

**Program Announcement**  
for the  
**Department of Defense**  
**Defense Health Program**  
**Congressionally Directed Medical Research Programs**

**Gulf War Illness Research Program**  
**New Investigator Award**

**Funding Opportunity Number: W81XWH-16-GWIRP-NIA**  
**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), October 6, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, October 20, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, October 25, 2016
- **Peer Review:** December 2016
- **Programmatic Review:** February 2017

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2016 (FY16) Gulf War Illness Research Program (GWIRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity 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 the effects of deployment in the 1990-1991 Persian Gulf War on U.S. Warfighters. Appropriations for the GWIRP from FY06 through FY15 totaled \$109 million (M). The FY16 appropriation is \$20M.

The GWIRP challenges the scientific community to design high-impact research that will improve the health and lives of Veterans who have Gulf War illness (GWI). GWI is characterized by multiple diverse symptoms that typically include widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, chronic headache, sleep problems, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests.

The population of Veterans affected by GWI is a subset of the nearly 700,000 who served during the Gulf War. Specifically, these Gulf War Veterans were deployed to the theatre of operations in Southwest Asia, including Iraq, Kuwait, and Saudi Arabia. Studies indicate that approximately 25% to 33% (or 175,000 to 210,000) of Gulf War Veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP focuses on innovative projects that have the potential to make a significant impact on finding treatments for GWI. While such projects may include identification of objective indicators of pathology that distinguish ill from healthy Gulf War Veterans or studies to understand the underlying pathobiology of GWI, projects should exhibit clear translational potential that leads to treatments for Veterans with GWI. Beginning in FY15, the GWIRP has included an additional focus on patterns of health and disease in Gulf War Veterans that is supported by the Gulf War Illness Epidemiology Research Award (GWIERA). For information about the GWIERA (Funding Opportunity Number: W81XWH-16-GWIRP-GWIERA), see <http://cdmrp.army.mil/funding/gwirp>.

### **B. FY16 Areas of Emphasis**

The GWIRP has identified several areas of emphasis for the FY16 New Investigator Award. The GWIRP has a special interest in the exploration of the areas listed below; however, these areas are optional and the applicant may propose studies in any other area of GWI research:

- Disruption in mitochondrial function including parameters/measures at both baseline and after challenge (stress, exercise, immune, etc.)

- Disruption in neurological function (peripheral and central) including parameters/ measures at both baseline and after challenge (stress, exercise, immune, etc.)
- Genetic factors predisposing some Gulf War Veterans to GWI including long-term (>20 years) reportable parameters
- Abnormal immune system function in GWI including long-term (>20 years) reportable parameters
- Symptom clusters and identification of mechanistic or diagnostic features specific to those clusters by multimodal “omic” investigations (e.g., molecular signatures from genomic, proteomic, metabolomic, or epigenetic technologies)

### **C. Award Information**

The GWIRP New Investigator Award mechanism was first offered in FY14. Since then, 33 New Investigator Award applications have been received, and 12 have been recommended for funding.

The intent of the GWIRP New Investigator Award is to support investigators new to the field of GWI research at different stages of career development. This award enables such investigators to compete for funding separately from investigators with established programs of GWI research. Previous experience in GWI research is allowed, but not required. However, Principal Investigators (PIs) with a limited background in GWI research are strongly encouraged to strengthen their applications through collaboration with investigators who are experienced in GWI research and/or possess other relevant expertise. It is the PI’s responsibility to describe how the collaboration(s) will augment his/her ability to address the research question.

All applicants for the New Investigator Award must meet specific eligibility criteria under one of the following categories, as described in [Section I.D., Eligibility Information](#).

