OFFICE OF RESEARCH OVERSIGHT

FOR-CAUSE REVIEW:
ANIMAL CARE AND USE PROGRAM

VA Greater Los Angeles Healthcare System
Los Angeles, California

February 8, 2016

Veterans Health Administration

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EXECUTIVE SUMMARY

INTRODUCTION

The Veterans Health Administration (VHA) Office of Research Oversight (ORO) conducted an unannounced On-Site For-Cause Review (FCR) of the Animal Care and Use Program (ACUP) at the Veterans Affairs Greater Los Angeles Healthcare System (VAGLAHS) on December 8-10, 2015.

This review was initiated in response to a number of factors, including: a report from the Research and Development Committee (R&DC) describing allegations of inadequate veterinary care and presenting an R&DC policy that provided detailed instruction on how the Veterinary Medical Officer (VMO) should manage the ACUP; allegations of Institutional Animal Care and Use Committee (IACUC) dysfunction; allegations that the R&DC was excluding the IACUC from participation in issues related to the ACUP; and multiple charges and counter charges by various individuals regarding inappropriate veterinary care and oversight and committee procedures and operations.

ORO's primary objectives in conducting this review were to determine if the VAGLAHS provided adequate veterinary care for the research animals and if the VAGLAHS IACUC was capable of providing effective, independent oversight for the ACUP.

The ORO review team conducted individual and group interviews with facility leadership, research service leadership and support staff, Principal Investigators (PIs), the VMO and veterinary care staff, and conducted a comprehensive review of research policies, procedures, memoranda, email correspondence, and other program documentation. The ORO team also conducted a physical inspection of the Veterinary Medical Units (VMUs) and other areas housing research animals at both the Sepulveda (SEP) and West Los Angeles (WLA) campuses.

FINDINGS AND REQUIRED ACTIONS

The ORO team conducted a physical inspection of all animal housing areas located on the SEP and WLA campuses. The inspection included the review of selected medical records and logs,

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with special attention to U.S. Department of Agriculture (USDA) regulated species. The team also conducted a comprehensive review of IACUC operations.

On the issue of veterinary care, ORO determined that the care provided and the recordkeeping met or exceeded the minimum standards required by Federal regulations and VHA policy. ORO notes however, that for a period of approximately 13 months, the VAGLAHS did not have a clinical veterinarian (CV) on staff and therefore had no routine back up veterinary care. Although no animal welfare concerns were identified during this period, the lack of back up veterinary support represented a significant vulnerability to the ACUP. Although a CV candidate was identified early on, delays in the recruitment and hiring process significantly prolonged this problem.

On the issue of IACUC operations, ORO determined that the R&DC had overstepped its authority by acting independently on matters that were clearly the purview of the IACUC and in doing so, usurped the authority of the IACUC. Federal regulations and VHA policy specifically assign matters of animal care and oversight to the IACUC. The VAGLAHS must ensure that the IACUC is free to exercise this authority without undue interference from outside entities or individuals and that matters involving the ACUP are reported to and investigated by the IACUC.

ORO further determined that the IACUC Chair had not acted in accordance with the wishes of the IACUC majority. The IACUC Chair, as any committee chair, must remain impartial in carrying out the decisions of the committee majority. Any committee member, including the Chair, is free to offer and document a minority opinion; however, the Chair cannot overrule the will of the majority of members and must execute actions approved by the committee. The VAGLAHS must ensure that the IACUC Chair fully understands the role, responsibilities, and duties of the Chair.

ORO's detailed regulatory findings and specific required actions are provided in the main body of this report.

CONCLUSIONS

Based on the FCR of the VAGLAHS ACUP, ORO determined that the allegations of inadequate veterinary care were not supported. The review of current policies, procedures, and health records, indicated that the level of veterinary care provided to animals at VAGLAHS met or exceeded the minimum requirements outlined in Federal regulations and VHA policies.

ORO determined that the function of the IACUC had been compromised, both through the involvement of the R&DC in IACUC matters without consultation of the IACUC, and by the actions of the IACUC Chair who in some cases did not carry out the wishes of the IACUC majority. Additionally, ORO identified a number of related regulatory concerns that must be addressed.

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The review team was also presented with multiple allegations of apparent intimidation among individuals involved in the ACUP, occurring both within and outside of committee meetings. Although this conduct does not specifically fall within ORO's regulatory jurisdiction, such conduct can significantly suppress the type of open discussion and expression of opinion that is a requisite component of committee operations and therefore has the potential to compromise effective oversight of the animal research program. The VAGLAHS leadership is strongly advised to address these allegations without delay.

Since the ORO onsite FCR, the VAGLAHS has taken a number of steps to ensure IACUC independence and to enhance IACUC operations. The IACUC Chair has been replaced with a more senior scientist and several experienced former members have been reappointed to the committee. The R&DC has rescinded its April 29, 2015, policy on VMO responsibilities and has voted to end all current R&DC-directed investigations into IACUC matters. ORO considers these actions as a positive step in support of the IACUC's role as the primary committee responsible for oversight of the ACUP.

