I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Investigator-Initiated Focused Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-17-GWIRP-IIFRA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 30, 2017
- **Invitation to Submit an Application:** August 2017
- **Application Submission Deadline:** 11:59 p.m. ET, September 21, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, September 26, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** January 2018

This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Gulf War Illness Research Program (GWIRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The GWIRP was initiated in 2006 to provide support for research of exceptional scientific merit for studying effects of deployment to the 1990-1991 Persian Gulf War on U.S. Warfighters. Appropriations for the GWIRP from FY06 through FY16 totaled $129 million (M). The FY17 appropriation is $20M.

Gulf War Illness (GWI) is characterized by multiple diverse symptoms that typically include widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, chronic headache, sleep problems, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests. The population of Veterans affected by GWI is a subset of the nearly 700,000 who served during the Gulf War. Specifically, these Gulf War Veterans were deployed to the theatre of operations in Southwest Asia, including Iraq, Kuwait, and Saudi Arabia. Studies indicate that approximately 25% to 33% (or 175,000 to 210,000) of Gulf War Veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP challenges the scientific community to design high-impact research that will provide a better understanding of the pathobiology underlying GWI, identify objective markers for improved diagnosis, and develop treatment and healthcare strategies for the complex of GWI symptoms. The GWIRP's vision is to make a significant impact on GWI and improve the health and lives of affected Veterans and their families.

II.A.1. The Gulf War Illness Landscape

The GWIRP has prepared an overview titled "The Gulf War Illness Landscape," which describes what is currently known about topics consistent with the mission of identifying treatments, improving definition and diagnosis, and understanding pathobiology and symptoms. ***Applicants are strongly encouraged to read and consider The Gulf War Illness Landscape before preparing their applications.*** The Landscape may be found at http://cdmrp.army.mil/gwirp/pdfs/GWIRP_Landscape.pdf.

II.A.2. FY17 GWIRP Investigator-Initiated Focused Research Award Topics of Special Interest

The FY17 GWIRP has a special interest in the exploration of the topics listed below. Research into these topics must be directly relevant to Veterans of the 1990-1991 Gulf War and the

complex of symptoms known as GWI. Elucidation of mechanisms outside the context of GWI is beyond the scope of this mechanism. Applicants are not restricted to this list and may propose studies in any other GWI research area relevant to the mission of the GWIRP.

The FY17 GWIRP Investigator-Initiated Focused Research Award (IIFRA) Topics of Special Interest are as follows:

- Epidemiology of comorbidities and mortality, including gender and ethnic differences
- Sinus, respiratory, sleep, or dermatological abnormalities as a component of GWI
- Genetic factors predisposing individuals to GWI
- Molecular signatures (e.g., biomarkers) underlying symptom clusters via genomic, proteomic, metabolic, or epigenetic technologies
- Dysregulation of, or abnormal crosstalk between, human body organ systems (e.g., neuroinflammation, autonomic dysfunction, etc.). Particular emphasis is placed on the systems listed below. *Note: Examination of parameters at both baseline and after challenge (stress, exercise, immune, etc.) and attention to long-term and latent effects of toxic exposures to closely represent the current status of GWI patients should be considered.*
    - Neurological system (central, peripheral, and/or neuromuscular)
    - Immune system
    - Endocrine, exocrine, and/or excretory systems, with special interest in kidney and liver (including Cytochrome P450 abnormalities)

II.B. Award Information

The GWIRP IIFRA mechanism was first offered in FY16. That year, 20 IIFRA applications were received, and 8 were recommended for funding.

The anticipated direct costs budgeted for the entire period of performance for an FY17 GWIRP IIFRA varies by Tier. Direct costs will not exceed **$230,000** for a Tier 1 award or **$700,000** for a Tier 2 Award. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The IIFRA supports research to promote new ideas or continued development of applied research in GWI that is aimed at diagnosis or therapeutic advancement. Applications must articulate the pathway to making a clinical impact for Veterans with GWI even if a clinical impact is not an immediate outcome. All applications must focus on Veterans of the 1990-1991 Gulf War affected by GWI. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's potential impact on GWI.

This award supports projects at different stages of development. PIs should apply to the IIFRA under one of two different Tiers. ***It is the responsibility of the applicant to select the Tier that is***

most appropriate for the research proposed. This choice should be based on the scope of the research proposed and not the funding level.

