



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.

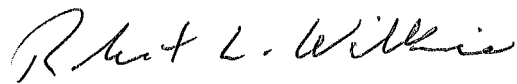
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The Honorable Dina Titus

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,

A handwritten signature in cursive script that reads "Robert L. Wilkie".

Robert L. Wilkie

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.

VA Response: 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?

VA Response: 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

Protocol Title	Location	Funding Source	Total Approved Budget for FY 2018	Budget for Research with Dogs	Funds spent on research with dogs since 3/23/18	Dates of initial Institutional Animal Care and Use (IACUC) approval, most recent IACUC approval, and Chief Research and Development Officer and Secretary approvals	USDA Pain Category approved, and actual	Comments
1 High Frequency Spinal Cord Stimulation to Restore Cough	Cleveland, OH	Federal-VA	\$105,893	\$57,209	\$11,715	4/1/14; 3/15/18; 3/28/18; 3/29/18	D; D	A contract worth \$42,721.50 was awarded to Marshall Farms for dogs through FY 2019; \$11,715 has been billed to date.
	Purpose of Research	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.						

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2	<p>Potentiation of Immunotherapy with Targeted Nanoporphyrin in Bladder Cancer</p>	<p>Pleasant Hill, CA</p>	<p>Federal-VA</p>	<p>\$0</p>	<p>\$0</p>	<p>\$0</p>	<p>5/4/17; 4/19/18; 3/28/18; 3/29/18</p>	<p>-</p>	<p>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.</p>
<p>Purpose of Research</p> <p>Development of a new treatment for bladder cancer that is not adequately controlled by existing treatments.</p>									
3	<p>Contribution of Inflammation and Oxidative Stress in Pericardial Fluid to Postoperative Atrial Fibrillation after Cardiac Surgery</p>	<p>St. Louis, MO</p>	<p>Federal-VA</p>	<p>\$147,528</p>	<p>\$9,000</p>	<p>\$0</p>	<p>11/30/16; 11/17/17; 3/28/18; 3/29/18</p>	<p>D; none used as of 8/14/18</p>	<p>Research with dogs has not yet begun.</p>

		Purpose of Research	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.						
4	Neuropharmacology of Pontine Control of Breathing Frequency	Milwaukee, WI	Federal-VA	\$150,000	\$26,490	\$2,288	6/10/15; 9/7/17; 3/28/18; 3/29/18	D; D	
		Purpose of Research	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.						
5	Mechanistic Insight of Premature Ventricular Contractions-induced Cardiomyopathy	Richmond, VA	Federal-NIH	\$114,076	\$47,000	\$13,568	8/29/16; 6/1/18; 3/28/18; 3/29/18	D and E; D	NIH budget year for this award is actually 5/15/18-4/30/19.
		Purpose of Research	Premature Ventricular Contractions (PVC) interfere with proper beating of the heart and can lead to chronic heart disease. This is research into the cellular mechanisms involved, which we need to understand in order to develop better ways to manage PVCs.						
6	Autonomic Nerve Activity and Cardiac Arrhythmias	Richmond, VA	Private Non-profit Research Foundation	\$76,832	\$23,417	\$0	12/16/13; 9/6/17; 3/28/18; 3/29/18	D; D	

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		Purpose of Research	Premature ventricular contractions interfere with nerve signals to the heart and can damage heart muscle. This is research into how the loss of nerve signals might be responsible for the damage, which we need to understand to develop better ways to protect the heart.
7	Effect of Chronic Premature Ventricular Contractions on the Remodeled Ischemic Heart	Richmond, VA	Private Non-profit Research Foundation
		Purpose of Research	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.
8	Nanoparticle Injection into Ganglionated Neural Plexi to Prevent Atrial Fibrillation	Richmond, VA	University
		Purpose of Research	Atrial fibrillation (AF) increases the risk of stroke, heart failure, hospitalization, and death, but currently treatments for AF are risky. This is research into new ways to treat AF with less risk than is currently possible.
9	A Comparison of Canine Anesthetic Regimens to Optimize Hemodynamic Stability and Quality of Electrophysiologic and	Richmond, VA	Federal- VA
			No specific amount
			No specific amount
			\$0
			8/3/17; 6/1/18; 3/28/18; 3/29/18
			C; C
			Research involves observations in dogs on other protocols. Budget covered by project 5 above.

