DEPARTMENT OF VETERANS AFFAIRS (VA)

Research Advisory Committee on Gulf War Veterans' Illnesses (RACGWVI)
2024 Recommendations

The Research Advisory Committee on Gulf War Veterans' Illnesses (RACGWVI) presents the following recommendations for consideration to the Secretary of Veterans Affairs. These recommendations are based on the work of several RACGWVI parent meetings and working group efforts, current Gulf War Illness (GWI) research priorities as well as the commitment passed into law with the Promise to Address Comprehensive Toxics Act of 2022 (PACT Act), and feedback from Gulf War Veterans (GWV) during subcommittee Veteran Engagement Sessions (VES).

Recommendation 1: Establish regional research units (GWI-RRU) to facilitate GWI research designed to accomplish the following:

1A. Increasing participation of Veterans in GWI-related clinical trials, observational studies, and basic research. **Concur-in-Principle.**

1B. Building capacity for GWI clinical trials and other research by enabling access of researchers and clinicians to repository and research resources. **Concur-in-Principle.**

1C. Leveraging past, current and future VA research investments by enabling protocol approval and subject recruitment by non-VA investigators. **Concur-in-Principle.**

1D. Increasing diversity of participants in clinical trials involving Veterans. **Concur.**

1E. Assisting with harmonization of (clinical/research) Case Definition and International Classification of Diseases (ICD)-10 code for GWI clinical trial capacity. **Concur.**

VA Response: Concur-in-Principle.
The principles of allowing non-VA investigators access to VA research resources such as biorepositories, recruitment of Veterans at VA medical facilities, and other programmatic resources is dependent on VA directives and regulatory oversight. Veterans Health Administration (VHA) Office of Research & Development (ORD) is the VA office for funding investigator-initiated projects and management of those projects. VA Science and Health Initiative to Combat Infectious and Emerging Life-Threatening Diseases (VA-SHIELD) is one of ORDs biorepositories that can serve as a tissue repository for consented 1990-91 Gulf War Veterans. VA-SHIELD is working on regulatory means to open this resource to non-VA funded investigators; however, at this time it is a VA resource accessible to VA funded investigators and their non-VA funded

collaborators. Similarly, VHA ORD is home of the Million Veteran Program, which at this time functions like VA-SHIELD. However, the VA Biorepository Brain Bank has a process to allow non-VA funded investigators access to tissue and data. Recruitment of Veterans for clinical trials, observational studies, and basic research using VA Medical Centers is at the discretion of the local Medical Director per VA Directive 1200.05.

We concur that it is important to ensure participant diversity in clinical research and biobanking and will continue to encourage inclusion of women and minorities. Additionally, the Gulf War Research Program has invested in, and continues to support, research aligned with identifying a case definition and common data elements for Gulf War illness clinical trials.

Recommendation 2: Establish mechanisms that facilitate interagency GWI research to increase and leverage aligned research efforts within the VA, Department of Defense (DoD), and other institutions that will:

2A. Actively encourage intra-VA and interagency collaborations to expand research into GWI and toxic exposures promoted under the PACT Act.

2B. Increase matching funds for jointly funded programs between the VA and other entities (e.g., DoD Congressionally Directed Medical Research Programs (CDMRP) conducting GWI and toxic exposure research.

VA Response: Concur-in-Principle.
The VA Gulf War Research Program has an extensive history of collaborating with the DoD CDMRP during their yearly vision and goal setting meetings on toxic exposures and previously GWI. This ensures research projects are not funded in a duplicative manner and that the programs are aligned to strategic goals.

VHA ORD research dollars have appropriation restrictions. VA research is an intramural program and can only fund clinician and non-clinician investigators with a 5/8th VA appointment. DoD CDMRP also has processes and congressional mandates on their research dollars. Besides the appropriations restrictions, co-funding of projects, or even matching funds is administratively a barrier due to review cycles, oversight, and management of projects by each corresponding agency.

VHA ORD does work with DoD closely to ensure a collaborative environment exists. For example, the DoD CDMRP Toxic Exposure Research Program manager and VA Gulf War Research Program Director have co-hosted state-of-the-science meetings to bring together investigators from both agencies to harmonize efforts and collaborations. Secondly, the VA Gulf War Program Director attends the DoD vision setting and funding meetings. Finally, VHA ORD Gulf War funded projects predominately have DoD and National Institutes of Health (NIH) funded investigators as collaborators. These collaborations ensure camaraderie within the Gulf War research community. The VA Gulf War Program Director will continue to work with the DoD CDMRP Toxic Exposure Research Program manager to ensure Gulf War investigators have the tools they need

to advance our understanding of the health consequences from serving in the Persian Gulf War.

Recommendation 3: Continue efforts and increase funding for 1990-91 Gulf War Research Innovation Centers (GWRIC).

VA Response: Concur.
VHA ORD will conduct a gap analysis of the Gulf War Research Program under the purview and blueprint of the PACT Act. We will consider novel means for standing up and supporting GWRICs through developing and releasing of requests for applications (RFA) to the field. We will encourage DoD and NIH transdisciplinary investigators as collaborators with the intent of thinking outside the box for building biorepositories and encouraging consenting mechanisms for Veterans to be recontacted for research and allowing any unused specimen to be banked in VA-SHIELD and used for future research. We anticipate these efforts could support some of the recommendations above that are labeled ‘Concur-in-Principle’ and within our scope and abilities.