



FRIENDS OF VA MEDICAL CARE
AND HEALTH RESEARCH

Fova@navref.org
friendsofva.org
Washington, D.C

September 3, 2024

Tracianna Winston
Chief Counsel, Ethics Specialty Team
Office of General Counsel
U.S. Department of Veterans Affairs
Washington, D.C.

Dear Ms. Winston,

On behalf of the Friends of VA Medical Care and Health Research (FOVA), a coalition of over 80 healthcare organizations vested in the success of the VA research program, we are submitting this letter to formally request that the VA delay the implementation of the new 18 U.S.C. Section 208 interpretation until a legislative solution can be enacted. As it currently stands, this interpretation is set to be implemented after September 30, 2024.

For the last several months, we have been concerned about the new interpretation of 18 U.S.C. Section 208, and the processes that will be needed to implement this new interpretation. We understand that while the Office of Government Ethics (OGE) has purview over ethics activities within federal departments and agencies, the VA Office of General Counsel (OGC) is key to how such efforts are carried out within the department. We thank you for your work to date, and want to recognize VHA's Office of Research and Development, and VA's Office of Congressional and Legislative Affairs for their commitment to addressing this new interpretation.

As you know, a new interpretation by OGE on how the conflict-of-interest statutes apply to VA employees with a dual appointment at its academic institutions or VA-affiliated nonprofit corporations (NPCs) is set to be implemented after September 30, 2024. This direction will impact all of these employees who are critical to the VA research mission. Estimates suggest this could impact more than 6,500 researchers across VA.

This interpretation will have an immediate and potentially devastating impact on VA's ability to conduct high quality research leveraging public and academic partners. Beyond the impact this will have on the ability to deliver high quality health care for our Veteran community, we are concerned this interpretation will also have far reaching implications on VHA health care operations, as Medical Center Directors and other busy facility leaders will likely bear the brunt of additional administrative procedures resulting in a cost burden for VHA.

We strongly believe that until legislative changes are made, VA should carefully and thoughtfully consider the impact of any processes to address OGE requirements. It is important to ensure that VA researchers, academic partners, and NPCs have adequate time to assess the potential impacts and to adjust to the new requirements.

In March 2024, our Executive Committee submitted a letter to Congressional Leadership underscoring the importance of a one-year delay (see Appendix). In response, Ranking Member Takano and Secretary McDonough have released letters recognizing the administrative burdens associated with this new interpretation (see Appendix).

VA has communicated its intent to establish a target of September 30, 2024, to implement waiver processes; but, we have yet to see the necessary protocols and processes to manage this transition effectively. We recommend that VA delay the implementation of any new process that will impact of so many across the health system. The administrative burden and potential delays to critical research efforts pose significant risks to the quality of care and innovation that our veterans depend on. VA has a proud history of fostering collaborations that have led to remarkable public health achievements. However, this new interpretation threatens to disrupt these partnerships, delaying the pace of biomedical discoveries that benefit both veterans and the broader public.

Given the complexity of the research landscape and the thousands of projects potentially impacted, we strongly urge the VA to postpone the implementation of the new interpretation until a comprehensive legislative fix can be enacted. This delay will provide the necessary time for all stakeholders to develop the appropriate frameworks and ensure that the quality and efficiency of VA research are not compromised.

We appreciate your attention to this urgent matter and look forward to your continued support in preserving the success of VA research initiatives.

Sincerely,

The FOVA Executive Committee

Roscoe Butler

Paralyzed Veterans of America

Gary Ewart

American Thoracic Society

Andrew Herrin

Association of American Medical Colleges

Jon Retzer

Disabled American Veterans

K. Conwell Smith

American Psychological Association

Rashi Romanoff

National Association of Veterans Research and Education Foundations

Jennifer Zeitzer

Federation of American Societies for Experimental Biology

Appendix:

- A. FOVA Executive Committee February 2024 Letter to HVAC and SVAC Leadership
- B. HVAC Ranking Member Takano's Letter to VA Secretary McDonough
- C. VA Secretary McDonough's Response to Ranking Member Takano



