DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

The Veterans Health Administration Did Not Get Secretary's Approval Before Using Canines for Medical Research

REVIEW | REPORT #19-06451-165 | JULY 14, 2020

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Executive Summary

The VA Office of Inspector General (OIG) reviewed the Veterans Health Administration's (VHA) approval process for research studies involving canine subjects. The use of canines in VA medical research came under public scrutiny in early 2017 after media reports of alleged animal welfare violations and a VA Office of Research Oversight review that identified animal welfare and oversight concerns at the Hunter Holmes McGuire VA Medical Center (VAMC) in Richmond, Virginia. Congress later placed restrictions on using appropriated funds for fiscal years (FY) 2018 and 2019 for medical research using canines, unless that research was consistent with policy and directly approved by the VA Secretary.

VA continued to conduct research using canines after the passage of the funding restrictions based, in part, on the perception of VHA executives that then VA Secretary Dr. David Shulkin had approved the continuation of the studies before his March 28, 2018, departure. However, a public controversy arose in November 2018, when Dr. Shulkin disputed reports made by VA leaders that he had directly approved continuing that research.

In response, five members of Congress asked the OIG to conduct a review to answer the following questions:

1. Did Dr. Shulkin and current VA Secretary Robert Wilkie directly approve research for FY 2018 and FY 2019 that used canines consistent with federal law?
2. How much research involving the use of canines did VA conduct between March 28 and November 1, 2018?
3. Did the Louis Stokes Cleveland VA Medical Center (VAMC) initiate purchases of canines for research before former Secretary Shulkin's FY 2018 approval?
4. Did VA purchase any canines using sole-source contracts and, if so, what was the justification?

What the Review Found

The OIG found that VHA conducted eight studies without the former or current Secretary's direct approval, including seven that were conducted between March 28 and November 1, 2018.[1] The eight studies continued for an average of 206 days before the Office of Research and Development obtained the required approval from Secretary Robert Wilkie. Each study was approved by local facility and VHA officials but lacked final approval by the VA Secretary. This

[1] One study at the VA St. Louis Health Care System was conducted between February 4 and April 18, 2019. While this study occurred outside the date range requested by the members of Congress, VHA disclosed the ongoing work to the OIG review team during the project.

resulted in researchers at four VA medical facilities conducting studies on 51 canines and the combined unauthorized use of appropriated funds totaling $393,606.[2]

While VA publicly took the position that former Secretary Shulkin approved each canine study for continuation after the funding restrictions were enacted, Dr. Shulkin, through a media report and his attorney, denied giving approval. A thorough review of the available evidence did not confirm VHA's contention that Dr. Shulkin had directly approved the continuation of studies in a meeting on his last day as Secretary on March 28, 2018. The OIG also found that VHA did not have a standard operating procedure to obtain and document the Secretary's approval.

Unclear communication, inadequate recordkeeping, and failure to ensure that the approval decisions were accurately recorded and verified all contributed to VHA's noncompliance. Providing unsupported and potentially inaccurate information on this topic could undermine the public's trust in VA and could unnecessarily detract attention from one of VHA's important statutory missions—supporting a wide range of authorized research concerning veterans' health issues.

The OIG also found that the Louis Stokes Cleveland VAMC purchased 21 canines at a total awarded amount of $42,722 on April 23, 2018, for one of the eight research studies. The study, to test a device being refined to aid patients with spinal cord injuries who lack an effective cough mechanism due to muscle paralysis, was not approved by Secretary Wilkie until November 6, 2018. The research protocol stated that canines were necessary subjects because they have a spinal cord of similar size and composition compared to humans. The purchase did not comply with FY 2018 funding restrictions and was therefore an unauthorized use of appropriated funds.

The Cleveland VAMC purchased these canines using a sole-source contract, which contained the justification required by the Federal Acquisition Regulation. The two other facilities obtaining canines during the review period did so by purchasing them through their affiliated nonprofit corporations or accepting donations from a private-sector corporation.

What the OIG Recommended

The OIG made five recommendations to the under secretary for health. They included establishing a formal approval process for research studies that use canine subjects as required by federal law, ensuring the Secretary's approval is documented, and establishing controls to prevent appropriated funds from being spent without approval. The OIG also recommended the under secretary review local accounting records and cost allocations to determine the total

[2] All dollar figures in this report have been rounded. Finding 1 discusses the appropriated funds spent on research studies using canine subjects totaling $393,606. In contrast, finding 2 identifies the contract amount awarded to purchase canines for the Louis Stokes Cleveland VAMC. The awarded amount is not an expenditure and therefore was not included in the review team's assessment of cost.

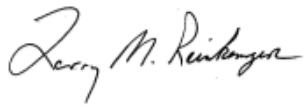
amount of FY 2018 and FY 2019 funds expended on canine research projects before approval by the VA Secretary and report this information to the House and Senate appropriations committees. Finally, the OIG recommended the under secretary for health work with the VA Secretary and chief financial officer to take steps required by Office of Management and Budget Circular A-11 to determine whether an Antideficiency Act violation occurred and, if so, to take appropriate action for the funds obligated and expended for research studies that used canine subjects.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with all recommendations and submitted corrective action plans. The OIG will monitor implementation of planned actions and will close the recommendations when VHA provides sufficient documentation demonstrating progress in addressing the issues identified.

The executive in charge's response indicated that actions related to recommendations 1, 2, and 3 were completed. However, the OIG was not provided sufficient evidence to assess and verify those actions. Additional action is also needed to demonstrate the extent to which VHA met the full intent of recommendation 2, which is detailed on pages 17 and 18. The OIG will close these recommendations when VHA provides sufficient evidence demonstrating the proposed actions have been completed.

Finally, as part of the response, the executive in charge acknowledged a lapse in formal documentation of the direct approval for ongoing canine research studies but stated that VHA stands behind its position that Dr. Shulkin provided verbal approval for ongoing canine research studies at the March 28, 2018, meeting with senior VHA executives. The executive in charge also provided a technical comment on the OIG's calculation of canine research expenses. The OIG responded to those remarks on pages 17 through 19 of this report.



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Abbreviations

FAR	Federal Acquisition Regulation
FY	fiscal year
OIG	Office of Inspector General
OLAW	Office of Laboratory Animal Welfare
ORD	Office of Research and Development
VAMC	VA medical center
VHA	Veterans Health Administration

Introduction

In March and June 2017, the use of canines in VA medical research came under public scrutiny after national media outlets released allegations of animal welfare violations at the Hunter Holmes McGuire VA Medical Center (VAMC) in Richmond, Virginia. As a result of these articles and the findings of an associated VA Office of Research Oversight review, a July 2017 bill was introduced in Congress—but did not pass—prohibiting canine research within VA that caused the animals significant pain or distress.[3] However, Congress did include language in the Consolidated Appropriations Act of 2018, signed into law on March 23, 2018, placing restrictions on VA's use of fiscal year (FY) 2018 appropriated funds to conduct research using canine subjects. Specifically, Section 254 states

> None of the funds appropriated or otherwise made available by this Act may be used to conduct research using canines unless: the scientific objectives of the study can only be met by research with canines; the study has been directly approved by the Secretary; and the study is consistent with the revised [VA] canine research policy document released on December 18, 2017.

A similar provision also went into effect for FY 2019 under the Energy and Water, Legislative Branch, and Military Construction and Veterans Affairs Appropriation Act of 2019, requiring direct VA Secretary approval for research involving canines.[4] However, the acts do not stipulate the method of recording approvals, such as requiring approval in writing. In addition, the acts do not require obtaining approval from the Secretary more than once per study.

VA continued using canines in research after the funding restrictions were enacted based, in part, on leaders' perception that former VA Secretary Dr. David Shulkin supported the continuation of the research using canine subjects before his March 28, 2018, departure. However, in a November 2018 media report, Dr. Shulkin disputed reports from the current VA leaders that he had directly approved continuing that research.

In December 2018, five members of Congress requested that the VA Office of Inspector General (OIG) conduct a review. The OIG began reviewing the Veterans Health Administration's (VHA) approval process for research studies involving canine subjects. Specifically, the OIG answered the following four questions from the members:

1. Did former VA Secretary David Shulkin and current VA Secretary Robert Wilkie directly approve research that used canines for FYs 2018 and 2019 consistent with federal law?[5]

[3] Preventing Unkind and Painful Procedures and Experiments on Respected Species (PUPPERS) Act of 2017, H.R. 3197, 115th Cong. (2017).

[4] Pub. L. No. 115-244, § 247 (2019).

[5] Dr. Shulkin's final day as VA Secretary was March 28, 2018. Robert Wilkie became Secretary on July 30, 2018.

2. How much research involving the use of canines did VA conduct between March 28 and November 1, 2018?
3. Did the Louis Stokes Cleveland VAMC initiate purchases of canines for research before former Secretary Shulkin's FY 2018 approval?
4. Did VA purchase any canines using sole-source contracts and, if so, what was the justification?

The OIG assessed activities associated with requesting and receiving approval for VHA research and the related procurement of canines, as well as relevant records management for canine research studies.