The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under each Tier:

- **Tier 1 – Discovery:** Tier 1 is intended to support exploratory, high-risk/high-reward research that is in the earliest stages of development. Research must have the potential to yield new approaches for diagnosis or treatment of GWI. ***Preliminary data are not required;*** however, the project should include well-formulated objectives and a study design based on a strong scientific rationale. Examples of activities supported by Tier 1 include, but are not limited to, investigations characterizing basic GWI pathobiology, symptom clustering aimed at molecular characterization, or concepts shown to be effective for other illnesses but not yet studied in 1990-1991 Veterans with GWI.

- **Tier 2 – Applied Research:** Tier 2 is intended to promote the advancement of more mature GWI research for the purposes of therapeutic development or diagnostic validation. Projects should include a well-formulated, testable hypothesis based on existing evidence in the GWI field that hold translational potential. The types of activities supported by Tier 2 include, but are not limited to, clinical validation of diagnostic approaches, advanced development of lead compounds, or the collection of various preclinical data for repurposing an existing approved drug or for new Investigational New Drug application submissions to the U.S. Food and Drug Administration (FDA). ***Presentation of preliminary data in the field of GWI and other supporting information is required.***

Applications Proposing Biomarker(s) Research: Applicants must present a rationale for why the proposed biomarkers would be specific for Gulf War-related exposures and not a result of unrelated factors or events subsequent to Gulf War deployment.

Activities not supported under this Program Announcement:

- Investigations involving derivation of GWI diagnostic biomarkers from animal models.

- Studies focusing on psychiatric disease or psychological stress as the primary cause of GWI.

- Applications focusing on amyotrophic lateral sclerosis (ALS) research. However, applications that focus on GWI symptomatology may include Gulf War Veterans with ALS if the latter disorder is included in the study's GWI case definition. For those interested in pursuing ALS-focused studies, the CDMRP offers funding opportunities in a separate ALS Research Program (see http://cdmrp.army.mil/alsrp).

- Clinical Trials. A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. For more information on clinical research, see the Human Subject Resource Document at https://cdmrp.org/Program_Announcements_and_Forms/. Investigators interested in clinical trials should consider applying under the

FY17 GWIRP Clinical Consortium Award (Funding Opportunity Number: W81XWH-17-GWIRP-CCA). For information about this award mechanism, see http://cdmrp.army.mil/funding/gwirp.

Access to Veterans of the 1990-1991 Gulf War: Applicants proposing clinical research involving Gulf War Veterans are encouraged to collaborate with an investigator who has demonstrated access to Gulf War Veterans, particularly investigators within the Department of Veterans Affairs (VA), to ensure access to Gulf War Veteran populations as applicable to the proposed project. Access to a Gulf War patient populations should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

Applicants intending to recruit Veterans for clinical studies are encouraged to leverage existing cohorts recruited in other GWIRP-supported studies and can refer to the Research Resources link (http://cdmrp.army.mil/gwirp/resources/gwirpresources) on the GWIRP website. Applicants are also encouraged to consider the "Outreach and Recruitment Best Practices" available on the GWIRP website http://cdmrp.army.mil/gwirp/pdfs/General%20_Guidance_for_Gulf_War_Veteran_Outreach_and_Recruitment.pdf.

Access to Data and/or Previously Collected Biospecimens from Veterans of the 1990-1991 Gulf War: The following repositories may contain 1990-1991 Gulf War Veteran data and/or specimens for various research topics related to GWI. ***Investigators intending to use banked specimens should include in their application a description of steps that will be taken to assess the quality of the materials received and to identify and correct for effects and/or artifacts of sample processing and storage.*** Researchers are not required to use any of the following limited examples or any one particular dataset.

- Defense Manpower Data Center (DMDC; https://www.dmdc.osd.mil) maintains the largest archive of personnel data in the Department of Defense (DoD). DMDC does not participate in distribution of data with non-U.S. Government entities. Investigators must partner with a DoD or VA entity to request DMDC data. Once a relationship is established, the institution's network must be DoD-accredited or have other Federal equivalent accreditation (Department of Defense Information Assurance Certification [DIACAP] or Federal Information Security Management Act [FISMA]) to release the requested sensitive information from the Federal entity to the institution.

