

**November 16, 2012**

**ANIMAL CARE AND USE PROGRAM**

Institutional Animal Care and Use Committee

1. **PURPOSE:** To provide policy and procedures for the operation of the Institutional Animal Care and Use Committee (IACUC).

2. **POLICY:**

a. The Veterans Health Administration Office of Research and Development (ORD) is responsible for establishing policy for laboratory animal use in the VA System. Local medical centers are responsible for ensuring proper oversight and care for research animals housed at VA or purchased with VA funds.

(1) The Director is the institutional official responsible for ensuring that the animal research program complies with federal regulations and guidelines that govern animal research and is the point of contact for correspondence with United States Department of Agriculture (USDA), Public Health Service (PHS), Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), and Office of Laboratory Welfare (OLAW).

(2) The medical center will maintain an IACUC, which is responsible for the oversight and evaluation of the institution's Animal Care and Use Program. The IACUC will function in accordance with guidelines provided by the ORD and assure compliance with other regulatory guidelines affecting animal research, e.g., PHS policy, Guide for the Care and Use of Laboratory Animals, USDA Animal Welfare Act requirements.

b. The Institutional Animal Care and Use Committee (IACUC), functions as a subcommittee of the Research and Development (R&D) Committee for the South Texas Veterans Health Care System. The IACUC reports to the hospital Director (Institutional Official) through the R&D Committee.

c. The institution, through the Research and Development office, will provide sufficient administrative and secretarial resources for the IACUC to conduct its prescribed duties.

d. The use of animals in VA research is a privilege granted with the understanding and expectation that such research will be conducted according to the highest ethical and legal standards. The basic principles governing animal research in the VA, to guide the IACUC, are as follows:

(1) The fewest number of animals needed to achieve scientific objectives should be used.

(2) The least sentient species that will permit the attainment of research objectives should be used.

(3) The least painful or distressful procedures needed to meet research objectives should be used.

(4) All reasonable measures to minimize pain and distress to animals should be utilized.

(5) The principles of replacement, reduction, and refinement should always be considered when planning and conducting studies.

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(6) Procedures that would be considered painful in a human should be considered painful in an animal.

### 3. ACTION:

a. **MEMBERSHIP:** The STVHCS Director shall appoint members of the IACUC in writing for renewable terms. Members may be appointed upon recommendation from the IACUC and the R&D Committee. The committee shall consist of not less than five voting members and shall include as a minimum one Chairperson (or alternate in if in absentee), Veterinary Medical Consultant (Ex-Officio) with laboratory animal experience, one practicing scientist experienced in research involving animals, one non-scientific member, one individual not affiliated member in compliance with VHA Handbook 1200.07.

(1) The Associate Chief of Staff (ACOS) for Research and Development, Administrative Officer, and VMU Supervisor appointments are termed local Ex-Officio members.

(2) Members shall serve three-year terms, renewable upon re-appointment by the Director. The ACOS for Research and Development, Administrative Officer and the Veterinary Medical Unit (VMU) Supervisor appointments are without voting privilege and serve in an advisory capacity only. IACUC chairs shall serve one-year renewable appointments. Chairs may not simultaneously chair another subcommittee and should be a more senior scientist with animal research experience.

b. **MEETINGS:** Meetings will be held at least monthly. Members unable to attend should promptly notify and send their protocol review comments to the IACUC Administrator.

(1) **Quorum:** A quorum (greater than 50% of voting members) will be required to conduct business. A member having a scientific, monetary, or personal conflict of interest for a protocol may not participate in the discussion, with the exception to provide answer(s) to committee's questions. The chairperson will excuse the member with the conflict of interest when all questions are answered satisfactorily for the protocol deliberation period.

(2) **Minutes:** Minutes will be maintained in accordance with VHA Handbook 1200.07, documenting actions taken, members present and recusal, and voting record. Minutes will be written and published within 3 weeks of the meeting date. Committee approval of previous month's minutes will be accomplished as the first order of business at the next scheduled meeting. A copy of minutes will be forwarded to the Institutional Official through the R&D Committee for review after the chair's signature.

c. **RECORDS MAINTENANCE:** Minutes of the IACUC meetings (including records of attendance, IACUC activities and deliberations), Semi-Annual Reports, PHS, USDA, AAALAC, and other reports and correspondence related to the animal care and use program will be maintained indefinitely.

### d. FUNCTIONS:

#### (1) **Oversight and evaluation of the institution's Animal Care and Use Program:**

(a) The IACUC is proactive in its evaluation and quality improvement activities related to the institution's Animal Care and Use Program.