VHA's Animal Research Program

Research using animals within VA is governed by VHA's Office of Research and Development (ORD), which works to "improve veterans' health and well-being through basic, translational, clinical, health services, and rehabilitative research" aimed at developing effective individualized care solutions.[6] ORD asserts that, to conduct research, VHA must sometimes work with animals when it is the only scientifically viable way to obtain knowledge needed to improve human health. VHA allows research with animals only if regulated by animal welfare safeguards.

Use of Canines

According to ORD's public website, more than 99 percent of animal subjects used in its research are mice or rats.[7] The website indicates that VHA used canine subjects in less than one-half of one percent of research involving animals in 2016.[8] ORD states that for a few specific areas of research, such as injuries to the spinal cord or heart conditions, the studies can only be performed using canine subjects because of the relative similarity in size and physiology of canines to humans when compared with other laboratory animals.

Approval Process for Research Involving Canines

All research studies involving canines must pass through a multilevel review process at the local and VA central office levels. After a researcher proposes a study involving canine subjects, it is first reviewed by committees associated with the local VA medical facility. The local

[6] For additional information on ORD and its organizational structure, see figure A.1 in appendix A.

[7] VA Office of Research and Development, "Animal Research in VA: Overview," VA webpage, accessed August 19, 2019, https://www.research.va.gov/programs/animal_research/overview.cfm.

[8] VA Office of Research and Development, "Frequently Asked Questions about VA Canine Research," VA webpage, accessed August 19, 2019, https://www.research.va.gov/programs/animal_research/canine_research/canine-research-faq.cfm.

Institutional Animal Care and Use Committee considers the justification for using the species and quantity, the rationale and purpose of the animals' use, the availability or appropriateness of alternative procedures, and several other factors.[9] Additionally, the local Research and Development Committee reviews the study for scientific merit and compatibility with VA's mission of serving veterans.[10]

Once the research protocol is approved locally, the study and necessary supporting documents are submitted to the central Office of the Chief Veterinary Medical Officer, which performs a secondary review of the study.[11] This review determines whether the research is needed, why using canines is necessary, if the canines will be well cared for, and how potential pain and distress will be minimized. The chief research and development officer then reviews and approves the canine research protocol.[12]

After the local review, the Office of the Chief Veterinary Medical Officer secondary review, and the chief research and development officer approval, the canine research study is submitted for review and approval through successive layers of VHA senior leaders. This includes the VA National Center for Ethics in Health Care; the deputy under secretary for discovery, education, and affiliate networks; and the under secretary for health.[13] After all other reviews have been completed and the research is approved, the VA Secretary must directly approve the study before it can begin.

Figure 1 summarizes the approval process for research studies involving canines.

[9] VHA Handbook 1200.07, *Use of Animals in Research*, sec. 8(f)(2), 8(f)(2)(a), November 23, 2011. Other factors considered by the Institutional Animal Care and Use Committee include the care of the animals, the minimization of pain and distress, the conduct of multiple major operative procedures, the limiting of unnecessary duplication of experiments, the adequacy of training and experience of research personnel, and the safety of the working environment for the research personnel.

[10] VHA Directive 1200.01, *Research and Development Committee,* sec. 12, January 24, 2019.

[11] Appendix A provides additional background information on the Office of the Chief Veterinary Medical Officer.

[12] As of March 2020, Dr. Rachel Ramoni serves as the chief research and development officer.

[13] Also as of March 2020, Dr. Carolyn Clancy is the deputy under secretary for discovery, education, and affiliate networks. The position of under secretary for health is vacant. Dr. Richard Stone serves as the executive in charge for the Veterans Health Administration.

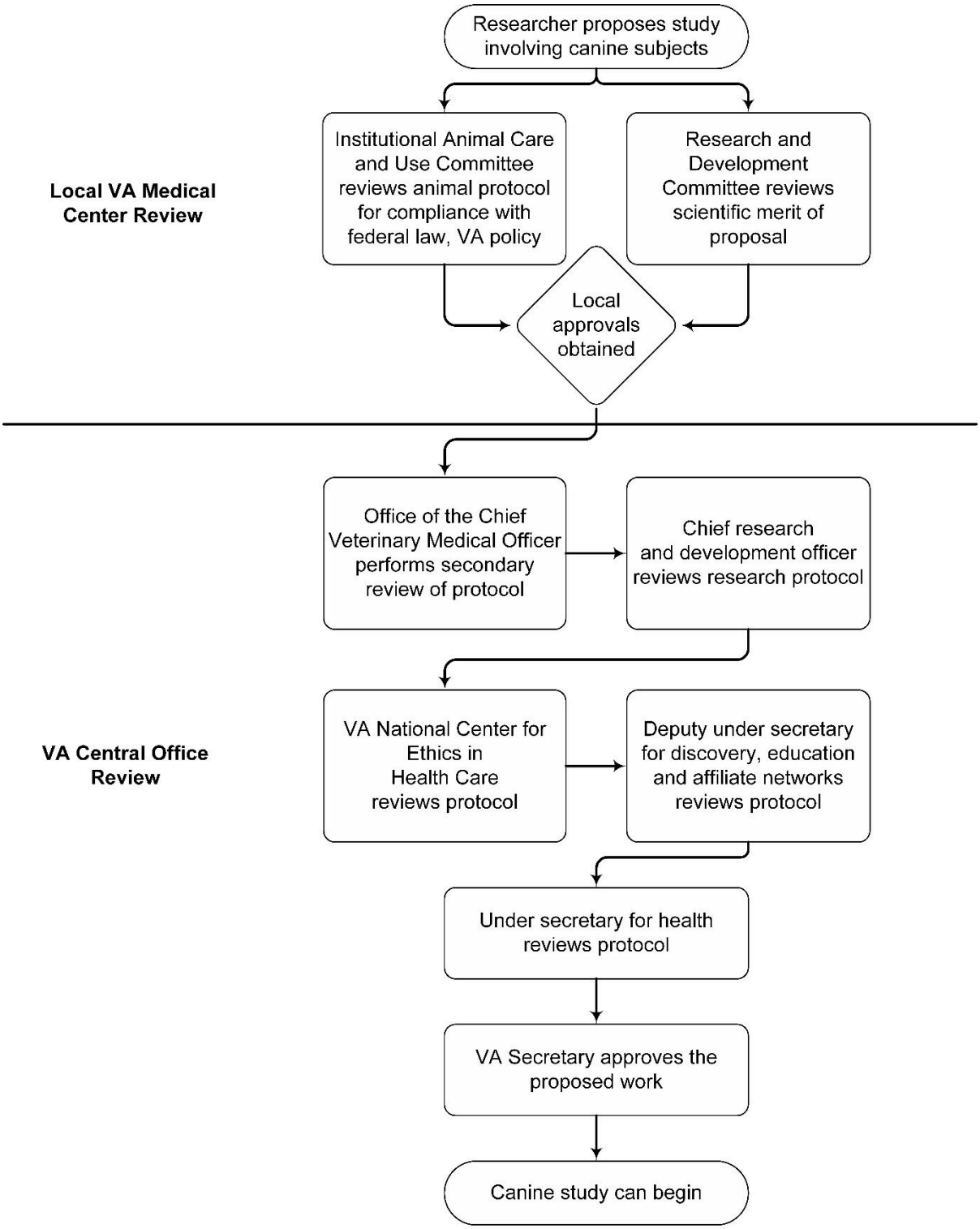

Figure 1. *VHA approval process for canine research.*
Source: VA canine research documents submitted to the National Academies, November 28, 2018
Note: The flowchart only depicts approval by the VA Secretary since VHA policy does not define the process in the event the Secretary denies approval of a study.

External Reviews of VHA's Research Studies Involving Canines

VHA's medical research involving canines has recently been reviewed by two external organizations—the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) and the National Academies of Sciences, Engineering, and Medicine. In January 2019, OLAW reported that the four VHA research facilities it visited complied with OLAW and National Academies guidance.[14] OLAW reported no animal welfare concerns and found that the local Institutional Animal Care and Use Committees were properly set up, engaged, and provided records of comprehensive oversight. OLAW concluded that the four facilities were humanely providing animal care and conducting research in compliance with policy, applicable rules, and regulations.

The National Academies assessment, published in July 2020, focused on the care and use of canines in biomedical research funded by VA or performed in VA facilities. The assessment concluded that VA's canine research program appeared to adhere to all relevant policies surrounding animal research. Additionally, canines remained scientifically necessary in certain areas of active VA biomedical research. The assessment said it was not able to fully evaluate the scientific review process for animal research protocols based on the documents provided by VA. However, it did provide conclusions and make recommendations related to (1) the justification for using canines instead of other species, (2) the relevance of the study to veterans' health, and (3) the examination of alternative models. The OIG examined the external reviews of VHA's canine research studies for background purposes only and did not evaluate or make conclusions on the need for research using canine subjects.

[14] The VA facilities visited were in Richmond, Virginia; Los Angeles, California; Milwaukee, Wisconsin; and Cleveland, Ohio.

