Program Announcement

Department of Defense (DOD) Post-Traumatic Stress Disorder and Traumatic Brain Injury (PTSD/TBI) Research Program

Funding Opportunity Number: W81XWH-07-CC-CSS

PTSD/TBI Clinical Consortium-Study Site

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I. HELPFUL INFORMATION

A. Agency Name

US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

B. Agency Contact(s)

1. Program announcement, proposal format, or required documentation: Principal Investigators (PIs) and Authorized Organizational Representatives (AORs) should submit questions as early as possible. However, response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

2. eReceipt system: A help line for questions relating to the submission of pre-application components through the CDMRP eReceipt system is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. However, response times will vary depending upon the volume of inquiries. Help also is available on the CDMRP website or by email as follows:

Website: https://cdmrp.org
Email: help@cdmrp.org

3. Grants.gov: Issues in submitting applications through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov at 800-518-4726 or email support@grants.gov. The Grants.gov hours of operation are Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time. Deadlines for proposal submission are set at 11:59 p.m. Eastern Time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov Help Desk will NOT be available to assist with Grants.gov submissions. Please plan ahead accordingly, as the CDMRP Help Desk is not able to answer questions about Grants.gov submissions.

Grants.gov will only notify the PI of changes made to this Program Announcement and/or Application Package if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. Please note that if the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted by Grants.gov.

C. Anticipated Instrument Type(s)

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request via:

Fax: 301-619-2937
Email: qa.baa@amedd.army.mil

D. Catalog of Federal Domestic Assistance (CFDA) Number 12.420

Military Medical Research and Development.

E. Commonly Made Mistakes

- Pre-application submission is not completed before the mandatory pre-application deadline (pre-application remains in draft status).
- Failure to request updates on any modifications made to the application package.
- Incorrect application package or award mechanism is used to submit a proposal through Grants.gov.
- Attachments are uploaded into the incorrect form on Grants.gov.
- Files are attached in the wrong location on Grants.gov forms.
- Attachments are not PDF documents.
- Page limitations are exceeded.
- DUNS number is not confirmed well before the proposal deadline.
- Responses by Grants.gov helpdesk may not occur in time for the proposal deadline.
- Failure to submit proposal by receipt deadline.

F. Grant Writing

The USAMRMC offers Grant Writing technical assistance through a tutorial titled "Writing Competitive Proposals". The tutorial can be accessed at http://www.mrmc.smallbusopps.army.mil/tutorial/index.htm; select Writing Competitive Proposals.

II. FUNDING OPPORTUNITY DESCRIPTION

Funding of proposals received in response to this program announcement is contingent on the availability of Federal funds appropriated in a bill for this program.

A. Award Description

The Post-Traumatic Stress Disorder and Traumatic Brain Injury (PTSD/TBI) Research Program intends to fund the development of a Clinical Consortium focused on clinical studies addressing military-relevant PTSD and TBI research gap areas. The inclusion of studies that involve overlapping areas of PTSD/TBI research is encouraged. The overarching goal of establishing the PTSD/TBI Clinical Consortium is to combine the efforts of the nation's leading investigators to bring to market novel treatments or interventions that will ultimately decrease the impact of military-relevant PTSD and TBI and improve the function, wellness, and overall quality of life for Service members as well as their families, caregivers, and the American public. The PTSD/TBI Clinical Consortium will be established via two Fiscal Year 2007 (FY07) PTSD/TBI Research Program Announcements, the Clinical Consortium-Coordinating Center Award and the Clinical Consortium-Study Site program announcement.

The PTSD/TBI Clinical Consortium-Study Site program announcement supports the selection of Clinical Study Sites whose function will be to participate in the design and execution of clinical studies within the Consortium. The PTSD/TBI Clinical Consortium will encompass multiple (up to 10) Clinical Study Sites to investigate patients diagnosed with military-relevant PTSD and/or TBI. It is expected that the Consortium clinical studies will be open at multiple Clinical Study Sites. A single award will be made to the Clinical Consortium Coordinating Center, and those funds will be used to support the Coordinating Center's efforts as well as Consortium-associated studies at each of the Clinical Study Sites.