FRIENDS OF VA MEDICAL CARE
AND HEALTH RESEARCH

Fova@navref.org
Navref.org/fova
Washington, D.C

February 22, 2024

The Honorable Mike Bost
Chairman
House Committee on Veterans' Affairs

The Honorable Jon Tester
Chairman
Senate Committee on Veteran's Affairs

The Honorable Mark Takano
Ranking Member
House Committee on Veterans' Affairs

The Honorable Jerry Moran
Ranking Member
Senate Committee on Veteran's Affairs

Dear Chairmen Bost and Tester, and Ranking Members Takano and Moran,

The Friends of VA Medical Care and Health Research (FOVA) coalition, comprised of more than 80 national academic, medical, and scientific societies, voluntary health and patient advocacy groups, as well as veteran-focused associations, writes to urgently request your support in advocating for a one-year delay in the implementation of the Office of Government Ethics (OGE) new interpretation of 18 U.S.C. Section 208 and by the Department of Veterans Affairs (VA) Office of General Counsel (OGC). This interpretation, affecting VA researchers with dual appointments at institutions outside of VA, is anticipated to have profound implications on the efficiency and effectiveness of collaborative research initiatives nationwide.

VA has a rich history of fostering collaborations between VA researchers, academic affiliates, and VA-affiliated research and education nonprofit corporations (NPCs). Notably, the VA trains more than 70% of our nation's physicians, and VA health care providers and researchers often have dual appointments with their local academic affiliate. NPCs are congressionally charged with facilitating VA research operations with external funders (including private sector pharmaceutical and biotechnology companies, charitable foundations, and other federal agencies such as the National Institutes of Health, Department of Defense, and Centers for Disease Control and Prevention). VA health care researchers often have a dual appointment with their local university and/or NPC. These unique partnerships – unlike any other in the federal agency landscape – have resulted in remarkable public health achievements and have accelerated the pace of biomedical discovery that has not only have benefitted millions of veterans, but also have advanced American public health.

However, a **new** interpretation of 18 U.S.C. Section 208 by OGE and VA OGC (provided to members of our coalition in January 2024) will result in a substantial overhaul of the current environment. Previously, the science and funding parts of a grant application by a dually appointed researcher were considered separate elements as it related to the “particular matter” as cited in the code. Therefore, under the prior interpretation, a dually appointed researcher was allowed to participate in the science part of a grant application, but not the business aspects of the grant. As of January 2024, OGE and VA OGC are now considering the science, funding, and research agreement to all fall into a single “particular matter.”

As a result, **ANY** VA researcher with a dual appointment (either at the academic affiliate, or the local NPC) will be required to secure a Section 208 waiver *before* engaging in any VA research project.

This new requirement – which OGE and VA OGC have asked sites to begin implementing on March 1, 2024 - will introduce a time-consuming and complex process that must be coordinated across the local VA Medical Centers and nationally with VA's Office of General Counsel (as each waiver must be approved individually at each level). We are concerned that this will cause **significant** delays to vital research efforts that aim to accelerate cures for Veterans.

The predicted additional work is notable. NPCs alone supported more than 2,000 principal investigators and administered more than 3,100 research projects in FY22 alone, representing more than \$310M in external funding. Moving forward with the new interpretation, a Section 208 waiver would be required for all 3,100 NPC administered projects plus all work being conducted at the affiliated universities moving forward given this new interpretation. Moreover, these figures only represent those projects that have been funded; VA's recent interpretation requires waivers to be submitted **before** investigators engage in any research project, potentially implicating **tens of thousands** of additional projects for which funding is being sought.

Estimating the impact of this for those investigators and care providers with dual appointments at medical centers is even more difficult to predict, as the numbers of personnel with dual appointments across VA is not currently captured.

We believe the impacts of this change will be far-reaching and have a potentially devastating impact on VA's ability to deliver the highest quality care to our nation's veterans. Beyond the immediate administrative hurdles to overcome and the impacts of efficiency, we are deeply concerned that this interpretation will create additional disincentives and barriers for our nation's leading scientists and experts to pursue research activities at the VA, further shutting out our nation's Veterans from clinical trial opportunities that can save lives.

