

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-08-GWIRP-IIRA

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## I. HELPFUL INFORMATION

### A. Contacts

**1. Program Announcement, proposal format, or required documentation:** To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)

**2. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**3. Grants.gov contacts:** Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: [support@grants.gov](mailto:support@grants.gov)

***Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.***

## **B. National Technical Information Service**

The technical reference facilities of the National Technical Information Service ([www.ntis.gov](http://www.ntis.gov)) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

## **C. Commonly Made Mistakes**

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (i.e., pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

## **II. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program History and Objectives**

The Gulf War Illness Research Program (GWIRP) was established in fiscal year 1994 (FY94) to study the health effects of warfighters deployed in the 1991 Persian Gulf War. Appropriations for the GWIRP from FY94 through FY07 totaled \$217.2 million (M). The FY08 appropriation is \$10.0M.

The GWIRP challenges the scientific community to design innovative research that will improve the health and lives of veterans who have Gulf War Illness (GWI), which refers to the complex of chronic symptoms that affect veterans of the 1990-1991 Gulf War at an excess rate. The illness is characterized by persistent symptoms such as chronic headache, widespread pain,

cognitive difficulties, unexplained fatigue, gastrointestinal problems, respiratory symptoms, and other abnormalities that are not explained by familiar medical or psychiatric diagnoses. The GWIRP focuses its funding on innovative projects that have the potential to make a significant impact on GWI. The GWIRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

## **B. Award Description**

The GWIRP Investigator-Initiated Research Award mechanism was first offered in FY06. Since then, 21 proposals have been received and 8 have been recommended for funding.

The Investigator-Initiated Research Award supports research to identify effective treatments for the complex of symptoms known as Gulf War Illness, improve its diagnosis, and better understand its pathobiology.

The GWIRP seeks proposals that will further its goal of improving the health and lives of veterans who have GWI. Of particular interest are proposals that will contribute to identification of effective treatments for GWI. Health outcomes of interest include effects of treatments on:

- Global health measures, functional status
- Symptom complexes (e.g. cognitive function, musculoskeletal/pain symptoms, gastrointestinal symptoms, fatigue, respiratory problems, skin abnormalities) individually and as they may interact with each other
- Measurable clinical outcomes, biomarkers
- GWI subgroups characterized by symptom or other clinical characteristics

The GWVIRP also seeks proposals from a variety of areas that can contribute to improved diagnostic testing for GWI and/or improved understanding of its pathobiology. Particular areas of interest include research on objective indicators of biological processes or abnormalities in GWI associated with:

- Central nervous system structure and function
- Central neuroinflammatory processes
- Neuroendocrine measures
- Autonomic nervous system function
- Immune parameters
- Indicators of chronic infection
- Overlaps between systems
- Genetic, genomic, proteomic, or metabolomic characteristics

***The Investigator-Initiated Research Award is designed to promote new ideas in GWI. Proposals are required to include preliminary data, but it does not necessarily have to come from the GWI research field.***

***It is the responsibility of the PI to clearly and explicitly articulate the project's potential impact on GWI.***

***Clinical trials are not acceptable under this mechanism.*** PIs wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism.

***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.***

***Please note that all Department of Defense (DOD)-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC's Office of Research Protections, 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 are rigorous and detailed and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects.***

***For further information about GWI and the intent of this award, see the Information Paper at <http://cdmrp.army.mil/funding/pdf/08gwirpinfopaper.pdf>***

### **C. Eligibility**

PIs must be independent investigators at any academic level (or equivalent).

Refer to Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

Funding for an Investigator-Initiated Research Award can be requested for up to \$600,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

Within the guidelines provided in the Application Instructions, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs (No clinical trials)
- Travel to scientific/technical meetings
- Travel between collaborating institutions

***The CDMRP expects to allot approximately \$4.8M of the \$10M FY08 GWIRP appropriation to fund approximately 5 Investigator-Initiated Research Award proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## E. Award Administration

Refer to the Application Instructions, Appendix 5, for general award administration information.

## III. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) proposal submission. *Pre-application submission is a required first step.*

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time, July 2, 2008
- **Invitation to Submit a Proposal:** August 8, 2008
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, October 15, 2008
- **Peer Review:** December 2008
- **Programmatic Review:** January 2009

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

## IV. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

### A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by **5:00 p.m. Eastern time on the pre-application deadline**. In addition to award-specific information provided below, refer to the Application Instructions for detailed information.