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Neurophysiologic Data Acquisition								
	Purpose of Research	Sedatives and anesthetics commonly affect how the heart works. This study is designed to sort out how 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

Protocol Title	Funding Source	Purpose of Research	VA Location	Status	Disposition of Remaining Dogs
What Causes Human Narcolepsy?	Federal-VA	To understand and develop improved therapeutics for narcolepsy.	Los Angeles	October 2017: Principal Investigator (PI) determined that scientific goals of the current study can be met with mice; protocol for research with dogs closed.	Although approved, no work had been done yet on this protocol.
Control of Blood Glucose Levels in Diabetes	Private Industry Sponsor	Collaborative work to develop new devices for monitoring blood glucose and refining insulin dosing to better control blood glucose and reduce complications of diabetes.	Los Angeles	June 2018: Collaborative work was completed; further studies will be conducted by the other party alone; VA protocol closed.	All dogs were either adopted out or transferred to the party that had previously collaborated with VA.
The Investigation of Novel Imaging Approaches to the Circle of Willis	University	To evaluate the use of an ultra-thin 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.	Milwaukee	March 2018: protocol on hold pending further review by VA Office of Research and Development.	No dogs were on hand when the project was placed on hold, so none were available for adoption.

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<p>Determining Organ Perfusion During Vascular Compromise</p>	<p>University</p>	<p>To evaluate the accuracy and precision of Near Infrared Spectroscopy for measuring blood flow to internal organs, which is crucial to monitor during and after transplantation.</p>	<p>Milwaukee</p>	<p>March 2018; New information suggests that pigs are now more suitable for accomplishing research goals, so the PI terminated this protocol.</p>	<p>No dogs were on hand when the decision was made to switch to a porcine model, so no dogs were available for adoption.</p>
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**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

**Adoption of Research Animals Covered by the USDA Animal Welfare Act
Regulations**

Date: June 27, 2018

Guidance Document: AR2018-001

For questions regarding this guidance, contact the office of the Chief Veterinary Medical Officer (CVMO).

1. **Summary.** VA has historically taken, and continues to take the position that whenever possible, animals retired from participating in approved VA research protocols are to be placed through adoption as pets. This guidance is intended to assist VA animal research programs in arranging adoptions that promote the safety and well-being of the retired animals, and to maintain compliance with all regulatory and legal requirements, including federal surplus property procedures. VA's responsibility for the animal ends when the animal is transferred to the organization that will manage placement of the animal with an adoptive family. VA Medical Centers must consult with appropriate authorities to ensure that all applicable federal, state, and/or local regulations are met. The office of the Chief Veterinary Medical Officer must be contacted, and that office will then arrange with the General Services Administration (GSA) for adoptions to placement organizations of retired research animals in compliance with applicable federal laws and regulations regarding federal property. A "placement organization" is defined as an organization that arranges placement of surplus research animals in adoptive private homes.
2. **Background.** Although the value of much research with animals depends on the analysis of tissues, organs, or data that can only be collected after euthanasia, some of the research does not require euthanasia. VA has an ethical obligation to arrange for placement of healthy and socially adjusted animals with suitable adoptive families whenever possible through placement organizations, and fully supports efforts to do so.
3. **Issue.** VA must provide adequate information about the temperament and health status of the animal to assist the placement organization with arranging a suitable and streamlined adoption. This includes VA providing information and records required for compliance with all applicable regulatory and legal requirements for transfer of ownership of the animal to the adoptive family. Best results are expected when:
 - a. Local VA responsibility for arranging for adoption is shared by the:

- Institutional Animal Care and Use Committee (IACUC) of record,
- Attending Veterinarian (whether a Veterinary Medical Officer or a Veterinary Medical Consultant), and
- Associate Chief of Staff for Research and Development of the VA Medical Center overseeing the research.

In case of any disagreements about the eligibility of specific individual animals for adoption, or significant difficulties with the adoption process, the Office of the CVMO must be contacted.

The VA Medical Center is responsible for providing the documents listed in Section 4 below to the placement organization in coordination with the CVMO's office. Any documents required by GSA will be provided by the CVMO's office after consultation with the VA Medical Center.

