Program Announcement

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Military Operational Medicine Joint Program Committee 5

Psychological Health/Traumatic Brain Injury Research Program

Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial Award

Funding Opportunity Number: W81XWH-11-PHTBI-PTSD-IHT-CTA

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 11, 2011
- **Invitation to Submit an Application:** October 2011
- **Application Submission Deadline:** 11:59 p.m. ET, November 16, 2011
- **Scientific Peer Review:** December 2011
- **Applicant Response to Scientific Peer Review Summary Statement (if applicable):** January 2012
- **Programmatic Review:** February 2012

New for fiscal year 2011 (FY11): The formal protocol for the proposed clinical trial should not be submitted as the Clinical Trial Award application. A formal protocol will be requested if the application is recommended for funding.

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

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP). The PH/TBI Research Program was established in FY07 for the purpose of complementing ongoing Department of Defense (DOD) efforts towards promoting optimal care for PH (including post-traumatic stress disorder [PTSD]) and TBI in the areas of prevention, detection, diagnosis, treatment, and rehabilitation. This includes research to benefit service members, their family members, veterans, and other beneficiaries of the Military Health System (MHS).

A total of $586 million (M) has been appropriated to support biomedical research focused on PH/TBI research efforts from FY07 through FY11, with $341.6M being assigned to the US Army Medical Research and Materiel Command (USAMRMC). The FY11 appropriation that has been assigned to USAMRMC is $100M. Approximately $5M of this appropriation has been assigned to the USAMRMC, Military Operational Medicine Joint Program Committee 5 for this Program Announcement/Funding Opportunity. The execution agent for this solicitation is the Office of the Congressionally Directed Medical Research Programs (CDMRP).

B. Award Information

The DHP objectives are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into optimal care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater, in the clinical facilities of the MHS, or through MHS coordination. The DHP funds basic research through advanced development to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. In FY11, the DHP has allocated funds to support clinical trials focused specifically on improving the treatment of combat-related PTSD and associated co-morbidities.

US Service Members are enduring demanding and high tempo in garrison and the combat field of operations in order to keep pace with ongoing Wartime mission requirements. The high tempo and increasingly common multiple deployments present many human physical and psychological challenges (Military Health Advisory Team IV [MHAT-IV], 2006; MHAT-V, 2008) that have a rippling effect on Soldier well-being as well as Army retention, recruitment, and successfully returning deployment-experienced Soldiers to a civilian environment. According to seminal work by Hoge (2004), an estimated 17% of Active Duty Soldiers screened positive for deployment-related PTSD post-deployment to Operation Iraqi Freedom or Operation Enduring Freedom (OIF/OEF). Information from MHAT-V, 2008 supported these estimates. As Soldiers return from deployment and reintegrate into their home and family environment, additional stressors and demands accrue upon psychologically and physically injured veterans beyond those strictly associated with deployment experiences. As a result, PTSD is often

complicated by other behavioral health problems, frequently with delayed onset, that include depression, alcohol and other drug use, and suicide/suicide-related behavior (Seal, 2007).

A Rand Corporation study (Tanielian, 2008) reported that 18.5% of US Service Members who have returned from Afghanistan and Iraq report current symptoms of PTSD and/or depression, and of these, about 70% will not seek treatment from the DOD or the Department of Veterans Affairs (VA). Existing research indicates that all evidence-based treatments, including cognitive-behavioral based exposure therapies (Foa, 2000), Eye Movement Desensitization and Reprocessing therapy (Rothbaum, 1997; Shapiro, 2001), and selective serotonin reuptake inhibitors (Brady, 2000), are only partially effective (Friedman, 2007). The complicated presentation of PTSD may likely contribute to the finding that existing evidence-based treatments are 20%-50% ineffective in treating PTSD symptoms. The discouraging nature of current treatment efficacy data, in combination with PTSD incidence statistics argue for continued effort to further extend the reach of psychological care opportunities within this population.

