Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-11-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), May 25, 2011
- **Invitation to Submit an Application:** June 24, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, August 24, 2011
- **Scientific Peer Review:** October 2011
- **Programmatic Review:** January 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Gulf War Illness Research Program (GWIRP) was established in FY94 to study the health effects of deployment to the 1990-91 Persian Gulf War on U.S. warfighters. Appropriations for the GWIRP from FY94 through FY10 totaled $243 million (M). The FY11 appropriation is $8.0M.

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 percent (or 175,000 to 210,000) of Gulf War veterans continue to experience symptoms associated with their deployment as described above.

The GWIRP focuses its funding on innovative projects that have the potential to make a significant impact on GWI. These may take the form of identification of objective indicators of pathology that distinguish ill from healthy Gulf War veterans, or studies to understand the underlying pathobiology of GWI. The GWIRP encourages risk-taking research; however, all projects must demonstrate solid judgment and sound rationale.

B. Award Information

The GWIRP Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY06. Since then, 94 IIRA applications have been received, and 29 have been recommended for funding**.**

The IIRA supports research focusing on the complex of symptoms known as Gulf War Illness (GWI), improving its definition and diagnosis, characterizing disease symptoms, and better understanding its pathobiology. It is intended to encourage basic or clinical developmental research aimed at identification of objective measures to distinguish ill from healthy veterans (e.g., biomarkers) or elucidate potential treatment targets for GWI. In addition, studies that characterize chronic effects of neurotoxic exposures at dosage comparable to that encountered during the Gulf War are acceptable. The IIRA provides investigators a mechanism to establish proof of principle for further development in future studies. 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 is designed to promote new ideas in GWI research. Proposals are not required to include preliminary data; however, preliminary data may be used to support the objectives of a proposal. These data are not required to have come from the GWI research field. Proposals 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. Using either approach, however, 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.

PIs 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, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/.

PIs wishing to apply 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). Refer to the General Application Instructions, Appendix 5, for helpful information about distinguishing clinical trials and clinical research. Retrospective studies or other non-interventional designs are acceptable under the IIRA 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.

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 proposals focusing on ALS research. However, proposals that focus on GWI symptomatology may include GW veterans with ALS if the latter disorder is included in the study's GWI case definition. The Office of the Congressionally Directed Medical Research Programs (CDMRP) has offered a separate ALS Research Program (see http://cdmrp.army.mil/alsrp).

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 US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local IRBs. 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. Refer to the General Application Instructions, Appendix 5, for detailed information. ***Proposals that include clinical research involving Gulf War veterans must clearly indicate how this population and/or data from Gulf War veterans will be accessed.*** PIs proposing clinical research are encouraged to collaborate with an investigator who has demonstrated access to ill and healthy GW veterans, particularly investigators within the U.S. Department of Veterans Affairs, to improve access to ill Gulf War veteran populations.

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to apply.
- Cost sharing /matching is not an eligibility requirement.
- 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**.** More cost-effective studies that do not request the full available funding amount are encouraged.
- 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 also request the entire maximum direct cost amount for a project that may be less than the maximum **3**-year period of performance.

- 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., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI to attend one DOD military research-related meeting to be determined by the CDMRP during the award performance period.

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

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $1.92M of the $8M FY11 GWIRP appropriation to fund approximately 2 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 multi-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 the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

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-11-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 application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at 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**
- **Required Files – Tab 4**

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

  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 research.
  - **Impact:** State how the study addresses an important problem related to GWI. State how, if successful, 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 relevant references 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). The inclusion of Internet URLs to references is encouraged.
  - PI and Key Personnel Biographical Sketches (four-page limit per individual)

- **Submit Pre-application – Tab 5**

- **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 Department of Defense (DOD) and CDMRP, 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 will advance GWI 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 research.
  - **Impact:** Whether the study addresses an important problem related to GWI. If successful, 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 of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

  Pre-application notification dates are 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 a letter 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 (AOR) through the Grants.gov portal (http://www.grants.gov/).

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

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   - **Attachment 1: Project Narrative (10-page limit):** Upload as "ProjectNarrative.pdf."

     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 Gulf War illness research. Proposals 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 would fund.
     - **Research Strategy:** Describe the study design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, 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 research proposed. ***This award may not be used to conduct clinical trials, research focused on Amyotrophic Lateral Sclerosis, 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. ***Each component has no page limit unless otherwise noted.***

     - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. 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, reflecting the laboratory space, equipment, and other resources available for the project. If the PI is a clinician, the organization must clearly demonstrate a commitment to the clinician's research.
- Letters of Collaboration (if applicable) (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 and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- 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.), if applicable.

- **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 Gulf War Illness research and/or ill Gulf War veterans.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

  Do not duplicate the technical abstract. The public abstract is used by consumer peer 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?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
  - 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.
- **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 Gulf War Illness research, and its impact on patient care. Describe the potential clinical applications, benefits, and risks.
- **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 (CDC) registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate 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.

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

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI 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 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 shall 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. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) 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 compares applications to each other and makes recommendations for funding to the Commanding General, US Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the Department of Defense (DOD) and CDMRP, 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.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application 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 corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the

confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (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.
     - In studies involving human subjects or anatomical samples, whether a published case definition for GWI was included in the protocol.
     - In 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.
   - **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.

   In addition, 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 determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
   - Ratings and evaluations of the peer reviewers
   - Programmatic relevance
   - Relative impact on Gulf War Illness
   - Program portfolio composition
   - Adherence to the intent of the award mechanism

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt 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:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

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, you 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:

- FY11 GWIRP IP member is found to be involved 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 FY11 GWIRP IP members may be found at http://cdmrp.army.mil/gwirp/panels/panels11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application that is or contains a clinical trial.

- Submission of an application that describes research on Amyotrophic Lateral Sclerosis.
- Submission of an application that 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 US Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2012. 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 C, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements. Annual technical progress reports will be required.

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, 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 and 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: 1-301-682-5507

Email: 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: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. 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

Grants.gov Application Components	Action	Completed
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 Public Abstract (PublicAbs.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 Chemicals or Biological Agents (Hazardous.pdf), if applicable, as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI 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 Current & Pending Support (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.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	
Project/Performance Site Location(s) Form	Complete form as instructed.	