



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Review of VA Use of Animals in Research Activities

To Report Suspected Wrongdoing in VA Programs and Operations

**Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time,
Monday through Friday, excluding Federal holidays**

E-Mail: yaoighotline@va.gov

Executive Summary

The Veterans Health Administration (VHA) actively supports the use of animals in research, teaching and testing. The VHA animal research program provides hope for veterans suffering from diseases that currently lack cures or effective treatments. In 2007, there were 824 active animal research projects at 71 VA facilities nationwide.

VHA adheres to the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals policy. These guidelines require facilities conducting PHS-sponsored research to provide a written assurance of compliance with this policy to the PHS. The Office of Laboratory Animal Welfare at the National Institutes of Health monitors compliance with PHS Policy to ensure the humane care and use of animals. The VHA developed its own policies and procedures – VHA Handbook 1200.7, *Use of Animals in Research*, issued May 27, 2005 – to ensure compliance with both PHS policy and the Animal Welfare Act of 1985.

The Office of Inspector General conducted a national review of VHA animal research to assess compliance with certain Handbook requirements, focusing on Institutional Animal Care and Use Committee (IACUC) minutes, semi-annual self assessments of the animal research program (SARS), and veterinary qualifications.

Our review disclosed overall good compliance with the documentation requirements for IACUC minutes, yet we found a wide variety in how the minutes were documented. The highest area of non-compliance was in the facilities' performance of the SARs. We found significantly lower compliance when the animal research program had an affiliate IACUC as the IACUC of record. We found most of the Animal Research Facilities (ARFs) to be clean, in good repair and adequately secured. We did not identify any instances of animal abuse or neglect. Sites we visited identified a lack of funding and the way funding is allocated as their greatest difficulties in maintaining active, robust animal research programs.

We recommended that VHA animal research programs require university affiliates' compliance with the requirements of the Handbook and that all VA animal research programs have an active occupational health program. We also recommended improvements in security at one facility and full implementation of Handbook requirements at another facility. Finally, we recommended that minimum qualification standards for Veterinary Medical Officers and Veterinary Medical Consultants. The Under Secretary for Health agreed with the findings and recommendations and provided acceptable improvement plans. We will follow-up on the planned actions until they are completed.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health (10)

SUBJECT: Review of VA Use of Animals in Research Activities

Introduction

Animal research contributes immeasurably to advancements in medical science. As recognized by principle number 3 of the Nuremberg Code of 1947, it is often a moral imperative to perform research or testing on animals before subjecting humans to new procedures, pharmacologics, or devices. Most research and testing involving human patients continues to be based on the results of animal experimentation. To provide hope for veterans suffering from diseases that currently lack cures or effective treatments, VA actively supports the use of animals in research, teaching, and testing. However, the use of animals in VA research is a privilege granted with the understanding and expectation that such research be conducted according to the highest ethical and legal standards.¹ In 2007, there were 824 active animal research projects at 71 VA facilities nationwide. The total fiscal year (FY) 2007 animal research budget was \$118 million, which included funding to support the animal research facilities.²

While societal concerns regarding the humane treatment of animals prompted many of the advances in animal care and use programs, “animal welfare is also of importance because of the link between healthy, well-cared for animals and sound science.”³ All VA-funded animal research must comply with Federal and VA regulations. Compliance with all VA and Federal regulations requires a significant investment of resources. Professional staff must perform necessary, labor-intensive activities associated with animal research, including educating and training clinician investigators and research staff, ensuring compliance with applicable regulations, maintaining the animal facilities, and participating in or operating the Institutional Animal Care and Use Committee (IACUC). IACUCs are committees constituted at the level of the medical center or

¹ Veterans Health Administration Handbook 1200.7, *Use of Animals in Research*, May 27, 2005.

² Research and Development Information Systems Part II report for VA-funded projects plus animal facility support dollars.

³ Gilles Demers, et al., “Harmonization of Animal Care and Use Guidance,” *Science*, Vol. 312, May 5, 2006.

institution conducting animal research that provide the oversight and assurance that the institution will comply with regulations.

Background

Legislative efforts to protect animals used in research activities essentially began with the Laboratory Animal Welfare Act of 1966. Enforced by the U.S. Department of Agriculture (USDA), this law describes the minimal standards for the care and use of animals in research activities. In accordance with this act, the Secretary of Agriculture announced regulations permitting USDA inspectors to conduct unannounced inspections and to require maintenance of certain records. The act was amended and renamed the Animal Welfare Act in 1970 and was subsequently amended in 1976 and 1985 to clarify the types of animals regulated and to provide additional standards for their care and use in research activities. The 1985 amendment resulted in regulations that required institutions conducting animal research to form IACUCs to oversee animal research activities.

