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Freedom of Information Act Services (005R1C)  
811 Vermont Avenue, NW  
Washington, DC 20420  
Fax: 202-632-7581  
[Veteran Affairs FOIA Public Access \(PAL\) Website](#)

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**DEPARTMENT OF VETERANS AFFAIRS**  
**Washington DC 20420**

September 30, 2021

In Reply Refer To: 001B  
**FOIA Request: 21-09262-F**

This is the Initial Agency Decision (IAD) to your Freedom of Information Act (FOIA) request to the Office of the Secretary, U.S. Dept. of Veterans Affairs (OSVA) dated and received September 14, 2021, and assigned FOIA tracking number **21-09262-F**. You requested: "Each report from the Secretary of Veterans Affairs to Congress since January 1, 2020 regarding research conducted using canines, felines or non human primates, as required by Public Law 116-94, Section 249. See, e.g. <https://www.congress.gov/116/plaws/publ94/PLAW-116publ94.pdf>"

**Reasonable Searches Dated 9/21/21**

On September 21, 2021, an OSVA FOIA Officer searched through the VA Integrated Enterprise Workflow Solution (VIEWS), VA's official System of Record for VA reports submitted to Congress, for responsive records. An OSVA FOIA Officer used the search term "116-94." This September 21, 2021, VIEWS search yielded four (4) responsive pages.

**Initial Agency Decision**

After reviewing the four (4) pages, OSVA releases them in full without any redactions.

**FOIA Mediation**

As part of the 2007 FOIA amendments, the Office of Government Information Services (OGIS) was created to offer mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. Under the provisions of the FOIA Improvement Act of 2016, the following contact information is provided to assist FOIA requesters in resolving disputes:

**VA Central Office FOIA Public Liaison:**

Name: Doloras Johnson

Email Address: [vacofoiaservice@va.gov](mailto:vacofoiaservice@va.gov)

**Office of Government Information Services (OGIS)**

Email Address: [ogis@nara.gov](mailto:ogis@nara.gov)

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College Park, MD 20740-6001

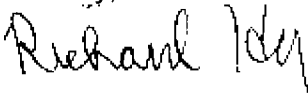
**FOIA Appeal**

This concludes OSVA's response to request **21-09262-F**. Please be advised that should you desire to do so, you may appeal the determination made in this response to:

Office of General Counsel (024)  
Department of Veterans Affairs  
810 Vermont Avenue, NW  
Washington, DC 20420

If you should choose to file an appeal, please include a copy of this letter with your written appeal and clearly indicate the basis for your disagreement with the determination set forth in this response. Please be advised that in accordance with VA's implementing FOIA regulations at 38 C.F.R. § 1.559, your appeal must be postmarked no later than ninety (90) days of the date of this letter.

Sincerely,

A handwritten signature in black ink that reads "Richard Ha". The signature is written in a cursive style with a large, stylized "H".

Richard Ha, JD, CIPP/G  
OSVA FOIA Officer

Attachment – unredacted four (4) pages

## DEPARTMENT OF VETERANS AFFAIRS (VA)

### REPORT TO CONGRESS ON CANINE RESEARCH (Biannual Report)

**Report Language** – The agreement maintains the Administrative Provision included in Public Law 116-94 related to VA animal research. The Department is directed to provide to the Committees, within 180 days of enactment of this Act, a report outlining their efforts to address each of the recommendations in the National Academies of Sciences, Engineering, and Medicine report on the Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs. *Joint Explanatory Statement, Page 47*

#### **Discussion:**

At the request of VA, the National Academies of Sciences, Engineering, and Medicine (NASEM) convened a committee to conduct an independent 18-month study of whether canines are or will continue to be necessary for biomedical research directly related to the VA's mission. The committee addressed the care and use of laboratory-housed dogs. VA received a pre-release briefing on the study findings on June 26, 2020 and the report was released to the public on July 1, 2020. The final version of the NASEM study report entitled "Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs (2020) is attached. The study offered six recommendations:

***NASEM Recommendation 1:*** *The Committee recommended that VA should adopt an expanded set of criteria for determining when it is scientifically necessary to use dogs in biomedical research. This criteria should take into consideration that:*

- 1) the study will advance understanding or medical practices related to Veteran's health,*
- 2) no alternatives to the dog exist that will yield scientifically valid results that meet the study objectives,*
- 3) anticipated harms to the dogs are outweighed by the potential benefits to Veterans,*
- 4) both the scientific review committee and Institutional Animal Care and Use Committee (IACUC) have documented in writing that no alternative to canines exist that can yield scientifically valid results.*

**VA Response:** VA concurs with recommendation one. Since 2018, VA has required documentation that

- 1) the study will advance understanding or medical care related to Veteran's health,
- 2) the use of dogs is scientifically valid and necessary to meet scientific objectives because no alternatives exist,
- 3) that the potential benefits to Veterans exceed the potential harms to the dogs used in research studies,
- 4) reviews document the necessity of using dogs to yield scientifically valid results.

***NASEM Recommendation 2:*** *The Committee also recommended that VA should adopt an expanded set of criteria for determining when the use of dogs in VA biomedical research is not scientifically necessary. The following criteria should be met before approving the use of dogs when other animal models are scientifically appropriate:*

- 1) the study will advance understanding or medical practices related to Veteran's health,*
- 2) study objectives cannot be met by non-animal alternatives, human subjects, or companion animals,*
- 3) the species that will incur the least harm should be used, if the dog and another species (excluding nonhuman primates) will meet objectives,*
- 4) the expected harms experienced by animals are outweighed by benefits to Veterans.*

**VA Response:** VA concurs with recommendation two. The studies described by this recommendation are currently not allowed in canines, felines, or nonhuman primates per P.L. 116-94 § 249. These animals may only be used for VA studies if no other species can substitute. Note this response is applicable to each statement listed below.