Massive research efforts in PTSD were launched in recent years in response to emerging anecdotal and empirical evidence that only estimate the enormous public health burden of PTSD on individuals, families, communities, and society at large. Many of these treatment studies employ face-to-face, in-office treatment modalities, with only a handful of alternative treatment delivery modalities such as tele-behavioral health being examined. In all cases, treatment is primarily focused upon the afflicted Service Member and management of their symptoms, in relative isolation from the contextual elements of the patient's life. Within the currently available treatment modalities, few options are available to those veterans needing behavioral health care who are, for example: (1) seriously injured and either bed ridden or engaged in home-based rehabilitation; (2) limited relative to transportation options due to either rural living or physical/psychological injury; (3) unable to get to a treatment facility due to child/family care limitations; or (4) unwilling/unable to go to care facilities due to scheduling, job, or stigma concerns. Additionally, current treatment options include little to no opportunity for the behavioral health provider to fully comprehend and incorporate components of the patient's current milieu into a coherent, realistic treatment and recovery plan.

Although in-office, face-to-face treatment for PTSD has been the established norm for treating military trauma-related PTSD, recent efforts to increase convenience, confidentiality, and service utilization while decreasing stigma have led to the development and use of tele-psychology as an alternative to in-office care. To further extend treatment flexibility, with the additional benefit of incorporating concepts of milieu therapy, the addition of in-home, face-to-face psychological care for PTSD-diagnosed veterans has been proposed as a target for further treatment-oriented research. Currently, in-home behavioral health care programs do exist within the VA Health Care System as a part of a broader in-home medical care program (Hicken, 2010), and a variety of similar programs exist for the broader, civilian population. This Program Announcement/ Funding Opportunity is specifically oriented toward evaluating the advantage of an in-home provider's perspective, which may allow for better insight into a patient's total life circumstances. This vantage point may allow the provider to better design and implement treatment strategies to address PTSD that simultaneously incorporate interventions addressing PTSD associated co-morbidities, as well as tools and techniques to assist the veteran with respect

to challenging home circumstances that often negatively impact PTSD treatment progress. Some examples might include spousal substance abuse, marital problems, or a child impacted by Attention Deficit Disorder (ADD).

The PH/TBI Research Program *Post-Traumatic Stress Disorder* In-Home Therapy Clinical Trial Award mechanism is being offered for the first time in FY11. This Program Announcement/Funding Opportunity seeks applications for funding to support randomized controlled trial comparative effectiveness research comparing behavioral health care delivered via three distinct treatment modalities:

- Face-to-Face In-Office,
- Face-to-Face In-Home, and
- Tele-Behavioral Health (provider-to-in-home patient)

The selected studies will employ a study design including at least three treatment arms. The target population is OIF/OEF veterans who have returned from deployment (e.g., post-deployment Active Duty Service Members, demobilized Reservists, discharged veterans) who are currently diagnosed with PTSD and have been referred for behavioral health treatment. This Program Announcement/Funding Opportunity seeks applications that will directly compare these treatment modalities across several dimensions. Proposed projects should be designed to include treatment outcome (e.g., patient symptom reduction to below diagnostic threshold) as the metric of primary importance. However, other comparisons and factors of importance include patient compliance, treatment satisfaction, optimizing patient match to treatment modality, ease of treatment delivery, provider/patient safety issues, cost, program management issues, and a resultant "best practice guide to implementation."

To be responsive to this Program Announcement/Funding Opportunity, researchers must clearly articulate the ability to access and recruit participants as described above. The applicant must be able to demonstrate sensitivity to issues specific to working with Active Duty Military and veteran populations (e.g., avoidance of bias, confidentiality, logistical limitations, etc.). Applicants should demonstrate an ability to adequately screen, assess, monitor, and manage risk of suicide and suicide-related behavior.