- Transitioning Postdoctoral Fellow
- Early-Career Investigator
- New GWI Researcher

The New Investigator Award is designed to promote new ideas in GWI research and establish proof-of-principle for further development in future studies. Basic through clinical research is allowed under this award mechanism. The types of studies that will be supported include those aimed at identification of objective measures (e.g., biomarkers) to distinguish healthy Veterans from those with GWI, studies to improve the understanding of the pathobiology underlying symptoms, and preclinical development of interventions for GWI. Applications are not required to include preliminary data; however, preliminary data may be used to support the objectives of proposed project. These data are not required to have come from the GWI research field. Applications not supported by preliminary data should be based on sound scientific rationale and may reflect clinical observations or discoveries made in other illnesses. Regardless of the approach, the focus should be clearly on Veterans with GWI. It is the responsibility of the PI to clearly and explicitly articulate the project’s potential impact on GWI.

**Applications Proposing Biomarker Research:** Applicants must present a rationale for why the proposed markers would be specific for GW-related exposures and not induced by independent factors or events unrelated to Gulf War deployment. Investigation involving derivation of markers from animal models does not address the intent of the biomarker focus area under this award.

***Research involving human subjects is permitted under this Program Announcement/Funding Opportunity but is restricted to studies without clinical trials.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information about distinguishing clinical trials from clinical research, a Human Subject Resource Document is provided at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/). PIs interested in applying for funding for a clinical trial should use the FY16 GWIRP Treatment Evaluation Award mechanism. For information about that mechanism, see <http://cdmrp.army.mil/funding/gwirp>. Retrospective studies or other non-interventional study designs are acceptable under the New Investigator Award.

***Studies whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI will not be funded under this Program Announcement/Funding Opportunity.***

While Gulf War Veterans are affected by amyotrophic lateral sclerosis (ALS) at twice the rate of Veterans who did not serve in the Gulf War, the GWIRP will not accept applications focusing on 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, CDMRP offers a separate ALS Research Program; see <http://cdmrp.army.mil/alsrp>.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (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.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

**Use of Banked Specimens:** Investigators intending to use banked specimens should include in their application a description of steps that will be taken to assess the quality of the materials received and to identify and correct for effects and/or artifacts of sample processing and storage.

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

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 data set.

- 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 (Department of Defense Information Assurance Certification [DIACAP] or Federal Information Security Management Act [FISMA]) to release the requested sensitive information from the Federal entity to the institution.
- DoD Serum Repository (formerly Armed Forces Serum Repository, <https://www.afhsc.mil/Home/DoDSR>). This repository contains Gulf War era specimens 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 a Government employee working for a U.S. military organization. There is a charge for specimens.
- MAVERIC Core Laboratory (Massachusetts Veterans Epidemiology Research and Information Center, <http://maveric.org>). One of four MAVERIC components, the Core Laboratory is a fully equipped, state-of-the-art biological specimen collection and processing center holding over 50,000 specimens, including samples from an estimated 1,500 Gulf War Veterans and an equivalent number of specimens from their spouses. Access to samples requires consent and approval from the VA Central Office.
- Millennium Cohort (<http://millenniumcohort.org>). Initiated in 2001, the Millennium Cohort Study is now closed, though data and specimens are available to investigators. Access requires collaboration with one of the Millennium Cohort Study investigators and approval of the Millennium Cohort Study oversight committee by way of a preproposal/proposal process.
- VA Gulf War Veterans' Illnesses Biorepository (GWVIB) and the Veterans Affairs Biorepository Brain Bank (VABBB) (respectively, [http://www.research.va.gov/programs/tissue\\_banking/gwvib/](http://www.research.va.gov/programs/tissue_banking/gwvib/) and [http://www.research.va.gov/programs/tissue\\_banking/als/](http://www.research.va.gov/programs/tissue_banking/als/)) 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 with the goal of building “one of the world’s largest medical databases by safely collecting blood samples and health information.” The MVP has enrolled over 250,000 Veteran volunteers, including Veterans from the Gulf War era. Researchers must submit a request to obtain access to specimens and data from this collection.