***NASEM Recommendation 3:*** *The Committee recommended that VA should:*

- 1) engage an independent literature review group to ensure evaluation of alternatives;*
- 2) determine if additional veterinary expertise is needed locally;*
- 3) engage independent statisticians to ensure good study design and statistical power;*
- 4) emphasize replacement of dogs versus reduction in the number of dogs used; and*
- 5) track impact and translation of funded research.*

**VA Response:** VA concurs with recommendation three.

- 1) The U.S. Department of Agriculture (USDA) Animal Welfare Information Center will be engaged to ensure evaluation of alternatives, which will help improve the quality of scientific and ethical review process.
- 2) The determination as to whether additional veterinary expertise is needed locally, will be addressed by both the local IACUC review and the secondary review performed by the Office of Chief Veterinary Medical Officer.
- 3) Independent statistical review and documentation in the animal protocol form will be required to ensure good study design and statistical power.
- 4) A total of \$2.5 million has already been committed to try to replace dogs in cardiac studies, as opposed to just reducing the number of dogs used.
- 5) Progress reports track impact and translation of funded research. The animal protocol form will be modified to capture this information more specifically.

***NASEM Recommendation 4:*** *The Committee recommended that VA should establish a strategic roadmap and accompanying framework to promote the development of alternate methodologies by:*

- 1) providing new VA grant funding opportunities to promote the development of non-animal alternatives,*

- 2) *developing training for researchers and IACUCs on the importance of looking for non-animal alternate methods,*
- 3) *implementing compulsory funding to promote the evaluation and optimization of alternatives that address research objectives identified in studies that currently require the use of laboratory dogs (i.e., parallel funding requirements).*

**VA Response:** As evidence of VA concurrence,

- 1) a program is currently under development to solicit proposals and fund meritorious proposals.
- 2) VA will develop training on the importance of looking for non-animal alternate methods; however, replacement of large animals with non-animal alternatives is not currently possible in many biomedical studies.
- 3) VA concurs with the conditions outlined in the last point. VA will not require compulsory funding unless the scientific objectives might reasonably be met with non-animal alternatives. Parallel studies looking at pigs and goats for canine cardiology studies have been funded (\$2.5 million).

**NASEM Recommendation 5:** *The Committee recommended that VA should:*

- 1) *establish long-term external collaborations to optimize the use of companion dogs in biomedical research through increased external and public-private partnerships,*
- 2) *foster collaborations with veterinary schools to conduct clinical trials in pets, and*
- 3) *encourage the use of human organs and tissues from human organ banks whenever possible.*

**VA Response:** VA concurs with recommendation five.

- 1) The VA funded melanoma study using companion dogs is underway and VA will seek additional collaborations of this type.
- 2) Additionally, a more formal program is under development to solicit and fund collaborative proposals for veterinary clinical trials in pets.
- 3) Animals may not be used if human tissues can meet the scientific objectives.

**NASEM Recommendation 6:** *The Committee recommends that VA should enhance the welfare of laboratory dogs used in biomedical research in their facilities by:*

- 1) *submitting to voluntary USDA inspections,*
- 2) *modifying dog runs and enhancing opportunities for social interaction,*
- 3) *exploring methods to promote socialization among dogs with implanted devices, and*
- 4) *conducting enhanced animal welfare assessments.*

**VA Response:** VA concurs with recommendation six.

- 1) VA animal research facilities are already open to USDA inspection upon request by the USDA. VA programs are evaluated at a frequency far beyond any other institution, federal, public, or private. Programs utilizing canines in research are visited by the Association for Assessment and Accreditation of Laboratory Animal

Care (AAALAC) International, every 18 months, as opposed to the standard three-year interval. AAALAC is the gold standard accrediting body for animal research. VA programs using canines were visited by the Public Health Service Office of Laboratory Animal Welfare in 2018. VA programs have also been evaluated by the VA Office of Research Oversight (ORO) and by the Office of the VA Chief Veterinary Medical Officer (CVMO). These visits utilize the USDA Animal Welfare Act Regulations as a key compliance document. Visits by AAALAC, ORO, and the CVMO will continue on a regular basis.

- 2) VA programs met and exceeded all animal welfare requirements regarding exercise and socialization. VA will continue to evaluate and consider making modifications where appropriate.
- 3) VA expects that improvements in wireless technology will allow dogs, implanted with telemetry devices, to be housed in pairs in the future. Currently, due to technology limitations, this is not possible.
- 4) Finally, VA will evaluate and consider adopting animal welfare assessment practices used by zoos and aquaria, as appropriate.

### **Conclusion:**

VA takes the recommendations seriously and appreciates the NASEM committee's acknowledgement that:

- 1) the laboratory dog is scientifically necessary for only a few areas of current U.S. Department of Veterans Affairs biomedical research, such as spinal cord research and heart disease,
- 2) if allowed, canines will likely be needed for future studies important to Veterans in areas such as cancer, infectious disease, and Alzheimer's disease, and
- 3) VA local animal research programs are meeting and exceeding Federal regulations and guidelines. As required, VA will continue to provide biannual reports on canine research.

Department of Veterans Affairs

June 2021