

**PROTECTION OF ANIMAL SUBJECTS IN RESEARCH
ESTABLISHING AN INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

1. **PURPOSE.** To outline the duties, responsibilities and membership of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) Institutional Animal Care and Use Committee (IACUC), as a Subcommittee of the Research and Development (R&D) Committee, according to VHA Handbook 1200.7

2. **POLICY.** The VA IACUC must perform the review and oversight functions required by PHS Policy, the Guide (Monitoring the Care and Use of Laboratory Animals), the Animal Welfare Act (7 U.S.C. §2143[b][1]), the USDA AWAR (9 C.F.R. §2.31), VA policy, and any other Federal regulations that impact IACUC function. These functions include: 1) reviewing and approving, requiring modifications to secure approval, or withholding approval of all research proposals involving species and activities included within the definition of an "animal"; 2) reviewing the conduct of all animal protocols annually; and 3) performing a self-assessment review of the program of animal care and research use, and inspecting the animal facilities and husbandry practices at least every six months.

This policy applies to all research involving animals that is conducted completely or partially in VA facilities, or conducted in approved off-site locations and facilities by VA researchers while on VA official duty time. The research may be VA-funded, funded from extra-VA sources, or conducted without external funding.

3. **DEFINITIONS.**

a. **Research.** The testing of concepts by the scientific method of hypothesis formulation, systematic and recorded collection of relevant data, and interpretation of the results in terms of the hypothesis or, more simply, a systematic investigation designed to develop or contribute to generalizable knowledge. Research and development in the VA includes the investigation and refinement of biomedical problems and hypotheses related to health and diseases.

b. **Animal.** Any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose. An animal for purposes of compliance with the Animal Welfare Act Regulations is any live or dead cat, dog, non-human primate, guinea pig, hamster, rabbit, or any other warm-blooded animal which is being used, or is intended for use in research, teaching, testing, or experimentation.

c. **Animal Research.** Any use of laboratory animals in research, testing, or training.

d. **Testing:** A means of determining the presence, quality, or truth of something.

e. **Training:** To make proficient with specialized instruction or practice.

4. RESPONSIBILITY:

a. The medical center Director is responsible for the R&D program, advised and assisted by the R&D Committee. He/she is the Institutional Official and the legally authorized signatory official for all Institutional Assurances with the VA, the Office of Laboratory Animal Welfare (OLAW), and the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). He/she is responsible for assuring that adequate resources, including funds, space, and personnel, are available for research and its administrative functions, including those of the IACUC. The medical center Director appoints in writing the chairperson and members of the IACUC.

b. The R&D Committee is responsible, through the Chief of Staff to the medical center Director, for maintaining the importance and quality of research design throughout the R&D Program, including the program for protection of animal subjects in research. The R&D Committee, the medical center Director, or the Office of Research and Development (ORD) may disapprove an IACUC-approved research activity. However, if a research activity is disapproved by the IACUC, the R&D Committee, or any higher authority cannot overrule the decision.

c. The Associate Chief of Staff for Research (ACOS/R) is responsible for the management of the R&D program, including the operations of the IACUC. With the Chief of Staff and medical center Director, he/she supervises the Veterinary Medical Consultant. The ACOS/R is responsible for submission of documentation necessary to obtain and/or maintain a properly executed institutional assurance in accordance with OLAW and AAALAC procedures and VA regulations.

d. The Administrative Officer (AO/R) provides staff support to the IACUC.

e. The Research Administrative Office is responsible for maintaining a database of all research personnel and assists the IACUC administrator in maintaining accurate records of personnel training and research projects.

f. The Veterinary Medical Consultant provides professional guidance and technical support to investigators in planning, executing, and directing R&D activities using animals; serves as a member of the IACUC; performs mandatory veterinary consultations with investigators prior to the submission of their animal protocol to the IACUC; participates in mandated semi-annual IACUC inspections of animal facilities and the animal care and research use program.

g. The Supervisor of the Animal Research Facility (ARF) acts as the IACUC Coordinator, and as such, assures that meetings are held as scheduled, minutes are recorded accurately and promptly, correspondence relating to committee actions is processed, required records and reports are maintained, actions mandated by the committees are executed, and that each committee member is fulfilling his/her responsibilities as a member of the IACUC. He/she is responsible for maintaining accurate, up-to-date records regarding mandatory training and certification in the protection of animal subjects in research for IACUC members, investigators, and

research staff.

As supervisor of the ARF the incumbent is responsible for the day-to-day management of the facility, including supervision of animal caretakers. The duties encompass administrative functions, personnel management, research training, animal husbandry, record keeping, equipment installation and maintenance, facility construction and maintenance, animal procurement (including importation/exportation of animals), and supply inventory.

5. PROCEDURES:

a. Membership

(1) IACUC members, in consultation with the R&D Committee, forward the name(s) of nominees for the IACUC to the medical center Director who officially appoints members in writing and includes the length of their appointments, usually three years. All members will be appointees of the LSCDVAMC, with or without compensation.