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VA Greater Los Angeles Healthcare System
Los Angeles, California

On-Site Review Dates: December 8-10, 2015
Date of Report: February 8, 2016

I. INTRODUCTION AND METHOD OF REVIEW

The Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office for advising the Under Secretary for Health (USH), and conducting compliance oversight, relative to the protection of human research subjects, laboratory animal welfare, research safety, research laboratory security, research information protection, and research misconduct. ORO also oversees Governmentwide debarments for research impropriety and conducts education programs for facility Research Compliance Officers (RCOs).

The ORO Research Safety and Animal Welfare (RSAW) group, with the assistance of a member from the ORO Western Regional Office (WRO), conducted an onsite For-Cause Review (FCR) of the Animal Care and Use Program (ACUP) at the VA Greater Los Angeles Healthcare System (VAGLAHS) in Los Angeles, California (CA) on December 8-10, 2015.

This review was initiated in response to a number of factors, including: a report from the Research and Development Committee (R&DC) describing allegations of inadequate veterinary care and presenting an R&DC policy that provided detailed instruction on how the Veterinary Medical Officer (VMO) should manage the ACUP; allegations of Institutional Animal Care and Use Committee (IACUC) dysfunction; allegations that the R&DC was excluding the IACUC from participation in issues related to the ACUP, and multiple charges and counter charges by various individuals regarding inappropriate veterinary care and oversight and committee procedures and operations.

ORO's primary objectives in conducting this review were to determine if the VAGLAHS was providing adequate veterinary care for research animals and if the VAGLAHS IACUC was capable of providing effective, independent oversight for the ACUP.

ORO's review process included: individual and group interviews with facility leadership, research service leadership and support staff, Principal Investigators (PIs), the VMO and veterinary care staff (Appendix A); and a review and evaluation of research policies, procedures, memoranda, email correspondence, and other program documentation (Appendix B). The ORO team also conducted a physical inspection of the Veterinary Medical Units (VMUs)

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and other areas where research animals were housed at both the Sepulveda (SEP) and West Los Angeles (WLA) campuses.

II. PROGRAM OVERVIEW

VAGLAHS' research portfolio included approximately 131 active animal research projects conducted by 68 PIs at the WLA and the SEP campuses. Major areas of research included neuroscience, gastrointestinal physiology, sleep disorders and physiology, psychiatry, neurology, oncology, endocrinology, and immunology. Animal research activities took place in two clean and well-maintained VMUs which offered enriched environments for the animals (one VMU was located on the WLA campus and one was located on the SEP campus, roughly 15 miles to the north); additional approved housing locations were located outside the VMUs on both campuses. Particularly notable were the outdoor canine exercise area at the WLA campus and the indoor/outdoor kennels that were constructed for housing a unique colony of narcoleptic dogs on the SEP campus. At the time of this review, rodent species and dogs were being housed in VAGLAHS facilities.

Oversight of the VAGLAHS research program was provided through an R&DC and corresponding subcommittees with delegated authority for specific program areas, including a properly constituted Subcommittee on Research Safety (SRS).

Primary oversight of the ACUP was provided by the VAGLAHS IACUC. The ACUP maintained a current Public Health Service (PHS) Animal Welfare Assurance (No. A 3002-01) with the National Institutes of Health - Office of Laboratory Animal Welfare (NIH-OLAW), a full accreditation with the Association for the Assessment and Accreditation of Laboratory Animal Care, International[1] (AAALAC; Unit No. VA-068), and was registered with the U.S. Department of Agriculture - Animal and Plant Health Inspection Service (USDA-APHIS; Registration No. 93-V-0006). The VAGLAHS was affiliated with the University of California, Los Angeles (UCLA) and the University of Southern California (USC); however, at the time of the review, no VA animal research was conducted at off-site locations.

III. TIMELINE OF RELEVANT EVENTS

October 2014 The VAGLAHS Clinical Veterinarian (CV) and the VMU Facility Manager (FM) resigned to pursue new employment opportunities.

November 2014 At a convened meeting on November 5, 2014, the IACUC discussed staffing issues and questioned if the R&DC and the facility Director should be notified

[1] AAALAC conducted an onsite evaluation of the VAGLAHS ACUP on July 22-24, 2014, which resulted in continued Full Accreditation.

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of the need to replace the FM and the CV. The Administrative Officer for Research (AO/R) told the committee that such notification would not be necessary, as the R&DC and the Medical Center Director (MCD) were aware of the problem.