The FY07 PTSD/TBI Clinical Consortium-Study Site program announcement supports the establishment of a Clinical Consortium whose focus must address multiple PTSD *and* TBI research gaps. These PTSD and TBI research gaps may include (but are not limited to) the following:

- ***Prevention of PTSD***
    - Projects focused on primary (pre-exposure) and secondary (immediate/early intervention) prevention.
    - Studies of post-deployment re-integration strategies.
- ***Measures in Screening, Detection, and Diagnosis of PTSD***
    - Projects focused on the development, improvement, and/or validation of resources to guide operational and clinical decision making.
    - Studies on the mechanisms of resilience and evaluation of existing interventions.

- ***Epidemiological Studies of PTSD***
    - Projects focused on the evolution of PTSD over time, the evaluation of both new and existing measures, and the association of PTSD with other injuries (particularly TBI). Emphasis placed on longitudinal studies.
- ***Treatment and Intervention of PTSD***
    - Projects related to both the deployed and non-deployed Military and civilian settings with a focus on novel treatment approaches or adaptations of existing treatments across a continuum of acute through chronic care. The ultimate goals include improved functioning and well-being of affected individuals.
- ***Families/Caregivers Projects of PTSD***
    - Projects focused on measuring the impact of PTSD on family/caregiver function as well as projects that assess efficacy of training and support programs.
- ***Neurobiology/Genetics of PTSD***
    - Projects focused on identifying predictors of susceptibility, exposure, or treatment response that may ultimately lead to improved prevention, detection, diagnostic, or treatment strategies.
- ***Treatment and Clinical Management of TBI***
    - Development and implementation of a TBI clinical trials network to test new therapeutic interventions and assess advanced diagnostic and monitoring technologies (imaging, proteomics, and others) with long-term outcomes.
    - Development of standardized diagnostic criteria that capture the dynamic nature of the injury.
    - Development of standardized clinical management procedures.
- ***Neuroprotection and Repair Strategy Research for TBI***
    - Advance the understanding of threshold of injury, role of repeated exposure, and identification of individual factors that may allow for risk stratification.
    - Research into neuron repair (e.g., regeneration, cell transplantation, etc.).
    - Research into the prevention of injury through protective equipment, prophylactic drugs, other agents, change in behavior, or education.
- ***Rehabilitation/Re-integration Strategies for TBI***
    - Development of a clinical research network that may assess short- and long-term outcomes in medical, vocational, interpersonal, and psychosocial arenas.
    - Research into the short- and long-term treatment of associated conditions, such as cognitive deficits, depression, substance abuse, PTSD, and epilepsy.
    - Research into educational tools for affected military members, units, leaders, families, providers, and communities.
    - Standardizing return-to-duty criteria.

- Family and Community re-integration.
- Research into neural plasticity, physical therapy, or neural prostheses (such as brain-computer interfaces).

- ***Field Epidemiology of TBI (with emphasis on mild TBI)***
  - Determination of baseline and periodic neuropsychological assessments with certification of validation and reliability in the various groups at risk of TBI.
  - Determination of the incidence of mild TBI and trajectory of symptoms among military relevant populations.
  - Determination of factors critical to non-subjective diagnosis of mild TBI and PTSD differentiation.
  - Comprehensive evaluation of brain pathology from theater injuries, with an emphasis on linking the relevant factors of the specific mechanism of injury, personal protective equipment (PPE), individual factors (gender, age, genetics, environmental, and other), and the effect of medical interventions.

- ***Physics of Blast as it Relates to Brain Injuries:***
  - Sensors to quantify and methods to analyze the degree of personnel exposure to blast events(s) (e.g., shockwave, pressure, acceleration, or other injury producing parameters of blast exposure).
  - Evaluation of the clinical relevance of field data generated by sensors, including accelerometers and dosimeters.

The PTSD/TBI Clinical Consortium-Study Site program announcement will support the initial selection of up to 10 Clinical Study Sites, which will work together collaboratively with the Coordinating Center to identify and implement new PTSD and TBI clinical studies. The selected Clinical Study Sites will receive oversight and support from the Consortium Coordinating Center, which will serve as the Consortium information, planning, data, and resource nexus (please refer to the Clinical Consortium-Coordinating Center Award Program Announcement for additional details).

