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

Qualitative Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-18-GWIRP-QRA

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), July 13, 2018

- **Invitation to Submit an Application:** August 2018

- **Application Submission Deadline:** 11:59 p.m. ET, November 8, 2018

- **End of Application Verification Period:** 5:00 p.m. ET, November 13, 2018

- **Peer Review:** January 2019

- **Programmatic Review:** February 2019

This Program Announcement must be read in conjunction with the General Application Instructions, version 20180329. 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

New for 2018: **Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their application Workspace package.**

II.A. Program Description

Applications to the Fiscal Year 2018 (FY18) 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 FY17 totaled $149 million (M). The FY18 appropriation is $21M.

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 32% (or 175,000 to 224,000) 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 identify effective treatments and accelerate their clinical application, identify objective markers for improved definition and diagnosis, and/or provide a better understanding of the pathobiology underlying 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.B. Award Information

Qualitative research is a form of social inquiry that seeks to understand the human experience by exploring how people interpret and make sense of their experiences and the world in which they live. The intent of the FY18 GWIRP Qualitative Research Award is to support *qualitative research studies* that seek to understand the experiences, perceptions, barriers, and beliefs of Veterans suffering from GWI and those responsible for their care. Observations that drive a research idea may be derived from basic discovery, population-based studies, a clinician's firsthand knowledge of patients, or anecdotal data. *Appropriate qualitative research topics include, but are not limited to, the explorative, descriptive, predictive, or explanatory study of:*

- Generation of data to inform **new and GWI-specific** clinical practice guidelines, with consideration of potential implementation strategies;

- Real or perceived barriers concerning access to treatment and healthcare or information about care;

- Impact of personal factors and comorbid medical conditions that influence or mediate a patient's health or quality of life;

- Impact of cultural values and beliefs on the success of treatment and/or healthcare behaviors;

- Impact of medical care decisions (e.g., choice of civilian versus Department of Veterans Affairs [VA] facility) on quality-of-life topics;

- Impacts on the spouses/partners and/or families of Veterans suffering from GWI to include career issues, emotional stress, physical strain and injury, intimacy, etc.;

- Factors and strategies for improving psychosocial adjustment and adjustment to disability for patients and their families and friends;

- Real or perceived barriers in the translation of research to clinicians; and

- Exploration of clinician-patient communication experiences.

The outcomes of this research should ultimately be translated into educational materials and tools to better inform Veterans, their caregivers, and/or their healthcare providers about GWI and its care. These tools should fall under **one** of the following categories based on the audience the information is intended to serve:

- Educational materials and tools (printed materials, webpage, mobile app, Massive Open Online Courses, wearable technology, etc.) targeting Veterans with GWI and their caregivers.

- Educational materials and tools (printed materials, interactive workshops, outreach visits, open register for patient treatment summaries, etc.) targeting healthcare providers who treat Veterans suffering from GWI.

This mechanism is specifically focused on Veterans of the 1990-1991 Persian Gulf War who are suffering from GWI. Collaboration with VA researchers and clinicians is encouraged. Preliminary and/or published data relevant to GWI are encouraged, but not required. Data from conditions with similar symptomatology may also be used to support the application.

Activities not supported under this Program Announcement:

- Studies focusing on psychiatric disease or psychological stress as the primary cause of GWI or implementation of care guidelines placing significance emphasis on psychiatric pathologies or psychiatric remedies.

- 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 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 Human Subject Resource Document at https://cdmrp.org/Program_Announcements_ and_Forms/.

The anticipated direct costs budgeted for the entire period of performance for an FY18 GWIRP Qualitative Research Award will not exceed **$450,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

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 the Department of Defense (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) and the award will identify the specific substantial involvement. 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.

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 Institutional Review Board (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*. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. 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 (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. 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

Use of DoD or VA Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the Principal Investigator (PI) is responsible for demonstrating such access at the time of application submission and should develop a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA PIs must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA PIs. If the VA NPC is not identified as the applicant institution for administering the funds, the application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Investigators should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD

and/or VA. If access cannot be confirmed at the time of application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Application Submission Components, for detailed information.

Gulf War Veteran Recruitment: Applicants intending to recruit Veterans are encouraged to leverage existing cohorts recruited in other GWIRP-supported studies and should refer to the Research Resources link (http://cdmrp.army.mil/gwirp/resources/gwirpresources) on the GWIRP website. Applicants recruiting Veterans are also highly 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. Researchers are not required to use any of the following limited examples or any one particular dataset.

