

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Gulf War Illness Research Program**

### **Investigator-Initiated Research Award**

**Funding Opportunity Number: W81XWH-13-GWIRP-IIRA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 12, 2013
- **Invitation to Submit an Application:** July 2013
- **Application Submission Deadline:** 11:59 p.m. ET, September 18, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** February 2014

*This Program Announcement 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](http://Grants.gov).*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2013 (FY13) Gulf War Illness Research Program (GWIRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). 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 FY12 totaled \$49 million (M). The FY13 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, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests.

The population of veterans affected by GWI is a subset of the nearly 700,000 who served during the Gulf War. Specifically, these Gulf War veterans were deployed to the theatre of operations in Southwest Asia, including Iraq, Kuwait, and Saudi Arabia. Studies indicate that approximately 25% to 32% (or 175,000 to 210,000) of Gulf War veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP will focus its FY13 funding 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, the FY13 GWIRP intends to focus on supporting research projects that exhibit *clear translational potential* to lead to treatments for ill Gulf War veterans. The GWIRP encourages high-risk/high-reward research; however, all projects must demonstrate solid judgment and sound rationale.

### B. Award Information

The GWIRP Investigator-Initiated Research Award was first offered in FY06. Since then, 156 Investigator-Initiated Research Award applications have been received, and 42 have been recommended for funding.

The Investigator-Initiated Research Award (IIRA) supports research focusing on the complex of symptoms known as Gulf War Illness, improving its definition and diagnosis, characterizing disease symptoms, and better understanding its pathobiology. It is intended to encourage basic through clinical research aimed at identification of objective measures to distinguish ill from healthy veterans (e.g., biomarkers), elucidate potential treatment targets for GWI, or improve understanding of the pathobiology underlying GWI symptoms. In addition, studies that characterize *chronic* effects of neurotoxic exposures at dosage comparable to that encountered

during the Gulf War are acceptable. Particular areas of interest include research on objective indicators of biological processes or abnormalities in GWI associated with:

- Central nervous system structure and function, in particular, the role of glial cells, astrocytes, and microglia in GWI symptomatology
- Central neuroinflammatory processes
- Autonomic nervous system function
- Neuroendocrine measures
- Immune parameters/Indicators of chronic infection
- Gastrointestinal complaints/symptoms
- Genetic, genomic, proteomic, or metabolic characteristics
- Respiratory symptoms
- Sexual dysfunction

The IIRA provides investigators a mechanism to establish proof of principle for further development in future studies. The IIRA can also be used for testing of GWI-targeted pharmacologic agents in Adsorption, Distribution, Metabolism, Excretion (ADME) studies, and toxicology testing, including Investigational New Drug (IND)-enabling pharmacology/toxicology testing. Preclinical development of non-pharmacological interventions is also acceptable.

The IIRA is designed to promote new ideas in GWI research. 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 a sound scientific rationale and may reflect clinical observations or seek to evaluate GWI discoveries made in relation to other chronic multi-symptom illnesses. Regardless of the approach, the focus should be clearly on ill Gulf War veterans. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's potential impact on GWI.

***Applicants proposing clinical research must provide a published case definition they intend to use to define their GWI population.*** Any case definition must recognize the multi-symptom nature of GWI. PIs proposing studies using animal models should focus on long-term and latent effects of toxic exposures to closely represent the current status of GWI patients. *Note:* The 2008 report of the Research Advisory Committee on Gulf War Veterans' Illnesses, *Gulf War Illness and the Health of Gulf War Veterans*, provides information on GWI case definitions (pp. 29-30, p. 57), previous treatment research in Gulf War veterans (pp. 36-39), and treatment research related to other multi-symptom conditions (pp. 285-287). The report can be found online at: <http://www1.va.gov/RAC-GWVI/>.

***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/](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 mechanisms (for information about those mechanisms, see <http://cdmrp.army.mil/gwirp>). Retrospective studies or other non-interventional designs are acceptable under the IIRA.

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DoD)-funded research involving human subjects and human anatomical substances 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 local Institutional Review Boards. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DoD. These laws and directives will require information in addition to that supplied to the local review board. Allow a minimum of 4 months for regulatory review and approval processes for studies involving human subjects. Refer to the General Application Instructions, Appendix 5, for detailed 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 ill and healthy Gulf War veterans, particularly investigators within the U.S. Department of Veterans Affairs, to improve access to ill Gulf War veteran populations.

***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, or Lou Gehrig's disease) 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 office of the Congressionally Directed Medical Research Programs (CDMRP) has a separate ALS Research Program (see <http://cdmrp.army.mil/alsrp>)].

***The CDMRP intends that 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 apply.
- Cost sharing/matching is not an eligibility requirement.

- Organizations eligible to apply include national, international, for-profit, non-profit, 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 maximum allowable direct costs for the entire period of performance are **\$600,000** plus indirect costs.
- 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.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement

Refer to the General Application Instructions, Section II.C.4., 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.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials are not allowed)
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Must be requested for:

- Travel costs for the PI(s) to disseminate project results at one DoD military-relevant research meeting. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 3 of the budget. 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.

*The CDMRP expects to allot approximately \$2.88M of the \$20.00M FY13 GWIRP appropriation to fund approximately 3 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 is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

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.

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

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-13-GWIRP-IIRA.

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

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.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@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY13 GWIRP Integration Panel (IP) members (<http://cdmrp.army.mil/gwirp/panels/panels13.shtml>) 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@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

- **Required Files – Tab 4**

**Preproposal Narrative (3-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. 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 application.

