

## **Gulf War Illness Common Data Elements Initiative**

### **Data Standards**

The US Department of Veterans Affairs and the Department of Defense CDRMP joined efforts to develop data standards for clinical research involving veterans diagnosed with Gulf War Illness. Through the efforts of two working groups, the first draft of Common Data Elements (CDEs) for Gulf War Illness (GWI) is included. The Core and Supplemental-Highly Recommended data elements that are to be used by an Investigator when beginning a research study in GWI are listed in the tables.

Many of the CDEs will overlap across study types, which allows for comparisons and meta-analysis across studies. With the aim of transferring significant medical information across studies, the tables display data elements for each domain in a consistent format. The goals of the GWI CDE initiative are to increase the efficiency and effectiveness of clinical research studies and clinical treatment, increase data quality, facilitate data sharing, and help to educate new clinical investigators.

### **Gulf War Illness (GWI) Common Data Elements Frequently Asked Questions**

Organized by 12 domains often used in clinical studies, data standards classify common data elements (CDEs) as Core, Supplemental - Highly Recommended, Supplemental, or Exploratory. These CDEs build on the process developed by the National Institute of Neurological Disorders and Stroke (NINDS) for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and are organized into domains that are intuitive and common in clinical research studies. Additional information is available about the development of the CDEs via email at [GWICDE@nova.edu](mailto:GWICDE@nova.edu).

### **Overview**

To develop the Gulf War Illness (GWI) Common Data Elements, two working groups were formed to identify and define data elements in symptoms or systems. Members of both groups are collaborating on the development of the military experience/environmental exposure module. Despite overlap, each group worked on these 12 domains:

#### **Symptoms Assessment**

- Baseline/Covariate
- Fatigue
- Post-Exertional Malaise
- Sleep
- Pain
- QOL/Functional Status/Exercise Challenge Tests/Activity

#### **Systems Assessment**

- Neurologic/Cognitive/CNS Imaging
- Autonomic
- Endocrine/Neuroendocrine
- Immune
- Biomarkers

#### **Military Experience/Environmental Exposure**

- Under Development

## **Feedback and Suggestions**

The GWI Common Data Element Project is committed to creating useful tools for the research community. To send questions, comments, or concerns regarding the Project, please email [GWICDE@nova.edu](mailto:GWICDE@nova.edu). All revisions or updates to the GWI CDEs will undergo a thorough review process including approval by the GWI CDE Working Group Oversight Committee or the GWI CDE Steering Committee prior to implementation. Thank you in advance for your feedback!

## **Acknowledgements**

The Gulf War Illness (GWI) CDE Working Group is comprised of two different subgroups who assumed the responsibility to define the CDEs for each domain and to recommend standardized, validated instruments for GWI research. The Gulf War Illness (GWI) CDE Working Group is supported by the GWI CDE Administrative Team. The subgroups began meeting by teleconference in February 2018, assembled in person in a field based meeting in March 2018, and continued meeting via conference calls as needed, to complete the work.