- b. Species-appropriate socialization and exposure of animals to circumstances and experiences common in private households are to be considered in the facility's husbandry procedures. For example, training dogs to walk on a leash and to respond to basic commands will facilitate eventual transition to an adoptive home as well as promote ease of handling while they are at the research facility or with the placement organization. This is particularly important when it is known in advance that an animal is to likely become a candidate for adoption.
 - c. Additional suggestions for adoption programs are available from the American College of Laboratory Animal Medicine (<https://www.aclam.org/about/position-statements>).
4. **Recommendations.** Research animals are considered to be government property, and the GSA must approve the adoption as an excess property transaction. The CVMO's office will coordinate with GSA regarding the excessing process and the VA Office of General Counsel for legal review as applicable. The animal may not be transferred to the placement organization until GSA provides approval. Because of the complexity of the adoption process, it is highly recommended that each VA program that conducts animal research with USDA species to establish a Standard Operating Procedure for adoptions, that addresses the following:
- a. Full disclosure of the current health status and behaviors of the candidate animal to the placement organization prior to its transfer to the placement organization. This disclosure will increase the likelihood of the placement organization arranging a successful adoption.
 - b. A pre-adoption veterinary medical examination (including a physical examination, bloodwork (for animals larger than rabbits), and an examination

for parasites) conducted by a qualified veterinarian helps to ensure that information about the health status of the animal is current and accurate. Generally, only healthy candidates are eligible for adoption, but some with chronic health conditions, even if they may involve costly or intensive care, may be suitable for adopters with appropriate experience, skills, and interest. Note that a health certificate may be required per item f.2 below.

- c. It is important to confirm that the animal is socially compatible with people and other animals, and has shown no signs of aggression toward people or other animals that would pose undue risk to the placement organization or another pet in the final adoptive home. Before the animal is placed, it is important for the placement organization to acknowledge in writing that VA has no further legal responsibility or liability for the animal and/or its behavior.
- d. Regarding dog and cat adoptions, to promote responsible pet ownership, VA generally considers as eligible for adoption only those dogs and cats that have been spayed or neutered, and animals of any species that are up-to-date on vaccinations according to current veterinary standards.
- e. Consultation with appropriate authorities is necessary to ensure that any local and state regulations are met, if not in contradiction to and to the extent permitted under federal law and regulations.
- f. For dog and cat adoptions, compliance with the USDA Animal Welfare Act Regulations in Section 2.35 paragraphs (b), (c), and (e), and Section 2.38 is required:
 1. The VA Medical Center must maintain records that correctly record the following information required for adoption (Animal and Plant Health Inspection Service (APHIS) forms 7006 and 7001 may optionally be used to record the required information):
 - The official USDA tag number or tattoo or microchip (see Page A-30 of the USDA Animal Welfare Inspection Guide);
 - A description of the dog or cat (date of birth or approximate age, species, breed, sex, color/markings);
 - Any additional ID numbers or marks assigned by the research facility
 - The name and address of the placement organization;
 - The date of departure of the animal from the facility;
 - The name of the owner of the private vehicle by which the placement organization will transport the animal from VA;

2. If a dog or cat will be transported across state lines as part of the transfer to the placement organization, VA must furnish a health certificate which states that a licensed veterinarian inspected the dog or cat on a specified date not more than 10 calendar days prior to delivery of the animal for transportation. The veterinarian must find that the animal appears to be free of any infectious disease or physical abnormality that could endanger the animal, other animals, or public health. APHIS Form 7001 may optionally be used for this purpose.
 3. The VA Medical Center must provide the placement organization one copy of the information in items f.1 and f.2 above, and must keep one copy in the VA facility for at least 3 years.
 4. The transfer to the placement organization must take place at the VA Medical Center.
 5. Acceptance by VA of any financial compensation from the placement organization will be interpreted by USDA as VA taking on the role of a "dealer," which requires compliance with many more regulatory requirements. Such activities are not covered by this guidance, and are prohibited.
- g. For USDA species other than dogs or cats, the relevant sections of the Animal Welfare Act Regulations must be consulted.
 - h. Agreement by the placement organization that VA cannot accept the return of an animal that has been adopted.
 - i. The expectation that any placement organization that accepts responsibility for the adoption process also agrees to arrange the final adoptions in keeping with VA's intention to encourage suitable adoptions by private citizens that promote the safety and well-being of both the animals and the adoptive families.
5. **Reporting.** Information on the status of each research dog and cat will be collected annually as part of the online Veterinary Medical Unit report software.