January 2015 At a convened meeting on January 7, 2015, the IACUC was informed that an individual had been appointed as the new FM. The committee was also informed that the Animal Program Compliance Officer (APCO) position would be vacated and the individual in that position would be reassigned as the SRS coordinator due to staffing shortages. The IACUC strongly objected to this change indicating that it had the potential to compromise IACUC operations, as the APCO had provided significant support and guidance to the committee.

February 2015 The R&DC met on February 25, 2015, in Executive Session[2] (ES) to discuss allegations of inadequate veterinary care raised by an R&DC member. The committee voted unanimously to assign members of the R&DC the task of drafting a memo to the VMO's supervisor (the Associate Chief of Staff for Research (ACOS/R)) on behalf of the R&DC Chair to address the issues.

March 2015 The R&DC Chair requested that two R&DC members and the IACUC Chair conduct an investigation into the frequency of VMO rounds. (Note: There was no mention of this request in the March 2015 R&DC minutes; this information was provided in the R&DC report to ORO, dated June 16, 2015)

April 2015 The R&DC met on April 29, 2015, in ES and discussed the adequacy of veterinary care, concerns regarding lack of veterinary rounds of animal housing areas, and overreliance of the VMO on veterinary staff. The R&DC unanimously approved a policy defining the role and responsibilities of the VMO. The R&DC unanimously approved submission of an initial report to ORO and other regulatory agencies and assigned the IACUC with determining potential animal welfare concerns. (Note: although this request was communicated to the IACUC Chair, ORO could not independently confirm that the request was communicated to the IACUC membership). The R&DC voted unanimously to assign the ACOS/R and Chief of Staff (COS) with the task of preparing a performance appraisal with a detailed analysis of assigned duties for the VMO, including providing regular briefings of the VMO's performance at the R&DC and IACUC meetings.

[2] Attendance at Executive Sessions is restricted to voting members and invited guests.

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May 2015

The R&DC Chair attended the May 6, 2015, IACUC Meeting to discuss the recently approved policy regarding the VMO. Many IACUC members indicated that they had not been previously advised of the issues that prompted the new policy and expressed concern that the IACUC had not been consulted on these matters. The IACUC convened an ES to further discuss the issues of veterinary care, the R&DC policy, and the role of the R&DC in oversight of the ACUP.

The R&DC met in ES again, on May 27, 2015, and continued their discussion of the R&DC concerns regarding veterinary care and responsibilities of the VMO. The ACOS/R indicated that he would not approve (i.e., would not sign) the R&DC policy regarding the VMO. The R&DC approved submission of a report to ORO detailing concerns of potential noncompliance due to inadequate veterinary care to include a copy of the policy regarding VMO responsibilities.

June 2015

ORO received an official communication, dated June 16, 2015, from the VAGLAHS MCD detailing results of the R&DC investigation into veterinary care issues along with an electronic copy of the R&DC policy regarding the VMO.

July 2015

ORO sent an official response to VAGLAHS acknowledging the seriousness of the issues, but reminding the facility that veterinary care and animal welfare concerns are by Federal regulations and VHA policy the specific purview of the IACUC. ORO requested that the facility submit a report detailing results of an IACUC investigation into these matters, along with relevant documents and an action plan for correcting any issues that were identified, by August 31, 2015.

August 2015

On August 31, 2015, ORO received a request from the IACUC Chair for an extension to the report deadline, citing that the IACUC did not meet in July due to the holiday and had been unable to meet in August due to lack of quorum. The chair stated that a meeting would be held in September and the report could be sent in October. ORO extended the deadline to October 16, 2015.

October 2015

ORO received allegations from a number of individuals who wished to remain anonymous, detailing extensive issues within the ACUP, including statements that the IACUC was dysfunctional and contrasting statements of interference with IACUC operations, along with charges and countercharges of providing false information to committees. ORO contacted the ACOS/R and discussed these troubling developments. On October 15, 2015, ORO received an email from the IACUC Chair requesting an additional extension of the deadline for

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the report that ORO had requested in July 2015. ORO responded that if the Chair provided preliminary findings and meeting minutes documenting the IACUC discussion of these matters, a one week extension would be granted (to October 23, 2015). The Chair agreed to this proposal and provided ORO with the preliminary documentation on October 16, 2015. On October 23, 2015, ORO received the final IACUC report along with supporting documents; however, the report was not routed through the Office of the VAGLAHS Director in accordance with official policy. ORO reminded the Chair of this requirement and requested that she forward all the information provided to the MCD along with an explanation of the situation.

November 2015 Upon review of the documents provided by the IACUC Chair and IACUC meeting minutes, ORO determined that the final report submitted by the IACUC Chair was not the report that had been approved by the IACUC. Additionally, ORO could not find evidence in the minutes that the IACUC had discussed the report that was submitted. This discrepancy, together with the prior conflicting information received by ORO, suggested a deteriorating situation within the ACUP. Consequently, ORO determined that an unannounced onsite FCR would be conducted as soon as possible. Pending that visit, ORO requested that VAGLAHS implement an immediate voluntary suspension of the review and approval of new animal research protocols, although previously approved research would be allowed to continue.

