

October 2, 2023

The Honorable Christi A. Grimm
Inspector General
U.S. Department of Health & Human Services
330 Independence Avenue SW
Washington, DC 20201

The Honorable Michael J. Missal Inspector General U.S. Department of Veterans Affairs 810 Vermont Avenue NW Washington, DC 20420

Via email: Christi.Grimm@oig.hhs.gov; Michael.Missal@va.gov

Dear Inspectors General Grimm and Missal,

On behalf of White Coat Waste Project (WCW) and its more than 3 million members and supporters, I am writing to request that your office enforce federal laws and policies and immediately suspend noncompliant taxpayer-funded animal experiments at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center and recover tax dollars wasted on unlawful experiments on cats and other animals by the abusive government laboratory.

WCW Exposes Cleveland VA's Cruel and Wasteful Cat Experiments

In recent years, WCW's investigations and work with Congress exposed and ended Cleveland VA experiments in which healthy kittens were subjected to invasive surgeries to implant electrodes to remotely stimulate their colons and bladders. Some of the cats had artificial stool made from "bran, potato flour and saline" inserted into their anuses for the experiments. Records show the experimental procedures caused cats distress, seizures, bloody urine, and even depression. At the end of the painful experiments, many of the cats were killed and dissected.

<u>VA Finds Extensive Violations of Federal Animal Welfare Laws and Policies in Cleveland VA Cat Labs</u>
Using the Freedom of Information Act (FOIA), WCW has obtained a 2021 VA Office of Research Oversight
(ORO) investigation documenting extensive violations of federal animal welfare laws and policies by cat
experimenters at the Cleveland VA and the facility's Institutional Animal Care and Use Committee (IACUC).²
Among other violations at the Cleveland VA, the VA ORO found:

- "cats did not receive adequate (or any) pain relief prior to invasive and painful procedures"
- "some animal procedures were not performed as described in the approved protocol"
- "the IACUC did not weigh potential animal welfare concerns against the benefits to be gained"
- "a Pl did not consider alternatives to procedures involving more than momentary or slight pain or distress"
- "The IACUC did not ensure that all protocols included complete, clear, congruent, and accurate descriptions of research activities...calling into question what procedures were actually approved and/or how the investigator actually intended to carry out the procedures"

²Focused Review Report - Feline Research, VA Northeast Healthcare System. Office of Research Oversight. 7/7/21

 $^{^1 \,} BREAKING: \, WCW \, Cuts \, the \, Crap, \, Ends \, VA \, \'s \, Million-Dollar \, Cat-Stipation \, Experiments. \, \underline{WCW \, Blog}. \, 10/14/21$

³ WCW recently uncovered a VA plan to revive one of these noncompliant, unnecessary and unlawful cat tests: WCW Ended Painful Gov't Cat Tests. Biden's VA Secretary Wants More. WCW Blog 7/11/23

• "The IACUC was not appropriately constituted between March 2 and December 7, 2020, due to lapses in the appointments of both the nonaffiliated and nonscientific members."

Federal Laws and Policies State that Cleveland VA Must Suspend Invalid Animal Experiments

The VA ORO report confirms that the Cleveland VA's IACUC—the federally-mandated committee that oversees animal experiments—failed to adequately review animal experiments and was missing key members, making it improperly- and illegally-constituted for over nine months during 2020, spanning fiscal years 2020 and 2021.

The Cleveland VA's failure to maintain a legitimate IACUC in violation of federal laws and policies deems all approvals and decisions made by the committee during this time null and void.

VA policy clearly states that, "Only a properly constituted IACUC may conduct official business."4

The NIH further clarifies:⁵

"[T]he requirement that the IACUC be properly constituted in order to conduct official business is explicit in not only the PHS Policy and USDA Animal Welfare Regulations, but also in the corresponding authorizing statutes. Accordingly, the validity of IACUC actions is always predicated on the existence of a properly constituted IACUC. [emphasis in original]

When it becomes apparent that an improperly constituted IACUC has approved a research proposal or taken other official action, that action is, by definition, invalid. It follows that animal-related activities without valid approval must be suspended until appropriate review and approval have occurred."

Thus, all taxpayer-funded animal experiments approved by the Cleveland VA during the period of noncompliance must be suspended and all other actions taken by the illegal oversight committee must be reevaluated and voted on by a properly composed committee.

<u>Federal Policy States that the Government Must Recoup Taxpayer Funds Wasted by Cleveland VA on</u> Illegal Animal Experiments from March-December 2020

The NIH clearly states, "When it becomes apparent that an improperly constituted IACUC has approved a research proposal or taken other official action, that action is, by definition, invalid."

Further, the NIH Grants Policy Statement is clear that, "No costs for activities with live vertebrate animals may be charged to NIH grants if there is not a valid IACUC approval."

The Cleveland VA IACUC was illegally and improperly constituted from March 2-December 7, 2020, deeming all IACUC decisions during this period—and related spending of taxpayer dollars—invalid.

The federal government is therefore obligated to reclaim the taxpayer funds wasted by the Cleveland VA on animal experiments with invalid IACUC approvals from March-December 2020. In the past, the NIH has clawed back taxpayer funds recklessly spent on non-compliant animal experiments.⁷

⁴ VA Exercise/Series number 3-2011, *IACUC Composition*, 9/5/11. Accessed 7/18/23

⁵ Maintenance of Properly Constituted IACUCs. NIH OPRR Reports. 6/2/1997. Accessed 7/18/23

⁶ NIH Grants Policy Statement §4.1.1: Animal Welfare Requirements. Accessed 7/18/23

⁷ Grace Merritt, <u>Violations of Animal Welfare Rules Prompt Order Against Health Center</u>. Hartford Courant (Archived). Accessed 7/18/23

VA ORO reported that there were 38 active animal experimentation protocols at the Cleveland VA at the time of its review. While complete data on the Cleveland VA's unlawful spending during this period are not publicly available, the lab's cat experiments alone received portions of \$1,228,799 in taxpayer funding during the noncompliant period from fiscal years 2020-21.8 We have identified millions in other taxpayer-funded animal testing conducted at the Cleveland VA during this noncompliant time as well.

Request For Action

Following WCW investigations and federal complaints, the VA has repeatedly identified non-compliant and abusive experiments on dogs, primates and other animals, and associated unlawful spending on them.^{9,10,11}

Regarding this current case, we respectfully request that your offices take swift and decisive action to enforce federal laws and policies by suspending all Cleveland VA animal experiments that received invalid approvals from March 2- December 7, 2020 and demanding the repayment of all taxpayer funding spent on animal experiments during this noncompliant period without valid IACUC approval and oversight.

Thank you for your attention to this matter. Please do not hesitate to contact me with any questions at <u>DL@whitecoatwaste.org</u> or 202-643-8453.

Sincerely,

Daniel Lopez

Research and Investigations Director

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White Coat Waste Project

⁸ NIH Grant OT2OD023873. NIH RePORTER. Accessed 7/18/23

⁹ Leaked Report Shows Rampant Vets Affairs Dog Lab Violations, Confirms WCW Allegations. WCW Blog. 6/26/17

¹⁰ BUSTED: IG Finds VA Spent \$400K Illegally Experimenting on 51 Dogs. WCW Blog. 7/14/20

¹¹ WCW Ends VA's \$7M Angel Dust Experiments on Primates. WCW Blog. 8/13/21