The Department of Health and Human Services formulated an important policy in 1971, which further defined and clarified the appropriate use of animals in research activities. Entitled the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS policy), this policy became the basis for National Institutes of Health guidelines required under the Health Research Extension Act of 1985. These guidelines required facilities conducting PHS-sponsored research to provide a written assurance of compliance (hereafter termed PHS Assurance) with this policy to the PHS. The Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) monitors compliance with PHS Policy to ensure the humane care and use of animals in PHS-supported research.⁴

The Veterans Health Administration (VHA) developed its own policies and procedures to ensure compliance with both PHS policy and the Animal Welfare Act. VHA Handbook 1200.7, *Use of Animals in Research*, issued May 27, 2005, describes VHA policy. It specifically requires compliance with both the Animal Welfare Act and PHS policy, regardless of whether or not the facility receives funding from PHS. A facility may execute its own PHS Assurance or be covered under an affiliated university's PHS Assurance, provided that the assurance specifies that the VA program is covered under that assurance. The term "animal" is defined in VHA policy as "any live vertebrate animal used or intended for use in research, research training, experimentation, or biological testing, or for a related purpose."

VHA policy also requires VA facilities conducting animal research to be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), although they may also be accredited as a component of their

⁴ OLAW Mission Statement.

affiliate's program. The facility director is the institutional official responsible for correspondence with the AAALAC and the PHS, unless the institution is covered by the affiliate's AAALAC accreditation or PHS Assurance.

While VHA Handbook 1200.7 covers many aspects of the appropriate care and use of laboratory animals, this review focuses on four major areas:

1. IACUC operations.
2. Semi-annual self-assessments of the animal research program.
3. Certification and availability of veterinarians used in animal research activities.
4. Certain aspects of animal macro-environments and occupational health and safety issues which surfaced during onsite inspections.

We discuss the regulatory background of each of these areas below.

General IACUC Operations

IACUCs are the institutional committees that review and approve all research protocols using animals. VA facilities must either maintain their own IACUC or use the affiliate's IACUC. If the affiliate's IACUC is used, the affiliate must agree to provide documents pertaining to IACUC review and AAALAC correspondence or USDA correspondence to the VA if requested. The VA's Veterinary Medical Officer (VMO) or Veterinary Medical Consultant (VMC) must sit on the affiliate's IACUC, and the facility director must officially appoint all members of the affiliate's IACUC.

IACUCs are required to approve all protocols involving animals and to review these projects at least annually. Facility Research and Development (R&D) Committees must also approve all animal research protocols. IACUCs also ensure that animal research staff receive necessary education and training to perform their duties. They prepare written minutes of their meetings and publish these within 3 weeks of the meeting date. These minutes must record the presence or absence of all voting members of the IACUC; whether a quorum is present; and deliberations relative to specific protocols, with identification of the protocol by title and principal investigator. Minutes must be signed by the IACUC Chairperson following approval at the next convened meeting.

IACUCs must also report serious and continuing noncompliance with PHS policy. Further, Animal Welfare Act regulations state that failure to correct any significant deficiency within 15 business days of an IACUC-imposed deadline must be reported to the USDA and any other Federal agency funding the research. IACUCs also have the authority to suspend research projects and to investigate allegations of noncompliance.

Semi-Annual Program and Facility Self-Assessment Reviews

A key responsibility of the IACUC is to perform a self-assessment review (SAR) of the animal care and use program every 6 months. This review is required to include all

facilities and areas where animals purchased with local VA funds are used in research or housed for longer than 12 hours; a random review of 5 percent of total active projects or a minimum of five total projects; any minority views relative to the findings; information regarding the IACUC members present during the review; and a number of specific data elements, which are more fully described in the text of this report. The IACUC members must also distinguish between major deficiencies, which are those which may threaten the health or welfare of the animals, and minor deficiencies, which are any findings not meeting the definition of major deficiency. The IACUC Chairperson, the veterinarian, and one or more research administrators must then discuss the report with the facility director, who ultimately is required to sign the report. The R&D Committee also receives a copy of the report.

Use of Veterinarians

Veterinary medical services must be provided by facilities conducting animal research activities but may be in the form of a full- or part-time VMO, a VMC, or a clinical veterinarian. VMOs and VMCs have many responsibilities, including directing the animal research programs, serving on the IACUCs, and participating in SARs. Clinical veterinarians who are not experienced in the care of laboratory animals may supplement but not replace VMOs or VMCs if appropriate care cannot be provided otherwise. A clinical veterinarian, however, can only provide care under a written plan developed by a VMO or VMC. When using a VMC, a schedule of visits must be arranged for provision of routine care, and such visits must be documented in writing. These visits cannot occur less often than once a month.