Results and Recommendations

Finding 1: VHA Conducted Canine Research Studies without Obtaining Required VA Secretary Approvals, Resulting in Unauthorized Use of Appropriated Funds

The five members of Congress asked the OIG to review whether the VA Secretary directly approved research studies involving canines in accordance with applicable FY 2018 and FY 2019 appropriations laws. The OIG found that VHA conducted eight studies without the Secretary's direct approval. These included seven that were conducted between March 28 and November 1, 2018, and one study conducted between February 4 and April 18, 2019.[15] The eight studies continued for an average of 206 days before ORD obtained the required approval from Secretary Robert Wilkie.[16] Each research study was routed through the required local and secondary approval processes but lacked final approval by the VA Secretary.[17] This resulted in VA researchers at four VA medical facilities conducting studies on 51 canines and the unauthorized use of appropriated funds totaling $393,606.[18]

What the OIG Did

To determine whether the VA Secretaries had approved canine research in accordance with the two governing laws, the OIG interviewed attendees from a March 28, 2018, meeting with then Secretary Shulkin.[19] The review team also interviewed attendees from a November 6, 2018, meeting with Secretary Wilkie, as well as other officials involved with the canine research program. Additionally, the OIG reviewed a meeting summary prepared for the November 6, 2018, meeting. Finally, the OIG reviewed email correspondence, approval memos, legal opinions by the Office of General Counsel, and applicable guidance.[20]

To obtain statistics on VA research studies using canine subjects conducted between March 28 and November 1, 2018, the review team acquired information from local facilities with custody

[15] One study at the VA St. Louis Health Care System was conducted between February 4 and April 18, 2019. While this study occurred outside the date range requested by the members of Congress, VHA disclosed the ongoing work to the OIG review team during the project.

[16] The total elapsed period of noncompliance ranged from 71 to 228 calendar days. Table 1 details this information for each of the eight studies.

[17] Secondary approval refers to the review conducted by the Office of the Chief Veterinary Medical Officer.

[18] All dollar figures in this report have been rounded.

[19] The Consolidated Appropriations Act of 2018 and the Energy and Water, Legislative Branch, and Military Construction and Veterans Affairs Appropriations Act of 2019 both contain language requiring the VA Secretary to approve research using canines.

[20] Appendix B includes additional information about the review work conducted to answer the congressional questions. Appendix D provides a timeline of significant events related to the issues discussed in this finding.

of these records. The team identified direct project costs by reviewing source documents, such as purchase orders and invoices, as well as records from a VA-affiliated research and education nonprofit corporation. The review team used this information to compile summary data for its review. The team cannot, however, provide assurances that local VA medical facility research services and their affiliated nonprofit corporation have recorded and presented related expenditure information in a complete and uniform manner.

VHA Continued Canine Research Studies in FY 2018 without the Required Approval by VA Secretary Shulkin

Increasing public scrutiny of VA's use of canine research and a reported high volume of email to then VA Secretary Shulkin alleging inhumane treatment of canines caught his attention in January and March 2018 in particular. In a March 7, 2018, email to VA officials, Secretary Shulkin said he was "not in favor of this research" and began discussions with VHA leaders concerning potential steps to reduce VA's use of canine subjects. A March 13, 2018, press release approved by Secretary Shulkin and VHA leaders said ORD would initiate a rapid, in-depth review of existing canine research projects. The review would include determining whether the use of canines should be phased out in advance of the studies' original end dates and asking researchers to develop plans to establish alternative subjects for the studies.

ORD reviewed 13 canine research studies. Four of the studies had ended or were discontinued before passage of the Consolidated Appropriations Act of 2018. The nine remaining projects were determined to be scientifically important and required the use of canines to meet their objectives. ORD summarized the studies in a briefing document for Secretary Shulkin and outlined two program-level options for his consideration.

Option 1: Limit dog research to that allowed in the Omnibus. Contribute to the overall reduction of dog research beyond the VA.	**Option 2:** Intentionally phase out all dog research on VA premises and all VA funding of dog research within a specified time.

Figure 2. *Research options presented to Secretary Shulkin.*
Source: Excerpt from ORD's "Summary of VA Dog Research Protocols as of March 2018."
Note: "Omnibus" refers to the Consolidated Appropriations Act of 2018.

The ORD briefing document did not explicitly recommend either option. However, it did recommend continuing the nine existing studies that used canine subjects that met criteria for importance and necessity. The chief research and development officer presented the briefing document at the March 28, 2018, meeting with then Secretary Shulkin.[21] The briefing document cited the Consolidated Appropriations Act of 2018 requirement for VA Secretary approval;

[21] The meeting was attended by Dr. Shulkin, then VHA executive in charge Dr. Carolyn Clancy, then VHA acting chief of staff Ms. Lisa Pape, then acting deputy under secretary for health for policy and services Dr. Lucille Beck, and VA chief research and development officer Dr. Rachel Ramoni.

however, it did not indicate that VHA leaders were specifically requesting Secretary Shulkin to review and approve decisions on any specific canine research projects.

VHA Asserted Project Approvals Were Obtained from Secretary Shulkin but Lacked Clear Evidence Supporting that Position

VHA claimed in numerous emails and documents that former Secretary Shulkin had approved each study continuing after the Consolidated Appropriations Act of 2018 was passed. This material was later provided to the Office of the Secretary. In response to an inquiry, Secretary Wilkie told congressional representatives in September 2018 that nine ongoing research studies "were approved for continuation by then-Secretary David Shulkin on March 28, 2018." Additionally, VHA records indicate that research continued for seven of those studies after that meeting. However, in a November 1, 2018, media report, Dr. Shulkin denied approving the continuation of specific canine studies before his departure.[22]

The OIG's thorough review of the available evidence did not confirm VHA's contention that then Secretary Shulkin had directly approved continuing with specific studies in the March 28, 2018, meeting. No memo or other record was created to document any approval action by the Secretary. Email records for the executives who attended the March 28 meeting also did not corroborate the Secretary's approval for the several months following that meeting. The only related correspondence was an email that day from the chief veterinary medical officer, who did not attend the meeting, to the VA Puget Sound Health Care System indicating that Secretary Shulkin had approved the continuation of canine research. The VA Puget Sound Health Care System, however, did not have a research study that used canine subjects, and the email did not indicate if any specific studies had been approved.

Dr. Shulkin, in responses provided through his attorney, confirmed to the OIG that he met with VHA executives "around" the day he left his position to discuss canine research projects.[23] He said he did not recall being asked to approve any research projects at that meeting and was in "listening mode." He also said the chief research and development officer said she planned to phase out certain research projects.

Email records related to October 2018 media inquiries to VA about continued use of canines in research also do not consistently support that Dr. Shulkin approved the studies. In response to the media inquiries, the then VA press secretary and the chief veterinary medical officer asked four

[22] Dr. Shulkin's final day as VA Secretary was March 28, 2018. His statement appeared in an article: Donovan Slack, "VA: Fatal dog experiments moving ahead despite criticism from Congress, veterans groups," *USA Today*, November 1, 2018, https://www.usatoday.com/story/news/politics/2018/11/01/veterans-affairs-fatal-dog-research-paralysis/1826889002/.

[23] The OIG review team submitted written questions to Dr. Shulkin. His personal counsel provided responses to those questions directly to the counselor to the inspector general. Those responses represent Dr. Shulkin's recollection about the issues in question.

senior VHA executives who attended the meeting to review and concur with draft answers to questions submitted by a reporter. The draft language asserted Dr. Shulkin's statement that he did not review or approve the ongoing canine studies was "false" and noted that the four VHA executives had witnessed the approval. Emails from the VHA executives did not provide consistent support—two of the executives concurred with the draft responses without offering any clarification, while the other two did not confirm they witnessed such approvals. Dr. Rachel Ramoni said the response "align[ed] with my recollection of the meeting" and Dr. Carolyn Clancy agreed.

In contrast, Ms. Lisa Pape stated

> I'm not totally comfortable with that […] response. He did delegate the reviews and he didn't approve anything new […] VHA did, in fact do the review of the nine studies. There were no new studies approved.[24]

Dr. Lucille Beck agreed with Ms. Pape's recollection. Despite the varying replies, VA's formal response said then Secretary Shulkin had approved the nine studies in question. However, due to the inconsistencies in these email responses, the review team concluded that these records did not corroborate Dr. Shulkin's approval of the research studies.

During interviews with the OIG review team in June 2019, the same VHA executives were unanimous in stating that Dr. Shulkin had not supported an eventual ban on canine research as outlined in option 2 of the briefing document. However, none of the VHA executives recalled asking for or witnessing Dr. Shulkin's direct approval of specific canine research studies.

The executives also told the review team they believed that Dr. Shulkin's support of canine research also provided implicit approval to continue the VHA-recommended studies presented in the briefing document. However, none of the executives indicated that Dr. Shulkin provided direct approval of the studies. For example, Dr. Ramoni told the review team

> I left the meeting with the understanding that […] we elected not to go with option two, mainly phasing out the research, but we were going with option one and […] had approval to continue the […] remaining existing studies.

Additionally, Dr. Clancy stated

> I do not recall that the question was called explicitly, as in, 'Dr. Shulkin, are you good with this?' […] My impression was that he was on board. He was nodding. He is someone who generally would let you know if he was not on board.

[24] According to the media inquiries, Dr. Shulkin stated that he delegated to VHA the responsibility for conducting reviews of ongoing studies. Further, he was not asked nor did he request to review the ongoing studies. He only asked to approve new studies and did not approve any. VA's draft response disagreed with the media inquiry.

