Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-15-GWIRP-IIRA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), August 13, 2015
- **Invitation to Submit an Application:** September 2015
- **Application Submission Deadline:** 11:59 p.m. ET, October 29, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, November 3, 2015
- **Peer Review:** January 2016
- **Programmatic Review:** March 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

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 2015 (FY15) 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, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The executing 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 to study the health effects of deployment to the 1990-1991 Persian Gulf War on U.S. Warfighters. Appropriations for the GWIRP from FY06 through FY14 totaled $89 million (M). The FY15 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 chronic headache, widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, 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 30% (or 175,000 to 210,000) of Gulf War Veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP will focus 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 to lead to treatments for Veterans with GWI.

For FY15, the GWIRP will include an additional focus on patterns of health and disease in Gulf War Veterans that will be supported by the new Gulf War Illness Epidemiology Research Award (GWIERA). For information about the GWIERA (Opportunity Number W81XWH-15-GWIRPGWIERA), see http://cdmrp.army.mil/funding/gwirp. The GWIRP encourages high-risk/ high-reward research; however, all projects must demonstrate solid judgment and sound rationale.

The GWIRP Investigator-Initiated Research Award mechanism was first offered in FY06. Since then, 208 Investigator-Initiated Research Award applications were received, and 57 were recommended for funding.

***New for FY15*:** The GWIRP Investigator-Initiated Research Award contains explicit prescriptive language (see below) to guide applicants proposing investigations of potential biomarkers of GWI.

The Investigator-Initiated Research Award is designed to promote new ideas in GWI research and establish proof of principle for further development in future studies. Applications are not required to include preliminary data; however, preliminary data may be used to support the objectives of an application. 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 seek to evaluate discoveries made in relation to other chronic multisymptom illnesses for their application in GWI. Regardless of the approach, the focus should be clearly on Veterans with GWI. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's potential impact on GWI.

The Investigator-Initiated Research Award supports research focusing on the complex of symptoms known as GWI, improving the case definition and diagnosis of GWI, characterizing disease symptoms, and better understanding the pathobiology. The purpose of the award is to encourage basic through clinical research aimed at identification of objective measures (e.g., biomarkers) to distinguish healthy Veterans from those with GWI, or improve understanding of the pathobiology underlying symptoms associated with GWI.

Studies that characterize chronic effects of neurotoxic exposures at dosages comparable to that encountered in-theatre during the Gulf War are of interest. 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.

The Investigator-Initiated Research Award can also be used for testing of GWI-targeted pharmacologic agents in absorption, distribution, metabolism, and excretion (ADME) studies, and toxicology testing, including Investigational New Drug (IND)-enabling pharmacology/ toxicology testing. Preclinical development of non-pharmacological interventions is also acceptable.

Applications Proposing Biomarker Research: The search for biomarkers of GWI is of interest to the GWIRP; however, GWI is a chronic, multisymptom illness resulting from exposures that occurred more than two decades ago. Applicants seeking to investigate biomarkers of GWI are strongly encouraged to employ one or more of the following approaches, which take into account confounding factors of biomarker investigations when applied to GWI populations, patient samples, and/or data:

- Use of pre-existing GWI patient samples (and matched control samples) that have been evaluated to ensure artifacts of sample treatment or storage are known and controlled for;
- Investigation of markers that have been identified in peer-reviewed scientific literature as having potential for diagnostic testing (e.g., markers of neural inflammation, mitochondrial dysfunction, hormonal imbalance, and others related to GWI pathobiology);

- Validation of markers for GW-specific exposures independent of later events unrelated to GW deployment;
- Focus on the identification of markers in subgroups that share symptomatology or on groups with known exposures to specific agents;
- Investigative strategies recognizing the distinction between biomarkers of agent exposures, biomarkers of specific effects of agent exposures, and biomarkers of GWI;
- For markers related to exposure, a wide survey of available GW exposure data should be performed.

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 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 on clinical research, see Human Subject Resource Document at https://cdmrp.org/Program_Announcements_and_Forms/.

PIs interested in applying for funding for a clinical trial should utilize either the Innovative Treatment Evaluation Award or the Clinical Trial Award mechanism. For information about those mechanisms, see http://cdmrp.army.mil/gwirp. Retrospective studies or other non-interventional study designs are acceptable under the Investigator-Initiated Research Award.

Research Involving Human Anatomical Substances 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), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 5, 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.

Applications that include clinical research involving Gulf War Veterans must clearly indicate how this population and/or data from Gulf War Veterans will be accessed. Applicants proposing clinical research are encouraged to collaborate with an investigator who has demonstrated access to Gulf War Veterans, particularly investigators within the U.S. Department of Veterans Affairs (VA), to ensure access to Gulf War Veteran populations as applicable to the proposed project.