Other Requirements

VHA policy concerning the appropriate care and use of animals in research also regulates certain components of facilities' physical plants and of their occupational health programs.

Animal research facilities require that facility heating, ventilation, and air conditioning (HVAC) systems have special features. For example, reheat coils in heating systems must fail in the "off" or "safe" position to prevent excessive temperatures, which could result in animal loss.⁵ Exposure of unadapted animals to excessive temperatures could also result in behavioral, physical, or morphological changes that could affect protocol outcomes.

In addition to physical plant safeguards, VHA policy mandates special safeguards for personnel engaged in the handling of research animals. While an evaluation of the full scope of the occupational health programs is beyond the scope of this review, VA facilities are required to develop guidelines for personal hygiene, eating and drinking

⁵ VHA Handbook 1200.7, Appendix. E, 3b(7).

practices in laboratory areas, and the provision of clean uniforms and laundry services. Further, the facilities are required to offer a rabies vaccine to all personnel who have significant contact with dogs, cats, bats, or wild carnivores.

Scope and Methodology

This review examines only the specific requirements of VHA Handbook 1200.7. It is not a comprehensive compliance review of all applicable animal research regulations or of all the provisions of VHA Handbook 1200.7. This review focuses on IACUC minutes, SARs, and veterinary qualifications, as well as other items found during the site visits.

We conducted the inspection in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Sample Selection

Prior to beginning this review, we obtained a list of all active VA animal research programs from the VA Central Office. We then sent the list of 77 programs to the Chief VMO for the VA for validation that these programs were still active. He told us that five of the programs were inactive. In January 2007, we requested that facilities with active animal research programs send us the following FY 2006 documentation:

- IACUC minutes.
- SARs.
- Memorandums of Understanding (MOUs) with affiliates.
- Veterinarian licenses and curriculum vitas.
- A list of all active protocols and the locations where the animals were housed.

We reviewed the submitted documentation for compliance with VHA Handbook 1200.7. If a facility did not provide all requested documentation, it was given a lower overall score even if the submitted documentation met handbook requirements. At the completion of the data review, we stratified the facilities based on 29 possible “no” answers (“no” equals noncompliance). We then divided the 29 into quintiles. Facilities that fell in the bottom two quintiles were selected for site visits. Twelve facilities met these criteria. However, prior to starting the site visits, we learned that two of the sites no longer had active animal research programs, and we canceled our planned visits to those two sites. In addition, we visited two other sites for the following reasons. One facility had a hotline complaint, which had resulted in multiple visits from Office of Research Oversight (ORO). The other facility was visited due to the poor quality of the IACUC minutes and the lack of documentation regarding the occupational health program.

We conducted site visits from February–August 2008. During the site visits, we reviewed FY 2007–2008 documentation, reviewed 5 percent of the active protocols, interviewed IACUC and animal research facility (ARF) personnel, and conducted ARF

inspections. The purpose of the ARF inspections was to identify any issues with cleanliness, temperature and humidity control, proper storage of food, and the general physical condition of the facility.

Results

Seventy-two active animal research programs submitted documentation from FY 2006 for review. Of these 72 programs, 12 were affiliated with a university IACUC. All 12 of these had MOUs with the affiliated university detailing the responsibilities of each institution. All 12 VA programs were covered under the affiliated institution's AAALAC accreditation and the affiliate's PHS policy. One of the other VA programs had an IACUC and was AAALAC accredited but came under the affiliate's PHS policy. No programs were 100 percent compliant with the requirements of VHA Handbook 1200.7.

I. IACUCs

A. Members.

All 72 sites we reviewed had the required five members on the IACUC; however, only 9 of the 72 sites had the required memorandum from the Institutional Official (IO) appointing the five members to the IACUC with the terms of the appointment described. All sites had a VMO or VMC on the IACUC.

B. IACUC Minutes.

IACUCs are required to approve all protocols involving animals and to review these protocols at least annually. In the IACUC minutes submitted for review, 64 sites met the requirement and had documentation to show that they reviewed all protocols involving animals. In addition, they documented the presence or absence of a quorum, the presence or absence of members, and any education and training completed during the meetings. There was documentary evidence that 56 of the IACUCs reviewed and investigated internal or external concerns or allegations about animal care and use. A lack of standardization of the minutes made it difficult to determine if the remaining IACUCs met all the requirements in the handbook. Only 12 sites submitted evidence that the R&D Committee reviewed the IACUC minutes. There was no distinction between the affiliate and the VA IACUCs in whether the minutes were submitted for review by the R&D Committee.