(2) The composition of the IACUC must meet existing requirements set forth in the Animal Welfare Act (7 U.S.C. §2143[b][1]) and PHS Policy (subpar. IV.3b). To establish an IACUC, a minimum of five voting members are required. They include a Chairperson, the Attending Veterinarian, one scientist with animal research experience, a non-affiliated member, and a lay member (who must not be involved in animal research).

Permanent voting members of the IACUC include the Consulting Veterinarian and the Supervisor of the ARF who are *ex-officio* with a vote. The ACOS/R, AO/R, the Research Compliance Officer and the Research Safety / Chemical Hygiene Officer are permanent members who are *ex-officio*, without a vote.

(3) One of the members, who is a more senior scientist with animal research experience, will serve as Chairperson of the IACUC. At least one of the members must not otherwise be affiliated with the VA medical center or be a part of the immediate family of a person who is affiliated with the medical center. The IACUC will include at least one member whose primary expertise is in nonscientific areas. Other members will include persons who will enable the IACUC to consider the veterinary, scientific, legal, and ethical issues relevant to the involvement of animal subjects in research. At least one member of the IACUC will be a member of the R&D Committee, and a member of the IACUC will be a member of the Subcommittee on Research Safety

(4) Length of Appointments

The IACUC Chairperson must be appointed by the medical center Director annually. There is no limit to how many times a chairperson may be reappointed; a lapse in service is not necessary.

Members, other than those who are designated *ex-officio*, may serve terms of up to three years, on staggered appointments and may be re-appointed without lapse in service to the IACUC.

Ex officio members may not serve as Chairperson. The Chairperson may not simultaneously chair the R&D Committee or any other Subcommittee of the R&D Committee.

b. Meetings

(1) The IACUC will meet on the 4th Thursday of each month (except December) or more often at the Chairperson's discretion. The Chairperson may cancel a meeting if the items for discussion do not warrant a convened meeting and can be held until the following month.

(2) A quorum will be established by the attendance of a majority of the voting members.

(3) Individual members may participate by video or teleconferencing. Approvals will require a majority of the voting members in attendance (or attending by video or teleconferencing). Proxy or in-absentia votes will not be permitted.

c. Review and Authority

(1) All testing, research or training procedures involving the use of vertebrate animals must be reviewed by the IACUC. The IACUC has authority to approve, require modifications in, or disapprove all ACORPs or revisions to approved ACORPs. The IACUC conducts a continuing review of approved research protocols at intervals appropriate to the degree of risk, but not less than once per year from the approval date of the ACORP.

(2) All research protocols involving animals must be approved by the IACUC. The R&D Committee will perform a pre-submission review of the protocol for scientific merit, resource allocation, feasibility and, if acceptable, will forward it to the IACUC. Once the IACUC has approved the protocol, it must receive final approval from the R&D Committee before it is initiated.

(3) The IACUC has the authority to observe, or have a third party observe, research procedures on animals.

(4) The IACUC Chairperson or his/her designee may review a minor revision to the ACORP under an expedited process. Expedited reviews are included in the minutes for the next convened meeting and acknowledged by all Committee Members.

(5) Requests for major revisions are sent to all members who have the options of calling for full committee review or accepting designated review by two voting members. The results of designated reviews are included in the minutes for the next convened meeting and acknowledged by all Committee Members.

(6) The IACUC Coordinator prepares the communications for the Chairperson's signature.

(7) The IACUC will consider and recommend action in any instance in which there is an incident of non-compliance with appropriate standards of animal care and use. This incident will be reviewed according to the Medical Center Policy 151-016 "Noncompliance in Research." If applicable, the Office of Research Oversight (ORO)

will be notified, and the violator may be subject to notification and sanctioning by the VA, OLAW and/or AAALAC.

(8) No recommendation by the IACUC, either in its evaluation of research proposals or in its investigation of purported violations or failure to comply with Federal policies, can be modified or reversed other than by action of the IACUC itself.

e. **Minutes:** Once minutes are approved by the IACUC at a subsequent meeting, they may not be altered. Minutes will be submitted to the R&D Committee for review, and they will be forward to VA Headquarters upon request.

6. **REFERENCES:** VHA Handbook 1200.7; Medical Center Policy 151-001, "Research and Development Committee"; Animal Welfare Standards – Federal Register, 9 CFR Part 3, dated February 15, 1991; Guide for the Care and Use of Laboratory Animals, 1996; IACUC SOP Manual; Medical Center Policy 151-016 "Noncompliance in Research."

7. **RESCISSION:** Medical Center Policy 151-003 dated September 1, 2004 has been rescinded. The review date of this policy is September 1, 2010.

8. **FOLLOW UP RESPONSIBILITIES:** Associate Chief of Staff for Research.

WILLIAM D. MONTAGUE
Medical Center Director