> ***NOTE: This funding opportunity will not consider: (a) Research that proposes off-label use of pharmacological agents; (b) research involving the use of animals; (c) preclinical research studies; or (d) Investigational New Drug or Investigational Device Exemption applications.***

The following are important aspects of submission for the PH/TBI Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial Award:

- Include a thorough review and knowledge of the scientific literature relevant to the nature of the proposed study.
- Ensure the research approach is both theoretically and hypothesis-driven.
- Demonstrate the potential to rapidly translate research findings into clinical practice.

- Demonstrate the ability to begin the proposed clinical trial no later than 12 months after the award date.
- Include preliminary data that are relevant to the proposed research project.
- Demonstrate availability of and access to a suitable human subject population that will support a meaningful outcome for the study. Discuss how accrual goals will be achieved.
- Describe appropriate and clearly defined endpoints for the proposed clinical trial.
- Clearly articulate the statistical analysis plan. Include a power analysis reflecting sample size projections that will clearly meet the objectives of the study.
- Discuss the potential impact of the study results for individuals affected by PTSD.
- Include the definition of PTSD being used and the diagnostic criteria used. Describe how PTSD will be distinguished from existing co-morbidities such as depression.
- PTSD diagnosis for study participants must be confirmed using the Clinician Administered PTSD Scale (CAPS) and/or the PTSD Symptom Scale, Interview Version (PSS-I). Evaluation of treatment progress must be consistent with respect to the instrumentation selected for initial diagnosis/severity measurement.
- Include a study coordinator(s) who will guide the clinical trial protocol through the local Institutional Review Board (IRB) of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate human subject accrual.
- Demonstrate institutional support.
- Applications may include a two-tiered approach that would include a limited-scope demonstration trial that transitions into a randomized, controlled, multi-arm research study.

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. Principal Investigators (PIs) seeking funding for a preclinical research project should consider one of the other PH/TBI award mechanisms/ funding opportunities being offered. The term "human subjects" is used in this Program Announcement/Funding Opportunity to refer to individuals who will be recruited for the proposed clinical trial.

Use of Human Subjects and Human Anatomical Substances: All DOD-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local IRB of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. Allow a minimum of 4 months for regulatory review

and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Multi-institutional research: Multidisciplinary and multi-institutional projects are allowed. If the proposed research is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included in the Project Narrative. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional research. Participating institutions must be willing to resolve potential intellectual and material property issues, and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

Encouraged DOD collaboration and alignment: Military relevance is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DOD areas of research interest.

Defense Technical Information Center
http://www.dtic.mil

Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury
http://www.dcoe.health.mil

Defense and Veterans Brain Injury Center
http://www.dvbic.org/

Center for Deployment Psychology
http://www.deploymentpsych.org/

Deployment Health Clinical Center
http://www.pdhealth.mil/

DOD PH/TBI Research Program Investigator-Initiated Research Award 7 Center for the Study of Traumatic Stress
http://www.centerforthestudyoftraumaticstress.org/

National Center for Telehealth and Technology
http://www.t2health.org/

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

Military Operational Medicine Research Program
https://momrp.amedd.army.mil/

U.S. Army Medical Research and Materiel Command
https://mrmc.amedd.army.mil

Air Force Research Laboratory
http://www.wpafb.af.mil/afrl

Navy and Marine Corps Public Health Center
www.nmcphc.med.navy.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
http://www.research.va.gov/

Office of Naval Research
http://www.onr.navy.mil/

U.S. Army Research Laboratory
http://www.arl.army.mil

U.S. Naval Research Laboratory
http://www.nrl.navy.mil/

Defense Advanced Research Projects Agency
http://www.darpa.mil/

U.S. Army Medical Research Acquisition Activity
https://www.usamraa.army.mil

Naval Health Research Center
http://www.nhrc.navy.mil/

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
http://www.acq.osd.mil/

Use of Active Duty Military and VA Populations: If possible, access to target Active Duty Military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving Active Duty Military, veterans, military and/or VA controlled study materials, and military and/or VA databases.

