Gulf War Era Cohort and Biorepository (CSP #585) Information Sheet

Dawn Provenzale, MD, MS Director, Durham Epidemiologic Research and Information Center Director, GI Outcomes Research Group, Duke University Professor, Division of Gastroenterology

GOALS

To develop a large cohort and biorepository of Gulf War Era Veterans and to obtain health information, survey data, and blood specimens. The data and specimens collected will be used for future research on a range of areas including genomics and genetics, biologics and immunologic studies, and epidemiology, and health care utilization and needs.

PROJECT OVERVIEW

This large-scale longitudinal study aims to create an active partnership with a cohort of veterans from the Gulf War era in order to develop a research database that integrates epidemiological, survey, clinical, and environmental exposure data. Blood specimens will also be collected to establish the biorepository to enable a deeper level of research. There will be an initial 2-year pilot study for determining the best methods for creating and managing a cohort and biorepository of Gulf War Era Veterans. The pilot study will 1) assess the feasibility and efficacy of recruiting, consenting, and blood collection and management processes for a geographically diverse sample of Gulf War Era Veterans, and 2) develop, test, and implement the technical and administrative aspects for maintaining the cohort.

After the pilot study, a full-scale project is planned that will last 5-7 years and will utilize the project infrastructure that was developed and tested during the pilot phase to enroll a larger cohort.

Initially, the research database will be populated with data collected from two surveys of participating veterans. These surveys will be supplemented by data collected from medical records, national VA resources and from prior studies of Gulf War era veterans.

The longitudinal research cohort database and biorepository will be used to enhance ongoing research, to facilitate new research on GWVI, and to study other chronic diseases that may affect veterans of this age. This combined resource will provide valuable tools to examine the prevalence and correlates of GWVI and other chronic diseases, and to target programs to meet the health care needs of Gulf War Era Veterans.

WHO IS ELIGIBLE FOR INCLUSION?

Any veteran who was an active duty member of the uniformed services during the Gulf War Era beginning in August 1990 and continuing through February 1991. A veteran is eligible without regard to deployment to or combat status in Southwest Asia and without regard to current or past user status of the Veterans Health Administration.

RECRUITMENT STRATEGY

Veterans of the Gulf War era will be identified through existing VA and Department of Defense registries and databases.

- Identified veterans will be mailed an invitational packet that will include information about the study, the procedures for enrollment and appropriate consent documents.
- Additional strategies will be incorporated as lessons are learned and input obtained through this process.

WHAT IS INVOLVED IN PARTICIPATION?

An enrolled subject's active involvement in this program includes:

- Completing the Genomic Medicine Short Form Survey and Follow-up Study of a National Cohort of Gulf War and Gulf Era Veterans Survey
- Providing a blood sample (about 2 tablespoons) at a location of his/her choice to be stored for future research
- Consent for access to VA and non-VA medical records
- Consent to have information and blood samples collected to be used for future research studies
- Consent to be contacted again for additional, future studies
- Being provided with updates on the cohort and related research activities.