- Boston Biorepository, Recruitment, and Integrative Network (BBRAIN) for GWI. Funded by the FY17 GWIRP, the BBRAIN is being established at the Boston University School of Public Health. The BBRAIN provides a centralized cataloguing and coordination of retrospective and prospective Gulf War Veteran biospecimens and data from institutions conducting GWI research. Applicants interested in collaborating with this network should refer to the Research Resources link (http://cdmrp.army.mil/gwirp/resources/biorepositories) on the GWIRP website.

- Defense Manpower Data Center (DMDC; https://www.dmdc.osd.mil) maintains the largest archive of personnel data in the 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 (DoD 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 Study (http://millenniumcohort.org). Initiated in 2001, the Millennium Cohort Study is ongoing and comprises a 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 VA 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 Cooperative Studies Program Epidemiology Center (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.

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, 2019. 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 academic institutions, biotechnology companies, foundations, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center.

Note: Applications from an intramural DoD organization or from an extramural 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

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 an organization to Grants.gov.

Intramural DoD Submission is defined as an application submitted by a DoD organization to eBRAP.

II.D.1. Address to Request Application Package

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.

Extramural Submissions: Pre-application content and forms must be accessed and submitted at eBRAP.org. Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions: Pre-application content and forms and full application packages must be accessed and submitted at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.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/).

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 a Grants.gov Workspace. 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. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

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.

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 full 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 submission 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 is required 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 will delay 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 to request a change in designation.

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.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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.

  FY18 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 FY18, 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.

    The Preproposal Narrative should include the following:

    – **Research Question:** Describe the research question(s) the project will address. State the ideas and reasoning on which the proposed research is based.

    – **Specific Aims and Study Design:** Concisely state the project's specific aims and describe the approach. Clearly identify whether the research is aimed at developing

educational materials or tool for Veterans, their caregivers or their healthcare providers.

- **Impact:** Describe the potential impact of this study on the quality of GWI patient care, and/or quality of life of Veterans with GWI.

○ **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 FY18 GWIRP, pre-applications will be screened based on the following criteria:

○ **Research Question:** Whether the research question is relevant for healthcare and/or quality of life for Veterans with GWI. Whether there is sufficient rationale to support the proposed research question(s) to be addressed.

○ **Specific Aims and Study Design:** How well the specific aims and proposed methodology will address the research question(s) to be explored.

○ **Impact:** To what extent the study (if successful) will make important contributions toward the goals of advancing GWI research, patient care, and/or improving quality of life.

- **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 timeframe 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.

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 must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in the Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. 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-18-GWIRP-QRA from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-18-GWIRP-QRA 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 Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable)	**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 **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.

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission. Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs 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 next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email.
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/ Task Area Manager or equivalent Business Official and PI will receive 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. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

Extramural Submissions	Intramural DoD Submissions
Further Information	
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. 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.

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. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before 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 have 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 (10-page limit):** 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.

  Describe the proposed project in detail using the outline below.

  Inclusion of preliminary and/or published data relevant to GWI and the proposed research project is encouraged, but not required.

  - – **Background:** Identify the major research question(s) to be addressed. Describe the specific theoretical perspective of qualitative research on which the study is based. Clearly demonstrate that there is sufficient evidence to support the proposed stage of research. Cite relevant literature, and describe previous experience most pertinent to this project, including data from pilot studies, if applicable.

  - – **Specific Aims:** Concisely explain the project's specific aims. If the proposed research project is part of a larger study, present only tasks that this GWIRP award would fund.

  - – **Study Design:** Describe the overall study design in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. The following important components of a qualitative study design, including methods, should be addressed:

    - ▪ *Data Collection:* Provide clear and detailed descriptions of data collection. Specify what counts as data and how the data will be obtained. Thoroughly describe methods for sampling, collection, interviewing, data mining, etc., and how the information will be recorded and documented. Discuss how these methods are systematic and rigorous and how they are appropriate with regard to addressing the qualitative research question(s). If methods will evolve from and be informed by the research itself, describe how the rigor of these processes will be maintained. Describe and articulate specific benchmarks that will be utilized to assess whether the research progresses in an efficient, timely, and thorough manner.