December 2015 The IACUC met in ES on December 2, 2015, and unanimously passed a vote of no confidence in the IACUC Chair and consequently drafted a letter to the VAGLAHS Director, who serves as the Institutional Official for the ACUP, requesting that the IACUC Chair be replaced.

On December 8-10, 2015, the ORO team conducted an unannounced FCR of the ACUP, focusing on issues of veterinary care and IACUC oversight and function.

On December 15, 2015, ORO conducted a telephone interview with the VAGLAHS RCO due to the inability to schedule this interview during the onsite review.

On December 15-17, 2015, the Office of Research and Development, Chief Veterinary Medical Officer and a VMO from another VA facility conducted an independent review of veterinary care issues at VAGLAHS.

The R&DC met on December 17, 2015, and voted to rescind its policy regarding VMO responsibilities and also to terminate all current R&DC-directed investigations into IACUC matters.

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IV. FINDINGS AND REQUIRED ACTIONS

The ORO team conducted a physical inspection of all animal housing areas located in the SEP and WLA campuses. The inspection included the review of selected medical records and logs, with special attention to USDA regulated species. The team also conducted a comprehensive review of IACUC operations.

On the issue of veterinary care, ORO determined that the care provided and the recordkeeping met or exceeded the minimum standards required by Federal regulations and VHA policy. ORO notes however, that for a period of approximately 13 months, the VAGLAHS did not have a CV on staff and therefore had no routine back up veterinary care. Although no animal welfare concerns were identified during this period, the lack of back up veterinary support represented a significant vulnerability to the ACUP. Although a CV candidate was identified early on, delays in the recruitment and hiring process significantly prolonged this problem.

The following items describe specific findings of noncompliance that must be addressed. The Required Action Plan (RAP) table, included as an attachment, must be completed and returned to ORO within 30 days after the report has been issued. The plan must include specific actions that will be implemented and proposed completion dates for each action item.

1. The R&DC failed to respect and, consequently, usurped the authority of the IACUC. As specified in the following four elements, ORO determined that the R&DC had overstepped its authority by acting independently on matters that were clearly the purview of the IACUC. Federal regulations and VHA policy specifically assign matters of animal care and oversight to the IACUC. The VAGLAHS must ensure that the IACUC is free to exercise this authority without undue interference from outside entities or individuals and that matters involving the ACUP are reported to and investigated by the IACUC.

1.a. The R&DC failed to communicate reports of animal care concerns to the IACUC.

Finding. A review of IACUC and R&DC minutes and interviews with key individuals indicated that concerns involving the ACUP were reported to the R&DC instead of the IACUC. ORO notes that the IACUC Chair was a non-voting member of the R&DC and therefore the committee might have reasonably believed that this individual would relay the concerns to the IACUC. However, this does not appear to have happened, and there is no evidence that the R&DC formally notified the IACUC that it had received reports related to the ACUP or afforded the IACUC an opportunity to investigate these matters (see item 1.b.).

References. *VHA Handbook 1058.01 §7.e states, "VA personnel, including WOC and IPA appointees, must ensure written notification of the IACUC within 5 business days after becoming aware of any incident that is reportable under relevant VHA Handbooks or applicable Federal requirements related to laboratory animal welfare or research safety."*

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Required Action 1.a. The R&DC must ensure that all concerns regarding the ACUP are referred to the IACUC. In addition, the VAGLAHS Research Service must ensure that ALL staff are aware of and comply with reporting requirements for the ACUP as outlined in VHA Handbook 1058.01.

1.b. The R&DC usurped the authority of the IACUC by independently conducting an investigation of animal care concerns.

Finding. A review of IACUC and R&DC minutes and interviews with key individuals confirmed that, upon receipt of reports of concerns regarding the ACUP, the R&DC independently initiated a number of investigations, rather than deferring such investigations to the IACUC.

References. *VHA Handbook 1058.01 §7.f states, "The IACUC must review any incident described at paragraphs 7.a. through 7.e. at its next convened meeting."*

VHA Handbook 1200.07 §8.k states, "All internal and external allegations of improper animal care and use at a medical facility must be reviewed promptly by the IACUC, and investigated if warranted."

Required Action 1.b. The R&DC, together with the VAGLAHS Research Service must ensure that investigations of ACUP concerns are conducted by the IACUC.

1.c. The R&DC usurped the authority of the IACUC by independently developing ACUP policy.

Finding. A review of R&DC and IACUC minutes and interviews with key individuals confirmed that the R&DC developed and approved ACUP policy (i.e., regarding VMO activity), rather than deferring the development of all such policy to the IACUC.