**GW Case Definitions:** In 2014, the Institute of Medicine (IOM) released a report titled “Chronic Multisymptom Illness in Gulf War Veterans: Case Definitions Reexamined” (available online at <http://www.iom.edu/Reports/2014/Chronic-Multisymptom-Illness-in-Gulf-War-Veterans-Case-Definitions-Reexamined.aspx>). In this report, the IOM recommends the use of both, the Centers for Disease Control and Prevention (CDC) definition of GWI and the Kansas definition for 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 for GWI for comparative purposes. Any additional project specific case definition must recognize the multisymptom nature of GWI.

Another resource includes the 2014 report of the Research Advisory Committee on Gulf War Veterans’ illnesses, “Gulf War Illness and the Health of Gulf War Veterans: Research Update and Recommendations, 2009-2013,” which provides information on GWI, including case definitions and research on epidemiology, etiology, pathobiology, and treatment. This report can be found online at <http://www.bu.edu/sph/files/2014/04/RAC2014.pdf>.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

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

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

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

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

*The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 4, Section K.*

#### **D. Eligibility Information**

- PIs may apply under one of the following three eligibility categories:
  - Transitioning Postdoctoral Fellow: Current senior postdoctoral fellows who have completed at least 3 years of postdoctoral training.
  - Early Career Investigator: Independent investigators who are within 5 years of their last training position.
  - New GWI Researcher: Independent investigators at all academic levels (or equivalent) who have received less than \$300,000 in Federally funded, non-mentored funding for GWI research.

- In addition, PIs must:
  - Be able to demonstrate the freedom to pursue independent research goals without formal mentorship; and
  - Not have received a New Investigator Award or similar career development award from any program within the CDMRP.
- Graduate students and junior postdoctoral fellows (i.e., with less than 3 years of postdoctoral training) are not eligible for this award.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *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.*
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## E. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$500,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$500,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) 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

- Research-related subject costs
- Veteran subject reimbursement and compensation
- Clinical research costs (*no clinical trials allowed*)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs for up to one investigator to travel to one scientific/technical meeting per year.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.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 Section II.C.4. of the General Application Instructions.***

***The CDMRP expects to allot approximately \$2.4M of the \$20M FY16 GWIRP appropriation to fund approximately three New Investigator Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## II. 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).***

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity.

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit 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](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.***

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-GWIRP-NIA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

***The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.***

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

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](mailto:help@eBRAP.org) or 301-682-5507.

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

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be 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 either be 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.
  - [FY16 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 IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto: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 application preparation, research, or other duties for submitted applications. For FY16, 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 conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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 Appendix 1, Section C of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**
  - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
- **Tab 6 – Submit Pre-Application**
  - This tab must be completed for the pre-application to be accepted and processed.

### **C. Full Application Submission Content**

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. 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. Refer to the General Application Instructions, Section II, for additional information.

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

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

Each application submission must include the completed Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

**Note:** *The Project Narrative and Budget Form cannot be changed after the application submission deadline.*

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form 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.*

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

**Grants.gov application package components:** For the New Investigator Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

## 2. Attachments Form

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov 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, etc.) 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. The Project Narrative may include preliminary data relevant to GWI and the proposed project, but these data are not required to have come from GWI research. Applications not supported by preliminary data should be based on sound scientific rationale and may reflect clinical observations or seek to evaluate discoveries made in relation to other illnesses for their application in GWI.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous research findings most pertinent to this project. If the application addresses one or more of the FY16 GWIRP Areas of Emphasis (see [Section I.B.](#)), indicate the area(s) addressed. For biomarker research, explain why the proposed biomarker would be expected to be indicative of exposures occurring in 1990-1991 as opposed to later events.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this application. If the proposed work is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If applicable, state which established GWI animal model will be used. If development of a new GWI animal model is proposed, present a clear justification for how it is necessary to support the proposed research. If clinical research is proposed, the Kansas and CDC definitions must be used. Describe and justify any additional case definition of GWI that will be used, including any targeted illness subgroups that will be defined for the study. Include a

detailed plan for the recruitment of subjects or the acquisition of samples and/or data (if applicable). Describe the statistical analysis plan in detail as appropriate for the proposed research. For studies involving the use of banked specimens, describe procedures to be used to assess the quality of the materials and identify and correct for effects and/or artifacts of sample processing and storage. Additionally, for biomarker research, describe procedures to be used to assure the fidelity of the proposed markers in archived specimens.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. **Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***
  - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
  - **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
  - **Letters of Collaboration:** 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.
    - ***For Transitioning Postdoctoral Fellows:*** If the PI is likely to change organizations during the award period of performance (e.g., investigators

transitioning into their first independent faculty position), describe how any proposed collaborations will be maintained.