- DoD Serum Repository (formerly, Armed Forces Serum Repository, https://www.afhsc.mil/Home/DoDSR). This repository contains Gulf War-era and other specimens and releases de-identified data and specimens to approved DoD investigators. Access requires an appropriate collaboration; requesters of data or analyses must be military Service members or Government employees working for U.S. military organizations. A fee is charged for specimens.

- MAVERIC Core Laboratory (Massachusetts Veterans Epidemiology Research and Information Center, http://maveric.org). One of four MAVERIC components, the Core Laboratory is a fully equipped, state-of-the-art biological specimen collection and processing

center holding over 50,000 specimens, including samples from an estimated 1,500 Gulf War Veterans and an equivalent number of specimens from their spouses. Access to samples requires consent and approval from the VA Central Office.

- Millennium Cohort (http://millenniumcohort.org). Initiated in 2001, the Millennium Cohort Study is ongoing and comprises collection of epidemiological data on Service members. Access requires collaboration with one of the Millennium Cohort Study investigators and approval of the Millennium Cohort Study oversight committee by way of a preproposal/proposal process.

- VA Gulf War Veterans' Illnesses Biorepository (GWVIB) and the Veterans Affairs Biorepository Brain Bank (VABBB) (http://www.research.va.gov/programs/tissue_banking/gwvib/ and https://www.research.va.gov/programs/tissue_banking/als/, respectively) contain biomaterial and clinical data from Gulf War Veterans. The GWVIB was initiated in 2012 but to date contains little material; however, the VABBB contains a more substantial collection of material from Gulf War Veterans, with and without GWI, particularly from Veterans with ALS (also known as Lou Gehrig's disease). Researchers must submit a request to obtain access to specimens and data from this collection.

- The Million Veteran Program (MVP; http://www.research.va.gov/MVP/default.cfm). The MVP is a national, voluntary research program funded by the VA Office of Research & Development. MVP is building one of the world's largest medical databases to study how genes affect health by safely collecting blood samples and health information from one million Veteran volunteers receiving their care in the VA Healthcare System. The MVP has enrolled over 550,000 Veterans, including Veterans from the Gulf War era. Researchers must submit a request to obtain access to specimens and data from this collection.

- VA Gulf War Era Cohort and Biorepository (GWECB), CSP#585. http://www.research.va.gov/programs/csp/585/repository.cfm. This dataset and biorepository was developed by the VA to learn about the health conditions and related factors among 1990-1991 Gulf War Veterans through research studies. Over 1,200 Veterans have been enrolled into the cohort and biorepository. Resources are available to VA and non-VA investigators through the CSPEC-Durham Data and Specimen Repository. Investigators may submit data requests to the CSPEC-Durham Data and Specimen Repository for research under an Institutional Review Board (IRB)-approved protocol. Interested investigators are encouraged to contact the repository coordinators to arrange a consultation prior to IRB review. Data use agreements and/or materials transfer agreements may be required.

GWI Case Definitions for Clinical Research: In 2014 the National Academy of Medicine (NAM) (formally the Institute of Medicine) released a report titled, "Chronic Multisymptom Illness in Gulf War Veterans: Case Definitions Reexamined" (available online at http://www.nationalacademies.org/hmd/Reports/2014/Chronic-Multisymptom-Illness-in-Gulf-War-Veterans-Case-Definitions-Reexamined.aspx). In this report, the NAM recommends the use of both the Centers for Disease Control and Prevention (CDC) definition of GWI and the Kansas definition of GWI. Therefore, applicants proposing clinical research may construct a definition of subgroups or symptom clusters as appropriate to the specific research; however, all

cases and controls must additionally be scored and analyzed according to both the CDC and the Kansas definitions of GWI for comparative purposes. Any additional project-specific case definition must recognize the multisymptom nature of GWI. Another resource for clinical investigations includes the 2014 report of the Research Advisory Committee on Gulf War Veterans' Illnesses, "Gulf War Illness and the Health of Gulf War Veterans: Research Update and Recommendations, 2009-2013," which provides information on GWI, including case definitions and research on epidemiology, etiology, pathobiology, and treatment. This report can be found online at http://www.bu.edu/sph/files/2014/04/RAC2014.pdf.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is ***not*** required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

Animal Models: Studies that characterize chronic effects of neurotoxic exposures at dosages comparable to those encountered in-theatre during the Gulf War and/or shed light on treatment targets are of interest. Such studies using animal models should focus on long-term and latent effects of toxic exposures to closely represent the current status of GWI patients. All studies using animal models should use an established model unless there is a compelling scientific

justification for the development or use of a new model. Development of new animal models is discouraged.