PTSD/TBI Clinical Consortium-Study Site proposals must clearly outline the qualifications and available resources that will enable the Clinical Study Site to successfully conduct multiple clinical studies on PTSD and/or TBI. The Principal Investigator (PI) should provide evidence of prior experience conducting clinical studies, availability of highly trained personnel experienced in clinical study data collection and analysis, prior success in recruiting and maintaining accrual numbers in clinical studies, and access to hospital and laboratory facilities to conduct multiple ongoing clinical studies. PIs should also provide evidence demonstrating the ability to recruit appropriate subjects into future clinical studies. In addition to demonstrating extensive experience in the conduct of clinical studies, PIs must also demonstrate knowledge of the fields of PTSD and/or TBI and present a range of scientifically based ideas for future clinical studies. The proposal should include descriptions of potential clinical studies that the Clinical Study Site would put forward to the Consortium for consideration and should note specifically how these studies would improve the function, wellness, and overall quality of life for those

Service members as well as their caregivers and families who are affected by TBI, PTSD, and/or PTSD and TBI. PIs should not prepare a proposal that focuses exclusively on one proposed clinical study, nor should they submit a clinical protocol as part of the Clinical Study Site application. Rather, PIs must demonstrate how their prior clinical study experience, institutional support, and scientific expertise make them suitable to serve as one of the Clinical Study Sites. PIs must also provide evidence of ability to enroll evaluable individuals with military-relevant PTSD and/or TBI into Consortium-sponsored studies. The PTSD/TBI Clinical Consortium is expected to integrate with DOD PTSD and TBI Centers of Excellence, which will be established at a later date.

The selected PTSD/TBI Clinical Study Sites will be required to collaborate with one another as well as with the recipient of the PTSD/TBI Clinical Consortium Coordinating Center Award. All sites will be responsible for working collaboratively to identify new PTSD and TBI clinical studies for implementation by the Consortium. Collectively, the Consortium PIs will constitute the Clinical Consortium Committee, which will be responsible for proposing, prioritizing, and conducting clinical studies focused on PTSD and/or TBI, with emphasis on those that address the prioritized research gap areas outlined above and for determining which Consortium institutions will participate in each study. Selected clinical studies will be maintained in a queue and prepared for implementation. The Coordinating Center will be responsible for facilitating this entire process. Additionally, the Clinical Consortium Committee will be responsible for developing a process for adding new Clinical Study Sites to the Consortium. The Clinical Consortium Committee will also choose individual core facilities at member institutions to serve as official Consortium research core facilities. Establishment of Consortium-wide core facilities will enable more consistent, high-quality, standardized data to be collected across sites for Consortium-supported studies. Additionally, representatives from USAMRMC must be invited to Clinical Consortium Committee sessions as well as any other formal meetings of the Consortium.

At any given time after the initial 12 months of the performance period of the award, the Consortium is expected to have a number of open clinical studies equal to or greater than the number of selected Clinical Study Sites. In addition, each participant Clinical Study Site is expected to present one or more clinical studies each year for the Consortium's consideration. For individual clinical studies, the Coordinating Center should ensure the maintenance of overall patient accrual per year appropriate for the target population. Each Clinical Study Site should maintain a ***minimum*** combined accrual across all Consortium-associated studies of at least 35 patients per year, with the expectation that 50 or more patients per year will be accrued. The Coordinating Center will be required to submit quarterly written reports that outline accrual and retention statistics as well as any problems with study execution.

Upon establishment of the Clinical Consortium, clinical studies will be selected. For those studies involving Military populations, it is envisioned that access to active duty, National Guard, Reserve troops, and/or Military patient populations will be coordinated through a centralized DOD coordinating office, to be established prior to final recommendation of proposals for funding. ***Please do not contact any Commander of active duty, National Guard, Reserve troops and/or Military patient populations at this time or during preparation of your proposal submission. However, we highly encourage you to collaborate with Military researchers and clinicians. Access to Military populations will be handled by the DOD***

coordinating office only. If selected for funding you will be provided guidance on how to obtain access to the appropriate population. The Clinical Consortium will work collaboratively with the coordinating office to facilitate successful completion of all clinical studies funded by the PTSD/TBI Research Program.

Protocols that propose to recruit patients from Department of Veterans Affairs (VA) Medical Centers or use information from VA data systems must include an investigator with a VA appointment. This individual may be the principal investigator for the entire proposal or a VA collaborator willing to assume the role of principal VA investigator for the VA component of the proposal.