References. *VHA Handbook 1058.01 §7.f(2) and (3) state that the "IACUC must notify the VA facility Director and the ACOS/R&D within 5 business days after reaching a determination that a reportable incident has occurred," and that the facility Director must then "report the incident to ORO within 5 business days of after receiving the report from the IACUC's notification."*

VHA Handbook 1200.07 §7.c states, "[…] The VMU Supervisor, with guidance and assistance from the VMO or VMC, must develop a manual of SOPs setting forth schedules and methods of cleaning animal housing and research areas, feeding and watering practices, staff training, equipment maintenance and related activities. At a minimum, the SOP manual must be reviewed annually by the VMU supervisor and the VMO, or VMC, to determine the need for any changes in procedures. ***NOTE:*** *This SOP manual should be reviewed and approved by the IACUC at least annually."*

Required Action 1.c. The R&DC, together with the VAGLAHS Research Service must ensure that the IACUC is responsible for the development and the initial approval of ACUP policy.

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1.d. The R&DC and the IACUC Chair submitted nominations of prospective IACUC members to the MCD in June 2015 without consultation or concurrence of the IACUC membership in violation of VHA and local policies.[3]

Finding. Interviews with key personnel and review of IACUC minutes revealed that the R&DC again usurped the IACUC's authority, by not consulting the IACUC membership regarding the nomination of individuals to be appointed to the IACUC by the Institutional Official (Facility Director). Instead, the R&DC conferred only with the IACUC Chair to identify individuals whose names were forwarded to the Institutional Official for appointment.

References. *VHA Handbook 1200.07 §8.a states, "IACUC members in consultation with the R&D Committee must forward the name(s) of nominees for the IACUC to the medical facility Director." Although the IACUC Chair was involved in the process, VHA policy clearly states "IACUC members."*

VAGLAHS Policy 151-CA(S)-01.06, "Institutional Animal Care and Use Committee," states in part, "Candidate IACUC members are recommended to the RDC by the current IACUC membership, and approved candidates are then recommended to the IO for appointment for a term of up to three years (renewable)."

Required Action 1.d. The R&DC and the VAGLAHS Research Service must ensure that IACUC members in consultation with the R&D Committee forward the name(s) of nominees for the IACUC to the medical facility Director as specified in VHA and local policies.

2. The IACUC Chair submitted a report to ORO that was not approved by the IACUC membership.

Finding. A review of documents submitted to ORO, including IACUC minutes, and interviews with IACUC members revealed that the report submitted to ORO on veterinary care issues had not been approved by a majority of a quorum of the convened IACUC. ORO further determined that the IACUC Chair had not acted in accordance with the wishes of the IACUC majority, which had approved a report that differed significantly from the submitted report. In effect, the IACUC Chair had substituted a report prepared solely by the Chair, without clearly identifying it as such. The IACUC Chair, as any committee chair, must remain impartial in carrying out the decisions of the committee majority. Any committee member, including the Chair, is free to offer and document a minority opinion; however, the Chair cannot overrule the will of the majority of members and must execute actions approved by the committee.

[3] Although the *nominations* were not made in accordance with VHA and local policy requirements, ORO considers the resulting IACUC to have been properly constituted because the actual appointments were made by the Institutional Official in accordance with Federal regulations and VHA Policy.

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Reference. *VHA Handbook 1200.07 §8.k states, "All internal and external allegations of improper animal care and use at a medical facility 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 medical facility Director through the ACOS for R&D."*

Required Action 2. The VAGLAHS Research Service must ensure that the IACUC Chair is aware that a majority of a quorum at a convened meeting must approve reports of investigations before they are submitted to the facility Director and reported to ORO, and that the Chair adheres to this requirement.

3. The IACUC Chair submitted a report to ORO outside of the required reporting structure.

Finding. A review of email correspondence and interviews with key individuals revealed that the IACUC Chair submitted an official report directly to ORO without sending the report to the MCD (facility Director) and the ACOS/R.

References. *VHA Handbook 1058.01 §7.f(2) and (3) state that the "IACUC must notify the VA facility Director and the ACOS/R&D within 5 business days after reaching a determination that a reportable incident has occurred," and that the facility Director must then "report the incident to ORO within 5 business days after receiving the IACUC's notification."*

VHA Handbook 1200.07 §8.k states, "A written report of the review or investigation needs to be approved by a majority of a convened IACUC quorum and sent to the medical facility Director through the ACOS for R&D."

Required Action 3. The VAGLAHS Research Service must ensure that the IACUC Chair is fully aware of the responsibilities related to reporting concerns and that the Chair fully understands and complies with the reporting requirements detailed in VHA Handbooks 1058.01 and 1200.07, and any additional local policies that are in place.