Standards for Animal Study Design: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 7, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

Collaborative Systems Biology Facility: SysBioCube is the USAMRMC medical research big data/omics suite whose operation is directed by the U.S. Army Center for Environmental Health Research Systems Biology Collaboration Center (SBCC). SysBioCube is hosted by the National Cancer Institute/National Institutes of Health. The SysBioCube comprises military-relevant medical research data repositories, data integration and analysis tools, and a networked portal that links databases to computational biology analysis tools. The SBCC facilitates systems biology collaborations among, and information sharing by, USAMRMC investigators and partnering investigators at other Army, DoD, and extramural organizations. Interested researchers should inquire at sysbiocube@mail.nih.gov.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1, Federal Award Notices.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.*

Note: Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator:

Independent investigators at all academic levels (or equivalent) are eligible to apply.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

There are no limitations on the number of applications for which an investigator may be named as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission is defined as an application submitted by a non-DoD organization to Grants.gov.

Intramural Submission is defined as an application submission by a DoD organization for an intramural investigator, who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.

II.D.1. Address to Request Application Package

Submitting Extramural and Intramural Organizations: Pre-application content and forms can be accessed at eBRAP (https://eBRAP.org).

Submitting Extramural Organizations: Full application packages can be accessed at Grants.gov.

Submitting Intramural DoD Organizations: Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Full Application Submission: Full applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.Gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

For both Extramural and Intramural applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

II.D.2.a. Step 1: Pre-Application Submission Content

During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application.*" The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

  It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the application.

  FY17 GWIRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Pre-applications or applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional

relationship). Refer to the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  - **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

    - **Tier:** Explicitly state which Tier is requested for the proposed research. Explain how the Tier and funding level is appropriate for the scope of research proposed.

    - **Topic(s) of Special Interest (if applicable):** State which FY17 IIFRA GWIRP Topic(s) of Special Interest the proposed research will address.

    - **Research Idea:** Describe the ideas and reasoning on which the proposed work is based. Preliminary data are allowed, but not required, for Tier 1 applications. For Tier 2 applications, provide preliminary data from the GWI field to support the feasibility of work proposed. Include a research hypothesis and a brief description of specific aims to address the hypothesis. ***This award may not be used to conduct clinical trials.*** The focus of the research project must be clearly on GWI. If supporting data or rationale comes from a field other than GWI, explain why the research idea is expected to be effective for GWI. If proposing biomarker investigations, it is important to describe why the proposed biomarker(s) is (are) expected to be indicative of symptoms resulting from deployment to the 1990-1991 Gulf War as opposed to unrelated factors or later events.

    - **Impact:** State how the study addresses a critical problem in GWI. Describe the potential immediate and/or long-range outcome(s) of the proposed research and its impact on Veterans with GWI.

    - **Personnel:** Briefly state the qualifications and expertise of the PI and key personnel to perform the described research project.

  - **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

    - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

- Key Personnel Biographical Sketches (five page limit per individual). ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the GWIRP, pre-applications will be screened based on the following criteria:

- **Tier:** To what extent the research proposed and preliminary data are consistent with the Tier for which the application is submitted.

- **Research Idea:** If applicable, how well the proposed research addresses one of the FY17 GWIRP IIFRA Topics of Special Interest. Whether the described research focuses on the health effects of deployment to the 1990-1991 Gulf War. How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data, if applicable (preliminary data are not required under Tier 1, but are required under Tier 2). For biomarker research, how strongly the rationale suggests that the proposed biomarkers are indicative of exposures that occurred in the 1990-1991 Gulf War as opposed to subsequent exposures or unrelated factors.

- **Impact:** Whether the study addresses a critical problem in GWI. To what extent the outcomes of the project have the potential for immediate and/or long-range impact on Veterans with GWI.

- **Personnel:** Whether the qualifications of the PI and key personnel are appropriate to perform the proposed research project.

Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated time frame for notification of invitation to submit an application is indicated in Section I, Overview of the Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

II.D.2.b. Step 2: Full Application Submission Content

Applications will not be accepted unless the PI has received notification of invitation.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. Refer to the General Application Instructions, Section III, for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-17-GWIRP-IIFRA from Grants.gov (https://www.grants.gov).	Download application package components for W81XWH-17-GWIRP-IIFRA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form	**Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Key Personnel • Budget • Performance Sites

Extramural Submissions	Intramural DoD Submissions
• R&R Subaward Budget Attachment(s) Form (if applicable)	**Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.
Application Package Submission	
Submit package components to Grants.gov (http://www.grants.gov). If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget need to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline.
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.	After eBRAP has processed the full application, the organizational Resource Manager/ Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information	
Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.

Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full

application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

II.D.2.b.ii. Full Application Submission Components:

- **Extramural Applications Only –**

  SF424 (R&R) Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications –**

  Attachments:

  Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (page limit varies by Tier):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

    Page Limit: Page limits depend on the Tier applied for:

    - **Tier 1 – Discovery:** Eight-page limit
    - **Tier 2 – Applied Research:** Twelve-page limit

    Outline for Project Narrative: Describe the proposed project in detail using the outline below.

- **Background:** Indicate if one or more of the FY17 GWIRP IIFRA Topics of Special Interest (see Section II.A.1, FY17 GWIRP IIFRA Topics of Special Interest) are addressed. Present the ideas and reasoning behind the proposed work. For Tier 2 applications, provide preliminary data from the GWI field to support the feasibility of the work proposed (preliminary data are not required for Tier 1 applications). Regardless of whether preliminary data are required for the Tier selected, the PI must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award. If the proposed work is part of a larger study, present only tasks that this award would fund.

- **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation.

  - Tier 1 applications should present exploratory approaches at the earliest stage of development supported by strong rationale.

  - Tier 2 applications should present applied testing and validation, including but not limited to, drug or diagnostic development based on mechanisms implicated in GWI.

- **For Both Tiers:**

  - Address potential problem areas and present alternative methods and approaches.

  - If applicable, state which established GWI animal model will be used. If development of a new GWI animal model is proposed, present a clear justification for how it is necessary to support the proposed research and why existing models are not appropriate or relevant.

  - Describe the statistical analysis plan in detail as appropriate for the proposed research approach.

  - Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

  - If clinical research is proposed, both the CDC and Kansas definitions must be used. Describe and justify any additional case definition of GWI, including any targeted illness subgroups that will be defined for the study. Include a detailed plan for the recruitment of subjects or the acquisition of samples and/or data (if applicable). *This award may not be used to conduct clinical trials.*

- For studies involving the use of banked specimens, describe procedures to be used to assess the quality of the materials and identify and correct for effects and/or artifacts of sample processing and storage.

- Additionally, for biomarker research, clearly demonstrate how the proposed biomarker(s) relates to GWI and not subsequent exposures or unrelated factors.

- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

  There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

  - References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

  - Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

  - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Access to Gulf War Veterans or Gulf War Veteran Biospecimens/Data (as applicable): Provide a letter showing approved access to Gulf War Veterans if proposing to access the Veteran population or use biospecimens/data from Veterans (e.g., from collaborating VA investigators, DMDC Data Request System). PIs whose applications will require use of data from VA or military databases should confirm the ability to meet database requirements prior to application submission. A letter of support, signed by the lowest-ranking person with approval authority, should be included for studies involving Veterans, VA- or military-controlled study materials, and/or VA or military databases.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf." The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  The programmatic reviewers may not have access to the full application and may rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

Technical abstracts should be structured as follows:

- Background: Present the ideas and reasoning behind the proposed work. Demonstrate direct relevance of the project to Veterans of the 1990-1991 Gulf War with GWI. State the Tier for which the application is being submitted and, if applicable, the FY17 GWIRP IIFRA Topic(s) of Special Interest being addressed.

- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- Specific Aims: State the specific aims of the study.

- Study Design: Briefly describe the study design including appropriate controls.

- Impact: Summarize briefly how the proposed project will have an impact on GWI research and/or Veterans with GWI.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf." The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information***. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  - Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize use of acronyms and abbreviations. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

  - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.

  - Describe the ultimate applicability of the research.

    - What are the potential clinical applications, benefits, and risks for Veterans with GWI?

    - What is the projected time it may take to achieve a patient-related outcome?

    - What are the likely contributions of this study in advancing the field of GWI research?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the IIFRA mechanism, use the SOW format example titled "SOW for basic Research." The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

Include the name(s) of the key personnel and contact information for each study site/ subaward site.

Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

Briefly state the methods to be used.

For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the FDA or other Government agency.

- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf." Explain how the project addresses one or more of the Topics of Special Interest or another critical problem in GWI. As applicable to the proposed research, describe how the outcomes of the project will advance the GWI field by increasing the understanding of GWI pathobiology, improving the definition and diagnosis of GWI, or elucidating potential treatments. Describe how the project has the potential to lead to improved health or quality of life for Veterans with GWI in the short and/or long term.

- **Attachment 7: Animal Research Plan (if applicable, one page limit per animal study):** Upload as "Animal.pdf." When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

  - Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.

  - Summarize the procedures to be conducted. Describe how the study will be controlled.

- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.

- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.

- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s). Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Attachment 8: Use of Hazardous Chemical or Biological Agents (if applicable, no page limit):** Upload as "Hazardous.pdf." The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as CDC registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from Government sites issuing any agent(s). Indicate if agents used are purchased commercially, and if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

- **Attachment 9: Outcomes Statement (if applicable, one-page limit):** Upload as "Outcomes.pdf." If applicable, list all prior research projects/awards relating to GWI, including resulting publications, abstracts, patents or other tangible outcomes. Only research and outcomes directly relevant to GWI should be listed. ***Note: This item will be made available for programmatic review.***

- **Attachment 10: DoD Military Budget Form(s), if applicable:** Upload as "MFBudget.pdf." If a military facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (PDF) that is not editable.

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

  R&R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.6, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

  - **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 10. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Application Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

II.D.5. Funding Restrictions

Funding varies by Tier. The requested Tier should be based on the scope and maturity of the research propose and not the funding level.

- **Tier 1 – Discovery:**
    - The maximum period of performance is **2** years.
    - The anticipated direct costs budgeted for the entire period of performance will not exceed **$230,000**. If indirect costs rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the

Government exceeding **$230,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

- All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

- **Tier 2 – Applied Research:**

  - The maximum period of performance is **3** years.

  - The anticipated direct costs budgeted for the entire period of performance will not exceed **$700,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$700,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

  - All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

  - The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

For all Tiers:

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Veteran subject reimbursement and compensation including
  - Transportation
  - Lodging
  - Participation incentives
- Research-related subject costs
- Support for multidisciplinary collaborations, including travel
- Travel costs for one investigator to travel to one scientific/technical meeting per year .

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct

transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.4, for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.4***.

The CDMRP expects to allot approximately $4.1M of the $20M FY17 GWIRP appropriation to fund approximately five IIFRA applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Research Strategy and Feasibility**
    - How well the proposed research and current state of knowledge fit the intent of the Tier applied for as explained in Section II.B, Award Information.
    - How well the preliminary data and/or scientific rationale support(s) the objective and feasibility of the approach (preliminary data are not required under Tier 1, but are required under Tier 2).
    - How well the hypotheses or objectives, aims, study design, methods, analyses, and statistical plan are developed and integrated into the project.
    - How well the application identifies potential problems and addresses alternative approaches.
    - For studies involving hazardous agents, whether the application includes an appropriate plan for acquiring, using, and maintaining the hazardous agents.

- For research involving access to archived Gulf War-era Veteran samples, whether the application includes documentation demonstrating that the PI will have access to specimens and samples in amounts sufficient to support the proposed study (or studies). Additionally, how adequately the procedures to assess the quality of the materials and correct for effects and/or artifacts of sample processing and storage are described.

- How well assurance that documentation will support a regulatory filing with the FDA is described, if applicable.

- ***For studies involving animal models:***

  - How clearly the study (or studies) is representative of the current status of ill 1990-1991 Gulf War Veterans in terms of choice of model and the endpoints/outcome measures to be used.

  - If a new animal model is proposed, to what extent the unique features of this model are required in order to conduct the proposed research.

  - How well the study (or studies) is (are) designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.

- ***For clinical research:***

  - Whether the application includes documentation demonstrating that the PI will have access to a suitable 1990-1991 Gulf War Veteran population in numbers that will support a meaningful outcome.

  - Whether the application describes use of the CDC and Kansas case definitions. If the application proposes use of a case definition in addition to the CDC and Kansas case definitions, how well that case definition is described and justified.

- ***For biomarker investigations:***

  - How well the application demonstrates that the proposed biomarkers relate to GWI and not unrelated factors or subsequent exposures.

