

## THE SECRETARY OF VETERANS AFFAIRS WASHINGTON

September 27, 2018

The Honorable Dina Titus U.S. House of Representatives Washington, DC 20515

Dear Congresswoman Titus:

Thank you for your June 28, 2018, and August 8, 2018, co-signed letters to the Department of Veterans Affairs (VA) regarding VA's animal research program. VA is committed to transparency and will continue to provide updated information on research with dogs as it becomes available.

VA has complied with all the requirements in Section 254 of the Consolidated Appropriations Act of 2018 (Public Law 115-141), which was signed on March 23, 2018. Section 254 has multiple requirements for utilizing Fiscal Year (FY) 2018 funds for VA canine research, including approval by the Secretary. No new dog studies have completed the approval process defined by Section 254 yet, but one new canine study is in the review process and others are anticipated. Nine studies ongoing at the time of Bill passage were re-reviewed by the Veterans Health Administration (VHA), the Chief Veterinary Medical Officer, and Chief Research and Development Officer, and were approved for continuation by then-Secretary David Shulkin on March 28, 2018. Accordingly, any purchases to support those ongoing studies with FY 2018 funds are fully compliant with the requirements of Section 254. The purchases made by the Louis Stokes Cleveland VA Medical Center described in your August 8, 2018, letter are in support of one of those nine studies, which include critical research to investigate how to restore the ability of Veterans with traumatic spinal cord injuries to breathe properly and avoid repeated bouts of pneumonia and early death.

Please see the enclosed detailed responses with information to address the specific questions posed in both your letters. Similar questions from the June 28, 2018, and August 8, 2018, letters have been integrated and answered together for clarity. The responses include a link to, and a hard copy of, VA's adoption guidance, which has been broadened to include not only dogs but animals of any species covered by the U.S. Department of Agriculture Animal Welfare Act Regulations. The latest version of this adoption guidance was released in July 2018 and formalizes practices that have long been standard within VA.

In support of our efforts to find the best possible loving homes for adopted research animals, I am pleased to report that as of August 16, 2018, VA signed an agreement with the non-profit organization Homes for Animal Heroes to facilitate placements.

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The Honorable Dina Titus

Should you have further questions, please have a member of your staff contact Mr. Jeremy Wheeler, Congressional Relations Officer, at (202) 224-2815 or Jeremy.Wheeler@va.gov. A similar response has been sent to Congressman Brat.

Thank you for your continued support of our mission.

Sincerely,

Robert L. Wilkie

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Enclosure

## Department of Veterans Affairs (VA) Response to Congresswoman Titus and Congressman Brat Regarding VA's Animal Research Program

Question 1. A list of all dog experimentation projects that have been approved by the Secretary and the Chief of Research and Development since July 2017, making particular note of any projects that have been approved since the law requiring their sign-off was enacted in March. Please include project titles, approval dates, approved budget, VA location, and USDA pain category.

<u>VA Response</u>: Since July 2017, no new VA canine studies have been initiated. One new proposed canine study is working its way through the approval process formalized in VA Guidance Document AR2017-001, revision 1, "Canine, Feline, and Non-Human Primate Research Protocols," dated May 15, 2018, but it has not yet reached my desk for review.

Of 13 canine studies ongoing in July 2017, 9 are currently active. Table 1 below lists these active studies, with the information requested in your letters. In accordance with Section 254 of the Consolidated Appropriations Act of 2018 (Public Law 115-141), these nine ongoing studies were evaluated and then approved for continuation by the Chief Research and Development Officer on March 28, 2018, and by then-Secretary Shulkin on March 29, 2018, making them eligible for use of Fiscal Year (FY) 2018 funds. Some of the studies have not yet begun, although the research with dogs was approved.

Question 2. The amount of taxpayer money spent on dog experimentation since the omnibus was signed into law in March.

VA Response: Table 2 summarizes data provided in Table 1. Table 2 provides approved total budgets for each project in FY 2018, the amounts budgeted for FY 2018 specifically for dog research, and the actual funds spent since March 23, 2018 (passage of the omnibus bill). A total of \$27,571 of Federal funds were spent (VA and National Institutes of Health (NIH)), and a total of \$7,105 of non-Federal funds (University and non-profit) for dog research since March 23, 2018. The Cleveland VA program awarded a contract to Marshall Farms and obligated \$42,721.50 for dogs through FY 2019, but only \$11,715 has been spent to date.

Question 3. For projects that were discontinued, what is the fate of the dogs no longer needed for the research? Provide specifics on each project and the disposition of the dogs.

**VA Response:** Table 3 below lists the four projects discontinued since July 2017. Since July 2017, there have been three research protocols involving dogs that have been discontinued and one is currently on hold pending further review. Another project currently active is expected to be discontinued shortly and will be added as the fifth

entry in Table 3 (please see Project #2 in Table 1). In all cases, the dogs that were eligible for adoption were placed with adoptive families.

