Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Investigator-Initiated Research Award

Funding Opportunity Number: W81XWH-10-GWIRP-IIRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

The Gulf War Illness Research Program (GWIRP) was established in fiscal year 1994 (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 FY09 totaled $235 million (M). The FY10 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 1990-91 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 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 Description

The Investigator-Initiated Research Award (IIRA) mechanism was first offered in FY06. Since then, 70 IIRA applications have been received, and 18 have been recommended for funding**.**

The 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 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. Studies that characterize chronic effects of neurotoxic exposures encountered during the Gulf War (and at comparable dosage) are also 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
- Neuroendocrine measures

- Autonomic nervous system function
- Immune parameters
- Indicators of chronic infection
- Gastrointestinal complaints/symptoms
- Genetic, genomic, proteomic, or metabolic characteristics

The IIRA is designed to promote new ideas in Gulf War Illness research. Proposals are not required to include preliminary data; however, preliminary data may be used to support the objectives of a proposal. This data does not necessarily have to 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, or clearly state their own case definition to distinguish ill from healthy Gulf War veterans in their proposals. 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/***.

Clinical trials are not allowed under this mechanism. 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***). 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) is offering a separate ALS Research Program in FY10 (see ***http://cdmrp.army.mil/alsrp***).

Use of Human Subjects and Human Biological Substances: All Department of Defense (DOD)-funded research involving human subjects and human biological 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

Investigators at all academic levels (or equivalent) are eligible to submit proposals. 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 funding for the entire period of performance is **$600,000** in direct costs.
- More cost-effective studies that do not request the full available funding amount are encouraged. 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 direct cost. In addition to direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials are not allowed)
- Travel between collaborating institutions
- Travel funds must be requested for the PI to attend one DOD military research-related meeting to be determined by the Office of the Congressionally Directed Medical Research Programs (CDMRP) during the award performance period.

- Travel costs of up to $1,800 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

The CDMRP expects to allot approximately $2.88M of the $8M FY10 GWIRP appropriation to fund approximately three 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.

E. Award Administration

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), May 14, 2010**
- **Invitation to Submit an Application: June 2010**
- **Application Submission Deadline: 11:59 p.m. ET, August 4, 2010**
- **Scientific Peer Review: October 2010**
- **Programmatic Review: December 2010**

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

III. SUBMISSION PROCESS

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/). ***Applications will be invited based on pre-application screening.***

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.

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 eReceipt help desk at help@cdmrp.org or 301-682-5507.

A. Step 1 – Pre-Application Components

Pre-application submission is the required first step. 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. ET on the deadline date***. Refer to the General Application Instructions for detailed information. 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.

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 for additional information on pre-application submission):

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**

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

  - **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.
  - **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 PI's qualifications 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.
- **Submit Pre-application – Tab 5**

  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 described research focuses specifically on ill Gulf War veterans. How the rationale will advance GWI research.

- **Research Strategy:** How the specific aims and objectives support the research idea.
- **Impact:** How 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:** How the PI's qualifications are appropriate to perform the proposed research project.

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., strengths and weaknesses) on their pre-application.

B. Step 2 – Application Components

Applications will not be accepted unless the PI has received a letter of invitation.

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (http://www.grants.gov/). Applications must be submitted **by *11:59 p.m. ET on the deadline.***

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission):

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

2. Attachments Form

- **Attachment 1: Project Narrative (12-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 does not necessarily have to 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 the DOD 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 biological samples will be used, include a published case definition or a description of the method 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.***

- **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 all 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.
  - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
  - 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 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.
- Show 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."

  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."

  Clearly describe, in a manner readily understood by laypersons, the rationale and objective for the proposal. Do not duplicate the technical abstract.

  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.B., for detailed information.
- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf."

Refer to the General Application Instructions, Section II.B., for detailed information.

- **Attachment 8: 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 9: Use of Hazardous Chemical or Biological Agents (if applicable) (no page limit):** Upload as "Hazardous.pdf."

  The applicant must submit a plan for acquiring, using, and maintaining hazardous agents if such agents are to be used in the study. The plan must contain all applicable information such as CDC registration, an approved organizational safety plan to use the agent(s), and letters of collaboration, agreement, or approval from government sites issuing any agent(s). Indicate 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.B., 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. Project/Performance Site Location(s) Form: Refer to the General Application Instructions, Section II.B., for detailed information.