    - ▪ *Access to Data/Subject Case Definition:* Include a detailed plan for the acquisition of Veteran or other subject data. When recruiting Veterans with GWI, both the CDC and Kansas GWI case definitions must be used to characterize the subjects. Describe and justify any additional case definition of GWI to be used in the study, including any targeted illness subgroups that will be defined for the study.

- ▪ ***Data Analysis:*** Thoroughly describe plans for data analysis, including how themes will be found, patterns identified, and comparisons made. The simple mention of the use of qualitative analysis software packages is insufficient. The design and analysis should link clearly to answering the research question. Describe how the analyses are systematic and rigorous and how they are appropriate to addressing the qualitative research questions. Describe how reliability will be measured and the steps taken to control biases and preconceptions. Demonstrate how the proposed design supports consistency, dependability, and duplicability of results. Discuss generalizability or significance beyond the specific cases selected.

- ○ **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.

    There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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.

- 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.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.

- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

○ **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:

- Research Question: Articulate a clear research question framed in terms of the theoretical and methodological paradigms both within and beyond GWI. Define and operationalize the project's key constructs and specify the expected relationships.

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

- Study Design: Describe the study design and type of analyses. Clearly state whether the research is aimed at educational materials or tools for Veterans and their caregivers or healthcare providers.

- Impact: Briefly describe the potential impact of this study on the quality of GWI patient care and/or quality of life of 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 research question(s) that the project will address. Clearly identify whether the research is aimed at educational materials and tools for Veterans, their caregivers, or their healthcare providers.

- Describe the projected timeline for achieving the desired outcome.

- Describe the likely contributions of the proposed research project to improving our understanding of individuals with GWI, their caregivers, or their healthcare providers and overall perceptions on access to and types of care.

○ **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 Qualitative Research Award mechanism, use the SOW format example titled, "SOW for Clinical 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.

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

○ **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf." Describe the impact of this study on the field of GWI research, patient care, and/or quality of life. Include a description of how this research is designed in such a way to expeditiously translate results into educational materials or tools for Veterans with GWI, their caregivers, or their healthcare providers.

○ **Attachment 7: Surveys, Questionnaires, and Other Data Collection Instruments (no page limit):** Upload as "Surveys.pdf." The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe the PI's prior experience using the proposed data collection tools, including, but not limited to, the psychometrics generated from their use and relevant information regarding instrument validation or reliability.

○ **Attachment 8: Gulf War Veteran Outreach and Recruitment Plan (five-page limit):** Upload as "Outreach.pdf." Outreach and positive recruitment and retention have historically been an issue in the study of Gulf War Veterans. Recruiting and retaining participants requires careful consideration. Outreach and recruitment activities need to be identified early in the planning process and should include the involvement of appropriate sources within the community and considerations for Veteran subject compensation. The Gulf War Veteran Outreach and Recruitment Plan must include the components listed below. A resource containing additional guidance for successful access to Gulf War Veterans titled, "Best Practices for Gulf War Veteran Subject Outreach and Recruitment" can be found on the GWIRP webpage at [http://cdmrp.army.mil/gwirp/pdfs/ General%20_Guidance_for_Gulf_War_Veteran_Outreach_and_Recruitment.pdf](http://cdmrp.army.mil/gwirp/pdfs/General%20_Guidance_for_Gulf_War_Veteran_Outreach_and_Recruitment.pdf).

  - **Gulf War Veteran Population:** Describe the nature, approximate number, and pertinent demographic characteristics of the target Gulf War population. Include information about specific symptom profiles relevant to GWI and the proposed clinical research.

  - **Subject Outreach and Recruitment:** Describe the activities that will be used to identify and recruit potential subjects using the outline below. All advertisements and

recruitment materials must be approved by the respective IRB/EC prior to use. Local IRB/EC approval at the time of application submission is not required.

- Specific Approaches: Summarize the outreach plan including advertising, appearances at events, direct mail, and other approaches.

- Organizations: Name the specific organizations that will participate in recruitment efforts.

  - When collaborating with VA researchers, a letter of support confirming access to VA patients and signed by the lowest-ranking person with approval authority, is required. Include this letter in Attachment 2.

  - Media Outlets: Name specific broadcast or social media outlets that will be used to advertise the study.

- Staff

  - Describe the composition and duties of the outreach/recruiting staff.