V. ADDITIONAL OBSERVATIONS AND SUGGESTIONS

ORO would like to offer the following observations and suggestions for the VAGLAHS ACUP. Observations are used to make note of unique practices or events related to the review, whereas suggestions are offered to further enhance your research oversight program and their implementation is voluntary. Your institution should consider the potential value of each suggestion prior to adoption.

Observations

1. ORO acknowledges that the R&DC has rescinded its April 29, 2015, policy on VMO responsibilities and has voted to end all current R&DC-directed investigations into IACUC

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matters. We commend these actions as a positive step in support of the IACUC's role as the primary committee responsible for oversight of the ACUP.

2. ORO notes that the APCO has been re-assigned in support of the IACUC. We view this as another positive step in support of IACUC operations.

3. ORO acknowledges that since the onsite FCR, the IACUC Chair has been replaced with a more senior scientist, one of the IACUC Vice-chairs has voluntarily stepped down to become a regular voting member, and a more experienced Vice-chair has been appointed. We support these actions and believe they will further enhance IACUC operations.

Suggestions

1. The VAGLAHS should consider providing additional training for IACUC members, in particular, attendance at external training events. Such events provide the opportunity for interaction with IACUC members from other institutions and often use mock IACUC meetings to facilitate training. This type of setting can be more valuable than basic computer-based training.

2. The APCO has extensive experience and knowledge of animal welfare regulations and policies and IACUC operations; the VAGLAHS Research Service should consider using this individual to provide in-person training sessions for the IACUC on an as-needed basis.

3. The personal relationship between the IACUC coordinator and the VMO could be perceived as a conflict of interest (COI); however, this appears to be appropriately managed. ORO suggests that management of this potential COI be formalized by consulting with the VAGLAHS COI committee.

4. During interviews with staff, ORO became aware that some IACUC members do not have a VA email account or do not regularly check their VA email accounts. This has the potential to delay distribution of critical information and potentially prevent transmission of encrypted information; the VAGLAHS Research Service should consider options for addressing this issue.

5. Although the VAGLAHS Research Service has implemented Standard Operating Procedures (SOPs) and policies for the VMU, none of the versions provided to ORO were signed and it was not possible to determine which versions were official. The Research Service should ensure that the final approved versions of all SOPs and policies are signed and dated to ensure that everyone can determine if they are reading the current official version that is being enforced.

6. The VMO and the IACUC should work together to review and revise the VMU SOPs to ensure that the SOPs are both consistent with and reflect actual practices that have been implemented for all species housed at VAGLAHS. As with the Research Service SOPs, the final approved versions should be signed and dated.

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7. Although VAGLAHS now has a CV, the facility should continue to pursue an arrangement for emergency backup veterinary care, to ensure that appropriate support would be accessible in the event that the VMO and the CV are not available.

8. During facility walkthroughs and document review, it was noted that the VAGLAHS ACUP had a reasonably comprehensive Whistleblower Policy that included multiple points of contact for reporting concerns, protection against reprisals and confidentiality. The policy was visibly posted in animal research areas; however, it did not include a mechanism for anonymous reporting. The *Guide for the Care and Use of Laboratory Animals*, 8th Edition (the Guide), page 24, states that procedures for reporting concerns should include a mechanism for anonymity. Because the Guide classifies this requirement as a "should", it is not a regulatory requirement, but inclusion of an anonymous reporting mechanism is strongly recommended.

9. During the site visit, the review team was made aware of multiple allegations of apparent intimidation that occurred both during and outside convened meetings. A number of individuals stated that they feared retaliation from committees or committee chairs for expressing their opinions. While such conduct matters are generally not the purview of ORO, the VA has implemented a zero tolerance policy for such behavior. Additionally, successful operation of research oversight committees is built upon free expression of opinions and ideas. Any behavior that undermines this free expression has the potential to stifle discussion, compromise committee operations, and put the research program at risk. The VAGLAHS leadership should aggressively address these allegations, enlisting the assistance of the VA National Center for Organizational Development (NCOD) if necessary.

VI. CONCLUSIONS

Based on the FCR of the VAGLAHS ACUP, ORO determined that the allegations of inadequate veterinary care were not supported. The review of current policies, procedures, and health records indicated that the level of veterinary care provided to animals at VAGLAHS met or exceeded the minimum requirements outlined in Federal regulations and VHA policies.

The review team determined that the function of the IACUC had been compromised, both through the involvement of the R&DC in IACUC matters without consultation of the IACUC and by the actions of the IACUC Chair who in some cases did not carry out the wishes of the IACUC majority. Additionally, ORO identified a number of related regulatory concerns that will need to be addressed to bring the VAGLAHS into full compliance with VHA and local policies. These additional concerns included: animal care issues not being reported to the IACUC for investigation and submission of official reports that were not approved by the IACUC majority or that were not submitted through required channels.

The review team was also presented with multiple allegations of apparent intimidation among individuals involved in the ACUP, occurring both within and outside of committee meetings.