- Access to Gulf War Veterans or Gulf War Veteran Biospecimens/Data (as applicable): Provide a letter showing approved access to Gulf War Veterans if proposing to access the Veteran population or use biospecimens/data from Veterans (e.g., from collaborating VA investigators, DMDC Data Request System). PIs whose applications will require obtaining and/or using data from VA or military databases should confirm the ability to meet database requirements prior to application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving Veterans, VA- or military-controlled study materials, and/or VA or military databases.
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

Technical abstracts should be structured as follows:

- **Background:** Present the ideas and reasoning behind the proposed work. If the application addresses one or more of the FY16 GWIRP Areas of Emphasis (see [Section I.B.](#)), indicate the area(s) addressed.
  - **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Briefly describe the study design including appropriate controls.
  - **Impact:** Summarize briefly how the proposed project will have an impact on GWI research and/or Veterans with GWI.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
    - What are the likely contributions of this study in advancing the field of GWI research?
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the New Investigator Award mechanism, use the SOW format example titled “SOW for Basic Research.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The GWIRP strongly encourages timely dissemination of the results of GWIRP-sponsored research as a product of the research program. Timely dissemination is critical to improvement of the lives of Veterans with GWI, the advancement of the

field, and the continued success of the program. Therefore, SOWs submitted to the GWIRP must include at least one task or aim focused on preparation and submission of publications. This task or aim must be scheduled to commence at least 6 months prior to the end of the performance period of the award.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**

Explain how the project addresses a critical problem in GWI and/or an area of emphasis. Describe how the anticipated outcomes of the project will advance the GWI field, such as improving the definition and diagnosis of GWI, elucidating potential targets for treatments, or increasing the understanding of GWI pathobiology. Describe how the project has the potential to lead to improved health or quality of life for Veterans with GWI.

- **Attachment 7: Animal Research Plan (if applicable, one page limit per animal study): Upload as “Animal.pdf.”**

If the proposed study involves animals, the applicant is required to submit an Animal Research Plan describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the IACUC as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
- Summarize the procedures to be conducted. Describe how the study will be controlled.
- Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
- Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- **Attachment 8: Use of Hazardous Chemical or Biological Agents (if applicable, no page limit): Upload as “Hazardous.pdf.”**

The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as CDC registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from

Government sites issuing any agent(s). Indicate if agents used are purchased commercially, and if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

- **Attachment 9: Eligibility Statement (one-page limit): Upload as “Eligibility.pdf.”**

Use the Eligibility Statement template (available for download on the Full Announcement page at <http://www.grants.gov/>) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met at the application submission deadline.

- **Attachment 10: (Required only for investigators not yet in an independent faculty position): Statement of Independence (one-page limit): Upload as “Independence.pdf.”**

For investigators not yet in an independent faculty position, complete and sign the Statement of Independence template (available for download on the Full Announcement page at <http://www.grants.gov/>). The Statement of Independence must also be signed by the investigator’s current mentor/supervisor.

- **Attachment 11: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility 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 II.C.7., for detailed information.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., 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 five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **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.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., 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.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 11, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. 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 II.C.7., for detailed information.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity 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/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or 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.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

## **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

## **F. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. 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. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

## **III. APPLICATION REVIEW INFORMATION**

### **A. 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 DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and GWIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. 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 III.B.2., Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