Question 4. The VA previously informed us that a new policy regarding the adoption of dogs no longer needed for research would be released in final form in mid-April. Was this document released? If so, can you please provide a copy? If not, when will it be available?

<u>VA Response</u>: The release of the adoption document was delayed when VA decided to proactively broaden the scope from research dogs to all research species covered by U.S. Department of Agriculture (USDA) Animal Welfare Act Regulations, formalizing the practices that have long been standard within VA. The language was reviewed by USDA and finalized after consultation with experts in the General Services Administration. The document has been distributed to all VA stations and is posted online as document AR2018-001 at:

https://www.research.va.gov/programs/animal\_research/guidance.cfm. A copy is included with this enclosure.

To help facilitate adoptions of research animals, VA is pleased to report that we recently signed an agreement with the non-profit organization Homes for Animal Heroes to assist us in facilitating adoption placements to loving homes.

Table 1. List of Ongoing, Previously Approved VA Dog Protocols

	High Frequency Spinal Cord Stimulation to Restore Cough	Protocol Title	
Purpose of Research	Cleveland, OH	Location	
Veterans with spinal cord injuries that impair their ability to cough are vulnerable to potentially fatal respiratory infections. This study evaluates how electrical stimulation of the spinal cord could be optimized to activate respiratory muscles appropriately to generate effective coughing.	Federal-VA	Funding Source	
	\$105,893	Total Approved Budget for FY 2018	
	\$57,209	Budget for Research with Dogs	
heir ability to bw electrical or opriately to g	\$11,715	Funds spent on research with dogs since 3/23/18	
cough are vulnerable to potenti stimulation of the spinal cord co generate effective coughing.	4/1/14; 3/15/18; 3/28/18; 3/29/18	Dates of initial Institutional Animal Care and Use (IACUC) approval, and Chief Research and Development Officer and Secretary approvals	
	D; D	USDA Pain Category approved, and actual	
ally fatal uld be	A contract worth \$42,721.50 was awarded to Marshall Farms for dogs through FY 2019; \$11,715 has been billed to date.	Comments	

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Contribution of Inflammation and Oxidative Stress in Pericardial Fluid to Postoperative Atrial Fibrillation after Cardiac Surgery		Potentiation of Immunotherapy with Targeted Nanoporphyrin in Bladder Cancer
St. Louis, MO	Research	Pleasant Hill, CA
Federal-VA	treatments.	Federal-VA
\$147,528	of a new treatme	\$0
\$9,000	Development of a new treatment for bladder can treatments.	
\$0	ancer that is r	\$0
11/30/16; 11/17/17; 3/28/18; 3/29/18	ncer that is not adequately controlled by existing	5/4/17; 4/19/18; 3/28/18; 3/29/18
D; none used as of 8/14/18	ontrolled by e	1
Research with dogs has not yet begun.	xisting	Clinical trial in dogs was approved and had not yet begun. This component of the study has now been replaced because an opportunity came up to pursue a different aspect of the work needed. Will move to Table 3 of discontinued protocols in coming months

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Autonomic Nerve Activity and Cardiac Arrhythmias		Insight of Insight of Premature Ventricular Contractions-induced Cardiomyopathy		gy of Pontine Control of Breathing Frequency	Neurophy
Richmond, VA	Purpose of Research	Richmond, VA	Purpose of Research	Milwaukee, Wl	Purpose of Research
Private Non- profit Research Foundation	Premature Ventricular chronic heart disease. understand in order to	Federal-NIH	Veterans with content analges increase under Veterans.	Federal-VA	Postoperative increased risks which we need
\$76,832		\$114,076	Veterans with certain head or neck injuries, or vecter analgesics, often experience impaired concrease understanding of that control, which is Veterans.	\$150,000	Postoperative atrial fibrillation is associated with increased risks of stroke and death. This is resewhich we need to understand to find treatments
\$23,417	Contractions (PVC) interf This is research into the develop better ways to m	\$47,000	neck injuries, or ence impaired of control, which is	\$26,490	s associated wi eath. This is re o find treatmen
\$0	rfere with prop e cellular mecl manage PVCs	\$13,568	who suffer fro control of brea s fundamental	\$2,288	th longer hosp search into the ts for postoper
12/16/13; 9/6/17; 3/28/18; 3/29/18	ere with proper beating of the heart and can lead to cellular mechanisms involved, which we need to anage PVCs.	8/29/16; 6/1/18; 3/28/18; 3/29/18	Veterans with certain head or neck injuries, or who suffer from pain that can only be controlled with potent analgesics, often experience impaired control of breathing and coughing. This work is to increase understanding of that control, which is fundamental to developing better ways to help these Veterans.	6/10/15; 9/7/17; 3/28/18; 3/29/18	Postoperative atrial fibrillation is associated with longer hospital stays after cardiac surgery, and increased risks of stroke and death. This is research into the mechanisms involved in atrial fibrillation, which we need to understand to find treatments for postoperative atrial fibrillation.
ס; ס	e heart and ca	D and E; D	only be contri iing. This wor better ways to	D; D	cardiac surger nvolved in atri lation.
	an lead to eed to	NIH budget year for this award is actually 5/15/18- 4/30/19.	olled with k is to help these		y, and al fibrillation,