Further, Dr. Beck said

> Dr. Shulkin did not indicate that the studies should be canceled. […] There was an implicit approval whereby option one that was the preferred option for Dr. Shulkin that we should, and we will need to, continue to do canine research for […] some studies…

Lastly, Ms. Pape told the review team

> I don't specifically remember him verbally approving it, but I do think it was implied. Like, no one said not to continue.

VHA did not communicate with its facilities in a consistent manner regarding the Secretary's purported approvals to continue specific canine research studies. Some facilities said that ORD informed them of approval in the spring or summer of 2018. However, one facility leader said they assumed such approval had been granted after not hearing otherwise. Furthermore, the chief veterinary medical officer told the review team in June 2019 that he originally learned of the approval in a March 2018 email from the chief research and development officer. However, after the review team requested a copy of the email, the chief veterinary medical officer responded in August 2019 that he had been mistaken.

Noncompliance with Research Restrictions Continued in FY 2019

After the November 1, 2018, media report in which Dr. Shulkin denied approving the continuation of specific canine research studies while Secretary, the VA chief of staff asked VHA officials to brief Secretary Wilkie on the issue. At a meeting on November 6, 2018, Secretary Wilkie verbally approved continuing seven research studies that required canine subjects. His decision was documented in a meeting summary shortly thereafter.

However, an eighth research study at the VA St. Louis Health Care System in Missouri was accidentally omitted from the briefing package.[25] Despite lacking approval, VHA procured canines for the St. Louis study in February and March 2019. The facility also conducted three canine surgeries in March and April 2019 before ORD became aware of the lack of specific approval. Email records indicated that the administrative officer for the VA St. Louis Health Care System research service suspended the canine study on April 17, 2019. On June 25, 2019, Secretary Wilkie verbally approved the St. Louis study in a meeting attended by the chief research and development officer, the chief veterinary medical officer, and others. The approval was recorded in a meeting summary document.

[25] The ninth study from the March 28, 2018, briefing document was to be conducted in three phases with only the third phase using canine subjects. Before the third phase began, ORD approved in August 2018 the researcher's request to remove the canine component.

As a result of continuing or beginning new canine research before obtaining approval from the VA Secretary, VHA conducted a total of eight studies, including the St. Louis study, that were not in compliance with the law for an average of 206 days. Table 1 outlines how long each study was noncompliant, in elapsed days.

Table 1. Elapsed Days of Canine Research Studies' Noncompliance with Funding Restrictions

Location	Effective date of approval requirement	Date closed or approved	Elapsed days
Cleveland, OH	March 23, 2018	November 6, 2018	228
Milwaukee, WI	March 23, 2018	November 6, 2018	228
Richmond, VA	March 23, 2018	October 16, 2018*	207
Richmond, VA	March 23, 2018	November 6, 2018	228
Richmond, VA	March 23, 2018	November 6, 2018	228
Richmond, VA	March 23, 2018	November 6, 2018	228
Richmond, VA	March 23, 2018	November 6, 2018	228
St. Louis, MO	February 5, 2019†	June 25, 2019	71‡
Average			**206**

Source: OIG analysis of the meeting summary for November 6, 2018, email documentation, the protocol closure memo, and canine acquisition records.
** This study was closed on October 16, 2018, before Secretary Wilkie's November 6, 2018, approval.*
† Before February 5, 2019, the St. Louis VAMC study was not conducting research using canine subjects. This date is used for the calculation because it was when canines were first purchased for research.
‡ The St. Louis study was suspended on April 17, 2019, until the Secretary's approval could be obtained on June 25, 2019. The elapsed days were adjusted to remove the time the project was suspended.

VHA Did Not Have a Standard Process to Obtain and Document the VA Secretary's Approval of Research Involving Canines

Delayed compliance with applicable funding restrictions occurred, in part, because ORD officials had not established sufficient procedures and documentation requirements for ensuring the VA Secretary's approval was obtained for studies involving canines. Although the two governing laws do not dictate a process for gaining and documenting approval, VA policy requires the chief research and development officer and chief veterinary medical officer to provide guidance and support to ensure animal research complies with applicable federal laws.[26]

[26] VHA Directive 1200, *Research and Development Program*, May 13, 2016; VHA Handbook 1200.07.

In December 2017, VHA began implementing requirements for central office review of canine research, including approval by the Secretary for new projects involving canine subjects. The Consolidated Appropriations Act of 2018 specifically referenced this policy document. However, the specific requirement for the Secretary's approval was not incorporated into formal guidance until May 2018.[27] Additionally, despite the approval provisions of the appropriations acts in 2018 and 2019, as of June 2019, VHA had not established standard procedures for obtaining and recording the Secretary's approval for new or ongoing studies involving canine subjects.

Developments during the OIG review underscored VHA's need for standard procedures for obtaining and documenting the Secretary's approvals for canine research. In February 2019, VHA requested a legal opinion from the Office of General Counsel about the congressional questions presented to the OIG for this review. In its August 23, 2019, response the Office of General Counsel stated in part that

> While there is no requirement for ***written*** Secretarial approval, or for reapproval of such projects, we nevertheless recommend he sign a Determination & Findings (D&F) decision document for each new canine research project, and for any existing canine research projects lacking written Secretarial approval. Doing so would provide clarity as to whether a particular study was approved and when. Given the clear intent of Congress regarding Secretarial approval of these research projects, VA must be able to document compliance with this requirement.

The delayed approval of the VA St. Louis Health Care System canine research study underscores the importance of a robust system of internal controls with documented and verifiable approvals. The chief veterinary medical officer told the OIG that the accidental omission of the St. Louis research study was discovered because a VA-affiliated researcher had pulled him aside at a meeting for laboratory animal veterinarians to inform him that canine studies were currently active at that facility. If not for the contact, the St. Louis study might have continued in violation of the law without ORD's awareness. As part of its remediation plan after discovering the omitted project, ORD reported that it would

- Maintain a master table of approved canine projects on the VA internet site,
- Send a quarterly email from the Office of the Chief Veterinary Medical Officer to all VA animal research programs to remind them that only the canine studies on the VA internet site have approval to continue, and

[27] VHA ORD Guidance Document AR2017-001 (rev. 1), *Canine, Feline and Non-Human Primate Research Protocols*, May 3, 2018.

- Copy all members of the Office of the Chief Veterinary Medical Officer on the quarterly correspondence related to canine project approvals.

As another example of internal control weaknesses, VHA asked Secretary Wilkie to sign an August 9, 2019, memorandum confirming he provided verbal approval of canine research projects.[28] However, that memo did not accurately summarize VHA's canine research studies. For example, the list failed to include a study at the Richmond VAMC that Secretary Wilkie had approved verbally on November 6, 2018. Moreover, the list unnecessarily included a study at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin, that Secretary Wilkie had approved in writing on May 31, 2019, thus needlessly submitting it for approval a second time.

VHA Inappropriately Used FY 2018 and 2019 Appropriated Funds to Conduct Canine Research before Securing Needed Approvals

The absence of sufficient procedures and documentation requirements for the VA Secretary's approvals resulted in the unauthorized use of appropriated funds. Based on invoices and other documents maintained by local researchers, the review team determined that three VA medical facilities incurred expenses related to canine research between March 28 and November 1, 2018.[29] Research expenses totaled $405,562, of which at least $360,749 was funded by VA and $44,814 was funded by outside sources such as the National Institutes of Health and the American Heart Association, as shown in table 2.

Table 2. Canine Research Expenditures between March 28 and November 1, 2018

Location	Number of studies	VA-appropriated funds*	Outside sources of funding†	Total expenses
Cleveland, OH	1	$147,996	$0	$147,996
Milwaukee, WI	1	$182,322	$0	$182,322
Richmond, VA‡	5	$30,431	$44,814	$75,245
Total	**7**	**$360,749**	**$44,814**	**$405,562**

Source: OIG analysis of invoices, charge reports, and other expense documentation.
Note: Values are rounded so numbers may not sum to totals.
** These amounts include salary and benefits for VA researchers (temporary and permanent), staff detailed to VA via intergovernmental personnel agreement, canine acquisitions, and other program support expenses such as per diem charges.*

[28] Secretary Wilkie signed the memorandum on August 30, 2019.

[29] Appendix C provides details on the seven ongoing studies during that period. The date range used for this analysis was specifically requested by the five members of Congress.

† The amount of funding from outside sources was included for completeness. However, this figure was not included in the review team's calculation of total appropriated funds used for canine research.
‡ While the Richmond VAMC's canine studies were partially funded by non-VA sources, the researchers were paid VA salaries for their work and received no additional grant funds.

Additionally, according to local records, VHA acquired 42 canine subjects and conducted experiments on 48 total canine subjects between March 28 and November 1, 2018. Table 3 summarizes VHA's use of canine research subjects.