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and 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 may be found at http://cdmrp.army.mil/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. Review Criteria

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

- **Research Strategy and Feasibility**
  - How well the preliminary data, if provided, and/or scientific rationale supports 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 acknowledges potential problems and addresses alternative approaches.
  - In studies involving human subjects or biological samples, whether a published case definition for GWI was included in the protocol, or if not, how clearly and appropriately GWI cases (and any targeted illness subgroups) are defined and how appropriate the methods are to the identified case definition.
  - In studies involving animal models, how clearly the study focuses on long term 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 accomplish the proposed work.

The following will not be individually scored, but may impact 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**
  - How the writing and components of the application influenced the review.

2. Programmatic Review: The following equally weighted criteria are used by programmatic reviewers to make funding recommendations.

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

V. ADMINISTRATIVE ACTIONS

After receipt of 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not sent.
- Submission of an application for which a pre-application was not submitted.

B. Modifications

- 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 V-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 application:

- FY10 GWIRP IP member(s) 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 FY10 GWIRP IP members may be found at http://cdmrp.army.mil/gwirp/panel10
- 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 detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- Submission of a proposal that is or contains a clinical trial.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be requested 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.

VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. 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
Email: cdmrp.pa@amedd.army.mil

B. CDMRP eReceipt System Help Desk: Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Email: help@cdmrp.org

C. Grants.gov Contact Center: Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726
Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. 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 Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Impact Statement (Impact.pdf) as Attachment 8	
	Upload Use of Hazardous Chemicals or Biological Agents (Hazardous.pdf) as Attachment 9 (if applicable)	
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	
Project/Performance Site Location(s) Form	Complete form as instructed	

Detailed Budget and Justification

Name of Principal Investigator: _____ _____ _____ _____
Last Name *First Name* *Middle Name* *Suffix*
CDMRP log number: _____
Period of Performance: **From:** _____ **Through:** _____

DETAILED BUDGET FOR YEAR ONE

SENIOR/KEY PERSON & OTHER PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED (OMIT CENTS)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	Principal Investigator						

A. SUBTOTAL PERSONNEL COSTS	$0	$0	$0

Detailed Budget and Justification

DETAILED BUDGET FOR YEAR ONE (CONTINUED)	
OTHER DIRECT COSTS	
MAJOR EQUIPMENT (ITEMIZE)	$0
TRAVEL COSTS	$0
MATERIALS, SUPPLIES, AND CONSUMABLES (ITEMIZE BY CATEGORY)	$0
CONSULTANT COSTS	$0
SUBAWARD/CONSORTIUM/CONTRACTUAL COSTS (ITEMIZE, INCLUDE TOTAL COSTS INCLUDING DIRECT AND INDIRECT COSTS)	$0
RESEARCH-RELATED SUBJECT COSTS	$0
OTHER EXPENSES (ITEMIZE BY CATEGORY)	$0
B. SUBTOTAL OTHER DIRECT COSTS FOR INITIAL BUDGET PERIOD	**$0**
C. TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (A+B)	**$0**
D. TOTAL INDIRECT COSTS FOR INITIAL BUDGET PERIOD	**$0**
TOTAL COSTS FOR INITIAL BUDGET PERIOD (C+D)	**$0**

Detailed Budget and Justification

BUDGET FOR ENTIRE PROPOSED PERIOD OF PERFORMANCE						
BUDGET CATEGORY TOTALS*	**BUDGET YEAR ONE**	**ADDITIONAL YEARS OF SUPPORT REQUESTED**				**TOTAL**
		2nd	**3rd**	**4th**	**5th**	
A. **PERSONNEL COSTS**	**$0**					**$0**
SALARY REQUESTED	$0					$0
FRINGE COSTS	$0					$0
B. **OTHER COSTS**	**$0**					**$0**
MAJOR EQUIPMENT	$0					$0
TRAVEL COSTS	$0					$0
MATERIALS, SUPPLIES, AND CONSUMABLES	$0					$0
CONSULTANT COSTS	$0					$0
SUBAWARD/CONSORTIUM/CONTRACTUAL COSTS	$0					$0
RESEARCH-RELATED SUBJECT COSTS	$0					$0
OTHER EXPENSES	$0					$0
C. TOTAL DIRECT COSTS	**$0**					
D. TOTAL INDIRECT COSTS	**$0**					
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						**$0**
TOTAL INDIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT						**$0**
TOTAL COSTS FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT **THIS AMOUNT MUST MATCH WITH THAT ENTERED ON THE SF 424, BLOCK 16A**						**$0**

*** Itemize all budget categories for additional years on the Justification page that follows.**

Detailed Budget and Justification

JUSTIFICATION

FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

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BIOGRAPHICAL SKETCH

Provide the following information for the key personnel on page 1 of the Detailed Budget and Justification form for the initial budget period.

NAME	POSITION TITLE

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.