

g. The IACUC will conduct regularly scheduled meetings to review all animal studies.

(1) Animal studies shall receive a review for scientific merit prior to consideration of the IACUC of the proposal. As defined in paragraph 6d, this responsibility may be performed by senior professionals in the same field as the investigators. The IACUC shall review the protocol specifically for animal husbandry, humaneness and ethical use, and may perform a supplementary review for science.

(2) Ongoing protocols will receive, as a minimum, an Annual Continuing Review (ACR). See Appendix D. Failure of ACR submission and IACUC acceptance within two months of the protocol anniversary shall result in immediate suspension of the study until ACR acceptance by the IACUC.

(3) All protocols shall be valid for a period of 3 years from the date of initial approval. Long-term protocols (including training protocols) which are expected to continue beyond 3 years' duration shall be resubmitted to the IACUC on the third year anniversary and will include an update of information (current literature review) and redefinition of protocol direction. Continuance beyond 3 years (without a new submission) may be granted by the IACUC if the study is within 6 months of completion.

h. The IACUC, and any of its subcommittees, will record proceedings of all meetings. Minutes will document protocol distribution, attendance at the meeting, action taken, vote on each action (total number for, against, abstaining and reason for abstaining), the basis for requiring changes in the proposed study, a brief narrative of the discussion held, and indicate that issues in subparagraph 8c(2) of AR 70-18 were addressed for each protocol or proposal, with inclusion of the views of the dissenting members, if any, how the dissent was resolved, and date of approval.

i. The IACUC will review and approve protocols, require modifications to protocols to secure approval, or withhold approval of proposed animal use studies. According to 9 CFR, Subpart A, Part 2 paragraph 2.31, "no official may approve an activity involving the care and use of animals if it has not been approved by the IACUC." Protocols are considered approved only after IACUC approval and approval of the IACUC minutes by the Institutional Official. The IACUCs disapproval of any protocol cannot be overridden (according to 9 CFR, paragraph 2.31).

j. The IACUC shall conduct semiannual (at least once every 6 months) assessment of:

(1) All animal facilities and the equipment used on animals.

(2) The animal care program, to include animal use policy, investigator handbooks, the protocol review process, use of and adherence to standing operating procedures, general management concerns, environmental concerns, general animal health care issues, general personnel concerns (training, occupational health program, protective clothing, etc.), veterinary care sufficiency, disease surveillance and prevention, facility engineering support, animal husbandry, behavioral enrichment, and animal welfare.

k. The IACUC chair may appoint a subcommittee of the minimum composition required by paragraph 9a for review of outlying or satellite facilities involved in the use of animals for which the IACUC has responsibility. The subcommittee's written report shall be voted on by the full committee and a copy of that report included in the IACUC minutes.

1. The IACUC chair may appoint a consultant (appropriately credentialed) to provide supplementary support to the committee for a specified duty (complex protocol review, satellite facility inspection, etc.). The consultant's written report shall be voted on by the full committee and a copy of that report included in the IACUC minutes.

10. Required documentation

a. All IACUCs shall submit one copy of the IACUC minutes within 30 days of approval by the IO to: Commander, AMEDD C&S, ATTN: HSMC-GCI (CIRO), Fort Sam Houston, TX 78234-6125.

b. One copy of each approved protocol, including all modifications shall be provided within 60 days of IACUC approval.

c. One copy of the USDA annual report (APHIS Form 7023 and 7023A, Aug 91) shall be forwarded by 1 December of each calendar year for the preceding fiscal year.

d. Additional program documentation (training, higher headquarters requirements, etc.) shall be defined as required. CIRO shall be used as a clearinghouse for reports and responses on program use of animals addressed under this memorandum.

11. Training requirements for persons using animals:

a. According to The Animal Welfare Act, it is the IACUC who is responsible for assuring training for scientists, animal technicians, and other personnel involved with the care and use of animals. The IO is responsible for providing training for scientists, animal technicians, and other personnel involved with the care and use of animals.

b. The mission of certain Army facilities (e.g. the MEDCEN DCI), the environment within which it functions, and the population to which it provides support, makes it difficult for some facilities to comply with the standard training methods (annual mega-workshops) for assuring that appropriately trained personnel are working with animals in research and training. The intent of the law requiring investigator training is that only trained personnel work with animals. While a variety of mechanisms are available to assure such competence of those working with animals, the system recommended as follows:

(1) The AMEDDC&S CIRO, Veterinary Programs Manager assures that veterinary officers assigned to the MEDCEN DCIs are adequately and appropriately trained to manage and care for animals used under MEDCEN IACUC authority.

(2) The attending veterinarian assures that animal care personnel are appropriately trained in the care of the species under their charge. Training will consist of regular training activities which will be recorded in the IACUC minutes.

(3) The attending veterinarian provides instruction to all investigators, as appropriate.

(4) The VSSA Commander assures that subordinate veterinarians, performing or supporting training exercises and/or supporting approved protocols, have been appropriately instructed on caring for and managing animals under their responsibility. Requirements extending beyond the care practices taught for domestic species in routine veterinary medical education, such as the care of rats, mice, etc., may be coordinated through the MEDCEN DCI attending veterinarian or the AMEDDC&S CIRO, Veterinary Programs Manager.

(5) The IACUC assures only trained investigators practice independent investigation. Facility support personnel so trained and under the direction of the attending veterinarian may be assigned to assist the investigator in providing care and performing manipulation duties for animals assigned to the study. It is prohibited to allow any untrained individual to care for or manipulate government-owned animals.

c. All personnel involved in animal care shall have training in:

(1) Appropriate husbandry practices for specific species being used.

(2) Appropriate research methodology and manipulation.

(3) Procedures for reporting suspected deficiencies in animal care and treatment.

(4) Point of contact for reporting suspected deficiencies in animal care and treatment.

(5) Ethical concerns for animal use.

(6) The IACUC and protocol approval process.

12. Points of contact: All commanders are encouraged to coordinate animal use activities closely with the regional MEDCEN DCI veterinarian or with the Veterinary Programs Manager, Clinical Investigation Regulatory Office, AMEDD Center and School, Fort Sam Houston, TX at DSN 471-9308 or Commercial 210-221-9308/5628. The mailing address is: Clinical Investigation Regulatory Office, ATTN: HSMC-GCI (MAJ Banks), 1608 Stanley Road, Fort Sam Houston, TX 78234-6125.

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