C. Eligibility Information

- PIs must be at or above the level of Assistant Professor (or equivalent)**.**
- 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 **4** years.
- The maximum allowable total costs for the entire period of performance is **$2.5M**.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award**.**
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total 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:

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Research supplies
- Equipment
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings
- Required travel costs:
    - Each PI must request travel funds to attend one program review per year during the award period of performance. For planning purposes, it may be assumed that

program reviews will be held in the Washington, DC – Baltimore, Maryland, metropolitan area.

- In addition, each PI must request travel funds, up to $1,800, to attend one Military Health Research Forum (MHRF) during the award period of performance. The MHRF is a DOD-sponsored meeting that is typically held every 2-3 years.

Direct transfer of funds to a government organization or agency is not allowed except under very limited circumstances and is subject to prior Grants Officer approval. **Funds provided through this award may not be used to support government salaries.** Details on exceptions to the prohibition of direct fund transfer to government entities can be found in Section II.C.4.K (Federal Agency Financial Plan) of the General Application Instructions.

The CDMRP expects to allot approximately $5M of the $100M FY11 PH/TBI Research Program appropriation to fund approximately 1-2 Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial 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/), (2) application submission through Grants.gov (http://www.grants.gov/), and (3) submission of Applicant Response to Peer Reviewed Summary Statement (if applicable) through the CDMRP eReceipt System (https://cdmrp.org/).

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-PHTBI-PTSD-IHT-CTA.

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.

Changes in PI or organization after submission of the pre-application will be allowed only at the discretion of the USAMRAA Contracting/Grants Officer.

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**
- **Required Files – Tab 4**

  Preproposal Narrative (two-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:

  - **Rationale:** Present the ideas and reasoning behind the proposed clinical trial, to include relevant literature citations. State how this project meets the intent of the Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial Award mechanism and the intent of the program. Describe how the study will focus on PTSD and not on other related psychological disorders.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Intervention:** Describe the intervention to be tested.
  - **Research Strategy:** Concisely state the project's objective and specific aims. Describe the proposed methods and how they will accomplish the project's aims. Describe the proposed project and the population(s) that will be enrolled in the study. Describe how this population will be screened for related disorders and co-morbidities in order to focus the treatment on PTSD.
  - **Military Benefit:** Describe the potential impact of this study on OIF/OEF veterans who have been diagnosed with PTSD. Discuss how the proposed treatment(s) will provide increased benefit over existing therapies and the current standard of care.
  - **Personnel:** Describe how the personnel's background and expertise are appropriate to accomplish the proposed research (i.e., expertise in PH/TBI Research, experience in behavioral health treatment and clinical studies). Demonstrate the ability to access and recruit Active Duty Military and veteran populations.

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

  Quad Chart: This document must be submitted by the pre-application submission deadline. The Quad Chart is a PowerPoint file that must be downloaded from the CDMRP eReceipt System and saved using Adobe Acrobat Reader as a PDF file. The Quad Chart must include the following sections:

- Problem and Military Relevance – Provide a bulleted summary of the problem to be studied and its military relevance.
- Proposed Solution – Provide a bulleted summary of the objectives of the work based on the Preproposal Narrative.
- Picture – Insert a picture or other graphic that is representative of the work to be performed; this may, for example, show some aspect of the research to be performed, the expected technology outcome of the work, or the military problem that is being addressed.
- Timeline and Cost – Identify the major planned activities or phases of the work and their duration on the chart provided, and provide the estimated direct costs by year.
  - References Cited (one-page limit)
  - 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 DOD and CDMRP, pre-applications will be screened by the FY11 PH/TBI Research Program Integration Panel (IP) based on the following criteria:

  - **Military Benefit:** What impact these studies will have on the outcomes of Service Members and/or veterans who have been diagnosed with PTSD. How will the proposed treatment(s) provide benefits beyond existing therapies and the current standard of care.
  - **Research Idea:** How the proposed project addresses the intent of the award mechanism and the program. How well delineated and appropriate is/are the hypothesis(-es) to be tested or the objective(s) to be reached.
  - **Research Strategy:** How the rationale and specific aims support the project's objective. How appropriate are the proposed methods and how will they accomplish the project's aims. How well described is the intervention to be tested. How well described are the proposed project and the population to be enrolled in the study.
  - **Personnel:** How the personnel's background and expertise are appropriate to accomplish the proposed research (i.e., expertise in PH/TBI research, experience in behavioral health treatment, and clinical studies).