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Although this conduct does not specifically fall within ORO's regulatory jurisdiction, such conduct can significantly impede the type of open discussion and expression of opinion that is a requisite component of committee operations and therefore has the potential to compromise effective oversight of the animal research program. The VAGLAHS leadership is strongly advised to address these allegations without delay.

OFFICE OF RESEARCH OVERSIGHT

(b)(6)

James M. Trout, PhD
Associate Director for
ORO Research Safety and Animal Welfare

February 8, 2016
Date

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APPENDIX A: FACILITY REPRESENTATIVES AND ORO REVIEW TEAM

Facility Representatives:

(b)(6)

ORO Review Team:

(b)(6)

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APPENDIX B: DOCUMENTS REVIEWED

1. Correspondence between VAGLAHS and ORO relating to ORO Case No. 691-0024-A[4]:
   a. Initial report from VAGLAHS R&DC to ORO regarding potential deficiencies in veterinary care, dated June 16, 2015
   b. Transmittal Memo from ORO to VAGLAHS, dated July 2, 2015
   c. Preliminary report/update from VAGLAHS IACUC Chair, dated October 16, 2015
   d. Final report from VAGLAHS IACUC Chair, dated October 23, 2015
   e. VAGLAHS Investigation of IACUC Role in Report to ORO Regarding VMO, dated August 5, 2015
   f. VAGLAHS IACUC Report from Nonaffiliated Community Representative to ORO ED and ORD CVMO, dated October 29, 2015
   g. Email response from IACUC Chair to questions raised by CVMO regarding GLA-IACUC report of potential animal welfare violations, dated November 17, 2015
   h. Transmittal Memo from ORO to VAGLAHS, dated November 19, 2015
   i. Response/update from VAGLAHS, dated December 4, 2015
2. VAGLAHS VMU Standard Operating Procedures (SOPs):
   a. 151-VMU-01, General duty instructions, dated July 2014
   b. 151-VMU-02, Approved vendors, dated July 2014
   c. 151-VMU-03, Requirements for entry into the veterinary medical unit, dated July 2104
   d. 151-VMU-04, VMU animal ordering and receiving procedure, dated July 2014
   e. 151-VMU-05, Autoclave operation, maintenance, and quality assurance in the veterinary medical unit, dated July 2014
   f. 151-VMU-06, Cage & rack washer operation, maintenance, and quality assurance in the veterinary medical unit, dated July 2014
   g. 151-VMU-07, Vehicle use log and maintenance checklist, dated July 2014
   h. 151-VMU-08, How to operate the Steris cage wash, dated July 2014
   i. 151-VMU-09, Animal feed and bedding ordering, receiving, and storage procedures, dated July 2104
   j. 151-VMU-10, Animal holding within the veterinary medical unit, dated July 2014

[4] ORO Case No. 691-0024-A was initiated in response to the initial R&DC report concerning inadequate veterinary care. Following the ORO's determination that a For-Cause Review was necessary, Case No, 691-0024-A was closed and all follow-up was transferred to the current For-Cause Review, ORO Case No. 691-0030-A.

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k. 151-VMU-11, Basic animal room care and maintenance, dated July 2014

l. 151- VMU-12 Dog husbandry, dated July 2013

m. 151- VMU-13, Cat husbandry in the veterinary medical unit, dated June 2013

n. 151- VMU-14, Rodent Husbandry, dated July 2013

o. 151- VMU-15, Gerbil Husbandry, dated July 2013

p. 151- VMU-16, Rabbit husbandry, dated July 2013

q. 151-VMU-17, Cage changing with sterile micro-isolator systems, dated July 2014

r. 151-VMU-18, Veterinary medical unit biocontainment procedures, dated July 2014

s. 151-VMU-19, Separating overcrowded cages in the veterinary medical unit, dated July 2014

t. 151-VMU-20, Entry and exit procedures in the SPF enhanced rodent barrier facility (BLDG. 337), dated July 2014

u. 151-VMU-21, Cage changing in the SPF enhanced rodent barrier facility (BLDG. 337), dated July 2014

v. 151-VMU-22, Providing exercise and enrichment for dogs, dated July 2014

w. 151-VMU-23, Cat environmental enrichment, dated July 2014

x. 151-VMU-24, Sentinel animal testing, dated July 2014

y. 151-VMU-25, Routine animal health monitoring and treatment of sick and injured animals, dated July 2014

3. Clarification letter from OLAW for CY2014 Annual Report #A-3002-01, dated February 12, 2015 and February 23, 2015

4. VAGLAHS PHS Assurance, dated November 15, 2013

5. VAGLAHS Institutional Animal Care and Use Committee (IACUC) meeting minutes, dated November 2014, December 2014, January 2015, February 2015, April 2015, May 2015, June 2015 and September 2015

