Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Gulf War Illness Research Program

Clinical Trial Development Award

Funding Opportunity Number: W81XWH-13-GWIRP-CTDA

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), August 28, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, September 18, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** February 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Gulf War Illness Research Program (GWIRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The GWIRP was initiated in 2006 to provide support for research of exceptional scientific merit to study the health effects of deployment to the 1990-1991 Persian Gulf War on U.S. warfighters. Appropriations for the GWIRP from FY06 through FY12 totaled $49 million (M). The FY13 appropriation is $20M.

The GWIRP challenges the scientific community to design high-impact research that will improve the health and lives of veterans who have Gulf War Illness (GWI). GWI is characterized by multiple diverse symptoms that typically include chronic headache, widespread pain, cognitive difficulties, debilitating fatigue, gastrointestinal problems, respiratory symptoms, and other abnormalities that are not explained by established medical diagnoses or standard laboratory tests.

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

The GWIRP will focus its FY13 funding on innovative projects that have the potential to make a significant impact on finding treatments for GWI. While such projects may include identification of objective indicators of pathology that distinguish ill from healthy Gulf War veterans or studies to understand the underlying pathobiology of GWI, the FY13 GWIRP intends to focus on supporting research projects that exhibit ***clear translational potential*** to lead to treatments for ill Gulf War veterans. The GWIRP encourages high-risk/high-reward research; however, all projects must demonstrate solid judgment and sound rationale.

B. Award Information

The GWIRP Clinical Trial Development Award (CTDA) mechanism was offered for the first time in FY11. The CTDA is intended to support planning activities necessary for the future conduct of a Phase II or Phase III clinical trial (or a trial of devices in U.S. Food and Drug Administration [FDA] classes I-III), since these activities usually represent a significant expenditure of time and effort. The CTDA is a 1-year grant intended to allow investigators time to undertake preparatory activities and have the study rationale for a future clinical trial scientifically reviewed. The CTDA is not intended for the collection of preliminary data or the conduct of pilot studies to support the rationale for a future clinical trial. Applications must demonstrate that the rationale for the proposed clinical trial has already been clearly established, with appropriate supportive preliminary data.

Clinical trial developmental activities allowed under a CTDA may include, but are not limited to:

- Developing the clinical protocol and experimental design
- Composing the research team and initiating collaborations necessary for the future clinical trial, and developing training procedures, as applicable
- Investigating potential intellectual or material property issues, as applicable
- Initiating access to an ill Gulf War veteran population and planning a recruitment strategy
- Developing quality control/assurance procedures
- Developing data collection/data management procedures
- Developing a data analysis/statistical plan
- Assessing potential issues regarding test article purity and formulation
- Developing a safety monitoring plan
- Determining a process for finalizing an FDA Investigational New Drug (IND)/ Investigational Device Exemption (IDE) application, if applicable
- Developing a transition plan with associated resources and collaborations to continue to the next phase of research or commercialization
- Conducting other preparatory activities needed to support the future clinical trial

These activities do not involve the collection of data supported by traditional investigator-initiated research awards. Investigators interested in generating proof-of-principle data should consider the GWIRP's Investigator-Initiated Research Award, aimed at basic research for GWI, or the Innovative Treatment Evaluation Award, which supports the initial evaluation of a treatment or intervention in small, early phase or pilot clinical trials (Phase II or I/II). For information about these award mechanisms, see http:/cdmrp.army.mil/funding.

Clinical trials supported by the GWIRP must recruit appropriately defined ill Gulf War veteran cohorts. ***Therefore, CTDA applicants 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. *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.

Investigators awarded a CTDA are expected to apply to the GWIRP's Clinical Trial Award in the program year following completion of the CTDA (i.e., FY13 CTDA awardees would apply for an FY15 or FY16 Clinical Trial Award, if that award is offered). The FY15 (or FY16) Clinical Trial Award application would include the results of the completed CTDA. *If an FY15 (or FY16) Clinical Trial Award is offered, the GWIRP reserves to right to limit applications to those investigators awarded an FY13 CTDA.* However, award of an FY13 CTDA is in no way

an assurance of funding for a future Clinical Trial Award. The funding of FY15 (or FY16) Clinical Trial Awards will be contingent upon the availability of federal funds for the program.

The GWIRP Clinical Trial Award supports Phase II or Phase III (or FDA device class I-III) clinical trials of treatments with the potential to have a significant impact on the health and lives of veterans with GWI. The Clinical Trial Award requires that an IND or IDE application, if applicable, must be submitted within 60 days of award. Thus, investigators would be expected to use the CTDA period to initiate the IND/IDE application process. Please note that all Department of Defense (DoD)-funded research involving human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections, Human Research Protections Office, in addition to the local Institutional Review Board of record. For more information about clinical trials and human subject research requirements, refer to the General Application Instructions, Appendix 5, D.

The GWIRP Clinical Trial Award application requires extensive descriptions of clinical trial components. CTDA applicants are encouraged to reference the GWIRP FY13 Clinical Trial Award Program Announcement to become familiar with these requirements and to help direct activities during the CTDA period. The GWIRP FY13 Clinical Trial Award Program Announcement can be accessed at http:/cdmrp.army.mil/funding.