- **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.

Please refer to pages 5-6 of this Program Announcement/Funding Opportunity for a list of important aspects of submission for the PH/TBI Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial Award.

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 Post-Traumatic Stress Disorder In-Home Therapy Clinical Trial 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**

   New for FY11: The Project Narrative is NOT the formal clinical trial protocol (as in previous years). Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-8 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf."

     Describe the proposed project in detail using the outline below.

     - **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or clinical data that led to the development of the proposed clinical trial. The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

       If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare

the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/ hypotheses.
- **Study Design:** Describe the type of study to be performed and outline the proposed methodology in sufficient detail to show a clear course of action.
  - Identify the intervention to be tested and describe the projected outcomes.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
  - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
  - Describe the reliability and validity of psychometric measures, if applicable.
- **Statistical Plan and Data Analysis:** Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Describe the data analysis plan in a manner that is consistent with the study objectives.

- **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 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.
- 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.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publically available.

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

  Technical abstracts should be written using 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.
  - Clinical Impact: Briefly describe how the proposed project will have an impact on PTSD research or patient care.

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

  Public abstracts should be written using the outline below.

  - Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability of the research.
    - How will it help PTSD patients?
    - What are the potential clinical applications, benefits, and risks?

- **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: Human Subject Recruitment and Safety Procedures (no page limit):** Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from which the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

  b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

  Inclusion of Women and Minorities in Study. Consistent with the Belmont Report and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

  c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

  - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements, and should accurately reflect the study.

  d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent.

- Include information regarding the timing and location of the consent process.
- Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study, and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=browse_usc&docid=Cite:+10USC980). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.
- Describe the plan for the consent of the individual's family members if they will also be participating in the clinical trial.
- Provide a draft in English of the proposed Informed Consent Form. A plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial should be included.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the

clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

- **Risk management and emergency response:**
  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel, or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
  - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.

- **Attachment 7: Intervention (no page limit):** Upload as "Intervention.pdf." The Intervention attachment should include the components listed below.

  a. Description of the Intervention: As applicable, the description of the intervention should include the following components: source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed. Description of devices should include detailed operational instructions, and any potential risks to users, and intended benefits. Other types of interventions should be fully described.

  b. Study Procedures: Describe the interaction with the human subject to include the study intervention that he/she will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will experience. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures.

- **Attachment 8: Data Management (no page limit):** Upload as "Data_Manage.pdf." The Data Management attachment should include the components listed below.

  a. Data Management: Describe all methods used for data collection to include the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

- **Confidentiality:**
  - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
  - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
  - Address requirements for reporting sensitive information to state or local authorities.
- **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

- **Attachment 9: Study Personnel and Organization (no page limit):** Upload as "Personnel.pdf." The Study Personnel and Organization attachment should include the components listed below.

  a. Principal Investigator/Study Staff: Provide an organizational chart identifying key members of the study team including institution/center/ department. Briefly describe their roles on the project. A medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.

  b. Study Management Plan: Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).

- **Attachment 10: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit):** Upload as "Surveys.pdf." The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study.
- **Attachment 11: Impact Statement (one-page limit).** Upload as "Impact.pdf."
  - Identify the volunteer population(s) that will participate in the proposed intervention, and describe the potential impact of the proposed clinical trial on the outcomes of individuals with PTSD.

- Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial.
- Describe the long-term impact: Explain the long-range vision for implementation of the intervention in the clinic or field and describe the anticipated long-term benefits for the targeted population.
- Compare the proposed intervention to pharmacologic agents, devices, and/or clinical guidance currently available, if applicable.