Currently, there is a very limited ability to conduct human research in the CENTCOM Area of Responsibility. At present, this capability exists solely within select elements of the Multi-National Corps Iraq (MNC-I). There is no ability to conduct human research in Afghanistan at present. All research conducted within MNC-I must be in collaboration with an in theatre Military investigator, undergo an in theatre review, and be approved by the MNC-I Command and the MNC-I designated Institutional Review Board. Given the constraints of wartime operations, investigators without an ongoing collaboration with a Military investigator should strongly consider alternatives to the conduct of research in the wartime theatre. Note: DOD-supported human subjects research can only be conducted by institutions (to include those in theatre) with approved Federal Assurances of Compliance from Human Research Protection. It is strongly suggested that PTSD and TBI research involve civilian and non-deployed Military trauma populations.

Selected members of the PTSD/TBI Research Program Joint Program Integration Panel (JPIP), the CDMRP Program Manager, and additional ad hoc representatives (as needed) will assume the role of an external advisory board (EAB) to the Consortium. The role of the EAB will be to provide Consortium oversight and progress review. Consortium PIs must present written and oral briefings to the EAB and USAMRMC staff at twice-yearly 1-day meetings typically held in the Baltimore-Washington, DC area. Based on these reports and presentations, the EAB and USAMRMC staff will evaluate progress, provide feedback, and invoke modifications and terminations as needed to facilitate the success of the Consortium.

A single award will be made to support the FY07 PTSD/TBI Clinical Consortium. The award will be made to the Consortium Coordinating Center Awardee. The Coordinating Center Awardee will provide funding support for the selected Clinical Study Sites as subcontracts/sub-awards.

Responsibilities of all Consortium Participants: Procedures for the Consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively at a pre-award planning meeting to be held in late March or early April 2008 and attended by representatives of the Coordinating Center, Clinical Study Sites, EAB, and USAMRMC. The process shall be codified in a Standard Operating Procedure, which will be provided to the EAB within 12 months of the Consortium pre-award planning meeting.

Responsibilities of the Clinical Study Site Participants:

- Full participation in the Consortium Coordinating Committee, including but not limited to clinical study introduction and selection, patient accrual for Consortium studies, data collection and timely submissions, meeting attendance, and adherence to the Consortium's operating procedures;
- The proposal of at least one new clinical study focused on PTSD and/or TBI to the Consortium per year; however, the expectation will be that two or more new clinical studies per year will be proposed;
- Integration with clinical studies at other Clinical Study Sites is expected. Clinical study sites must participate in at least three (3) other Consortium-associated clinical studies; however, participation in six (6) studies is optimal.
- Maintain a ***minimum*** combined accrual across all Consortium-associated studies of at least 35 patients per year, with the expectation that 50 or more patients per year will be accrued;
- Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Study Sites and the Consortium Clinical Research Manager (at the Coordinating Center) to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across Sites;
- Implementation of the Consortium's core data collection methodology and strategies;
- Compliance with Consortium-developed quality assurance and quality control procedures, as appropriate, including:
    - Participation in an on-site monitoring program to be managed by the Coordinating Center,
    - Implementation of the Consortium-developed management plan for acquisition and aggregation of protocol-specified specimens, biological fluids, and relevant clinical data to the appropriate laboratories for testing or storage necessary for the conduct and analyses of clinical studies during the performance period of the award,
    - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use;
- Implementation of procedures established by the Coordinating Center for ensuring compliance with Food and Drug Administration (FDA) requirements for investigational agents, as appropriate;
- Implementation of procedures established by the Coordinating Center to meet the local Institutional Review Board (IRB) and the Army Surgeon General's Human Research Protection Office (HRPO) requirements for the conduct of clinical studies and the protection of human subjects;
- Serving as a resource or core for the conduct of protocol-specified laboratory projects (such as genomic/proteomic studies), as appropriate;

- Participation in Consortium-developed procedures for the timely publication of major findings;
- Participation in Consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the Consortium;
- Attend a pre-award planning meeting with all Consortium members to develop the operational features of the Consortium, outline the requirements for progress and evaluation, identify target initial clinical studies, align selected studies with appropriate Clinical Study Sites, and facilitate the award negotiations process (to be held in late March or early April 2008);
- Participation in the preparation of written and oral twice-yearly briefings to the EAB and USAMRMC staff at 1-day meetings typically held in the Baltimore-Washington, DC area;
- Submission of quarterly written progress reports and a final written comprehensive report;
- Preparing for the possibility of a Site visit audit; and
- Additional responsibilities based on recommendations and guidance from the Consortium EAB and USAMRMC staff.