Table 3. Canine Acquisition and Usage between March 28 and November 1, 2018

Location	Number of studies	Funding source	Canine acquisition expenses*	Canines acquired†	Canines studied
Cleveland, OH	1	VA	$15,781	9	8
Milwaukee, WI	1	VA	$566‡	19	19
Richmond, VA	5	Non-VA	$26,511	14	21
Total	**7**		**$42,858**	**42**	**48**

Source: OIG analysis of invoices, canine health records, and disposition documentation.
** Including the cost of the canines, transportation, and health certificates.*
† Canines purchased by or donated to VA that were in VA's possession between March 28 and November 1, 2018.
‡ A private-sector company donated canines to the Milwaukee VAMC, but the facility spent $566 for animal handling and transportation.

In addition to resources used to support the seven studies active throughout FY 2018, VHA spent at least $32,858 conducting research using three canines at the VA St. Louis Health Care System in 2019 before obtaining the Secretary's approval in June 2019.[30] When accounting for this instance, the review team found that VA researchers at four VA medical facilities conducted studies on 51 canines and the unauthorized use of appropriated funds totaled $393,606.

The review team was not able to identify all VA appropriations used to support the studies due to limitations in VHA's tracking of research costs. Instead, the review team relied on documentation and responses provided by local facility staff. The review team's analysis only included direct project costs, not indirect costs such as expenses related to electricity, water, sewer, and other overhead. VHA needs to review its accounting records to determine the amount spent for these studies before their approvals by the VA Secretary and to ensure VHA takes appropriate action to address the unauthorized use of appropriated funds.

[30] The St. Louis study occurred outside the date range requested by the members of Congress. However, because the facility purchased canines and conducted research, the review team included the information for completeness.

Finding 1 Conclusion

From March 2018 through April 2019, VHA conducted eight studies using canine subjects without first obtaining and documenting the VA Secretary's direct approval. This occurred due to several factors, including unclear communications, inadequate recordkeeping, and no standard operating procedures that were adequate to ensure approval decisions would be accurately recorded and verified before continuing or beginning such studies. As a result, VA used $393,606 in appropriated funds for unauthorized purposes. Providing unsupported and potentially inaccurate information on research using canines could undermine the public's trust in VA and unnecessarily detract attention from one of VHA's important statutory missions—supporting a wide range of authorized research concerning veterans' health issues.

In the absence of improved internal controls and documented, verifiable approval procedures, VHA remains at risk of similar omissions or violations of law that fail to safeguard and ensure proper use of appropriated funds. Moreover, the legislation related to VA's canine research was enacted because of concern about proper oversight and controls regarding the need and implementation of studies involving canines. Failing to ensure study approvals are properly obtained and documented undermines congressional intent and is unresponsive to the public's concerns. Until consistent and controlled measures are fully implemented, Congress, the public, and VHA research staff lack assurances that canine research at VA complies with the law. There can also be no confidence that research on canines is limited to necessary studies of scientific importance that cannot be otherwise conducted for advancing human healthcare.

Recommendations 1–5

The OIG made the following recommendations to the under secretary for health:[31]

1. Establish a formal process for requesting and obtaining the approval of the VA Secretary for research studies that use canine subjects to comply with applicable restrictions on the use of appropriated funds.
2. Develop and implement processes for documenting and maintaining records of the VA Secretary's approval of canine research studies, including the study at the Richmond VA medical center that was not included in the Secretary's August 30, 2019, approval document.
3. Establish controls for ensuring appropriated funds are not spent for canine research studies before obtaining the VA Secretary's approval.
4. Review local accounting records and cost allocations to determine the total amount of fiscal years 2018 and 2019 funds spent on canine research before the VA Secretary

[31] Recommendations directed to the under secretary for health were submitted to the executive in charge, who has the authority to perform the functions and duties of the under secretary for health.

approved the studies and report this information to the House and Senate appropriations committees.

5. Work with the VA Secretary and the chief financial officer to take the steps required by OMB Circular A-11 to determine whether an Antideficiency Act violation occurred and, if so, take appropriate action for the funds obligated and expended for research studies involving canine subjects.

Management Comments

The executive in charge, Office of the Under Secretary for Health, concurred with the OIG's recommendations. The executive in charge acknowledged a lapse in formal documentation of the direct approval for ongoing canine research studies by Dr. Shulkin at the March 28, 2018, meeting with senior VA executives. However, the executive in charge stated that VHA stands behind its position that Dr. Shulkin provided verbal approval at that meeting. He also said VHA had no intent to circumvent the act's requirements or mislead Congress.

For recommendation 1, the executive in charge said a formal process had been in place since mid-2018 to submit requests for approval through established VHA and VA concurrence channels as evidenced by the documentation of the VA Secretary's approval in November 2018. The process was revised periodically, most recently in May 2020. Further, the last new canine study was approved by the VA Secretary on May 24, 2019, and the approval was documented in writing. The executive in charge stated that VHA will provide supporting documentation that describes the internal ORD concurrence process and requested closure of the recommendation.

For recommendation 2, the executive in charge said ORD maintains a single master reference list as documentation of the VA Secretary's approved canine studies on its animal research website. Further, the executive in charge said all stakeholders can refer to that master web table to determine which studies currently have approval across the agency. Regarding the Richmond VAMC canine study, the executive in charge said the Office of the Chief Veterinary Medical Officer was informed in January 2019 that the protocol was closed on September 6, 2018. Based on that information, ORD purposely removed the Richmond VAMC study from the list of studies submitted for the VA Secretary's signature in August 2019 in the interest of maintaining accurate and up-to-date approval and records. The executive in charge stated that VHA will provide supporting documentation and requested closure of the recommendation.

For recommendation 3, the executive in charge said the requirement for the VA Secretary's approval prior to spending VA funds has been added to the process for studies involving canine research. The executive in charge also said notification was sent to all VA animal research programs in May 2020 to reemphasize the need to obtain the Secretary's approval before initiating any canine studies. Further, key research administrators were reminded that no requests for VA-funded expenditures can be approved unless directly related to canine studies with

documented secretarial approval. The executive in charge said VHA will provide documentation to support completion of these actions and requested closure of the recommendation.

For recommendations 4 and 5, the executive in charge said an on-site review of financial records will be conducted to determine the amount of VA funds spent on canine research. That information will be provided to Congress. Further, the executive in charge said the VHA chief financial officer and the VA Secretary will be consulted once on-site review data are available.

The executive in charge also provided a technical comment related to the OIG's inclusion of salary and benefits for VA employees in the calculation of canine research expenditures. The executive in charge said expenses for animal care staff, Institutional Animal Care and Use Committee support staff, and veterinarians should not be included because those costs are reflected in per diem charges paid by the researchers, which were not referenced in the report. The executive in charge asserted that the cost of canine research appeared to be inflated. Appendix E provides the full text of the executive in charge's comments.

OIG Response

The executive in charge's corrective action plans were generally responsive to the intent of the recommendations. However, the OIG was not provided sufficient evidence to support that actions detailed in responses for recommendations 1, 2, and 3 were completed. As a result, the OIG could not verify and assess the corrective actions. Additional action is also needed to demonstrate the extent to which VHA met the full intent of recommendation 2, which is detailed on the following pages. The OIG will close these recommendations when VHA provides sufficient and appropriate evidence demonstrating the stated actions are complete. For recommendations 4 and 5, the OIG will monitor implementation of planned actions and close each recommendation when VHA provides sufficient evidence demonstrating those actions are complete.

The OIG has several clarifications concerning the executive in charge's comments relating to former Secretary Shulkin's approval and to recommendations 1 and 2. As indicated on page 9 of this report, the four senior VHA executives told the review team in June 2019 that they did not recall asking for or witnessing Dr. Shulkin's direct approval of specific canine research studies. Additionally, the executives told the review team they believe Dr. Shulkin's support of canine research provided implicit approval to continue VHA-recommended studies. Neither of these positions by the four senior VHA executives who attended the March 28, 2018, meeting supports that Dr. Shulkin provided "verbal approval."

For recommendation 1, as indicated on page 12 of this report, the review team found that VHA did not have a formal process in place for requesting and obtaining the Secretary's approval for these research studies. In response to a documentation request, the Office of the Chief Veterinary Medical Officer provided ORD's May 2018 guidance document. This document did not specify the process for requesting and obtaining the Secretary's approval and instead only stated that "no

new canine research may begin until reviewed and approved by the VA Secretary." Similar language remains in the April 2020 revision of the document posted on ORD's public website; however, that revision does specify that written VA Secretary approval must be obtained.

Further, the varying methods used to record the VA Secretary's approval since November 2018 do not support that a consistent process is in place. As indicated on page 10 of this report, Secretary Wilkie's November 2018 verbal approval was documented in a post-meeting summary. Also, the Secretary's verbal approval for the St. Louis VAMC study was recorded in a similar document. Differently, as indicated on page 13 of this report, Secretary Wilkie signed official memos indicating his approval on separate occasions in May and August 2019.

VHA included as part of its response to the OIG a May 2020 revision to the ORD standard operating procedure "Process to Complete Decision Actions on NHP [Nonhuman Primates], Cat, and Dog Applications." The review team assessed this new information and found that it discusses a process internal to VHA but does not include higher-level reviews. Consequently, the review team concluded that the revised version does not establish sufficient procedures or documentation requirements for ensuring the VA Secretary's approval.