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A Comparison of Canine Anesthetic Regimens to Optimize Hemodynamic Stability and Quality of Electrophysiologic and		Nanoparticle Injection into Ganglionated Neural Plexi to Prevent Atrial Fibrillation		Premature Premature Ventricular Contractions on the Remodeled Ischemic Heart	
Richmond, VA	Purpose of Research	Richmond, VA	Purpose of Research	Richmond, VA	Purpose of Research
Federal- VA	Atrial fibrillation treatments for possible.	University	Heart attacks in This is researc function, which	Private Non- profit Research Foundation	Premature ver muscle. This i we need to un
No specific amount	(AF) increases AF are risky. Th	\$119,970	njure heart mus h into how the ii we need to und	No specific amount	tricular contracts research into derstand to dev
No specific amount	Atrial fibrillation (AF) increases the risk of stroke, treatments for AF are risky. This is research into possible.	\$38,000	Heart attacks injure heart muscle and make it muscle and make it muscle and make it muscle is research into how the injury produced by function, which we need to understand in order t	No specific amount	Premature ventricular contractions interfere with nerve signals to the muscle. This is research into how the loss of nerve signals might to the need to understand to develop better ways to protect the heart.
<b>. . . . .</b>	te, heart failun	\$5,585	more prone to by a heart atta r to improve h	\$1,520	ith nerve signanerve signals to protect the
8/3/17; 6/1/18; 3/28/18; 3/29/18	Atrial fibrillation (AF) increases the risk of stroke, heart failure, hospitalization, and death, but current treatments for AF are risky. This is research into new ways to treat AF with less risk than is currently possible.	8/10/16; 6/1/18; 3/28/18; 3/29/18	Heart attacks injure heart muscle and make it more prone to PVCs, which can cause further damage This is research into how the injury produced by a heart attack interacts with PVCs to impact heart function, which we need to understand in order to improve heart function after heart attacks.	9/9/16; 6/1/18; 3/28/18; 3/29/18	ire ventricular contractions interfere with nerve signals to the heart and can damage heart. This is research into how the loss of nerve signals might be responsible for the damage, which to understand to develop better ways to protect the heart.
c; c	า, and death, less risk than	D,	an cause furth PVCs to imp er heart attach	m îù	and can dama
Research involves observations in dogs on other protocols. Budget covered by project 5 above.	but current is currently		ner damage. act heart <s.< td=""><td>Sub-project covered by the budget for study 5, above</td><td>ge heart lamage, which</td></s.<>	Sub-project covered by the budget for study 5, above	ge heart lamage, which

	Neurophysiologic Data Acquisition
Purpose of Research	
Purpose of Sedatives and anesthetics commonly affect how the heart works. This study is designed to sort out how Research to improve anesthesia for future studies of cardiac function.	

Table 2. Summary of Funds Spent on Research with Dogs since March 23, 2018 (Summary of Data in Table 1)

Source of Funds	Total research budget approved for FY 2018	Amount in FY 2018 budget for dog studies	Amount spent on dog studies since March 23, 2018
Federal- VA and NIH	\$517,497	\$139,699	\$27,571
University and Private Non-Profit Research Foundations	\$196,802	\$61,402	\$7,105

Table 3. List of VA Protocols for Research with Dogs Discontinued or on Hold Since July 2017

The Investigation of Novel Imaging Un Approaches to the Circle of Willis	Control of PBlood Glucose In Spanned S	What Causes Human Narcolepsy?	Protocol Title S
University	Private Industry Sponsor	Federal-VA	Funding Source
To evaluate the use of an ultrathin camera for direct viewing of the inside and outside of brain blood vessels, which could increase the accuracy and safety of procedures to treat aneurysms, deploy stents to hold blood vessels open, and remove clots that cause strokes.	Collaborative work to develop new devices for monitoring blood glucose and refining insulin dosing to better control blood glucose and reduce complications of diabetes.	To understand and develop improved therapeutics for narcolepsy.	Purpose of Research
Milwaukee	Los Angeles	Los Angeles	VA Location
March 2018: protocol on hold pending further review by VA Office of Research and Development.	June 2018: Collaborative work was completed; further studies will be conducted by the other party alone; VA protocol closed.	October 2017: Principal Investigator (PI) determined that scientific goals of the current study can be met with mice; protocol for research with dogs closed.	Status
No dogs were on hand when the project was placed on hold, so none were available for adoption.	All dogs were either adopted out or transferred to the party that had previously collaborated with VA.	Although approved, no work had been done yet on this protocol.	Disposition of Remaining Dogs