II. Semi-Annual Program and Facility Self-Assessment Reviews

The semi-annual program and facility SARs are performed by members of the IACUC. If VA-funded research is performed at the affiliate, areas housing the animals for more than 12 hours must be inspected in conjunction with this review. The IACUC of record

completes the review. One site did not submit any SARs. Six sites only submitted one SAR for FY 2006, and all six of these sites had affiliated IACUCs.

VHA Handbook 1200.7 requires that the front page of the SAR contain the name of the facility, the station number, the address, and the date of the review. Thirty-one SARs did not contain the station number, 17 did not contain the address, 12 did not have the name of the facility, and 9 did not have the date. Of these 31 SARs, 6 SARs were completed by the affiliates, using their own forms.

During the SAR, the IACUC must perform an audit of at least 5 percent or a minimum of five protocols. The purpose of the audit is to ascertain that the initial and annual reviews contain the required documentation and that the annual reviews are performed within the required timeframe. Twenty sites did not document completion of these audits at the time of the SARs. In addition 1 of the 20 sites did not submit any documentation. At the completion of the SAR, the IACUC documents the individuals who participated in the SAR. Twenty-five sites failed to record this information. Additionally, 16 sites failed to list the educational degrees of the individuals participating, and 6 of those 16 sites failed to document the roles of the IACUC participants. The VMO or VMC is required to participate in SARs, and 46 sites had no documentation that the VMO or VMC participated.

At the completion of the SAR, the participants compile a report, detailing the deficiencies identified, and a plan for correction including the timeframe for estimated completion, and any actions taken during the SAR to correct the deficiency. All the SARs we reviewed had this plan of correction documented. At the completion of the SAR, all the participants are required to review the findings and sign a document stating whether or not they agree with the findings. The participants then meet with the IO to discuss their findings and the plans for correction. We identified 12 SARs that did not have the IO's signature indicating that he/she had met with the IACUC members and discussed the SAR. Of these, eight had affiliate IACUCs.

VHA Handbook 1200.7 requires that the IACUC send the signed documentation of the completed SAR to the VA VMO within 60 days of the completion of the SAR. Thirty-five sites submitted documentation that this was completed.

III. Veterinarians

All sites conducting animal research are required by VHA Handbook 1200.7 to provide veterinary medical services. These services may be provided through appointment of a full- or part-time VMO, appointment of a qualified VMC, or a combination of a qualified consultant and a clinical veterinarian. Only 37 of the 72 sites we reviewed submitted documentation that the veterinarian had current license. Currently, all 50 states and the District of Columbia require veterinarians to be licensed when caring for animals. In February 2009, all positions listed for veterinarians in the Federal government required

licensure as a condition of employment. VHA policy, however, does not explicitly state that licensure is a requirement for employment.

In addition to licensure, individuals providing veterinary services to research programs must be qualified to care for laboratory animals. However, nothing in PHS policy or the Animal Welfare Act defines what is considered to be the minimum additional training or experience required to qualify a veterinarian in laboratory animal science. While VA policy defines some minimum experience requirements for veterinarians on the General Schedule (GS), it does not define standards for veterinarians who do not have a GS appointment.

The American College of Laboratory Animal Medicine (ACLAM) offers a certification examination for the purpose of establishing an individual's qualification to practice in the area of laboratory animal medicine. To take this examination, applicants must have, among other requirements, a minimum of 2 years in a post-doctoral training or residency program or at least 6 years' experience (previously 4 years) in laboratory animal medicine. Of the 72 sites we reviewed, 57 had VMOs or VMCs that were either ACLAM diplomates or had a minimum of 4 years' experience in laboratory animal medicine at an institution with a biomedical research program.

IV. Other Findings

During our review of the minutes and the SARs, we noted that 19 sites reported problems with their HVAC systems. Exposure of unadapted animals to excessive temperatures can result in behavioral, physical, or morphological changes that could affect protocol outcomes or cause the death of the animals. Of these 19 sites, 3 had complete failures of their HVAC systems, endangering all the animals in their program. Other deficiencies noted were difficulties maintaining temperature and humidity and HVAC systems that were not connected to emergency power systems in case of power failure at the facility. During our review, we interviewed the Chief VMO for VHA. He indicated that VHA recognized that many facilities had HVAC problems and planned to send a team of engineers out to each VHA site by the end of FY 2009 to document the current HVAC systems in use and to identify any problems the sites have with these systems. Once this is completed, the plan is to seek funding to replace or repair any problematic systems.