  - Describe training they will receive for interacting with and recruiting Veterans.

- Recruitment Materials: The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study. Encouraging themes describing how the research might benefit fellow Gulf War Veterans or Veterans of later deployments suffering from similar exposures are acceptable. Describe electronic, paper, or other recruitment materials to be employed.

  - If advertising materials are to be posted at VA or civilian facilities, a signed statement indicating permission must be included. Include this letter in Attachment 2.

  - Compensation and incentives: Include a description of the compensation plan for travel, meals, lodging, participation incentives, and any other compensation or incentives.

- **Physical and Logistical Accommodation of Subjects:** Describe measures that will be taken at the research facility to accommodate subjects including aid in reaching the facility, moving or navigation within the facility, and assignment of and access to staff points of contact for inquiries or requests for assistance.

- **Alternate Approaches:** Include detailed plans for alternate approaches to be employed if recruitment lags in schedule.

- **Sharing of Study Results:** The Department of Health and Human Services Secretary's Advisory Committee on Human Research Protections has published several recommendation regarding the sharing of research data and findings with

research subjects. Applicants are encouraged to review these recommendations for incidental findings, individual study results, Health Insurance Portability and Accountability Act (HIPAA), and Clinical Laboratory Improvement Amendments (CLIA) considerations, and general study results at the hyperlinks given. Describe plans for dissemination of study results to participants including:

- Aggregate, final study results including any lay-oriented materials other than scientific publications.

- Individual study test results for individual subjects.

○ **Attachment 9: Transition Plan (three-page limit):** Upload as "Transition.pdf." Describe/discuss the methods and strategies proposed to move the anticipated research outcomes to the next phase of development. Provide a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications.

○ **Attachment 10: Data and Research Resources Sharing Plan (two-page limit):** Upload as "SharingPlan.pdf." Describe how data and resources generated during the performance of the project will be shared with the research community. Describe whether the proposed plan for data sharing includes databases most relevant to GWI and whether the plan describes organizational and technical capabilities sufficient to share project data in a timely manner. 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. Include plans for making raw data publicly available in appropriate databases at the time of publication or at the time of conclusion of the funding. The Government reserves the right to identify repositories for submission of data for archive. Any costs associated with submission will be addressed during award negotiations.

○ **Attachment 11: 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.

○ **Attachment 12: Representations, if applicable (extramural submissions only):** Upload as "MandatoryReps.pdf." All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

○ **Attachment 13: DoD Military Budget Form(s), if applicable:** Upload as "MFBudget.pdf." If a military facility (Military Health System facility, research laboratory, medical 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**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, or mathematics disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  Research & Related Personal Data: 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.

  Research & Related Senior/Key Person Profile (Expanded): 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.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 PDF format 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.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  ○ **Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (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 Data 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 at 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

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.

Extramural Submission: 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.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the 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. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$450,000**. 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 **$450,000** 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 this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary

- Research supplies

- Veteran subject reimbursement and compensation including subject travel, lodging, and 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 to present project outcomes or disseminate project results.

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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. 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 $720,000 of the $21M FY18 GWIRP appropriation to fund approximately one Qualitative Research Award application, 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.

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

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 Question**

  ○ How relevant the study questions are to issues surrounding treatment and quality of life for Veterans with GWI.

  ○ How well the rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature and/or logical reasoning.

  ○ How clearly the specific theoretical basis for the study is stated and is shown to drive the framing of the research question(s).

  ○ How well the proposed research describes a research question(s) important to the development of educational materials or tools for Veterans suffering from GWI, their caregivers or their healthcare providers.

- **Study Design**

  ○ How well the specific aims and proposed methodology will address the research question(s) to be explored.

  ○ If methods will evolve from and be informed by the research itself, how well the application describes the method(s) used to maintain the rigor of these processes.

  ○ As applicable to the proposed research, how well the application demonstrates access to the appropriate population(s) (Veterans or their family members, caregivers, and/or healthcare providers) or demonstrates access to the proposed resources/databases.

  ○ The extent to which the approaches described in the Gulf War Veteran Outreach and Recruitment Plan are sufficient for attaining recruitment goals.

  ○ The extent to which the proposed compensations, incentives, and accommodations will reduce barriers to participation.

