

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

**Gulf War Illness Research Program**  
**Clinical Partnership Award**

**Funding Opportunity Number: W81XWH-16-GWIRP-CPA**

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

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 15, 2016
- **Invitation to Submit an Application:** August 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. Award Information**

The GWIRP Clinical Partnership Award mechanism is being offered for the first time in FY16.

The Clinical Partnership Award supports research into the diagnosis and treatment of GWI that will accelerate the movement of promising ideas in GWI research into clinical applications to benefit Veterans with GWI in a manner that would be less readily achievable through independent efforts. The intent of this award is to inform and advance clinical practice, not just from testing/evaluating treatments in a translational model, but also by individualizing treatment

plans, experimenting with potential treatments, or informing biomarker or pathophysiology research from a clinical case series and/or other research-informing clinical modalities. The award is designed to encourage multi-institutional, multidisciplinary research partnerships among **two or three** investigators, referred to as the Initiating Principal Investigator (PI) and the Partnering PI(s), each of whom will receive a separate award. ***There must be at least one laboratory scientist and at least one clinician participating in the partnership.*** A clinician is defined as an individual who is credentialed (possesses the necessary degrees, licenses, and other certifications) as a care provider in any relevant capacity at the institution of record. Applicants must have in place, or have well-justified prospects of, a suitable and sufficient GWI patient clinical care population. In addition, ***at least one partner must have significant experience in GWI research.*** Biographical sketches should include appropriate documentation of credentials.

Observations that drive a research hypothesis may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge from providing care to patients. While the ultimate goal of translational research is to move an observation forward into clinical application, members of the partnership should view translational research as a two-way continuum between bench and bedside. The research plan should involve a reciprocal flow of ideas and information within the partnership. The Initiating and Partnering PI(s) have different submission requirements; however, ***all partners must provide substantial intellectual input into the design of the research project*** and both PIs should contribute significantly to the development of the Project Narrative, Statement of Work (SOW), and other required components. A proposed project in which a clinical partner merely supplies tissue samples or access to patients does not meet the intent of this mechanism. Developmental pathways for translational research that may be useful for designing translational research studies for support under this mechanism may be found within the following resource: [Hawk ET, Matrisian LM, Nelson WG, et al. 2008. The Translational Research Working Group Developmental Pathways: Introduction and Overview, Clin Cancer Res 14:5664-71.](#) These pathways, while created for cancer research initiatives, have broad applicability to other areas of research, are comprehensive, and span the entire translational research continuum from discovery of a target to clinical trials.

The Clinical Partnership Award is not intended to support clinical trials, but may support correlative studies that are associated with an existing clinical trial or projects that optimize the design of future clinical trials. Limited exploratory clinical testing to establish feasibility of a potential approach or to aid in device or intervention refinement may be supported. ***Investigators seeking support for a clinical trial should utilize the FY16 GWIRP Treatment Evaluation Award mechanism;*** see <http://cdmrp.army.mil/funding/gwirp>. A clinical trial is defined as a prospective accrual of patients for a study 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 safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on 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/).

***Applications are required to include preliminary data, which do not necessarily have to come from the GWI research field.*** The proposed research project should be based on sound scientific

rationale that is established through logical reasoning and critical review and analysis of the literature. If the practicing clinician(s) and researcher(s) have an established working relationship, evidence of that relationship should be clearly presented.

***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 VA, to ensure access to Gulf War Veteran populations as applicable to the proposed project. Access to a Gulf War Veteran 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.

**GWIRP 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 may construct a definition of subgroups or symptom clusters as appropriate to the study design; 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. The 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.

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).

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

**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.*

### C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
  - There must be at least one laboratory scientist and at least one clinician participating in the partnership (minimum of 2 and maximum of 3 partners).
  - At least one partner must have significant experience in GWI research or Gulf War Veteran clinical care.
- 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.

## D. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$750,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** 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 applicants may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 3 years.
- The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed **\$750,000**. The combined total direct costs of Initiating PI and the Partnering PI(s) awards will not exceed **\$750,000** direct costs. If the Initiating PI or Partnering PI(s) budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **\$750,000** or use an indirect rate exceeding each organization's negotiated rate.
- A separate award will be made to each PI's organization.
- The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

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

- Salary
- Research supplies
- Research-related subject costs
- Clinical research costs
- Veteran subject reimbursement and compensation
- Support for multidisciplinary collaborations, including travel between the collaborating organizations
- Travel costs for up to three investigators to travel to two scientific/technical meetings 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 two Clinical Partnership 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.

The Clinical Partnership Award mechanism is structured to accommodate two or three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in this email in order to associate his/her Grants.gov application package with that of the Initiating PI.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Do not delay completing these steps. If they are not completed, the Partnering PI(s) will not be able to view and modify his/her application during the verification period in eBRAP.