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). The DMDC 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 (Massachusetts Veterans Epidemiology Research and Information Center, http://maveric.org). One of four components, the MAVERIC Core Laboratory is a fully equipped, state-of-the-art biological specimen collection and processing center holding over 50,000 specimens. MAVERIC maintains a repository of 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 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 group 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/ and 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 amyotrophic lateral sclerosis (ALS, also called Lou Gehrig's disease). Researchers must submit a request to obtain access to specimens and data from this collection.
- The Million Veteran Program (MVP, scroll to the bottom of 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.

Investigators intending to access 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 processing and storage.

GWI Case Definitions for Clinical Research: In 2014 the Institute of Medicine (IOM) released the report "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 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 project-specific case definition must recognize the multisymptom nature of GWI.

Note: 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," provides information on GWI, including assessments of case definitions and research on epidemiology, etiology, pathobiology, and treatment. The report can be found online at http://www.bu.edu/sph/files/2014/04/RAC2014.pdf.

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 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, the CDMRP offers a separate ALS Research Program (see http://cdmrp.army.mil/alsrp].

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. 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 3 to 4 months for regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 5, for additional information.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S.C., et al., A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 (www.nature.com/nature/journal/v490/n7419/

full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. Projects that include research on animal models are required to submit Attachment 7, Animal Research Plan, as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at http://www.elsevier.com/__data/promis_misc/622936arrive_guidelines.pdf.

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 3, Section L.

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **$450,000**. Associated indirect costs can 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 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.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions***.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI(s) to disseminate project results at one DoD military-related meeting. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Veteran subject reimbursement and compensation
- Clinical research costs
- Publication costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required meeting described above

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. 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. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, 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 Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately $3.6M of the $20M FY15 GWIRP appropriation to fund approximately five Investigator-Initiated Research 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.

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.

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.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

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. Any other application component cannot be changed after the end of the application verification period.

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-15-GWIRP-IIRA in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

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

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

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
    - 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 SF-424 Form). The Business Official must be either selected from the eBRAP 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.
- **Collaborators and Key Personnel – Tab 3**
    - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
    - FY15 GWIRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
    - 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).
- **Pre-Application Files – Tab 5**

  Notes: Upload document(s) 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, etc.) 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 Idea:** State the ideas and reasoning on which the proposed work is based. The focus of the research project should be clearly on Veterans with GWI. ***For biomarker research,*** additionally explain the rationale suggesting that the proposed biomarkers have diagnostic potential and are directly relevant to the 1990-1991 GW Veteran population.
- **Research Strategy:** Concisely state the project's objectives and specific aims. Describe and justify any case definition of GWI other than the CDC and Kansas definitions that will be used in the proposed clinical research, if applicable. Development or use of new animal models must be justified by a substantial advantage or unique purpose that is central to the proposed research. ***For biomarker research,*** additionally explain how the research strategy employs one or more of the approaches prescribed in the award description (see Section I.B., page 4). Describe the source and availability of any archived samples to be employed.
- **Impact:** State how the study addresses a critical problem in GWI. Describe how the outcomes of the project will advance the field of GWI research, such as improving GWI definition and diagnosis, elucidating potential treatment targets, or increasing the understanding of its pathobiology.
- **Personnel:** Briefly state the qualifications of the PI and expertise of key personnel to perform the described research project.

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

- 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, 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 used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (five-page limit per individual).

- **Submit Pre-Application – Tab 6**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

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

  - **Research Idea:** Whether the described research focuses specifically on Veterans with GWI. How the rationale supports the proposed research. ***For biomarker research,*** how strongly the rationale suggests that the proposed biomarkers have diagnostic potential and are directly relevant to the 1990-1991 Gulf War Veteran population.
  - **Research Strategy:** Whether the specific aims and objectives support the research idea. If applicable, whether there is sufficient justification for any case definition to be used other than the CDC or Kansas case definitions in the proposed clinical research. If the research plan includes development or use of a new animal model, how well the application justifies that model in terms of unique advantages or functions central to the proposed research. ***For biomarker research***, how well the research strategy employs one or more of the approaches prescribed in the award description (see Section I.B., page 4). How well access to sufficient quantities of archived samples and/or data to carry out the proposed investigation is described.
  - **Impact:** Whether the study addresses a critical problem in GWI. How the outcomes of the project will advance the GWI field, such as improving GWI definition and diagnosis, elucidating potential treatment targets, or increasing the understanding of its pathobiology.
  - **Personnel:** Whether the qualifications of the PI and key personnel are appropriate to perform the proposed research project.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity.

C. 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 Grants.gov application package provided in Grants.gov 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***.

Grants.gov application package components: For the Investigator-Initiated Research 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. **SF-424 (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 chronic multisymptom illnesses for their application in GWI.

     - **Background:** State the rationale for the proposed research project as it relates directly to GWI. Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous research findings most pertinent to this project. Preliminary data are allowed, but not required.