In addition to physical plant safeguards, VHA policy mandates special safeguards for personnel engaged in the handling of research animals. For example, if the site conducts research using dogs, cats, bats, or wild carnivores, the site is required to offer all personnel who have significant contact with these animals the opportunity to receive a rabies vaccination. In addition, all personnel engaged in the handling of research animals are to have an annual occupational health assessment. In the SARs and minutes we reviewed, we noted the lack of an occupational health program in at least three facilities. At one site with a vervet monkey colony, which increases the occupational health requirements, the IACUC minutes discussed the lack of an occupational health program.

V. Site Visits

We visited 10 sites that were deemed to be low performers after the initial document review. Nine sites had agreements with the affiliated IACUC. Two other sites were visited for reasons listed in the Scope and Methodology section of this report.

The research program at the Facility #1 was suspended by ORO in August 2006, due to multiple deficiencies in the animal care and use program. In addition, the OIG received a complaint detailing problems with this program. The animal care and use program is supported by an affiliate agreement with a local university. The purpose of our site visit in February 2008 was to monitor the progress of action plans this site submitted to ORO for the correction of identified deficiencies.

During the site visit, we interviewed IACUC, ARF, and engineering personnel from the facility and members from the affiliate IACUC. In addition, we toured the ARF and reviewed IACUC and SAR documentation from all of FY 2007–February 29, 2008. Since program suspension, the facility has made major improvements to their animal research program. A new animal research compliance officer is in place to ensure that the program meets all Federal and VA requirements. In addition, there is a new chairperson on the IACUC. Also, the facility’s safety officer is now a member of the R&D Committee, enabling him to understand ARF issues and helping the site to quickly correct any ARF issues that occur. The facility is building a new ARF and replacing the HVAC in the old ARF. New standard operating procedures are in effect for the ARF and the IACUC. Animal husbandry staff make rounds twice a day every day to ensure the safety and health of the animals.

The suspension was lifted in January 2007. The chairman of the R&D Committee stated that in FY 2007 they had a funding deficit of approximately \$750,000. According to the chairman, the lack of funding contributed to not getting and maintaining staff, training, and ARF maintenance. Our review of the IACUC minutes, the protocols, and current SARs revealed no major problems. We toured the ARF. It was clean, and security was maintained. We did not find any major deficiencies during our site visit case, and this hotline was administratively closed.

When we started our review, Facility #2 had vervet monkeys. During our review of the submitted 2006 IACUC documentation, the IACUC minutes contained documentation of a discussion regarding the lack of an adequate occupational health program for the surveillance of personnel working with the monkeys. In addition, the 2006 IACUC minutes were very poorly documented. When we conducted a site visit at the facility, we discovered that the monkeys had been relocated to a non-VA facility in 2007. Also, at the time of our site visit, the facility had a functional occupational health program. We toured the ARF and found it to be clean, well maintained, and tightly secured. Our review of the documentation did not reveal any major deficiencies, and the documentation had greatly improved since our initial review.

Facility #3 is addressed in this report individually due to the deficiencies we found during our site visit. The animal research program is located on two campuses. During our site visit to campus A, we noted that temperatures in the animal rooms were not monitored during the night shift or at other times when ARF personnel were absent from the building. The IACUC and the health care system engineer had discussed purchasing a new central temperature monitoring system, but at the time of our visit, it was uncertain when this would occur due to the expense. If the HVAC system were to fail during one of the times it was not being monitored, no one would be aware, and repairs would be delayed, which could lead to changes in behavior or physical harm to the animals.

In addition, we noted that visitors to the ARF at campus A were not required to sign in and that there were no security cameras at the door to monitor who was entering. Also, there are many entrances into the ARF. During our site visit, we noted that there were workmen in the ARF doing repairs. They did not sign in, and they had no escort. If a security incident occurred, there would be no record of who was in the building at the time of the incident. In addition there were delays in completing work orders for this ARF. Also, we noted that the personnel working with the animals had not been offered routine vaccines or the annual health questionnaire. We spoke with the Director of Occupational Health who stated that he thought it was the responsibility of the IACUC and ARF personnel to monitor the Occupational Health program.

In July 2008, the ARF instituted a program to monitor the temperatures off shift, developed an occupational health program, and instituted improved security measures at the campus A ARF.

We toured campus B, which has an older ARF and a new ARF. The new ARF has not yet opened due to the difficulty in recruiting a qualified ARF supervisor. This campus had delays in work order completion. During our tour of the ARF we found an outside dishwasher with a patch of cement that was disintegrating and very rough, with visible mold on the cement in front and under the dishwasher. A work order to replace the cement and remove the mold was submitted a year ago. The most recent AAALAC accreditation noted the delay in processing work orders at both campuses as well.