#### **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-CPA 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 Initiating 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](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.
  - The Initiating PI must enter the contact information for each Partnering PI in the Partnering PI section.
  - 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**

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

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

**The Preproposal Narrative must describe preliminary data to support the feasibility of the proposed project; however, these data may come from fields other than GWI research.** The Preproposal Narrative should include the following:

- **Research Idea:** Describe the ideas and reasoning that form the basis of the proposed research; include relevant literature citations and preliminary data. State the hypothesis and show how the perspective of each partner contributed to the development of the hypothesis. Describe how the rationale and any preliminary data support the proposed research. If a significant portion of the project will depend on concepts repurposed from other diseases or conditions, explain why the approach should be expected to work for GWI.
- **Research Strategy:** Concisely state the project's objectives and specific aims. Briefly describe the experimental approach. If the proposed research is part of a larger study, present only tasks that this GWIRP award would fund.
- **Partnership and Two-way Continuum:** Describe how the project depends on the unique skills of each partner and establishes a reciprocal flow of ideas between basic and clinical science to advance diagnosis or treatment of GWI. Describe how the proposed partnership involves a substantial contribution by each partner. If the practicing clinician(s) and researcher(s) in the proposed partnership have an established working relationship, provide evidence of that relationship.
- **Impact:** Describe how the proposed partnership and research will provide a significant benefit in the near-term and long-term to Veterans suffering from GWI.

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

- **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): Include biographical sketches for the Initiating and Partnering PIs. Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished. *All biographical sketches should be uploaded as a single combined file.*
- **Tab 6 – Submit Pre-Application**
    - This tab must be completed for the pre-application to be accepted and processed.

### Pre-Application Screening

- **Pre-Application Screening Criteria**

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

- **Research Idea:** How well the rationale and preliminary data support the research idea and the degree to which the proposed research addresses the intent of the GWIRP FY16 Clinical Partnership Award mechanism.
  - **Research Strategy:** How well the specific aims and proposed methodology supports the research objectives.
  - **Partnership and Two-way Continuum:** The degree to which the proposed research allows for the reciprocal transfer of ideas between basic and clinical science. How the partners' backgrounds, expertise, and working relationship are appropriate to accomplish the proposed research.
  - **Impact:** The degree to which the proposed partnership and research, if successful, will ultimately improve the health and lives of Veterans suffering from GWI in the near-term and long-term.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, Initiating 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. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

### 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 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.

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

*All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. 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 CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each Grants.gov application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.*

#### **Application Components for the Initiating PI:**

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 Clinical Partnership 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 must include preliminary data to support the feasibility of the proposed project; however, these data may come from fields other than GWI research.***

- **Background:** Present the ideas and reasoning behind the proposed research. Cite relevant literature. Describe previous experience most pertinent to this application. If a significant portion of the project will depend on concepts derived from other diseases or conditions, explain why the approach should be expected to work for GWI.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If the proposed research is part of a larger study, present only tasks that this GWIRP award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. Describe the statistical plan for the research proposed. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the GWI patient clinical care population in place or provide a well-justified prospect of a GWI patient clinical care population. If case definitions, in addition to the CDC or Kansas definition, are to be used, describe the definition(s) and explain the rationale behind their inception and use. If applicable, explain why the established GWI animal models proposed are appropriate. If a new animal model is proposed, explain why an existing model cannot be used. For studies involving the use of banked specimens, describe procedures to be used to assess

the quality of the materials and to identify and correct for effects and/or artifacts of sample processing and storage. Additionally, for biomarker research, describe the fidelity of the proposed markers in archived specimens.

- **Partnership:** Describe how the research project depends on the unique skills of each member of the partnership. Describe how the proposed partnership involves a substantial contribution by each partner, with a reciprocal flow of ideas and information. Demonstrate how the partnership will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide evidence of institutional support for resolving potential intellectual and material property issues and removing institutional barriers to achieve high levels of cooperation. If applicable, describe previous working relationships between the investigators that demonstrate effective collaboration.
- **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. For PI(s) who are practicing clinicians, the institution must clearly demonstrate a commitment to the clinician’s research. 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.
- 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 VA, Defense Manpower Data Center Data Request System). 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.
  - Background: Present the ideas and reasoning behind the proposed work.

- Objective/Hypothesis: State the objective/hypothesis to be tested. Describe the overall research goals for the study.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Partnership: Describe how the proposed partnership will accelerate the movement of promising ideas in GWI research into clinical applications to benefit Veterans with GWI in a manner that would be less readily achievable through independent efforts.
  - Impact: State briefly how the proposed project, if successful, will have an impact on the care or quality of life of Veterans suffering from 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.
      - Do not duplicate the technical abstract.
    - Describe the ultimate applicability and impact 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?
      - How will this study accelerate the movement of promising ideas in GWI research into clinical applications to benefit Veterans with GWI in a manner that would be less readily achievable through independent efforts?
  - **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 Clinical Partnership Award mechanism, use the SOW format example titled “SOW for Collaborative PI Projects.” 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.