For recommendation 2, as indicated on page 12 of this report, the VA Office of General Counsel recommended in its August 23, 2019, legal opinion that the Secretary sign a "Determination & Findings" decision document for each new canine research project and for any existing projects lacking written secretarial approval. As such, the intent of the OIG's recommendation is for VHA to establish processes to both memorialize and maintain the VA Secretary's approvals of canine research studies.

The executive in charge said the Office of the Chief Veterinary Medical Officer purposely removed the Richmond VAMC study because the office was informed in January 2019 that the study had closed on September 6, 2018. However, ORD requested and obtained Secretary Wilkie's verbal approval for this study on November 6, 2018. The OIG holds that, given the Office of General Counsel's opinion and the Richmond study's inclusion in that request, it should have been included in the formal August 30, 2019, approval document.

Additionally, ORD's maintenance of a master reference list of studies with current approval only partially addresses this issue. VHA should implement processes to document and maintain records of the VA Secretary's approval of canine research studies since the March 23, 2018, enactment of the Consolidated Appropriations Act of 2018, to include the Richmond VAMC study.

Finally, the OIG reviewed VHA's technical comment and noted that the description of expenses using VA-appropriated funds for table 2 on pages 13 and 14 could be refined. The review team's methodology considered any cost incurred using VA-appropriated funds within the project scope that could be attributed to a given study. Those costs included

1. Salary and benefits for permanent or term-limited VA researchers assigned to a study;

2. Reimbursements for staff detailed to VA from an academic institution via intergovernmental personnel agreement;
3. Costs of canine acquisitions including items such as shipping costs, health certificates, and transportation; and
4. Other support expenses such as supplies and per diem charges.

To improve the clarity of the costs presented, the review team updated the descriptive note following table 2 to more precisely define the items included in the calculation of canine research expenses using VA-appropriated funds.

Finding 2: The Cleveland VA Medical Center Purchased Canines in the Absence of Mandatory VA Secretary Approval

While finding 1 addressed the first two congressional questions, this finding addresses the third congressional request that the OIG review purchases of canines for a research study at the Cleveland VAMC and determine if the facility initiated acquisitions before the former VA Secretary's approval. The OIG identified one procurement action that purchased 21 canines for the Cleveland VAMC after the Consolidated Appropriations Act of 2018 was passed. The contract for canine purchases was signed by the contracting officer and the supplier on April 23, 2018. As addressed in finding 1, the OIG did not find sufficient evidence that the sitting VA Secretary approved canine research studies, including the Cleveland VAMC protocol, until November 6, 2018. As a result, this purchase of canines was considered an unauthorized use of FY 2018 appropriations.

What the OIG Did

To determine whether the Cleveland VAMC canine purchases were initiated before mandatory Secretary approval, the review team obtained contract documentation for canine purchases supporting the research study and reviewed email correspondence. Additionally, the review team conducted a site visit to the Cleveland VAMC in May 2019; interviewed key officials; and collected and reviewed guidance documentation, invoices, approval memos, and the costs associated with the canine research study.

One Ongoing Cleveland VAMC Research Study Involved Canine Purchases

The Cleveland VAMC had an ongoing research study that used canine subjects. Initially proposed in April 2013, the *High Frequency Spinal Cord Stimulation to Restore Cough* study was approved to start on July 1, 2014. In general terms, the study's purpose was to test a device that was being refined to aid patients with spinal cord injuries who lack an effective cough mechanism due to muscle paralysis. The protocol stated that canines were necessary subjects because their spinal cord is similar in size and composition to those of humans.

The local Institutional Animal Care and Use Committee conducted annual reviews and reapproved the study each year from 2015 through 2018. From the start of FY 2017 through April 2018, the Network Contracting Office 10 awarded six contracts supporting the study, totaling 42 canine subjects. The Cleveland VAMC canine research study was closed on October 11, 2019.

Table 4 represents the quantities, costs, and award dates for each of the six Cleveland VAMC contracts that procured canines for research.

Table 4. Cleveland VAMC Canine Contracts from January 2017 through April 2018

Contract	Award date	Quantity	Total awarded cost
1	January 13, 2017	4	$6,264
2	March 3, 2017	3	$3,480
3	May 26, 2017	4	$7,800
4	July 28, 2017	4	$7,476
5	January 5, 2018	6	$13,038
6	April 23, 2018	21	$42,722

Source: Cleveland VAMC contract files.

One Canine Purchase Occurred After VA Secretary Approval Was Required by Law

The review team found that Network Contracting Office 10 awarded five of the six contracts to obtain canines for the Cleveland VAMC research study between January 13, 2017, and January 5, 2018. The resulting purchases acquired 21 canine subjects at a total cost of $38,058 from two contractors. Since these contracts were awarded and funded before the enactment of the Consolidated Appropriations Act of 2018 on March 23, 2018, the research study was not subject to the mandatory VA Secretary approval.

In contrast, on April 3, 2018, a new procurement was initiated to order canines for the Cleveland VAMC research study. Network Contracting Office 10 later awarded a supplier a $42,722 contract to deliver 21 canines. The document was signed by both the contractor and the contracting officer on April 23, 2018. The contract was broken out into seven "shipments," with three canines in each. The dates ranged from June 2018 through April 2019.

The contract's price and cost schedule indicated that FY 2018 and FY 2019 appropriated funds would be used for purchasing the canines. The applicable Consolidated Appropriations Act of 2018 required direct VA Secretary approval before funds could be used to conduct canine research. However, as discussed in finding 1, the review team did not find sufficient evidence to support VHA's assertion that then Secretary Shulkin directly approved the canine research studies, including Cleveland's, as required. The Cleveland VAMC protocol was eventually approved by Secretary Wilkie on November 6, 2018. However, due to the absence of approval before that date, the OIG concluded that the Cleveland VAMC's April 2018 purchase of canine research subjects did not comply with FY 2018 funding restrictions and was therefore an unauthorized use of appropriations.

The lack of clear evidence meant the review team could not determine whether the Cleveland VAMC relied on information from ORD about the approval status of the project when using appropriated funds for this purpose. Witness statements were vague on the issue and did not

corroborate the flow of information. Specifically, the Cleveland VAMC associate chief of staff for research told the review team he did not recall the specific time when he first learned of the reported approval. He said he was informed by telephone in the spring or summer of 2018 by the chief veterinary medical officer that the Secretary had approved the canine research protocol, but he did not create any written records and only discussed this with others verbally.

Finding 2 Conclusion

The OIG found that Network Contracting Office 10 awarded six contracts from the start of FY 2017 through April 2018 for the Cleveland VAMC to obtain canines for an ongoing research study. However, only one of those contract awards occurred after the law mandating VA Secretary approval took effect on March 23, 2018. The associated contract, dated April 23, 2018, purchased 21 canines using $42,722 of appropriated funds. As described in finding 1, the OIG did not find sufficient evidence that the VA Secretary approved canine research studies as required by law, including the Cleveland VAMC protocol, until November 6, 2018. Therefore, the Cleveland VAMC's April 2018 purchase of canine research subjects did not comply with FY 2018 funding restrictions and was an unauthorized use of appropriations. Recommendations 1–5 in finding 1 also address the causes of finding 2 and so are not repeated here.

Finding 3: One VA Medical Facility Used a Sole-Source Contract to Purchase Canines

The five members of Congress also asked the OIG to determine the extent to which VHA used sole-source contracts to purchase canines and the justifications for doing so (the fourth and final question). As addressed in finding 1, VHA acquired 42 canines for research between March 28 and November 1, 2018, supporting ongoing studies at three facilities.[32] The review team found that each location used a different method for obtaining those canines for research subjects. The Cleveland VAMC purchased canines for research using a sole-source contract on April 23, 2018. The Richmond VAMC obtained canines through its affiliated nonprofit corporation, and the Clement J. Zablocki VAMC in Milwaukee, Wisconsin, received canines donated by a private-sector company.

What the OIG Did

To determine whether any VA canine acquisitions between March 28 and November 1, 2018, employed sole-source contracts, the team reviewed contract files from the Electronic Contract Management System and obtained other supporting documentation, such as invoices, canine disposition forms, and email correspondence. To evaluate the justification for those procurements, the team reviewed the Federal Acquisition Regulation (FAR) to determine the requirements for sole-source contracting.

Methods Used to Acquire Canines for Research Studies

Network Contracting Office 10 awarded a $42,722 sole-source contract to a supplier on behalf of the Cleveland VAMC on April 23, 2018, for 21 canines.[33] The FAR states that, for purchases not exceeding the simplified acquisition threshold of $150,000, contracting officers may solicit from one source if they determine that the circumstances of the contract action deem only one source reasonably available.[34] The FAR further requires that the purchasing offices in such instances maintain documentation explaining the absence of competition.[35]

The review team found that the Cleveland VAMC sole-source contract was supported by the required documentation. The Justification for Single Source Award, signed by the contracting officer on April 17, 2018, cited specific requirements such as breed, age, and weight, as well as

[32] The five members of Congress asked the OIG to identify the number of canines purchased in the specific date range of March 28 to November 1, 2018. The St. Louis study identified in finding 1 acquired canines outside this date range and therefore was not included in this total. However, the review team verified that St. Louis did not use a sole-source contract for its acquisition.

[33] Finding 2 details the Cleveland VAMC's April 2018 purchase of canine research subjects.