  ○ To what extent the proposed design of the study, including data collection, recording, and analysis, is appropriate and will address the research question.

    – How well the rationale for decisions and conclusions supports consistency, dependability, and duplicability of results, and prevents biases and preconceptions.

- How consistent the data analysis plan is with the research problem and theoretical basis of the study.

- How well the project will obtain ongoing feedback from the participants, especially regarding interpretation of data and intermediate study conclusions.

○ How well the application has described and articulated specific benchmarks that will be utilized to assess whether the research is progressing in an efficient, timely, and thorough manner.

○ How well the application acknowledges potential problems and addresses alternative approaches.

- **Impact**

○ If successful, how the study will have an impact on the field of GWI research, patient care, and/or quality of life.

○ Whether the information collected can be rapidly translated into an educational materials or tools for Veterans suffering from GWI, their caregivers, or their healthcare providers.

- **Personnel**

○ How appropriate the relevant education, training, and experience of the PI and key personnel are to carrying out the proposed qualitative research.

○ How well the application reflects the applicant's knowledge of and respect for the needs of the community of Veterans with GWI.

○ Whether plans for outreach and recruitment staff training are described and are appropriate for interacting with and recruiting Veterans.

○ Whether the PI and key personnel levels of effort are appropriate for successful conduct of the proposed work.

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

- **Environment**

○ To what extent the scientific environment is appropriate for the proposed research project.

○ How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

○ To what extent the quality and extent of institutional support are appropriate for the proposed research project.

○   If applicable, to what degree the intellectual and material property plan is appropriate.

- **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.

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 FY18 GWIRP, as evidenced by the following:

    ○   Adherence to the intent of the award mechanism

    ○   Program portfolio composition with consideration of "The Gulf War Illness Landscape"

    ○   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 the 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 and approval 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 and approval 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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, 2019. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through 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 document.

Federal 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of application review results through 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. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization 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) period of performance or any extension thereof.

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

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

If additional conference travel is proposed, prior to the re-budgeting and in advance of the incurrence of the travel costs, the Grants Officer should be consulted to determine the reasonableness of the expense in accordance with 2 CFR 200.407.

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 with Institutions of Higher Education, Hospitals, and Non-Profit Organizations](#): Addendum to the DoD R&D Terms and Conditions 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. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required.

Quarterly technical progress reports will be required.

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

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template titled, "Award Expiration Transition Plan," available on the on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

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 (see General Application Instructions, Section III.A.4).

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 20180329e. The Program Announcement numeric version code will match the General Applications Instructions version code 20180329.

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 FY18 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 FY18 GWIRP Programmatic Panel members can be found at http://cdmrp.army.mil/gwirp/panels/panels18.*

- 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 FY18, 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 or approval 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.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The invited application does not propose the same research project described in the pre-application.

- The application proposes a clinical trial.

- The PI does not meet the eligibility criteria.

- The application describes research focusing on ALS.

- The proposed research focuses on psychiatric disease or psychological stress as the primary cause of GWI.

- 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."	
	Surveys, Questionnaires, and Other Data Collection Instruments: Upload as Attachment 7 with file name "Surveys.pdf."	
	Gulf War Veteran Outreach and Recruitment Plan: Upload as Attachment 8 with file name "Outreach.pdf."	
	Transition Plan: Upload as Attachment 9 with file name "Transition.pdf."	
	Data and Research Resources Sharing Plan: Upload as Attachment 10 with file name "SharingPlan.pdf."	
	Outcomes Statement: Upload as Attachment 11 with file name "Outcomes.pdf," if applicable	
	Representations (extramural submissions only): Upload as Attachment 12 with file name "MandatoryReps.pdf," if applicable.	
	DoD Military Budget Form(s): Upload as Attachment 13 with file name "MFBudget.pdf," if applicable.	
Research & Related Personal Data	Complete form as instructed.	

Application Components	Action	Completed
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.	
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

ACOS/R&D	Associate Chief of Staff for Research and Development
ALS	Amyotrophic Lateral Sclerosis
BBRAIN	Boston Biorepository, Recruitment, and Integrative Network
CDC	Centers for Disease Control and Prevention
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
COI	Conflict of Interest
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
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
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
HIPAA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protection Office
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

NPC	Non-Profit Corporation
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
SAM	System for Award Management
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	Department of Veterans Affairs Biorepository Brain Bank