



FRIENDS OF VA MEDICAL CARE  
AND HEALTH RESEARCH

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[friendsofva.org](http://friendsofva.org)  
Washington, D.C.

September 9, 2024

The Honorable Mike Bost  
Chairman  
House Committee on Veterans' Affairs

The Honorable Mariannette Miller-Meeks  
Chairwoman, Subcommittee on Health  
House Committee on Veterans' Affairs

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

The Honorable Julia Brownley  
Ranking Member, Subcommittee on Health  
House Committee on Veterans' Affairs

Dear Chairman Bost, Chairwoman Miller-Meeks, and Ranking Members Takano and Brownley,

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 writing to share our serious concerns regarding the Office of Government Ethics' (OGE) new interpretation of 18 U.S.C. §208. **We believe this interpretation will have an immediate and potentially devastating impact on VA's ability to conduct high quality research and deliver the highest quality of care to our nation's veterans.** We are requesting your support for the existing proposed legislative solution to this issue.

### Historical Context and Enduring Success

VA's collaborations with academic and nonprofit affiliates have been a cornerstone in delivering high-quality care to millions of veterans, while also driving major public health advancements across the United States<sup>1</sup>. These partnerships were established in the aftermath of World War II as a foundational element of veteran healthcare, ensuring that returning and injured service members had access to the most advanced and high-quality care available. **For more than 75 years, this system has worked and served veterans well.** These collaborations have driven groundbreaking innovations—including (but not limited to): the invention of the nicotine patch and pacemaker, the first successful liver transplant, development of advanced prosthetics & bionic limbs, development of the pneumonia vaccine and CPAP therapies for sleep, and many, many more.

However, this **new** interpretation of 18 U.S.C. Section 208 by OGE will result in a substantial overhaul of the current environment and compromise the quality of care provided to our veterans. Beyond the immediate administrative hurdles to overcome the impacts on 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.

## Complexity of Waiver Process

This new interpretation by OGE 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. The new process of issuing waivers is far from simple – the resulting process will involve *thousands* of waivers, each requiring review and approval at several layers across the Department. As mentioned by Secretary McDonough (see appendix), there are approximately 6,500 VA researchers, of which more than 90% have a position at an academic affiliate. The sheer volume of waivers necessary to address the needs of dually appointed VA researchers would impose a significant administration burden on the VA. We are concerned that this will cause **significant** delays to vital research efforts that aim to accelerate cures for Veterans.

## Unique Status of Dually Appointed VA Researchers

We believe it is crucial to recognize the unique role that dually appointed VA researchers play within the VA-Academic partnerships. Dually-appointed researchers operate at the intersection of academia and the VA, bringing specialized knowledge and expertise that directly benefits veterans. The unique nature of their dual roles justifies the need for tailored legislative measures to support their work, without being unduly constrained by conflict-of-interest laws that were not designed with their circumstances in mind.

**We urge the Subcommittee to consider the practical implications of the current waiver process impacting dually appointed researchers in sustaining the high standard of care our veterans deserve, and to implement existing proposed legislation to solve the 18 U.S.C. Section 208 dilemma.** For over seven decades, the VA's partnerships with academic institutions have delivered exceptional care to veterans and driven significant medical advancements. The proposed changes risk disrupting a system that has proven successful in advancing both veteran healthcare and American public health.

Thank you for your attention to this matter. FOVA stands ready to work with you all to ensure that our veterans continue to receive the best possible care, and that the VA's research mission remains strong.

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 HVAC Ranking Member Takano



FRIENDS OF VA MEDICAL CARE  
AND HEALTH RESEARCH

[Fova@navref.org](mailto: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**

American Psychological Association

**Rashi Romanoff**

National Association of Veterans Research and  
Education Foundations

**Jennifer Zeitzer**

Federation of American Societies for  
Experimental Biology

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 DEMOCRATIC STAFF DIRECTOR

# U.S. House of Representatives

## COMMITTEE ON VETERANS' AFFAIRS

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**