Gulf War Illness Common Data Elements Frequently Asked Questions

1. **What are the Gulf War Illness (GWI) Common Data Elements (CDE) project goals**?

The goal for the project is to select assessment tools for GWI research subjects based on a set of clinical and biologic common data elements that will increase the efficiency and effectiveness of clinical and laboratory studies that rely on clinical data and material. This will benefit veterans diagnosed with GWI by increasing data quality, facilitating data sharing, improving comparability between studies, and helping to educate new GWI investigators.

2. **How is the GWI CDE initiative organized?**

The GWI CDE group divided into 2 working groups to focus separately on symptoms and systems issues and then tackled 11 subgroups to develop recommendations. These subgroups initially focused on the common data elements described in the CDC/NINDS ME/CFS proposed CDE modules. The group then proposed additional modules and measures specific to GWI, which relate to military occupational exposure, military experience, and the management of specific clinical symptoms experienced by veterans diagnosed with GWI.

3. **Who are the GWI CDE working group participants?**

The working group is comprised of clinical, research, and laboratory GWI experts who work at a variety of institutions who may have received grants for GWI research from the Department of Veteran Affairs (VA) or the Department of Defense (DoD) and their colleagues. Veterans and their advocates participate as members of both working groups in order to recommend and comment on all of the documents that are created.

4. **How will the GWI CDEs be validated?**

Refinements to CDEs will be an ongoing process. The CDEs will be evaluated over time based on their usefulness. Validation of the GWI CDEs and the recommended instruments will be based on research conducted over at least 3-5 years.

5. **What are the expectations for researchers to use the GWI CDEs?**

It is anticipated that the CDEs will be adopted for GWI research and public health studies. Funded researchers from the VA, DoD, and NIH/NINDS strongly encourage researchers who receive funding from these sources to use these common data elements (CDEs) in their clinical research. Investigators are asked to use the common definitions.and instruments identified by the CDE initiative whenever possible. For clinical trials and large epidemiological studies, these funding sources strongly encourage researchers to use the GWI CDEs available or document how they will ensure their data collection is compatible with the CDEs. The CDE Project will develop uniform formats by which clinical research data can be systematically collected, analyzed, and shared across the research community.

6. **Will the GWI CDEs be released for Public comment?**

Release of draft modules is scheduled for January 2019 and a period of public comment will be announced on the VA, DoD, and NINDS websites and via email blasts. The CDEs also will be promoted through conference presentations, posters, and eventually an overall publication. It is estimated that Public Review comments will be collected from January 2019 through February 2019.

7. **What type of comments are accepted?**

As the GWI CDE is a collaborative project with the VA, DoD, and the CDC/NINDS, valued comments include any type of comment applicable to the measures and instruments being recommended. Veterans, advocates, clinical and research professionals, and others can provide comments. We ask that reviewers send comments first in the areas in which they have the most expertise. Feedback will be accepted via email at GWICDE@nova.edu. Comments can be sent in the text of an email, in the provided template response spreadsheet, or as annotations within the documents.

8. **Who are the reviewers who will decide on the modifications of the CDEs based on Public Comments?**

Comments received during public review will be brought to the GWI CDE working groups who will review and determine the changes to be made. Responses are sent as needed to the reviewer who has made the comments.

9. **How will the GWI CDEs process be managed over time?**

After the first final version is released, an oversight committee (OC) will be created. The OC will review updates to the CDEs, usually on an annual basis. Typically, membership will be 8-10 individuals from both the original working group and new members. Clinicians, researchers, investigators, veterans, and advocates will be represented on the OC. This committee may include representatives from the VA Research and Development and Department of Defense CDMRP programs.

10. **How is the GWI CDE initiative integrated with VA Office of Research and Development and the Department of Defense CDMRP programs?**

The GWI research funded Investigators will utilize the GWI CDEs, when appropriate for their studies. There will be mapping from the study to the recommended CDEs. The oversight committee will report the results to the VA Research Advisory Committee (RAC) and the CDMRP Integration panel, including the annual review report once the GWI CDEs are established. The GWI CDEs will be made available to the investigators, GWI program officers, and the oversight committees such as the VA central and local Data Safety Monitoring Boards (DSMBs), as well as to the DoD Human Relations Protection Office (HRPO) to assist in the implementation and review process. The VA and DoD programs will not develop CDEs, but will be involved in the implementation and review process.