## Complete Gulf War Illness (GWI) Common Data Elements Group Roster

### SYMPTOMS ASSESSMENT WORKING GROUP

- **Rebecca McNeil, PhD, Chair** – RTI International, Durham, NC
- **Wes Ashford, MD, PhD** -- War Related Illness and Injury Study Center, VA Palo Healthcare System, Palo Alto, CA
- **Alison Bested, MD** --Nova Southeastern University, Ft. Lauderdale, FL
- **James Bunker** --Veteran, US Army, National Gulf War Resource Center, Inc., Topeka, KS
- **Amanpreet Cheema, PhD** --Nova Southeastern University, Ft. Lauderdale, FL
- **Devra Cohen, MPH** -- Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **Dane Cook, PhD** -- University of Wisconsin-Madison, Madison, WI
- **Jeffrey Cournoyer** -- Nova Southeastern University, Ft. Lauderdale, FL
- **Travis Craddock, PhD** -- Nova Southeastern University, Ft. Lauderdale, FL
- **Julia Golier, MD** -- James J. Peters VA Medical Center; Icahn School of Medicine at Mount Sinai, Bronx, NY
- **Anthony Hardie** -- Veterans for Common Sense and former U.S. Army; Bradenton, FL
- **Drew Helmer, MD, MS** --War Related Illness and Injury Study Center, VA New Jersey Health Care System, East Orange NJ
- **Jacob B. Lindheimer, PhD** -- William S. Middleton Veterans Memorial Hospital; University of Wisconsin-Madison, Madison, WI
- **Patricia Janulewicz Lloyd, DSc** -- Boston University, Boston, MA
- **Kathleen Kerr, MD** -- University of Toronto, Toronto, Canada
- **Maxine Krengel, PhD** -- Boston VA Healthcare System; Boston University, Boston, MA
- **Shree Nadkarni** --War Related Illness and Injury Study Center, VA New Jersey Health Care System, East Orange, NJ
- **Shannon Nugent, PhD** -- VA Portland Health Care System, Portland, OR
- **Bonnie Paris, PhD** -- VA Information Resource Center (VIREC), Hines, IL
- **Matthew Reinhard, PsyD** -- War Related Illness and Injury Study Center, Washington DC VA Medical Center, Washington, DC
- **Peter Rumm, MD, MPH** -- US Department of Veterans Affairs, Washington, DC
- **Aaron Schneiderman, PhD** -- US Department of Veterans Affairs, Washington, DC
- **Kellie J. Sims, PhD** -- VA Cooperative Studies Program Epidemiology Center, Durham, NC
- **Lea Steele, PhD** -- Baylor College of Medicine, Houston, TX
- **Marsha Turner, MS** -- Durham VA Cooperative Studies Program, Durham, NC

### SYSTEMS ASSESSMENT WORKING GROUP

- **Kimberly Sullivan, PhD, Chair** -- Boston University, Boston, MA
- **Laila Abdullah, PhD** -- Roskamp Institute, Sarasota, FL
- **Maria Abreu, PhD** -- Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **Mohamed Abu-Donia, PhD** -- Duke University Medical Center, Durham, NC
- **Kristina Aenlle, PhD** -- Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **Jimmy Arocho** -- Sergeant First Class (Retired), United States Army, Nova Southeastern University, Ft. Lauderdale, FL
- **Elizabeth Balbin, MS** -- Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **James Baraniuk, MD** -- Georgetown University, Washington, DC
- **Karen Block, PhD** -- Office of Research and Development, US Department of Veterans Affairs, Washington, DC
- **Michelle Block, PhD** -- Indiana University, Indianapolis, IN
- **Bryann DeBeer, PhD** -- Texas A&M Health Science Center, Central Texas Veterans Healthcare System, Waco, TX
- **Brian Engdahl, PhD** -- Minneapolis VA Health Care System; University of Minnesota, Minneapolis, MN
- **Nikolay Filipov, PhD** -- University of Georgia, Atlanta, GA

- **Mary Ann Fletcher, PhD** -- Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **Victor Kalasinsky, PhD** -- Office of Research and Development, US Department of Veterans Affairs, Washington, DC
- **Efi Kokkotou, MD, PhD, ScD** -- Harvard University, Beth Israel Deaconess Medical Center, Boston, MA
- **Kristy Lidie, PhD** -- CDMRP- US AMRMC, Fort Detrick, MD
- **Deborah Little, PhD** -- Baylor College of Medicine, Houston, TX
- **William Loging, PhD** -- Veteran, US Marine Corps, Ft. Lauderdale, FL
- **Marianna Morris, PhD** -- Nova Southeastern University, Ft. Lauderdale, FL
- **Lubov Nathanson, PhD** -- Nova Southeastern University, Ft. Lauderdale, FL
- **Montra Denise Nichols, RN (Retired), MSN** – USAFR MAJ (Retired), Desert Storm Disabled Veteran
- **Giulio Pasinetti, MD, PhD** -- Icahn School of Medicine at Mount Sinai, Bronx, NY
- **Dikoma Shungu, PhD** -- Weill Cornell Medical Center, New York, NY
- **Paula Waziry, PhD** -- Nova Southeastern University, Ft. Lauderdale, FL
- **Jon VanLeeuwen, PhD** –University of California; VA Research Advisory Committee on Gulf War Veterans' Illnesses, San Francisco, CA
- **Jarred Younger, PhD** -- The University of Alabama, Birmingham, AL

#### **GWICDE Administrative Team**

- **Nancy Klimas, MD** – Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL
- **Devra Cohen, MPH**– Miami VA Healthcare System; Nova Southeastern University, Ft. Lauderdale, FL