(b) Veterinary Medical Unit (VMU) standard operating procedures will be annually reviewed by the Veterinary Medical Consultant and VMU Supervisor and approved by the IACUC.

#### (2) **Research Proposal Review.** The IACUC must review and approve, require

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modifications to, or withhold approval of all research proposals when the animal research is supported by VA funds, conducted on VA premises, or conducted on VA investigator time. Research protocols may be approved through reciprocity with the affiliate IACUC in accordance with the applicable MOU.

The IACUC must assure protocol meets all animal regulatory guidelines. Animal research involves any live vertebrate animal used or intended for use in research, research training, experimentation, biological testing, or a related purpose as defined in VHA Handbook 1200.07.

(a) Investigators must consult with the VMC prior to submission of a protocol to the IACUC.

(b) All proposals will be full committee. Review materials include proposal abstract, grant research aims, ACORP and appendices. Each proposal is assigned to two voting members, termed primary and secondary reviewers, who are expected to lead the proposal discussion.

(c) The VA Animal Component of Research Protocol (ACORP) must be used for review of applications being submitted to the VA for funding. The grant proposal research aims, abstract, and protocol forms are provided to all IACUC members. If UTHSCSA IACUC is the initial approval of a non-VA funded study, this study is reviewed by the IACUC for reciprocity approval. In this case, the UTHSCSA IACUC approval letter, protocol, abstract, and grant proposal research aims are provided to the committee.

1. The affiliate and the VA IACUC agreed to use the application forms for the use of animals in research used by the IACUC at the grant recipient site to reduce unnecessary duplication of effort by investigators.

2. Investigators and faculty members must use the standard VA protocol form when applications for Department of Veterans Affairs funding are submitted to VA Central Office, whether the study is being conducted at the STVHCS site or being conducted under an approved partial off-site waiver at the affiliate.

3. If a protocol has been approved by the University of Texas Health Science Center at San Antonio (UTHSCSA) IACUC, the VA IACUC may accept the final approved version of the UTHSCSA animal form for review. NOTE: VA IACUC may impose more stringent criteria for approval.

(d) The IACUC will consider the following in the review of an animal protocol:

1. Scientific validity and experimental design.

2. Relevance to the VA and appropriateness for the local institution (e.g. appropriate expertise and availability of the necessary resources).

3. Rationale and purpose of the proposed use of animals.

4. Justification of the species and number of animals requested, including statistical justification if necessary.

5. Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.

6. Adequacy of training and experience of personnel in the procedures used.

7. Unusual housing and husbandry requirements, including food or fluid restriction.

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8. Appropriate sedation, analgesia, and anesthesia.
  
9. Unnecessary duplication of experiments.
  
10. Use of prolonged physical restraint.
  
11. Conduct of multiple major operative procedures.
  
12. Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
  
13. Post-procedure care.
  
14. Method of euthanasia or disposition of animal.
  
15. Safety of the working environment for personnel.

(e) The R&D Administrative staff will ensure all staff listed on the protocol have met CITI training prerequisites, certified participation in the UTHSCSA or VA Occupational Health Program on file, have an appropriate VA affiliation, and have a scope of animal work and financial conflict of interest on file..

(f) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol initial and continuing reviews are as follows:

1. If the full committee recommends withholding approval due to extensive revisions, the administrator prepares the IACUC feedback and electronically sends it to the investigator. Upon receipt of the revision, the administrator compares the recommended changes against the initial IACUC feedback. If all recommendations were accepted or clarifications provided, the revised proposal is reproduced and added to the following month's IACUC agenda for full committee review. Should the committee approve the revision, the administrator prepares an approval letter notification for the chair's signature. Once the chair signs the letter and the protocol, and other required signatures are secured, the revised proposal and approval letter is electronically sent to the principal investigator, in pdf format, for them to print a copy for their paper files.

2. There have been occasions that the revisions' responses required further review by designated member review (DMR) before approval. If an IACUC quorum of voting members agrees to use the DMR approval process after the full committee review, the IACUC administrator forwards an electronic pdf copy of the revision and all other documents to the designated reviewers. Designated reviewers are responsible for reviewing and/or approving the changes. Upon receipt of DMR approval, the administrator will prepare an approval letter for the chair's signature. The entire proposal is then given to the chair for review and signature. Once the chair signs the letter and the protocol, and other required signatures are secured, the revised proposal and approval letter is electronically sent to the principal investigator, in pdf format, for them to print a copy for their paper files.