- **Impact**

  - To what extent the anticipated outcomes of the project will make an important contribution to the goal of advancing the GWI field, increasing the understanding of GWI pathobiology, improving the definition and diagnosis of GWI, or elucidating potential treatments for Veterans of the 1990-1991 Gulf War.

  - To what extent the proposed project has the potential to lead to improved health or quality of life for Veterans with GWI in the short and/or or long term.

- **Personnel**
    - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of the project.
    - How well the PI's record of accomplishment demonstrates his/her ability to perform the proposed work.
    - How appropriate the PI and research team's background and expertise are with regard to accomplishing the proposed work.

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the application:

- **Budget**
    - Whether the maximum direct costs are equal to or less than the allowable maximum direct costs as published in the Program Announcement.
    - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.
- **Environment**
    - To what extent the scientific environment is appropriate for the proposed research.
    - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - Whether the quality and extent of organizational support are appropriate for the proposed research.
    - If applicable, to what degree the intellectual and material property plan is appropriate.

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 GWIRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism

- Program portfolio composition with consideration of the FY17 GWIRP IIFRA Topics of Special Interest
- Relative impact
- Relative outcomes from the PI's previous GWI-related research (if applicable)

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and GWIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the

applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

Intramural Organizations: Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request

(MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. Award Transfers

Unless otherwise restricted, changes in PI will be allowed at the discretion of the USAMRAA Grants Officer, provided that the intent of the award mechanism is met.

An organizational transfer of an award will not be allowed in the last year of the (original) performance period or any extension thereof.

Refer to the General Application Instructions, Appendix 2, Section B, for general information on organization or PI changes.

II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

In addition to written progress reports, Annual Award Charts will be required. For the IIFRA mechanism, use the format example titled, "Generic Award Charts," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm).

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil,

criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations is available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations is available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516a. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur:

II.H.2.a. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY17 GWIRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY17 GWIRP Programmatic Panel members can be found at http://cdmrp.army.mil/gwirp/panels/panels17***.
- The application fails to conform to this Program Announcement description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY17, the identities of

the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Grants Officer. Refer to the General Application Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- The invited application does not propose the same research project described in the pre-application.
- The application describes research focusing on ALS.
- The application describes research whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.
- The application includes a clinical trial.
- The application describes derivation of GWI diagnostic biomarkers from animal models.
- The PI does not meet the eligibility criteria.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population or resources.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

II.H.3. Application Submission Checklist

Application Components	Action	Completed
SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)**	Complete form as instructed.	
Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)**	Complete these tabs as instructed.	
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Animal Research Plan: Upload as Attachment 7 with file name "Animal.pdf," if applicable.	
	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 8 with file name "Hazardous.pdf," if applicable.	
	Outcomes Statement: Upload as Attachment 9 with file name "Outcomes.pdf," if applicable	
	DoD Military Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget **(Extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	

Application Components	Action	Completed
Budget **(Intramural submissions only)**	Complete the DoD Military Budget Form and justification.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed.	

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
ALS	Amyotrophic Lateral Sclerosis
ARRIVE	Animal Research: Reporting *In Vivo* Experiments
CDMRP	Congressionally Directed Medical Research Programs
CDC	Centers for Disease Control and Prevention
COI	Conflict of Interest
CFR	Code of Federal Regulations
CSPEC	Cooperative Studies Program Epidemiology Center DHA Defense Health Agency
DHP	Defense Health Program
DIACAP	Department of Defense Information Assurance Certification
DMDC	Defense Manpower Data Center
DoD	Department of Defense
DoDGAR	Department of Defense Grant and Agreement Regulations
DoDSR	DoD Serum Repository (formerly Armed Forces Serum Repository)
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FISMA	Federal Information Security Management Act
FY	Fiscal Year
GWECB	Gulf War Era Cohort and Biorepository
GWI	Gulf War Illness
GWIRP	Gulf War Illness Research Program
GWVIB	Gulf War Veterans' Illnesses Biorepository
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IIFRA	Investigator-Initiated Focused Research Award
IRB	Institutional Review Board
M	Million
MAVERIC	Massachusetts Veterans Epidemiology Research and Information Center
MIPR	Military Interdepartmental Purchase Request
MVP	Million Veteran Program
NAM	National Academy of Medicine
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
RM	Resource Manager
SAM	System for Award Management
SBCC	Systems Biology Collaboration Center

SOW	Statement of Work
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs
VABBB	Veterans Affairs Biorepository Brain Bank