Additionally, for biomarker research, as appropriate:

- Describe published research indicating the potential diagnostic utility of the proposed biomarkers. Describe how they relate specifically to GWI and are independent of or can be controlled for downstream exposures.
- For markers related to specific exposures, review known exposure data in the proposed subject population. Demonstrate that sufficient exposure data exists to support the proposed investigation.
- Describe the prevalence and pathobiological relevance of subgroups to be investigated with respect to the proposed biomarkers.

- **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 will 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 both the CDC and Kansas 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. Describe the statistical analysis plan in detail as appropriate for the proposed research approach. Address potential problem areas and present alternative methods and approaches.

  Additionally, for biomarker research, as appropriate:

  - Describe the source of any archived specimens and/or data to be used.
  - Describe procedures to be used to assure the fidelity of the proposed markers in archived specimens and to correct or control for artifacts of treatment/handling and storage.
  - Describe how the research strategy employs one or more of the approaches prescribed in the Award Information section.
  - Describe how the markers measured have diagnostic potential and are directly relevant to the 1990-1991 GW Veteran population.

- ***This award may not be used to conduct clinical trials, research focused on ALS, or studies whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.***

- **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 Patent Abstracts: 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 (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.
    - 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., collaborating investigators from the Department of Veterans Affairs, Defense Manpower Data Center Data Request System, etc.). PIs whose applications will require obtaining and/or using Veterans' 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
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - 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 3, Section L 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."** 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. Demonstrate direct relevance of the project to Veterans with GW
  - **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."** 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 used by all reviewers. It is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without scientific or medical backgrounds.
- Describe the ultimate applicability of the research.
  - What 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 Investigator-Initiated Research 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.3., 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 six months prior to the end of the award's period of performance.

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

  Explain how the project addresses a critical problem in GWI. Describe how the 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."

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

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

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

  The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as CDC registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from Government sites issuing any agent(s). Indicate if agents used are purchased commercially, and if so, confirm that the amount is under regulated limits. Include a statement addressing this requirement along with accompanying letters of collaboration, approvals, and certifications.

  Attachment 9: Outcomes Statement (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 10: 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), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information**.**

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

    - 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.
    - 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.5., 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.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** 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, 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 application rejection.

F. Other Submission Requirements

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

All 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 applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP, and the GWIRP, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. 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 nondisclosure 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 application identifies potential problems and addresses alternative approaches.
     - 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.
       - 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 studies proposing a new animal model, to what extent the unique features of this model are required in order to conduct the proposed research.
     - For studies involving hazardous agents, whether the application includes an appropriate plan for acquiring, using, and maintaining the hazardous agents.
     - For research involving access to archived Gulf War-era Veteran samples, whether the application includes documentation demonstrating that the PI will have access to specimens and samples in amounts sufficient to support the proposed study (or studies).
     - 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.
       - If the application proposes use of a case definition other than CDC and Kansas case definitions, how well that case definition is described and justified.

   Additionally, for biomarker investigations, as applicable:

     - How well the background information supports the feasibility of the proposed biomarkers as diagnostic tools.
     - How well the application demonstrates that the proposed biomarkers relate to GWI and not to subsequent exposures.

- How well the research strategy employs one or more of the approaches prescribed in the award description (see Section I.B., page 4).
- How adequate the procedures are for assuring the fidelity of the biomarkers in archived specimens and controlling for artifacts.
- For markers related to exposure, the adequacy of available exposure data for the proposed subject population for the purpose of correlation with biomarker signals.
- For investigations involving population stratification, how relevant the proposed markers are to the pathobiology underlying the defining features of the subgroup.

- **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, or increasing the understanding of GWI pathobiology.
  - To what extent the proposed project has the potential to lead to improved health or quality of life for Veterans with GWI.
- **Personnel**
  - Whether the levels of effort by the PI and other key personnel are appropriate to ensure success of the project.
  - How well the PI's record of accomplishment demonstrates his/her ability to perform the proposed work.
  - How 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 budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.
- **Environment**
  - If applicable, to what degree the intellectual and material property plan is appropriate.
  - 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.

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

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP and FY15 GWIRP, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Program portfolio composition
   - Programmatic relevance
   - Relative impact and innovation
   - Relative outcomes from the PI's previous GWI-related research, if applicable

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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

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.
- 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 pre-application or application:

- A FY15 GWIRP IP 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 FY15 GWIRP IP members can be found at http://cdmrp.army.mil/gwirp/panels/panels15.
- 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).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., 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 invited application does not propose the same research project described in the pre-application.
- If a clinical trial is proposed, the application will be withdrawn.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- 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.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution 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, 2016. Refer to the General Application Instructions, Appendix 3, 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 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. 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

B. 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

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/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
SF-424 (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	Outcomes from prior GWI research awards: Upload as Attachment 9 with file name "Outcomes.pdf," if applicable.	
	10	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 10 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		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.	