6. VAGLAHS IACUC semiannual reports to the MCD, dated July 17, 2014; March 4, 2015; August 11, 2015

7. VAGLAHS Research and Development Committee (R&DC) meeting minutes, dated February 25, 2015

8. VMU Room Check Sheets, all VMU animal rooms and laboratory areas where rodents are housed (BLDG 337, 113, and 114), month of December 2015.

a. Building 113 (Rooms 137, 136, 121, 120)

b. Building 114 (Rooms 136, 133, 310, 312, 304)

c. Building 115 (Rooms 128C, 113B, 114, 109B, 326, 320)

d. Building 103 (empty)

e. Building 47 (Rooms 102, 105, 106, 104, 107, 101A1)

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f. Building 7 (Rooms A119, B-11, D-122, C106A, C106E, C103, C100D, C116, C117, C-111, C-109, C-115)

g. Canine Social Housing Unit (Sepulveda campus)

9. Selected animal medical records, canines ("Boomer," "Bobbie," "Bonnie," "Bennet" and "Holly")

10. VAGLAHS Internal Memoranda and correspondences

a. Memorandum from R&DC Chair to ACOS/R, dated May 1, 2015

b. VAGLAHS Research and Development Policy Draft Policy 151-XX(X)-XX.xx, dated April 2015

c. VAGLAHS Research and Development Policy Draft Policy 151-XX(X)-XX.xx, dated April 2015 (with VMO commentary)

d. Memorandum from IACUC Chair to VMO, Animal transportation in unapproved vehicle by VMU personnel , dated June 5, 2015

e. Memorandum from VMO to IACUC regarding VMO response to draft SOP/Policy for the VMO, dated July 31, 2015

f. Memorandum from VMO to IACUC regarding Inaccurate ORO Report regarding Veterinary Care and Oversight and Multiple Violations of VHA Animal Handbook Policies by the RDC regarding reporting of animal welfare issues, dated July 15, 2015

g. Memorandum from VMO to MCD regarding recent Correspondence with the VA Office of Research Oversight, dated June 28, 2015

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REQUIRED ACTION PLAN
ORO CASE NO. 691-0030-A

PLEASE READ THIS SECTION BEFORE COMPLETING THE TABLE.

The following actions are required to bring the Research Safety and Security Program (RSSP) into full compliance with VHA requirements. Please provide the Facility's Planned Action(s) and Projected Completion Date(s) for each required action in the designated space in the table below.
When available, please provide supporting documentation (e.g., meeting minutes, new or revised standard operating procedures or policies, memoranda, work orders, etc.) verifying that each required action item has been completed.
Please return the completed table to our Office in Word Format.

Required Action 1.a. The R&DC must ensure that all concerns regarding the ACUP are referred to the IACUC. In addition, the VAGLAHS Research Service must ensure that ALL staff are aware of and comply with reporting requirements for the ACUP as outlined in VHA Handbook 1058.01.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY **Action(s):** **Projected Completion Date:** MM/DD/YYYY	*ORO's response to Facility Response #1 will be provided in this space.*
Require Action 1.b. The R&DC, together with the VAGLAHS Research Service must ensure that investigations of ACUP concerns are conducted by the IACUC.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY **Action(s):** **Projected Completion Date:** MM/DD/YYYY	*ORO's response to Facility Response #1 will be provided in this space.*
Required Action 1.c. The R&DC, together with the VAGLAHS Research Service must ensure that the IACUC is responsible for the development and the initial approval of ACUP policy.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY	*ORO's response to Facility Response #1 will*

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Action(s): **Projected Completion Date:** MM/DD/YYYY	*be provided in this space.*
Required Action 1.d. The R&DC and the VAGLAHS Research Service must ensure that IACUC members in consultation with the R&D Committee forward the name(s) of nominees for the IACUC to the medical facility Director as specified in VHA and local policies.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY **Action(s):** **Projected Completion Date:** MM/DD/YYYY	*ORO's response to Facility Response #1 will be provided in this space.*
Required Action 2. The VAGLAHS Research Service must ensure that the IACUC Chair is aware that a majority of a quorum at a convened meeting must approve reports of investigations before they are submitted to the facility Director and reported to ORO, and that the Chair adheres to this requirement.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY **Action(s):** **Projected Completion Date:** MM/DD/YYYY	*ORO's response to Facility Response #1 will be provided in this space.*
Required Action 3. The VAGLAHS Research Service must ensure that the IACUC Chair is fully aware of the responsibilities related to reporting concerns and that the Chair fully understands and complies with the reporting requirements detailed in VHA Handbooks 1058.01 and 1200.07, and any additional local policies that are in place.	
Facility Response	***ORO Response***
Response (#1) Date: MM/DD/YYYY **Action(s):** **Projected Completion Date:** MM/DD/YYYY	*ORO's response to Facility Response #1 will be provided in this space.*

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