Each CTDA application can only request support for preparations for a single clinical trial. However, investigators may submit more than one CTDA application supporting preparations for different clinical trials.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **1** year.
- The maximum allowable direct costs for the entire period of performance are **$100,000** plus indirect costs.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Administrative costs
- Support for establishing collaborations
- Teleconferences and other means of communication
- Software development
- Support for multidisciplinary collaborations
- Travel between collaborating organizations

Shall not be requested for:

- Equipment
- Research supplies

The CDMRP expects to allot approximately $0.16M-$0.32M of the $20.00M FY13 GWIRP appropriation to fund approximately 1-2 Clinical Trial Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

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

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/).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the preapplication, 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 – Tab 3**

  FY13 GWIRP Integration Panel (IP) members (http://cdmrp.army.mil/gwirp/panels/panels13) should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

  Letter of Intent (LOI) (one-page limit): Provide a brief description of the proposed intervention, the future clinical trial and the supporting rationale. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

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

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

  No additional documents are required.

C. Application Submission Content and Form

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

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

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (10-page limit):** Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.
   - Describe the rationale for the future clinical trial and include a literature review, preliminary studies, and preclinical data that led to its development.
   - Describe the hypothesis and/or objectives of the future clinical trial.
     - Describe the intervention, drug, or device to be tested.
     - Describe plans to develop the clinical protocol and finalize the experimental design.
     - Describe the published case definition of GWI that will be used in the future clinical trial.
     - Describe the PI's background and expertise in conducting large-scale clinical trials.
     - Describe plans for developing the research team and any proposed research resource or professional collaborations that will be established, and plans for training team members, as applicable.
     - Describe plans to investigate potential intellectual or material property issues, as applicable.
     - Describe the preliminary management plan for the clinical trial, including key participants and their contributions (additional information on collaborators can be included in the biographical sketches; see Section II.C.3, Research & Related Senior/Key Person Profile (Expanded) below).

- Describe plans to develop data collection/monitoring procedures, a data analysis plan, and other data collection tools.
- Provide a preliminary estimate of sample size and preliminary data analysis/ statistical methods plan for the future clinical trial.
- Provide evidence of access to an appropriate ill Gulf War veteran patient population and a preliminary recruitment/accrual plan.
- If applicable, provide evidence that drug product is available in sufficient quantity under current Good Manufacturing Practice (GMP) production. Describe plans for carrying out the FDA IND application process, including tentative milestones, if applicable.
- Identify potential challenges that could be expected in conducting the clinical trial.
- Describe how other preparatory activities will be accomplished.
- *Note:* Applicants are not expected to have these items fully developed in the CTDA application, but the application should reflect that these items will be addressed in the conduct of the award.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
  - References Cited (five-citation limit): List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
  - Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate

organization official, confirming the laboratory space, equipment, and other resources available for the project.

- Letters of Collaboration (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.

- **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.

  - Present the background and rationale behind the future clinical trial.
  - Describe the intervention and state the objectives of the future clinical trial.
  - Provide an overview of activities to be undertaken during the award period as described in the Project Narrative.
  - Summarize briefly how the proposed project will have an impact on ill Gulf War veterans.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.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 rationale and objectives of the future clinical trial in a manner that will be readily understood by readers without scientific or medical backgrounds.
  - Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
  - What are the likely contributions of this study in advancing treatment for GWI?

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf." State how the future clinical trial will, if successful, impact the goal of improving the health and lives of Veterans with GWI.

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

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

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

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

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

D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and GWIRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

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

   - **Potential Clinical Impact**
     - How the anticipated results of the future clinical trial, if successful, will impact the goal of improving the health and lives of veterans with GWI.
   - **Scientific Rationale and Feasibility**
     - How appropriate are the background, rationale and objectives behind the future clinical trial and the intervention, drug, or device to be tested.
     - How appropriate are plans to develop the clinical protocol and finalize the experimental design.
     - How appropriate is the preliminary management plan for the future clinical trial.
     - How appropriate are plans to develop data collection/monitoring plans, the data analysis plan, and other data collection tools.
     - How appropriate are plans to accomplish other preparatory activities, including investigation of potential intellectual and material property issues, as applicable.
   - **Intervention**
     - If applicable for the proposed intervention, how appropriate is evidence of the availability of drug product in sufficient quantity under current GMP production.
     - If applicable for the proposed intervention, how appropriate are plans for carrying out the FDA IND/IDE application process.
   - **Patient Recruitment and Accrual**
     - Whether a published case definition of GWI is provided for use in the future clinical trial.
     - How appropriate are the estimated sample size and proposed recruitment/ accrual plan.

- Whether the PI provided evidence of access to an appropriate ill Gulf War veteran patient population.

- **Personnel**
  - How the PI's background and expertise are appropriate to accomplish the current work and future trial.
  - How appropriate are plans for developing the research team and any proposed research resource or professional collaborations, and plans for training team members, as applicable.

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

- **Environment**
  - Whether there is evidence of institutional support demonstrated for the future clinical trial.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To make funding recommendations, the following criteria are used by the programmatic reviewers:

   a. Ratings and evaluations of the peer reviewers

   b. Relevance to the mission of the DHP and FY13 GWIRP, as evidenced by the following:
   - Relative impact and innovation
   - Programmatic relevance
   - Program portfolio balance
   - Adherence to the intent of the award mechanism

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

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

C. Withdrawal

The following may result in administrative withdrawal of the application:

- A FY13 GWIRP Integration Panel (IP) member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 GWIRP IP members can be found at http://cdmrp.army.mil/gwirp/panels/panels13.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.

- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed study is or contains a clinical trial or preclinical research.
- The PI does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

Transfer of a CTDA to a different PI or institution is discouraged. A change in PI or institution will only be allowed under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the USAMRAA Contracting/Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

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 Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	