The unique elements of these public-private partnerships across VA, academic institutions, and the NPCs has been vital for the success and sustainability of the collaborative research initiatives that have made significant contributions to veteran healthcare and public health at large. VA has begun efforts to implement this new interpretation, citing a March 1, 2024 deadline. Given the complexity of the research landscape and the thousands of projects that may be impacted, a **one-year delay** in the implementation of this new OGE interpretation is imperative. This delay would provide the necessary time to thoroughly assess the implications and refine the procedures involved in obtaining 208 waivers. We would also request that VHA provide a report detailing the impact of this new interpretation on VA research and clinical operations (including the number of VA personnel with dual appointments across VA).

We believe that your support and influence will play a pivotal role in addressing our concerns and ensuring the continued success of collaborative research efforts within the VA system. We appreciate your attention to this matter and look forward to working together to address this urgent concern.

Sincerely,

The FOVA Executive Committee

Roscoe Butler

Paralyzed Veterans of America

Gary Ewart

American Thoracic Society

Erica Froyd

Association of American Medical
Colleges

Jon Retzer

Disabled American Veterans

K. Conwell Smith

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ONE HUNDRED EIGHTEENTH CONGRESS

364 CANNON HOUSE OFFICE BUILDING

WASHINGTON, DC 20515

<http://veterans.house.gov>

February 28, 2024

The Honorable Denis R. McDonough
 Secretary
 U.S. Department of Veterans Affairs
 810 Vermont Avenue NW
 Washington, DC 20420

Dear Mr. Secretary:

I write with concern about a change in interpretation by the Department of Veterans Affairs (VA) Office of General Counsel (OGC) and the Office of Government Ethics (OGE) regarding implementation of 18 U.S.C. §208, which governs potential financial conflicts of interest for federal employees. It is my understanding this change will take effect on March 1, 2024, and I am troubled by the impact this new interpretation of the law will have on dually appointed VA researchers and the disruption to their important work. I am also concerned that VA has not yet communicated with the Committee about this change, and I have many questions and concerns I would like addressed about how this will affect VA's important research efforts.

As you know, VA has a long history of conducting world-class research and developing groundbreaking technologies and products to support not only our nation's veterans, but the population at large. This research work is possible in no small part thanks to VA's collaboration with academic affiliates and nonprofit corporations. In fact, VA healthcare researchers often receive dual appointments to VA and a local academic affiliate or nonprofit corporation in order to carry out their research.

I understand from stakeholders that OGE and VA OGC have issued a new interpretation of 18 U.S.C. Section 208 that could significantly impact the ability of dually appointed researchers at VA to begin or continue their work, and create unnecessary delays in VA's current research process. I am seeking to understand VA's rationale for this change and the guidance it has shared thus far with researchers and institutions that will be affected.

Section 208 and its waiver requirements play a very important role in ensuring that there are not conflicts of interest as dually appointed employees carry out their research. I am committed to upholding the ethics and world class reputation of VA's research contracts with our nation's institutions. However, we must also ensure that this work can continue without undue administrative burdens. I understand that with the

The Honorable Denis R. McDonough

February 28, 2024

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new interpretation, waivers will have to be reviewed by the individual VA Medical Centers where the researchers are appointed, as well as by VA OGC. I am very concerned about the potential for unnecessary bottlenecks and delays in the waiver approval process.

I am also concerned that VA OGC has informed research stakeholders, including members of the Friends of VA Research Coalition, that all dually appointed researchers will be required to obtain Section 208 waivers beginning on March 1, 2024. Given the uncertainty over how many individuals this will impact, how VA's OGC workforce will be able to handle the demand this requirement will create, and the lack of clear guidance for this process, I encourage VA to delay the implementation of this new requirement until the appropriate analysis is conducted and guidance issued to those who will be impacted by this requirement.

I also request that VA provide answers to the questions below and ensure that the Committee is fully briefed on this matter before VA moves forward with implementation:

1. Please provide any documentation that explains the new interpretation of Sec. 208.
2. How did VA come to determine the need for new implementation? What factors contributed to the timeline for implementation being set to March 1?
3. Has VA provided any guidance to those impacted by this new requirement about how the waiver process will work now that it is expanded to a larger population? If so, please provide a copy of that guidance, and if not, provide information on when VA will complete and disseminate this guidance.
4. Has VA done any analysis about potential impacts from this new requirement on dually appointed researchers, including estimates on the number of researchers impacted? If so, please provide that analysis, and if not, provide information on when VA will complete such an analysis.