3. If a quorum of the full committee recommends approval after minor administrative changes, the administrator prepares the IACUC feedback and electronically sends it to the principal investigator.

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Upon receipt of revision, the administrator compares the changes against the feedback notification. If the changes are acceptable, the administrator prepares the approval letter, affixes the revision and forwards

the approved proposal to the Chair for signature. Once the chair signs the letter and the protocol, and other required signatures are secured, the revised proposal and approval letter is electronically sent to the principal investigator, in pdf format, for them to print a copy for their paper files.

(g) No animal work may begin before receipt of IACUC and R&D Committee approvals. The IACUC Administrator will coordinate with the Personnel Coordinator to ensure all personnel have been granted clearance to conduct research activities. Study personnel delinquent on their training or appropriate VA affiliation documentation for IACUC-approved research will be notified that they cannot participate in project related activities until requirements are completed. The IACUC will not approve a project when the principal investigator is training deficient.

1. Annual Review of Proposals. The IACUC must review the conduct of all animal protocols annually. The funding period of a project has no bearing on the need for annual reviews and triennial reviews. Protocols originally approved based on reciprocity with the affiliate must provide the latest UTHSCSA continuing review approval to confirm active UTHSCSA status

a. Annually, prior to first and second continuing review approval, the IACUC will review and approve a continuing review request form. The IACUC Administrator will send a pre-filled continuing review form for VA studies to the principal investigator for completion within 45 days of the protocol expiration, with a suspense date. The form must be completed to include at a minimum the IACUC approval number, IACUC approval date, title of project, species used, whether animal use is ongoing or to be terminated, number of animals used to date, personnel actively participating in the animal research, progress during the previous year, and any proposed changes to the protocol. If a response from the PI is still pending 1 week prior to the expiration date, the IACUC administrator will send a follow up notification to the PI, copied to the ACOS/R explaining a possible protocol expiration if response is not received. If no response is received by the due date, the protocol will be considered "Expired". The IACUC administrator will notify the VMU staff that the IACUC approval to use animals has expired. Both offices will coordinate actions if there are active animals on the protocol.

b. The IACUC administrator will ensure the PI is notified of the expiration and will work with the PI to resolve the issue as soon as possible. The Attending Veterinarian and IACUC Chair will be notified of any expired protocols..

c. The expired protocol notification will state that all work on this protocol must cease and that no more animals can be ordered.

d. To ensure appropriate care for any animals, the PI must coordinate continued care and treatment of any animals remaining on this protocol with the veterinary staff.

e. Payment of all per diem charges will remain the responsibility of the PI.

2. The issue will be presented at the next regularly scheduled IACUC meeting where a motion will be entertained for "inactivation". The PI may present information, written or in person, at the IACUC meeting to provide information relative to the decision for inactivation. If a committee decision is made for inactivation, the IACUC Chair will notify, through the Medical Center Director, the NIH, USDA and relevant funding agencies (as appropriate).

3. Reactivation of an inactivated protocol requires IACUC action based on completion of a progress report form and a letter from the PI requesting that the protocol be reactivated. A progress report

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form will not be accepted any later than 6 months after expiration; a complete new protocol application will be required.

4. Modification requests with an amended ACORP or approved amended UTHSCSA animal research protocol must be submitted with the form for IACUC review and approval of any change.

(h) **Third Year Annual Review.** Prior to the third year anniversary of VA-funded or non-funded protocols, the IACUC must conduct a complete re-review of each approved protocol. The IACUC Administrator will send the principal investigator a blank ACORP and a prefilled Third Year Review form for completion within 45 days of the protocol expiration. The investigator will submit a new protocol utilizing the latest version of the protocol form, provided by the IACUC Administrator, to incorporate modifications, adding or removing personnel, secure a new veterinary consult, and update database searches at a minimum. Failure of the PI to submit the third year annual review will result in expiration of the protocol as described above for annual reviews. UTHSCSA employs an annual review process that satisfies their De Novo requirement. The VA IACUC reviews and approves reciprocity annual reviews. In this case, the appropriate investigator will submit the UTHSCSA IACUC approval letter and the request for continuing review. The investigator will include in the packet on bond paper or email reply if there are any changes in data security procedures, scope of practice or financial conflict of interest for research personnel.

(3) **Semiannual Program Review and Semiannual Facility Inspection.** The IACUC must conduct a self-assessment review of the program for animal care and use and must inspect all animal facilities and investigator areas used for animal procedures or housing longer than 12 hours every six months.