We visited nine other sites. In the documentation we reviewed, we found that five of the nine sites had not sent the completed SARs to the VA VMO, five had not documented completion of the protocol audits during the SARs, and four were missing various parts of the heading on the first page of the SARs. The IACUC chairmen from the university affiliates reported good working relationships with the VA programs. Three of nine sites had modified their university protocol submission forms so that the new format met both the VA and university requirements.

When we visited Facility #4, we found that the animal research program continued to have significant deficiencies. In 2000, the facility shut down all research due to damage sustained in an earthquake. At the time of our visit, they had just finished restoring the

human research program and were now focusing on the animal research program. Most of the research involving animals takes place at the affiliate ARF under the approval of their IACUC. Our visit revealed problems with IACUC minutes and SARs, which the health care system was in the process of improving.

VI. Best Practices

During our site visits, we noted several best practices. Facility #5 has one of the largest animal research budgets in the VA. It houses more than 15,000 animals in four buildings—the oldest one built in the 1850s—covering 20,000 total square feet. We found the entire program to be exceptional. When we toured the ARFs, we found them clean and well maintained with good security. Researcher compliance with the rules and regulations of the animal research program is strictly enforced. If a researcher fails to maintain compliance, his/her key to the ARF is de-activated until the issue is resolved. Many of the researchers are from other countries, so to increase compliance, cage signs are frequently in English and the language of the researcher.

We reviewed the facility's IACUC minutes for all of FY 2007 and through July 31, 2008, and SARs. Also, we reviewed protocol documentation for 5 percent of the active protocols and found only one discrepancy—the lack of documentation that the protocol audit was performed during the semi-annual review. The occupational health program is also a best practice. It encompasses an extensive training program that researchers and their staff are required to complete online. The occupational health nurse who supervises the program is an active participant in the IACUC and is well versed on the vaccinations, health assessments, and tests that are required for each species studied at the site.

Another best practice comes from Facility #6. Animal husbandry personnel at the facility ARF are required to complete an associate's degree in animal technology and must be certified prior to working in the ARF. The increased level of education improves the care of the animals by providing staff that are able to identify animals in the beginning stages of decline. This identification allows early intervention by veterinary staff. In addition, staff have the ability to take care of minor problems as they occur without the delay of contacting the veterinarian.

Conclusions

Overall the 72 sites we reviewed were compliant with the documentation requirements for IACUC minutes. There was a wide variety in how the minutes were documented. Cases of non-compliance were generally due to the format of the minutes. The highest area of non-compliance was with the SARs. We found significantly lower compliance when the animal research program had an affiliate IACUC as the IACUC of record. During our site visits, we found most of the ARFs to be clean, in good repair and adequately secured. We did not identify any instances of animal abuse or neglect. We found that the ARF staff we met were genuinely interested in the welfare of the animals

they cared for. Sites we visited identified a lack of funding and the way funding is allocated as their greatest difficulties in maintaining active, robust animal research programs.

Recommendations

Recommendation 1. We recommended that the Under Secretary for Health work with all VA animal research programs require university affiliates' compliance with the requirements of VHA Handbook 1200.7.

Recommendation 2. We recommended that the Under Secretary for Health ensure that all VA animal research programs have an active occupational health program.

Recommendation 3. We recommended that the Under Secretary for Health ensure that Facility #3 improve the security at the main campus ARF.

Recommendation 4. We recommended that the Under Secretary for Health ensure that the VHA ensure that work orders submitted for repairs to ARFs are completed in a timely fashion.

Recommendation 5. We recommended that the Under Secretary for Health ensure that the VA ensure that the Facility #4 Animal Care and Use Committee comply with all requirements of VHA Handbook 1200.7.

Recommendation 6. We recommended that the Under Secretary for Health define minimum qualification standards for VMOs and VMCs performing duties described in VHA Handbook 1200.7.

Comments

The Under Secretary agreed with the findings and recommendations and provided an acceptable improvement plan. See Appendix A (pages 13–19) for the full text of his comments. We will follow up on all recommendations until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: March 30, 2009

From: Under Secretary for Health

**Subject: Healthcare Inspection – Review of VA Use of Animals in
Research Activities**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the report and the recommendations. Your report highlights the tremendous commitment of VA animal care staff across the Nation to care for laboratory animals involved in research activities. Although the review found best practices already implemented at several VA animal research programs, VHA's Office of Research and Development (ORD) will take several actions to implement the report recommendations for enhanced compliance with VHA Handbook 1200.7, Use of Animals in Research, dated May 27, 2005.