- **Proposal Information:** The PI must enter the Proposal Information before continuing the pre-application.
- **Proposal Contacts:** The PI must enter his or her contact information.
- **Collaborators and Conflicts of Interest (COI):** The PI must enter the contact information for any collaborators.
- **Preproposal Narrative:** The Preproposal Narrative has a *three-page limit* inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preproposal. The preproposal narrative should address the following:

- **Research Idea:** State the ideas and reasoning on which proposed work is based.
- **Research Strategy:** Concisely state the project's objective and specific aim.
- **Impact:** State explicitly how the proposed work will have an impact on accelerating the movement of a promising idea in GWI research into clinical applications.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
  - **References:** One-page limit.
  - **Biographical Sketches:** Include biographical sketches for the PI and other key collaborators.
  - **Use of Hazardous Chemical or Biological Agents (if applicable):** 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 (CDC) registration, an approved institutional safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate also 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.

**Pre-Application Screening:** Pre-applications will be screened by the GWIRP Integration Panel (IP), composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** How the rationale and collaboration will advance the GWI research field.
- **Research Strategy:** How the specific aims support the research idea.
- **Impact:** How the study addresses an important problem related to GWI. If successful, how the aims of the application are likely to accelerate the movement of promising ideas in GWI research into clinical applications.

## **B. Step 2 – Proposal Components and Submission**

***Proposals will not be accepted unless the PI has been invited. Do not submit a proposal unless a letter of invitation has been received.*** Proposals must be submitted electronically by the Authorized Organizational Representative through Grants.gov ([www.grants.gov](http://www.grants.gov)). No paper copies will be accepted. The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or Organization after submission of the pre-application, the PI must contact the CDMRP eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in [www.grants.gov](http://www.grants.gov) for the US Army Medical Research Acquisition Activity program announcement. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

**1. SF-424 (R&R) Application for Federal Assistance Form**

**2. Attachments Form**

- Attachment 1: Project Narrative (12-page limit)

Describe the proposed project in detail using the outline below. *Proposals must include preliminary data relevant to the proposed project, but it does not necessarily have to come from the GWI research field.*

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this proposal.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. These aims should agree with the primary aims and associated tasks described in the Statement of Work. If this proposal is part of a larger study, present only aims that the DOD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials.*

- Attachment 2: Supporting Documentation

- References Cited
- Acronyms and Symbol Definitions
- Facilities & Other Resources
- Description of Existing Equipment
- Publications and/or Patent Abstracts
- Letters of Institutional Support

If the PI is a practicing clinician, the institution must clearly demonstrate a commitment to the clinician's research.

- Intellectual and Material Property Plan (if applicable)
- Letters of Collaboration (if applicable)

- Attachment 3: Technical and Public Abstracts
- Attachment 4: Statement of Work
- Attachment 5: Impact Statement

Describe the potential impact of this study on research and/or patient care in the topic area addressed. The following are examples of ways in which proposed studies, if successful, may have an impact. *Although not all-inclusive*, these examples are intended to help PIs frame the impact of their proposals:

- Has the potential to advance the field of research and/or patient care in the topic area addressed
- Has the potential to change the standard of care for the disease or condition of the topic area
- Proposes new paradigms or challenges existing paradigms in the field of research and/or patient care in the topic area addressed in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies
- Contributes to development or validation of evidence-based policy or guidelines for patient evaluation and care
- Attachment 6: Use of Hazardous Chemical or Biological Agents (if applicable) (no page limit)

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

- Attachment 7: Federal Agency Financial Plan (if applicable)

### **3. Research & Related Senior/Key Person Profile (Expanded)**

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches
- Key Personnel Current/Pending Support

### **4. Research & Related Budget Form**

- Budget Justification

### **5. Research & Related Project/Performance Site Location(s) Form**

### **6. R&R Subaward Budget Attachment(s) Form (if applicable)**

## V. INFORMATION FOR PROPOSAL REVIEW

### A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement).

### B. Review Criteria

**1. Peer Review:** All proposals will be evaluated according to the following criteria, which are listed in order of decreasing importance:

- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning.
  - How the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How the PI acknowledges potential problems and addresses alternative approaches.
- **Impact**
  - How the proposed study addresses an important need in GWI treatment, diagnosis, or understanding of its pathobiology.
  - The potential contribution of the proposed study to research and/or patient care.

- **Personnel**
  - How the background and expertise of the PI and other key personnel demonstrate their ability to perform the proposed work.
  - How the levels of effort by the PI and other key personnel are appropriate to ensure success of this project.
- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support.
- **Budget**
  - How the budget is appropriate for the proposed research.

**2. Programmatic Review:** Criteria used by programmatic reviewers to make funding recommendations that maintain the program’s broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC.

## **VI. COMPLIANCE GUIDELINES**

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

The following will result in administrative rejection of the entire pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- FY08 IP members are included in any capacity in the pre-application process (excluding references). A list of the FY08 IP members may be found at <http://cdmrp.army.mil>.

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- FY08 IP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at <http://cdmrp.army.mil>.

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.