[34] FAR 13.106-1(b).

[35] FAR 13.106-3(b) and (b)(3)(i).

specific delivery targets that could only be met by one company at that time. The document further indicated that market research had determined only one company had the canines available that met all the specifications required to have them available between June 2018 and April 2019.

The canines for the other facilities were not purchased by VA and were not subject to the FAR. The Richmond VAMC obtained canines from its affiliated nonprofit corporation.[36] The associated research studies were funded by non-VA organizations and administered through the nonprofit corporation. During the review period, Richmond VAMC's affiliated nonprofit corporation paid $3,292 for two canines from one supplier and $23,219 for 12 canines from another supplier.[37]

The third facility obtaining canines during the period—the Milwaukee VAMC—accepted an in-kind donation of canines from a private-sector company. The facility received 19 canines from April 9 through August 31, 2018. Even though the dogs were donated, the Milwaukee VAMC spent $566 for animal handling and van use to transport the canines to the facility. Table 5 summarizes the three facilities and their canine acquisitions.

Table 5. Facility Canine Acquisitions between March 28 and November 1, 2018

Facility	Acquisition method	Quantity	Total cost
Cleveland, OH	Contract	9	$15,781
Milwaukee, WI	Donation	19	$566
Richmond, VA	Nonprofit corporation	2	$3,292
Richmond, VA	Nonprofit corporation	12	$23,219
Total		**42**	**$42,858**

Source: OIG analysis of facility contract files, animal request and disposition forms, and invoices.
Note: Values are rounded.

Finding 3 Conclusion

The review team found that only the Cleveland VAMC used a sole-source contract to purchase canines for an ongoing research study in April 2018. That procurement contained the sole-source justification as required by the FAR. The two other facilities obtaining canines during the period

[36] Nonprofit corporations can accept funds from gifts, grants, contracts, agreements, fees, and other types from individuals and public and private entities and spend these funds on approved VA research and education activities. Unless as otherwise prescribed by the United States Code or under regulations by the VA Secretary, the nonprofit corporation is required to comply only with those federal laws, regulations, and executive orders and directives that apply generally to private nonprofit corporations.

[37] The amounts listed include the cost of the canines, transportation, and health certificates.

did so by purchasing them through their affiliated nonprofit corporation or accepting donations from a private-sector corporation. The OIG made no recommendations related to this finding.

Appendix A: Background

Office of Research and Development

ORD is responsible for developing research policies and for developing and implementing educational programs in support of VHA's research mission. It is also the primary VHA office responsible for allocating appropriated research funds. The chief research and development officer is the senior oversight official in ORD and is responsible for the overall policy planning, coordination, and direction of all human, animal, and laboratory research and development activities within VHA. Figure A.1. outlines the general ORD structure.

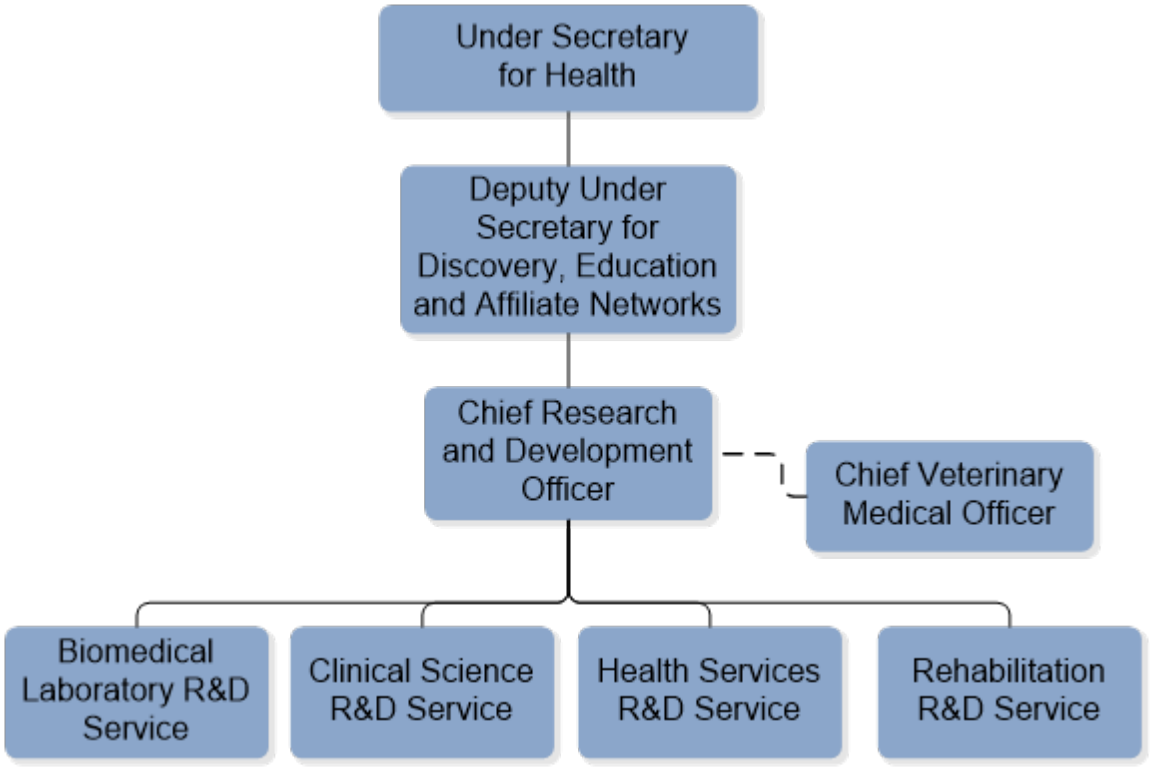

Figure A.1. *ORD organizational structure.*

Source: OIG analysis of organizational charts and program responsibilities.

ORD has four research services under the chief research and development officer's supervision. However, only the Biomedical Laboratory Research and Development Service and the Rehabilitation Research and Development Service conduct experiments that use canine subjects. Biomedical Laboratory Research and Development is focused on preclinical research to understand life processes at the molecular, genomic, and physiological level regarding diseases affecting veterans. This includes research on animals and human tissues, blood, or other specimens, but does not include studies with people. In contrast, Rehabilitation Research and

Development is focused on research to restore functional capacity to veterans who have become disabled due to injury or disease.

The Office of the Chief Veterinary Medical Officer also resides in ORD and is under the supervision of the chief research and development officer. The chief veterinary medical officer is primarily responsible for creating VHA animal research policy, advising senior VA officials on animal research issues, and providing support and guidance to field personnel.

Office of Research Oversight

The Office of Research Oversight, which reports to the under secretary for health by law, is the primary office responsible for overseeing the conduct of VHA research through periodic prospective and for-cause reviews and investigating alleged research misconduct.[38] It serves as the chief VHA research compliance and assurance office for coordinating with other federal departments and agencies, such as OLAW, the Food and Drug Administration, and the Department of Health and Human Services' Office of Research Integrity.

[38] Veterans Health Care, Capital Asset, and Business Improvement Act of 2003, Pub. L. No. 108-170, § 401 (2003).

Appendix B: Scope and Methodology

Scope

The OIG conducted its review work from March 2019 through April 2020. The OIG reviewed activities associated with VHA's canine research approval process from November 1, 2017, through August 30, 2019.

Methodology

To conduct this review, the review team identified and reviewed applicable laws, regulation, VHA policies, and operating procedures. The review team also interviewed and obtained relevant information from 23 VHA employees from the VA central office, Office of Research and Development, Office of Research Oversight, Network Contracting Office 10, and the Cleveland VAMC.

In addition, the review team reviewed canine disposition records, local and VA central office research study approvals, research protocols, contract files, veterinary medical records, invoices, and email correspondence. The team further reviewed the FY 2018 annual report from the Research and Development Information System. Finally, the review team performed a site visit at the Cleveland VAMC in May 2019. During the site visit, the review team interviewed managers and other staff regarding topics related to the review objective.

Data Reliability

The review team did not evaluate the reliability of computer-processed data or use VA's research data to support the findings or conclusions. The team used VA's cost data and reported background information without performing independent analysis or testing of their reliability. The team used the information to compile summary data for this review but is not providing assurance that local entities have recorded and presented their expenditure information in a complete and uniform manner.

Government Standards

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation.*

Appendix C: VA's Canine Research Studies

Table C.1. Studies Included in the March 28, 2018, Briefing Document to Former Secretary Shulkin

	Location	Study name	Funding source
1	Cleveland, OH	High Frequency Spinal Cord Stimulation to Restore Cough	VA
2	Los Angeles, CA	Glucose Sensing and Physiologic Insulin Delivery	Non-VA
3	Los Angeles, CA	What Causes Human Narcolepsy?	VA
4	Mather, CA	Development of Targeting Nanotherapeutics Against Bladder Cancer	VA
5	Milwaukee, WI	Neuropharmacology of Pontine Control of Breathing Frequency	VA
6	Milwaukee, WI	The Investigation of Novel Imaging Approaches to the Circle of Willis	Non-VA
7	Milwaukee, WI	Determining Organ Perfusion During Vascular Compromise	Non-VA
8	Richmond, VA	Mechanistic Insight of Premature Ventricular Contractions-Induced Cardiomyopathy	Non-VA
9	Richmond, VA	Nanoparticle Injection into Ganglionated Neural Plexi to Prevent Atrial Fibrillation	Non-VA
10	Richmond, VA	Autonomic Nerve Activity and Cardiac Arrhythmias	Non-VA
11	Richmond, VA	A Comparison of Canine Anesthetic Regimens to Optimize Hemodynamic Stability and Quality of Electrophysiologic Data Acquisition	Non-VA
12	Richmond, VA	Effect of Chronic Premature Ventricular Contractions on the Remodeled Ischemic Heart	Non-VA
13	St. Louis, MO	Contribution of Inflammation and Oxidative Stress in Pericardial Fluid to Postoperative Atrial Fibrillation after Cardiac Surgery	VA

Source: OIG analysis of documentation associated with studies noted.

