

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

February 22, 2024

The Honorable Mike Bost Chairman House Committee on Veterans' Affairs

The Honorable Mark Takano Ranking Member House Committee on Veterans' Affairs The Honorable Jon Tester Chairman Senate Committee on Veteran's 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