(a) At least two voting members and one non-voting member (includes the veterinarian) must conduct the review and inspection.

(b) The VA assessment form designated by the VA Central Office Chief Veterinary Officer will be used to document and report the IACUC's program review and inspection. The report will identify any significant deficiencies (a threat to the health or safety of the animals) and will distinguish these from minor deficiencies. If facility or program deficiencies are identified, the report will contain a specific plan of action with a timeline to correct the deficiencies. Any departures from the Guide for the Care and Use of Laboratory Animals or PHS policy will be described, and the reasons for the departure provided.

(c) The VA IACUC will review and evaluate the UTHSCSA IACUC semi-annual self-assessment in lieu of its own review for any VA-approved research conducted at the affiliate. The UTHSCSA IACUC semi-annual self-assessment will be approved by the convened VA IACUC.

(d) As part of the program review, the IACUC will randomly review IACUC records representing at least 5% of VA approved active projects (or a minimum of five).

(e) The report of the Semi-annual Program Review will be evaluated and approved by the convened IACUC.

(f) The report approved by the IACUC, with inclusion of any minority opinions and views, will be reviewed during a meeting that includes the IACUC chair, Veterinary Medical Consultant, one or more research administrators, and the hospital Director (Institutional Official) and the Director will sign to indicate his/her review. The IACUC Semi-annual Report may not be altered by any local official after a majority of voting IACUC members have approved the report.

(g) The report is submitted through the Hospital Director/Institutional Official to the Chief Veterinary Medical Officer within 60 days of review.

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(4) **Suspension of Projects:** The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the Principal Investigator and approved by the IACUC, or if there are concerns regarding the safety or welfare of laboratory animals or the safety, rights, or welfare of research staff or others. The IACUC may suspend an activity only after review of the matter at a properly-convened IACUC meeting and with the suspension vote by a majority of the quorum. The IACUC will notify the ACOS for R&D, Institutional Official, Office of Research Oversight, VA Chief Veterinary Medical Officer, USDA (if regulated species), PHS, and AAALAC within 15 business days of suspensions of protocols.

(5) **Allegations of Improper Animal Care or Use:** All allegations of improper animal care and use must be reviewed promptly by the IACUC, and investigated if warranted. A written report of the review or investigation needs to be approved by a majority of a convened IACUC quorum and sent to the Director through the ACOS for R&D. If preliminary findings suggest that an allegation represents a reportable deficiency, i.e., any serious or continuing non-compliance with PHS policy, suspensions of protocols, or failure to correct a significant deficiency, the appropriate agencies will be contacted. The IACUC follows the institution's procedures to ensure prevention of reprisals against whistle blowers who report potential deficiencies in the animal care and research use program, and to protect anonymity to the extent required by law.

(6) **Reporting:** Any unanticipated incidents, loss of animal life, work-related serious injury to personnel involved in animal research, suspensions or terminations, or serious or continuing noncompliance with VA or other Federal requirements related to animal research (e.g., VHA Handbook 1200.07, the Animal Welfare Act at 9 CFR 1, 2, and 3; the PHS Policy on Humane Care and Use of Laboratory Animals; the Guide for the Care and Use of Laboratory Animals) will be reported to the ACOS for R&D and Institutional Official, and the appropriate oversight agencies such as the Office of Research Oversight, VA Chief Veterinary Medical Officer, USDA (if regulated species), PHS, and AAALAC within 15 business days as detailed in VHA Handbook 1200.7 and VHA Handbook 1058.01.

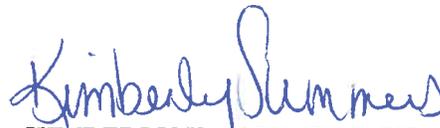
(7) **Use of Equipment designated for Humans:** Requests for use of human diagnostic or treatment resources for animal use will be reviewed and approved by the IACUC per VHA Handbook 1200.7.

4. **REFERENCES:** VHA Handbook 1200.7  
VHA Handbook 1058.01  
Animal Welfare Act at 9 CFR 1, 2, and 3  
PHS Policy on Humane Care and Use of Laboratory Animals  
Guide for the Care and Use of Laboratory Animals Eighth Edition

5. **RESPONSIBILITY:** ACOS for R&D

6. **REVISIONS:** Research Service Policy Memorandum 11-11, dated October 3, 2011

7. **RECERTIFICATION:** November 2017



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