***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) must be explicitly defined for each task.***

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: Two-way Continuum and Impact Statement (two-page limit): Upload as “Continuum-Impact.pdf.”** This statement will be made available to the Programmatic Panel during Programmatic Review.
  - State explicitly how the proposed research allows for a two-way continuum of ideas between basic and clinical science to advance concepts for diagnosing or treating GWI.
  - Explain how the experience and expertise of the partners are complementary and will accelerate the movement of the results to clinical application, inform pathophysiology research (i.e., from a case series), or consist of other research-informing clinical modalities. Provide information on the methods and strategies proposed to move the anticipated research outcomes to the next phase of development, clinical trials, and/or delivery to Veterans suffering from GWI after successful completion of the award.
  - Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed research.
  - Describe the long-term impact: Explain the long-range vision for implementation of the anticipated research outcomes in the clinic or field, and describe the anticipated long-term benefits 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: Outcomes Statement (if applicable, three-page limit): Upload as “Outcomes.pdf.”** This statement will be made available to the Programmatic Panel during Programmatic Review. For Initiating or Partnering PIs with experience in GWI research, list all prior research projects/awards directly relevant to GWI, including resulting publications, abstracts, patents or other tangible outcomes. Only research and outcomes directly relevant to GWI should be listed.
  - **Attachment 9: 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.
- Include biographical sketches for the Partnering PI(s).
  - **PI Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf.”
    - Include previous/current/pending support for the Partnering PI(s).

- 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.
  - *Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed \$750,000. The combined total direct costs of Initiating PI and the Partnering PI(s) awards will not exceed \$750,000 direct costs. If the Initiating PI or Partnering PI(s) budget contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted direct costs approved by the Government will not exceed \$750,000 or using an indirect rate exceeding each organization’s negotiated rate.*
- 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 9, 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.

## Application Components for the Partnering PI(s):

Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package that includes:

- 1. SF424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**
  - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) must be explicitly defined for each task.*
- 3. 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.”
  - *Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI(s) applications will not exceed \$750,000. The combined total direct costs of the Initiating PI and the Partnering PI(s) awards will not exceed \$750,000 direct costs. If the Initiating PI or Partnering PI(s) budget contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted direct costs approved by the Government will not exceed \$750,000 or using an indirect rate exceeding each organization’s negotiated rate.*
- 4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.5., for detailed information.

Collaborating DoD Military Facilities Form: Refer to the General Application Instructions, Section II.C.7., for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

## **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 the 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:

- **Two-way Continuum and Impact**
  - The degree to which the project establishes a reciprocal flow of promising, well-founded laboratory and clinical research findings and has the potential to advance GWI diagnosis and treatment in a way that could not be accomplished by investigators working independently. How well the project, if successful, will lead to new research areas and/or clinical applications for GWI treatment and patient care.
  - To what degree the proposed project could, if successful, make a significant impact on the lives of Veterans affected by GWI.
  - How the potential outcomes of the proposed research will provide/improve both *short-term* and *long-term* benefits for ill Gulf War Veterans.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility, as demonstrated by preliminary data, a critical review and analysis of the literature and/or logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and support completion of the aims.
  - How well the PIs acknowledge potential problems and address alternative approaches.
  - If applicable, how appropriate are the proposed GWI animal model(s). How well justified is use of any new animal model(s).

- For research involving access to banked specimens, whether the application includes documentation demonstrating that the PIs will have access to the necessary specimens in amounts sufficient to support the proposed studies. How adequate the procedures are for assessing the quality of the materials received and identifying and correcting for effects and/or artifacts of processing and storage. If proposed, how adequate the procedures are for assuring the fidelity of biomarkers in archived specimens.
- Whether the PI(s) have in place, or have well-justified prospects of, a suitable and sufficient GWI patient clinical care population and the degree to which the plan to study the population, if applicable, is feasible.
- 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.
- How well the statistical methods described in the application are appropriate for the proposed research.
- **Partnership and Personnel**
  - How well the partners' backgrounds, expertise, and levels of effort will support the proposed project. To what extent the proposed partnership meets the requirement to include at least one clinician, one laboratory scientist, and at least one partner with previous experience in GWI research or clinical care.
  - How well the application supports the requirement that all partners contribute substantially to the development and implementation of the research plan.
  - If applicable, how well any previous working relationships between the investigators are described and whether they demonstrate effective collaboration.

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

- **Budget**
  - Whether the sum of the direct maximum costs for all PIs is 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 degree the scientific environment, clinical setting, and the accessibility of institutional resources support the research at each participating institution.
  - Whether there is evidence for appropriate institutional commitment from each participating institution.

- 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
    - Two-way continuum and relative impact
    - Relative outcomes from the PIs' previous GWI-related research, as 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.
- All associated (Initiating PI and Partnering PI(s)) applications are not submitted by the deadline.
- Two-way Continuum and Impact Statement (Attachment 6) is missing.

## **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:

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

- The application describes research focusing on ALS. (Exception: 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, including post-traumatic stress disorder, as the primary cause of GWI.
- The PI(s) does not meet the eligibility requirement.

#### **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	Initiating PI Completed	Each Partnering PI 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	Two-way Continuum and Impact Statement: Upload as Attachment 6 with file name "Continuum-Impact.pdf."		
	7	Animal Research Plan: Upload as Attachment 7 with file name "Animal.pdf," if applicable.		
	8	Outcomes Statement: Upload as Attachment 8 with file name "Outcomes.pdf," if applicable.		
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 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 form 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.		