**Note:** *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

The Preproposal Narrative should include the following:

- **Research Idea:** State the ideas and reasoning on which the proposed work is based.
- **Research Strategy:** Concisely state the project's objectives and specific aims. Describe a published case definition of GWI that will be used in the proposed clinical research, if applicable.
- **Impact:** State how the study addresses an important problem related to GWI. State how the study will help the research community better understand GWI pathobiology, improve the diagnosis of GWI, or lead to an effective treatment for GWI.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described research project.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application 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 (four-page limit per individual).**

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

No additional documents are required.

## 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 ill Gulf War veterans. How the rationale supports the proposed research.
- **Research Strategy:** Whether the specific aims and objectives support the research idea. Whether the PI described a published case definition that will be used in the proposed clinical research.
- **Impact:** Whether the study addresses an important problem related to GWI. How the study will help the research community better understand GWI pathobiology, improve the diagnosis of GWI, or lead to an effective treatment for GWI.
- **Personnel:** Whether the qualifications of the PI and key personnel are appropriate to perform the proposed research project.

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

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## C. Application Submission Content and Form

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

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

**Grants.gov application package components:** For the IIRA, 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**
  - **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 will 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 Gulf War Illness 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 a sound scientific rationale and may reflect clinical observations or seek to evaluate GWI discoveries made in relation to other chronic multi-symptom illnesses.

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience most pertinent to this project.
- **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. Studies using animal models should focus on long-term and latent effects of toxic exposures to closely represent the current status of GWI patients. If clinical research is proposed, include a published case definition by which GWI cases (and targeted subgroups, if applicable) will be defined. Also include a detailed plan for the recruitment of subjects or the acquisition of samples. Specifically demonstrate plans to access veterans and/or obtain personal data on veterans. Describe the statistical plan if appropriate for the proposed research.
- ***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 may result in the removal of those items or 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 (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support (two-page limit per letter): 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 Collaboration (two-page limit per letter): 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.
- Intellectual Property
  - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any 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.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to market, competitors, and management team. Discuss the scope of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
- Access to Gulf War veterans (if applicable): Provide a letter showing approved access to Gulf War veterans if proposing to access the veteran population or use

data from veterans (e.g., collaborating investigators from the Department of Veterans Affairs, Defense Manpower Data Center Data Request System, etc.).

- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects.

Use the outline below.

- **Background:** Present the ideas and reasoning behind the proposed work.
- **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 ill Gulf War veterans.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Do not duplicate the technical abstract. The lay abstract is used by consumer peer and programmatic reviewers along with other components of the application package.

- 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.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

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

Explain how the expected results of the study will make an original and important contribution to the goal of advancing GWI research. Results may address understanding the pathobiology of GWI, its diagnosis, identifying potential treatment targets, and potential impact on patient care.

- **Attachment 7: 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 Centers for Disease Control and Prevention 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.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (four-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., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

**5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

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

#### **D. 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 any one of the deadlines will result in application rejection.

#### **E. 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 Data Universal Numbering System (DUNS) number to

submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a 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 Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and GWIRP and 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 review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure 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 Criteria**

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

- **Research Strategy and Feasibility**
  - How well the preliminary data, if provided, and/or scientific rationale support(s) the research project.
  - How well the hypotheses or objectives, aims, study design, methods, and analyses are developed and integrated into the project.
  - How well the PI identifies potential problems and addresses alternative approaches.
  - For clinical research, whether a published case definition for GWI was included in the application.

- For studies involving animal models, how clearly the study focuses on chronic and/or latent effects of toxic exposures, representative of the current status of GWI patients.
- **Impact**
  - How the project addresses a critical problem in GWI research.
  - How the project makes an original and important contribution to the goal of advancing research, diagnosis, pathobiology of, or identifying potential treatment targets for GWI, or on the quality of life of veterans affected by the disease.
  - How the project exhibits clear translational potential to lead to treatments for ill Gulf War veterans.
- **Personnel**
  - The appropriateness of the levels of effort by the PI and other key personnel to ensure success of the project.
  - How the PI's record of accomplishment demonstrates his/her ability to perform the proposed work.

The following unscored criteria will *also* contribute to the overall evaluation of the application:

- **Environment**
    - How the scientific environment is appropriate for the proposed research.
    - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - How the quality and extent of organizational support are appropriate for the proposed research.
  - **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 influenced the review.
- 2. Programmatic Review:** To make funding recommendations, the following criteria are used by the programmatic reviewers:
- a. Ratings and evaluations of the peer reviewers**
  - b. Relevance to the mission of the DHP and FY13 GWIRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio balance
- Programmatic relevance
- Relative impact on Gulf War Illness

### **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 notification of the funding recommendation. 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 the CDMRP eReceipt System 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 exceeds page limit.
- 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 specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.

- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

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

- A FY13 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 document. A list of the FY13 GWIRP IP members can be found at <http://cdmrp.army.mil/gwirp/panels/panels13.shtml>
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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 proposed research is or contains a clinical trial.
- The application describes research on ALS.
- The application describes research whose principal focus is on psychiatric disease or psychological stress as the primary cause of GWI.
- The PI does not meet the eligibility criteria.

### **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, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### **B. Administrative and National Policy Requirements**

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

### **C. Reporting**

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

### **D. Award Transfers**

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the 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](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 application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Use of Hazardous Chemical or Biological Agents (Hazardous.pdf) as Attachment 7.	
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 (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.	