- **Attachment 12: Transition Plan (one-page limit).** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product to the next phase of clinical trials and/or delivery to the military and/or civilian market after successful completion of the award. The transition plan should include the components listed below.
  - Details of the funding strategy that will be used to bring the outcomes to the next level of clinical trials and/or delivery to the military and/or civilian market (e.g., specific potential industry partners, specific funding opportunities to be solicited).
  - A description of collaborations and other resources that will be used to provide continuity of development.
  - A brief schedule and milestones for bringing the outcome(s) to the next phase of clinical trials and/or delivery to the military or civilian market.
  - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 13: Military Benefit Statement (one-page limit):** Upload as "MilBen.pdf."

  State explicitly how the proposed work, if successful, will have an impact on the movement of promising treatments into clinical practice for Service Members and/or veterans with PTSD.

  Describe how the proposed studies are responsive to the health care needs of the Armed Forces and/or the US veteran population. Describe the military or veteran population(s) that are to be utilized, and their appropriateness for the proposed studies. Show how the proposed studies complement ongoing DOD and VA areas of research interest.
- **Attachment 14: Letters Confirming Access to Target Military or VA Patient Population(s) (one-page limit):** Upload as "Access.pdf."

  If applicable, provide a letter(s) signed by the lowest ranking person with approval authority for studies involving Active Duty Military, veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- **Attachment 15: Current Quad Chart (one-page limit):** Upload as "Quad.pdf."

  Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.

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. Applicant Response to Scientific Peer Review Summary Statement (if applicable) (five-page limit):

The Grants Officer reserves the right to require that ALL applicants provide written responses to issues or concerns identified by reviewers in the Scientific Peer Review Summary Statements. In the event that the DOD determines that such is required, a response template will be provided to applicants (for use in crafting replies) at the time of Summary Statement distribution to applicants via the CDMRP eReceipt system.

This will not be an opportunity to introduce new elements to the application, only clarify elements of the original submission. Every section of the response template must have a statement provided.

All responses will be reviewed by the primary, secondary, and tertiary peer reviewers responsible for the original scientific review. Reviewers' supplemental comments will be forwarded to Programmatic Review for consideration along with the original Summary Statements. Failure by applicants to submit the responses by the deadline identified in the email notification of the requirement will result in administrative withdrawal of the application.

E. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/ Funding Opportunity. Pre-application, application, and Applicant Response to the Scientific Peer Review Summary Statement submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

F. 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, USAMRMC, for concurrence and then to the Office of the Assistant Secretary of Defense for Health Affairs for final approval, based on technical merit, the relevance to the mission of the 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.shtml.

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 of equal importance:

    - **Clinical Impact**
        - How the results of the proposed clinical trial will affect the magnitude and scope of potential clinical applications (e.g., detection, diagnosis, treatment, management, and/or quality of life).

- How relevant the anticipated outcomes of the proposed clinical trial are to individuals with PTSD.
- How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
- How the potential outcomes of the proposed clinical trial will provide/improve the short-term benefits for individuals.
- How significantly the long-term benefits for implementation of the intervention may impact patient care and/or quality of life.

- **Ethical Considerations**
  - How the level of risk to human subjects is minimized.
  - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
  - To what degree privacy issues are appropriately considered.
  - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
- **Intervention**
  - To what degree the intervention addresses the clinical need(s) described.
  - How the intervention advances patient care beyond the currently available interventions.
- **Recruitment, Accrual, and Feasibility**
  - How well the PI addresses recruitment of OIF/OEF veterans who have returned from deployment and who are currently diagnosed with PTSD and have been referred to behavioral health treatment for the clinical trial and the prospect of their participation.
  - Whether the PI has demonstrated access to the proposed target population as listed above.
  - How the recruitment, informed consent, screening, and retention processes for the target population will be conducted to meet the needs of the proposed clinical trial.
  - Whether the PI has discussed possible delays in the trial (e.g., slow accrual, attrition) and provided evidence of an adequate contingency plan.
  - To what extent the proposed clinical trial affects the daily lives of the target population participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial?).
- **Research Strategy**
  - How well the scientific rationale for testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or prior clinical evidence.

