



**DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON**

August 28, 2023

The Honorable Brian J. Mast
U.S. House of Representatives
Washington, DC 20515

Dear Representative Mast:

Thank you for your April 19, 2023, cosigned letter to the Department of Veterans Affairs (VA) concerning plans to initiate a new invasive experiment on cats. I am responding on behalf of the Department.

We appreciate your continued support of the VA research program and our efforts to reduce or eliminate the use of dogs, cats and non-human primates in our research. Cats will not be euthanized as part of this study, and each cat will be paired with a forever home. VA is committed to adhering to the provisions of P.L. 117-328, § 247, including paragraph (e), to “eliminate or reduce research conducted using canines, felines or non-human primates.”

The VA Office of Research and Development has made excellent progress on this important issue such as developing training for our investigators and research staff on our program to reduce the use of sensitive species in research; funding studies of alternatives to the use of animals in cardiovascular research; adding additional funding opportunities for similar work; and sponsoring a meeting with the National Center to Advance Translational Science on alternatives to the use of animals in research.

The project about which you inquired, Optimization and Pre-clinical Testing of Implantable, In-Line High Density 32-Channel Connector, underwent a stringent review. The study uses miniaturized implants to translate electrical signals from a prosthesis to the nervous system, and it is part of a broad effort to provide Veterans who have lost an arm or leg with a prosthesis that provides better balance and motion to fingers and joints and a refined sense of touch. This work aligns with our sacred mission to care for those who have served in our Nation’s military. Further, it meets the criteria of P.L. 117-328, § 247, paragraph (b):

- (A) “The scientific objectives...can only be met by using...felines;”
- (B) “Those “scientific objectives are directly related to...injury that is combat-related”;
and
- (C) “The research is consistent with the...Department of Veterans Affairs...research policy.”

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The work with adult cats was found to be necessary, as there is no other viable model available. In this situation, cats are ideal for testing the durability of the new high-density connectors because the cat torso is approximately the girth of a human limb, and cats have a naturally athletic temperament. For example, cats enjoy running, jumping and stretching. This will allow us to ensure that the channel connectors are sufficiently robust to be implanted into Veterans who will benefit from the device.

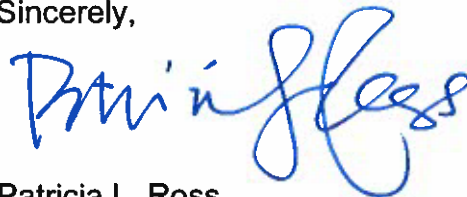
After 6 months of painless observation and evaluation, the cats in this study will have the implants removed and will then be placed in forever homes. The Louis Stokes Cleveland VA Medical Center has successfully placed retired laboratory cats in forever homes in the past. In addition, VA is currently working with other Federal agencies to create a robust, standardized adoption policy recognized by the Government Services Administration.

In closing, I would like to affirm our commitment to reducing or eliminating the use of dogs, cats and non-human primates in VA research by adhering to the plan we submitted to Congress. This type of research represents an exceedingly small fraction of our research appropriation. The study in question is in accordance with that plan and it allows us to fulfill our obligation to Veterans while ensuring that the cats being studied are subsequently placed in forever homes.

The responses to the bulleted questions in your letter are enclosed. Should you have additional questions, please have a member of your staff contact [REDACTED] Congressional Relations Officer, at [REDACTED].

Thank you for your continued support of our mission. A similar letter has been sent to the co-signer of your letter.

Sincerely,



Patricia L. Ross
Assistant Secretary for Congressional
and Legislative Affairs

Enclosure

**Department of Veterans Affairs (VA)
Response to Representatives Mast and Titus
Regarding Experiments with Cats**

Question 1: Has the Stokes VA's new cat experiment commenced? If so, when did it begin and when is it scheduled to end?

VA Response: No, the work with cats has not yet begun.

Question 2: How much taxpayer money is the VA planning to spend on the cat experiments?

VA Response: VA has budgeted \$50,000 for the work involving cats.

Question 3: In light of the December 29, 2022, change in federal law removing the only justification you provided for personally approving this experiment, is it your continued position that the feline study is:

- a) a justified use of taxpayer funds,
- b) the only way that the scientific objectives of this research could be met, and
- c) required for the regulatory approval of the experimental medical devices in question?

VA Response: Yes, it is VA's position that this experiment is a justified use of taxpayer funds; the only way that the scientific objectives of the research can be met; and is required for the regulatory approval of the experimental medical devices.

Additionally, this study uses miniaturized implants to translate electrical signals from a prosthesis to the nervous system as part of a broad effort to provide Veterans who have lost a limb with a prosthesis that provides better balance; improved motion to digits and joints; and a sense of touch. This position meets the criteria of P.L.117-328, Division J, Title II, § 247. There are no adequate alternatives available for evaluating these connectors, as determined by the U.S. Food and Drug Administration (FDA) recommendations posted at: www.fda.gov/media/142388/download. FDA guidance cites [International Standards Organization \(ISO\) 10993-18-2020 for Biological Evaluation of Medical Devices](#) for the determination of biocompatibility. In this situation, cats are ideal for testing the durability of the connectors because a cat's torso is about the girth of a human limb. Cats exhibit behavioral traits such as stalking, pouncing and swatting that provide motions similar to the intended use of the prosthetic. After 6 months of painless observation and evaluation, the cats involved will have the implants removed and be adopted into forever homes. FDA recommends testing medical devices for biocompatibility before allowing their use in humans. The guidance on quality-controlled production of medical devices intended for submission to FDA may be found at [21 C.F.R. §820](#).

Question 4: When was the last time the Stokes VA explored alternatives to the use of cats in this experiment?

VA Response: Alternatives are continually under consideration and were last formally evaluated before the current protocol was reviewed and approved in 2022. The current overviews for the testing of biomaterials for bio compatibility are as follows:

["Biocompatibility assessment of biomaterials used in orthopedic devices: An overview \(Review\) - PMC \(nih.gov\)"](#) and ["Achieving Neural Compatibility With Human Sensorimotor Control in Prosthetic and Therapeutic Devices | IEEE Journals & Magazine | IEEE Xplore"](#).

Question 5: Has the VA met with the FDA to specifically discuss whether the use of cats is necessary to meet regulatory requirements? If so, when, with whom, and what was discussed?

VA Response: FDA expects developers of medical devices to follow their published guidance (i.e., [Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" | FDA](#)). At this early stage of pre-clinical investigation, the research team has not specifically solicited FDA input. FDA recommends contacting them for a pre-market meeting when the device is ready for human implantation.

**Department of Veterans Affairs
August 2023**