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

## B. Application Review Process

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

- **Research Strategy and Feasibility**

- How well the hypotheses or objectives, aims, study design, methods, analyses and statistical plan are developed and integrated into the project.
- How well the preliminary data, if provided, and/or scientific rationale support(s) the research project.
- How well the PI identifies potential problems and addresses alternative approaches.
- For studies involving hazardous agents, whether the application includes an appropriate plan for acquiring, using, and maintaining the hazardous agents.
- For research involving access to archived Gulf War era Veteran samples, whether the application includes documentation demonstrating that the PI will have access to specimens and samples in amounts sufficient to support the proposed studies
- ***For studies involving animal models:***
  - How clearly the study (or studies) is representative of the current status of ill Gulf War Veterans in terms of choice of model and the endpoints/outcome measures to be used.
  - If a new animal model is proposed, to what extent the unique features of this model are required in order to conduct the proposed research.
  - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization, and data handling.
- ***For clinical research:***
  - Whether the application includes documentation demonstrating that the PI will have access to a suitable Gulf War Veteran population in numbers that will support a meaningful outcome.
  - Whether the application uses the CDC and Kansas case definitions. If the application proposes use of a case definition, in addition to the CDC and Kansas case definitions, how well that case definition is described and justified.
- ***For biomarker investigations:***
  - How well the application demonstrates that the proposed biomarkers relate to GWI and not unrelated factors or subsequent exposures.
  - How adequate the procedures are for assuring the fidelity of the biomarkers in archived specimens and whether the procedures to assess quality and

correct for effects and/or artifacts of sample processing and storage are adequately addressed.

- **Impact**

- To what extent the anticipated outcomes of the project will make an original and important contribution to the goal of advancing the GWI field, improving the definition and diagnosis of GWI, elucidating potential targets for treatments, and/or increasing the understanding of GWI pathobiology.
- To what extent the proposed project has the potential to lead to an improved health or quality of life for Veterans with GWI.

- **Personnel**

- How well the PI's record of accomplishments demonstrates his/her potential for contributing to the field of GWI research and completing the proposed work.
- If applicable, how well the proposed contributions of collaborators will complement the PI's ability to perform the proposed work.
- Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of the project.
- How the research team's background and expertise are appropriate to accomplish the proposed work.

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

- **Budget**

- Whether the direct maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement/Funding Opportunity.
- Whether the budget is appropriate for the proposed research.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

- **Environment**

- To what extent the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- Whether the quality and extent of organizational support are appropriate for the proposed research
- If applicable, to what degree the intellectual and material property plan is appropriate.

- 2. 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:
- a. Ratings and evaluations of the peer reviewers**
  - b. Relevance to the mission of the DHP and FY16 GWIRP, as evidenced by the following:**
    - Adherence to the intent of the award mechanism
    - Program portfolio composition with consideration of the FY16 GWIRP Areas of Emphasis
    - Relative impact

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **E. Notification of Application Review Results**

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.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

## 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.

## C. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY16 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 FY16 GWIRP Programmatic Panel members can be found at <http://cdmrp.army.mil/GWIRP/panels/panels16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity 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 FY16, 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 Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The application describes research focusing on ALS. (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.)
- The application describes research whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.
- The PI does not meet the eligibility requirement.
- The application proposes a clinical trial.

## **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.

## **V. AWARD ADMINISTRATION INFORMATION**

### **A. Award Notice**

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

### **C. National Policy Requirements**

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

### **D. Reporting**

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

### **E. Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

## **VI. VERSION CODES AND AGENCY CONTACTS**

### **A. Program Announcement/Funding Opportunity and General Application Instructions Version**

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

### **B. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application 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](mailto:help@eBRAP.org)

### **C. Grants.gov Contact Center**

Questions related to 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](mailto: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/Funding Opportunity 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.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Animal Research Plan: Upload as Attachment 7 with file name "Animal.pdf," if applicable.	
	8	Use of Hazardous Chemical or Biological Agents: Upload as Attachment 8 with file name "Hazardous.pdf," if applicable.	
	9	Eligibility Statement: Upload as Attachment 9 with file name "Eligibility.pdf."	
	10	Statement of Independence (for investigators not yet in an independent faculty position only): Upload as Attachment 10 with file name "Independence.pdf," if applicable.	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	