2. To ensure that VA animal research programs require affiliates to comply with VHA Handbook 1200.7 requirements, ORD will develop a specific monitoring checklist for all VA animal research programs that utilize an affiliate Institutional Animal Care and Use Committee (IACUC) for the VA IACUC. This checklist will be used to identify any changes in affiliate IACUC procedures that must be made to ensure compliance with Handbook 1200.7. VA's contract with the Association for Assessment and Accreditation of Laboratory Animal Care will be changed to add compliance with Handbook 1200.7 policies as part of site review criteria. Evaluation of IACUCs compliance with the Handbook during on-site reviews of affected Animal Care and Use Programs will also be emphasized. To further ensure compliance with all requirements of VHA Handbook 1200.7, the Chief Veterinary Medical Officer will work with Facility #4 research administrators to bring their animal research program into full compliance with VA policies, including the format of IACUC minutes and self-assessment reviews (SARs).

3. VHA also agrees that defined minimum qualification standards for Veterinary Medical Officers (VMO) and Veterinary Medical Consultants (VMC) performance duties are needed. Since the current qualification standards do not require licensure, VHA will work with the Office of Human Resource Management (OHRM) to define the minimum qualification standards for VMOs and VMCs performing duties. In fact, ORD has already contacted a Human Resources Specialist in the Office of Human Resource Management, Recruitment and Placement Office (059), regarding the issue of adding licensure as one of the qualifications for a VMO.

4. Thank you for the opportunity to review the draft report and for incorporating our technical comments and a revised recommendation 6 in the final report. An action plan to implement all report recommendations is attached. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 461-8470.

(original signed by:)

Michael J. Kussman, MD, MS, MACP

Attachment

Under Secretary for Health's Comments to Office of Inspector General's Report

The following comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendation 1. We recommended that the Under Secretary for Health work with all VA animal research programs require university affiliates' compliance with the requirements of VHA Handbook 1200.7.

Concur

The Office of Research and Development (ORD) will develop a specific monitoring checklist for all VA animal research programs that utilize the affiliate Institutional Animal Care and Use Committee (IACUC) for the VA IACUC. This checklist will be constructed with input from the Office of Research Oversight (ORO) and sent out to be completed by VA animal research programs that utilize the affiliate's IACUC by May 1, 2009 (requested return date will be June 1, 2009). The individual checklists will be used to identify any changes in affiliate IACUC procedures that must be made to ensure compliance with VHA Handbook 1200.7. Correction of any deficiencies will be requested with a completion date of August 1, 2009. Changes in affiliate IACUC policies require changes in VA-affiliate Memorandums of Understanding (MOUs), and could delay implementation past August 1, 2009; these delays will be evaluated on a case-by-case basis.

ORD will change the VA accreditation contract with AAALAC to add compliance with Handbook 1200.7 policies as site review criteria. AAALAC has already been contacted, and they are amenable to this change. Specific review criteria based upon Handbook 1200.7 will be developed by ORD with assistance from ORO for the use of AAALAC site visitors by July 1, 2009. A formal change order will be made in the AAALAC contract to reflect this additional review criterion for VA programs with a completion date of June 1, 2009.

ORO agrees to place increased emphasis on evaluating the compliance of affiliate IACUCs with Handbook 1200.7 during its on-site reviews of affected Animal Care and Use Programs.

During reviews of VA-affiliate animal research MOUs, ORD and ORO will continue to ensure that MOUs make clear that affiliate IACUCs must comply with Handbook 1200.7 if the affiliate IACUC serves as the VA IACUC.

In process - August 1, 2009

Recommendation 2. We recommended that the Under Secretary for Health ensure that all VA animal research programs have an active occupational health program

Concur

The presence of an animal research occupational health and safety program (OHSP) is required for all VA animal research programs per VHA Handbook 1200.7, and the OHSP for each animal research program is evaluated at least every 3 years by AAALAC, which is the accrediting body for VA animal research. However, complete implementation of field OHSP is challenging due to the resources required to provide continuing services and track personnel on a regular basis.

ORD, with assistance from ORO, will develop a survey of all field animal research programs so that the need for specific improvements in OHSPs can be identified and targeted guidance to field programs developed. This survey will be developed and distributed by May 1, 2009 (required return date will be June 1, 2009). Data tabulation and development of individual station corrective action plans will be completed by July 1, 2009. Due to the complexity of making major changes in OHSPs, stations will be given until October 1, 2009, to make corrections.

In process - October 1, 2009.

Recommendation 3. We recommended that the Under Secretary for Health ensure that VHA Facility #3 improve the security at the main campus ARF.

Concur

Security requirements for VA animal research facilities are found in VA Handbook 0730, Security and Law Enforcement, dated August 11, 2000, Appendix B. This Appendix is the primary source of security feature mandates for animal research facilities and lists closed circuit TV surveillance with central monitoring as an optional feature.