I ask that you respond to these questions no later than March 8, 2024. Additionally, I request that you provide a briefing to my Committee staff no later than March 16, 2024. Thank you for your review and response to these concerns, and I look forward to continuing to work with you to support VA and the vital research it is accomplishing for our veterans.

Sincerely,



Mark Takano
Ranking Member



**THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON**

March 28, 2024

The Honorable Mark Takano
U.S. House of Representatives
Washington, DC 20515

Dear Representative Takano:

Thank you for your February 28, 2024, letter to the Department of Veterans Affairs (VA) regarding 18 U.S.C. § 208 and potential research conflicts of interest. I appreciate the opportunity to provide more information.

VA faces unique challenges regarding the application of Federal ethics laws because many VA employees are dually appointed personnel who are employed by their affiliated academic institution with clinical and/or research expertise. There is an inherent tension between 1) a VA employee's obligation to comply with Federal ethics laws and 2) VA's statutory mission to conduct clinical, research, and education operations in coordination with affiliates and non-profit research and education corporations (NPCs), given that many employees participating in those operations are also employed by affiliates and NPCs.

Responses to the questions enumerated in your letter are enclosed. I trust this information is helpful to you. We also welcome the opportunity to discuss this issue further with your staff.

Thank you for your continued support of our mission.

Sincerely,

A handwritten signature in black ink, appearing to read "DMcDonough", written over the printed name "Denis McDonough".

Denis McDonough

Enclosures

**Department of Veterans Affairs (VA)
Response to Representative Mark Takano
Regarding 18 U.S.C. § 208 and Potential Research Conflicts of Interest**

Question 1: Please provide any documentation that explains the new interpretation of Sec. 208.

VA Response: Please see the enclosed December 19, 2023, memorandum (Subject: Updated Ethics Guidance for Researchers) from the VA Office of General Counsel (OGC) to the Office of Research and Development (ORD).

Question 2: How did VA come to determine the need for new implementation? What factors contributed to the timeline for implementation being set to March 1?

VA Response: In 2023, OGC was preparing guidance and training regarding research conflicts of interest. As part of that preparation, OGC was involved in discussions with Office of Government Ethics officials regarding OGC's application of section 208 to research personnel. Those discussions resulted in the conclusion that OGC's section 208 analytical framework was not supported by the ethics laws and helped inform the analysis and timeline contained in the December 19, 2023, memorandum. On February 27, 2024, ORD formally requested that OGC delay the implementation of the updated framework for approximately 6 months, to allow an integrated project team (IPT) to develop processes, guidance, and education necessary to ensure that VA could fully comply with the updated framework. OGC agreed on February 28, 2024, to delay implementation to no later than September 30, 2024.

Question 3: Has VA provided any guidance to those impacted by this new requirement about how the waiver process will work now that it is expanded to a larger population? If so, please provide a copy of that guidance, and if not, provide information on when VA will complete and disseminate this guidance.

VA Response: After its review and consideration of the December 19, 2023, memorandum, ORD determined that its ability to comply with the guidance required more extensive input from impacted groups, including investigators, academic affiliates, and non-profit research and education corporations (NPC). ORD and OGC will develop further guidance as part of the IPT process that they have established.

Question 4: Has VA done any analysis about potential impacts from this new requirement on dually appointed researchers, including estimates on the number of researchers impacted? If so, please provide that analysis, and if not, provide information on when VA will complete such an analysis.

VA Response: This new section 208 framework will create a major administrative burden. There are approximately 6,500 VA researchers. More than 90% of VA researchers have a position at an academic affiliate. Each dually-appointed personnel has a potential conflict if they seek to work on VA research that affects the financial interests of their affiliate-employer. Further, the new section 208 framework will affect

studies involving NPCs, as NPCs frequently employ individuals who work on VA research studies. Such individuals are required by VHA policy to have a VA appointment, which makes them subject to Federal ethics laws.

Department of Veterans Affairs
March 2024