Appendix D: Timeline of Significant Events Associated with VHA's Canine Research from December 2017 to August 2019

December 13, 2017	ORD notified VA researchers by email that all new studies using canine subjects would require VA Secretary approval before research could begin.
March 13, 2018	VA issued a press release stating that ORD would initiate a rapid, in-depth review of existing canine research studies and determine whether the research should be ended early. The review would also ask researchers to develop plans to establish alternative models for those studies.
March 23, 2018	The Consolidated Appropriations Act of 2018 was signed into law and established the requirement that the VA Secretary approve canine research before appropriated funds made available by this act could be used for those studies.
March 28, 2018	VHA officials met with then Secretary David Shulkin to discuss canine research. Briefing documents show that two options were presented to Dr. Shulkin for consideration: (1) limit research to that allowed in the Consolidated Appropriations Act of 2018, or (2) phase out all canine research.
March 28, 2018	Dr. Shulkin's final day as VA Secretary.
May 3, 2018	ORD formally implemented the requirement that all new studies involving canine subjects must be approved by the Secretary before research could begin.
July 30, 2018	Robert Wilkie sworn in as VA Secretary.
September 21, 2018	The Energy and Water, Legislative Branch, and Military Construction and Veterans Affairs Appropriations Act of 2019 was signed into law and continued the secretarial approval requirement for appropriated funds made available by this act.
November 1, 2018	In a media report, Dr. Shulkin denied approving the continuation of specific canine research studies.

November 6, 2018	VHA officials met with Secretary Wilkie and obtained verbal approval to continue specific canine research studies. The approval was documented in a corresponding meeting summary.
April 17, 2019	VHA suspended a research study at the VA St. Louis Health Care System after learning that experiments had been conducted using canine subjects without secretarial approval of that study.
May 31, 2019	Secretary Wilkie provided written approval for a canine research study at the William S. Middleton Memorial Veterans Hospital in Madison, Wisconsin.
June 25, 2019	VHA officials met with Secretary Wilkie and obtained verbal approval for the St. Louis canine research study.
August 9, 2019	VHA requested that Secretary Wilkie sign a memo confirming his previously provided verbal approval of specific canine research studies.
August 30, 2019	Secretary Wilkie signed the August 9, 2019, memo documenting his approval of specific canine research studies, including the St. Louis project.

Appendix E: Management Comments–Executive in Charge, Office of the Under Secretary for Health

Department of Veterans Affairs Memorandum

Date: June 10, 2020

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, VHA Did Not Get Secretary's Approval Before Using Canines in Medical Research (Project Number 2020-06451-D2-0003) (VIEWS 02680192)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review the Office of Inspector General draft report, VHA Did Not Get Secretary's Approval Before Using Canines in Medical Research. VHA acknowledges a lapse in formal documentation of the direct approval by Dr. Shulkin of ongoing VA canine studies during a key meeting on March 28, 2018, with senior VA executives. VHA also stands behind its position that Dr. Shulkin provided verbal approval for the studies presented to him during that meeting. There was no intent whatsoever to circumvent the requirements in the Consolidated Appropriations Act of 2018 or to mislead Congress in any way.
2. VHA notes that the table on page 14 of the report lists expenditures that include, per footnote 33, "salary and benefits for VA employees (temporary and permanent), staff detailed to VA via intergovernmental personnel agreement, canine acquisitions, and other program support expenses." It is not clear which personnel are included, but the expenses for animal care staff, institutional animal care and use committee support staff, veterinarians should not be included because those costs are reflected in the per diem charges paid by the investigators, which are not reported or referenced in the report. The net effect is that the cost of canine research to VA appears to be inflated as it reflects more than actual costs
3. VHA noted a minor discrepancy on page 16. Recommendation #3 "appropriate funds" should be "appropriated funds."

The OIG removed point of contact information prior to publication.

*Due to final formatting, the page numbers referenced in paragraphs 2 and 3 refer to material located on pages 13 and 15, respectively. The footnote referenced in paragraph 2 is now Table 2, note * on page 13.*

(Original signed by)

Richard A. Stone, M.D.

Attachment

Attachment

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

Office of Inspector General (OIG) Draft Report: VHA Did Not Get Secretary's Approval Before Using Canines in Medical Research

Date of Draft Report: April 21, 2020

Recommendations/ Actions **Status** **Completion Date**

<u>Recommendation 1:</u> The Under Secretary for Health establish a formal process for requesting and obtaining the approval of the VA Secretary for research studies that use canine subjects to comply with applicable restrictions on the use of appropriated funds.

VHA Comment: Concur

A formal process has been in place since mid-2018 to submit requests for approval through established VHA and VA concurrence channels, as evidenced by the documentation of the VA Secretary's approval in November 2018. The last new canine study was approved by the VA Secretary on May 24, 2019 and his approval is documented in writing. There have been no new studies submitted for VHA and VA leadership approval since then. VHA will provide supporting documentation that describes the internal Office of Research and Development (ORD) concurrence process. The process has been revised periodically since March 2019, and most recently in May 2020. Once a study is approved by the Chief Research and Development Officer (CRADO), standard forms and processes are followed for concurrence by leadership and the VA Secretary. VHA will provide supporting documentation. VHA respectfully requests OIG consider closure of this recommendation.

Status: Competed **Completion Date:** May 2020

<u>OIG Recommendation 2:</u> The Under Secretary for Health develop and implement processes for documenting and maintaining records of the VA Secretary's approval of canine research studies, including the study at the Richmond VAMC that was not included in the Secretary's August 30, 2019, approval document.

VHA Comment: Concur

VHA's Office of Research and Development maintains a single master reference list as documentation of the VA Secretary's approved canine studies on its animal research website. All stakeholders can refer the master web table to ensure consistency and transparency in determining which studies currently have approval across the agency.

Regarding the Richmond canine study, the office of the Chief Veterinary Medical Officer (CVMO) was informed in January 2019 that the protocol was closed on September 6, 2018. This information was provided in response to a request from the office of the CVMO to all VA locations conducting research with canines, to update the status of all current protocols for those studies. The office of the CVMO initiated this request as part of the corrective action for preventing recurrence of situations in which research with canines might begin without the knowledge of the office of the CVMO and Secretarial approval. Given that the protocol was closed, it was purposely removed from the list of studies in the memo that was submitted for VA Secretary's signature in August 2019. It was not included in the interest

of maintaining accurate and up to date approvals and records. VHA will provide supporting documentation. VHA respectfully requests OIG consider closure of this recommendation.

Status: Completed **Completion Date:** May 2020

OIG Recommendation 3: The Under Secretary for Health establish controls for ensuring appropriate funds are not spent for canine research studies before obtaining the VA Secretary's approval.

VHA Comment: Concur

The requirement for the VA Secretary's approval prior to spending VA funds has been added to the process for studies involving canine research.

Notification has been sent to all VA animal research programs in May 2020 to re-emphasize the need to obtain Secretarial approval before initiating any canine studies. Key research administrators in local research programs have been reminded through email that no requests for VA fund expenditures can be approved unless the spending is directly related to the canine studies with Secretarial approval documented on the master web table.

VHA will provide OIG with documentation to support completion of this action. VHA respectfully requests OIG consider closure of this recommendation.

Status: Completed **Completion Date:** May 2020

OIG Recommendation 4: The Under Secretary for Health review local accounting records and cost allocations to determine the total amount of FY 2018 and 2019 funds spent on canine research before the VA Secretary approved the studies and report this information to the House and Senate appropriations committees.

VHA Comment: Concur

An on-site review of financial records will be conducted at the stations listed in the report to determine the amount of VA funds spent, and this information will be provided to Congress. Due to ongoing coronavirus operations and travel disruptions, the target completion date for this task is set for the end of calendar year 2020.

Status: In progress **Target Completion Date:** December 2020

OIG Recommendation 5: The Under Secretary for Health work with the VA Secretary and the chief financial officer to take the steps required by OMB Circular A-11 to determine whether an Antideficiency Act violation occurred and, if so, take appropriate action for the funds obligated and expended for research studies involving canine subjects.

VHA Comment: Concur

The VHA Chief Financial Officer and the VA Secretary will be consulted once on-site review data are available, and actions taken as are deemed appropriate. As noted above, timing of the on-site review is dependent upon the status of ongoing coronavirus operations and travel disruptions.

Status: In progress **Target Completion Date**: March 2021

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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