Regardless, given the particularly challenging security environment for animal research in its locale, Facility #3 Veterinary Medical Unit (VMU) will further improve security for its animal facility by adding video camera surveillance to the two external doors not already covered by video surveillance.

The VMU supervisor will now maintain a log of visits by workers and arrange for escorts when workers must be in the facility, as determined by a security risk assessment of the individuals involved.

- a. The Facility #3 VMU will request installation of additional security cameras for two building entrances by April 15, 2009, with an installation deadline of September 15, 2009.
- b. By May 1, 2009, the Facility #3 IACUC will review updated relevant standard operating procedures (SOPs) listing the procedures to be followed when workers must enter the animal facility. The SOPs will include requirements for an entry log, and guidelines regarding the need for escort when work is performed. Final IACUC approval of these updated SOPs will be by June 1, 2009.
- c. The ORD Chief Veterinary Medical Officer (CVMO) will assist Facility #3 as needed, and monitor progress toward meeting action plan items 1 and 2.
- d. ORO will monitor these security items whenever it conducts on-site Animal Care and Use Program reviews at Facility #3.

In process - September 15, 2009

Recommendation 4. We recommended that the Under Secretary for Health ensure that the VHA ensure that work orders submitted for repairs to ARFs are completed in a timely fashion.

The CVMO, with assistance from ORO, will modify the standard semi-annual IACUC self-review forms to include specific items addressing delays in work order completion. This will ensure that each VA IACUC can report the delays and readily bring the problems to the attention of the medical center Director. The CVMO will also be notified. As needed, the CVMO will make ORO aware of persistent problems in work order completions for further action on a station-by-station basis. If consistent barriers to completing animal facility work orders in a timely fashion are identified, a Directive will be issued to highlight problem(s), provide relevant solutions, and express expectations for timely corrections.

In process - June 1, 2009 (modification of semi-annual IACUC form)

Recommendation 5. We recommended that the Under Secretary for Health ensure that the VA ensure that the Facility #4 Animal Care and Use Committee comply with all requirements of VHA Handbook 1200.7.

Concur

The CVMO has contacted Facility #4 research administrators to determine what assistance may be needed to bring their IACUC minutes and self-assessment reviews (SARs) into compliance.

ORO will perform a targeted review of the deficiencies referenced by OIG, and conduct a comprehensive on-site Animal Care and Use Program review at the facility no later than July 1, 2009. Standard ORO on-site review procedures will be followed in following up to make sure appropriate corrections are made.

In process - July 1, 2009

Recommendation 6. We recommended that the Deputy Assistant Secretary for Human Resource Management in collaboration with the Under Secretary for Health define and revise the minimum qualification standards for Veterinary Medical Officers (VMO) and Veterinary Medical Consultants (VMC) performing duties described in VA Handbook 5005 “Staffing” Appendix F32 “Qualification Standards” dated April 15, 2002, and VHA Handbook 1200.7.

Concur

VHA will work with the Office of Human Resource Management (OHRM) to define the minimum qualification standards for VMOs and VMCs performing duties. ORD has already contacted a Human Resources Specialist in the OHRM’s Recruitment and Placement Office (059) regarding the issue of adding licensure as one of the qualifications for a VMO. It is our understanding, as discussed with OHI that the qualifications for a VMO (Laboratory Animal Medicine) as listed in VA Handbook 5005 “Staffing” Appendix F32 “Qualification Standards” dated April 15, 2002, would need to be revised first, in order for ORD to require that all veterinarians obtain a license. The current qualification standards do not require licensure. ORD will work with the Recruitment and Placement Office to redraft this appendix.

Until the qualification standards are changed to require licensure, ORD will strongly encourage all current VMOs and VMCs to obtain a license in one of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, or a U.S. territory. In addition, ORD will give preference in hiring to new applicants who hold such licenses for the position of VMO.

For veterinarians who do not hold a General Schedule (GS) appointment, ORD will develop policy that would require them to have the same qualifications as veterinarians holding a GS appointment.

ORD will encourage all current VMOs and VMCs to obtain American College of Laboratory Animal Medicine certification as soon as they are eligible to obtain it. In addition, ORD will use this criteria to differentiate between best qualified candidates who hold such certifications for the position of VMO.

In process - November 2009

Note: A timeline for changing the qualification standards in Appendix F32 can not be provided because the processes to accomplish this are not under the authority of VHA.

OIG Contact and Staff Acknowledgments

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Acknowledgments	Donna Giroux, RN, BSN, CPHQ ,Project Manager Gail Bozzelli, RN Nelson Miranda, LCSW Randall Snow, J.D. Carol Torczon, RN, MSN, ACNP

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