- How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to clearly answer the clinical objective.
- How well the research design incorporates treatment outcome as the metric of primary importance and compares factors including patient compliance, treatment satisfaction, optimizing patient match to treatment modality, ease of treatment delivery, provider/patient safety issues, cost, program management issues, and a resultant "best practice guide to implementation."
- Whether study participants were screened using the CAPS and/or PSS-I.
- How well the applicant demonstrates an ability to adequately screen, assess, monitor, and manage risk of suicide, suicide-related behavior and other co-morbidities.
- How well the inclusion and randomization criteria meet the needs of the proposed clinical trial. How the inclusion criteria address related disorders and existing co-morbidities.
- How well the exclusion criteria are justified and maintain focus on PTSD.
- How well the "in-home" arm of the study addresses participants coping skills related to in-home environmental confounding factors (e.g., spousal substance abuse, child impacted by ADD).

- **Statistical Plan (as appropriate for the proposed clinical trial)**
  - How the statistical plan, including sample size projections and power analysis, is adequate to achieve the study objectives and is appropriate to the type and phase of study.
- **Transition Plan**
  - Whether the funding strategy described is appropriate to bring the outcome(s) to the next level of clinical trials and/or delivery to the military and/or civilian market.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
  - How the schedule and milestones are appropriate or bringing the outcome(s) to clinical trial and/or delivery to the military and/or civilian market.
  - How well the potential risk analysis for cost, schedule, manufacturability and sustainability is developed.

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

- **Personnel and Communication**
  - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
  - To what degree the study team's background and expertise are appropriate to

accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).

- How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
- To what degree the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer, standardization of procedures) are adequate.

- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
  - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed 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 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:

- Adherence to the intent of the award mechanism
- Applicant Response to Scientific Peer Review Summary Statement (if applicable)
- Military Benefit
- Program portfolio composition
- Programmatic relevance
- Ratings and evaluations of the peer reviewers
- Relative impact and innovation

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 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.
- Pre-application was not submitted.
- Submission of an application for which a letter of invitation was not received.
- Human Subject Recruitment and Safety Procedures attachment (Attachment 6) is missing.
- Intervention attachment (Attachment 7) is missing.
- Data Management attachment (Attachment 8) is missing.

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:

- Applicant Response to Scientific Peer Review Summary Statement was not submitted prior to specified deadline (if applicable).
- FY11 PH/TBI Research Program 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 PH/TBI Research Program IP members may be found at http://cdmrp.army.mil/phtbi/panels/panels11.shtml.
- 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.
- Total 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).
- The proposed research is not a clinical trial.
- 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 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.

Quarterly 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.

The transfer of an award to another institution is strongly discouraged. A transfer will not be allowed for any institution that includes a study site/clinical trial at its location. Approval of a transfer request from an institution that does not include a study site at its location will be at the discretion of the USAMRAA Contracting/Grants Officer.

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 Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 6.	
	Upload Intervention (Intervention.pdf) as Attachment 7.	
	Upload Data Management (Data_Manage.pdf) as Attachment 8.	
	Upload Study Personnel and Organization (Personnel.pdf) as Attachment 9.	
	Upload Surveys, Questionnaires, and Other Data Collection Instruments (Surveys.pdf), if applicable, as Attachment 10.	
	Upload Impact Statement (Impact.pdf) as Attachment 11.	
	Upload Transition Plan (Transition.pdf) as Attachment 12.	
	Upload Military Benefit Statement (Military.pdf) as Attachment 13.	
	Upload Letters Confirming Access to Target Military or VA Patient Population(s) (Access.pdf) as Attachment 14.	
	Upload Current Quad Chart (Quad.pdf) as Attachment 15.	
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.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	