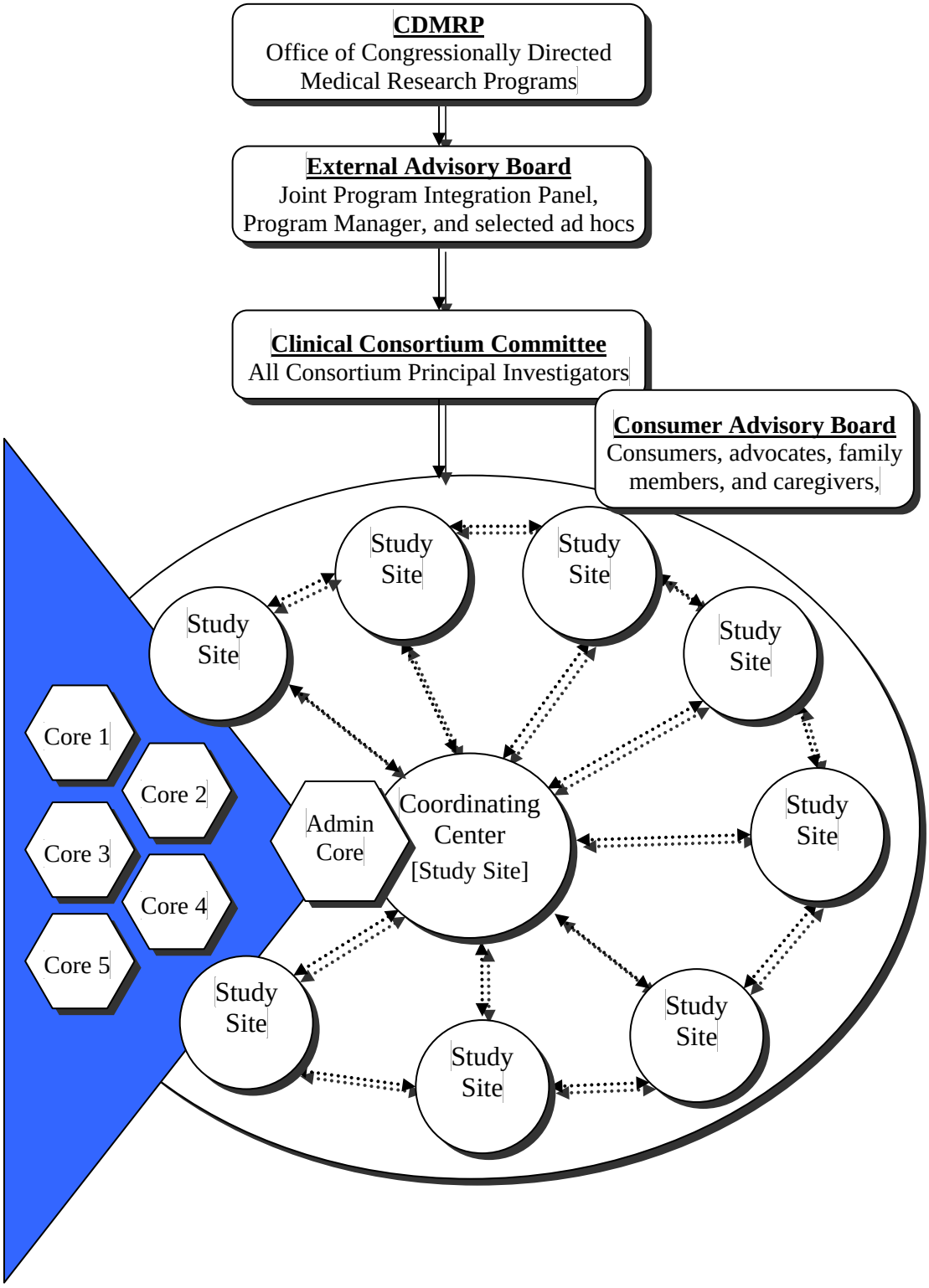

Figure 1: Basic Architecture of the Clinical Consortium

B. Eligibility

Investigators at all levels are eligible to submit proposals. Additional information about individual and institutional eligibility may be found in Appendix 1.

C. Funding

This mechanism does not provide direct funding; however, Clinical Study Sites will be subawardees to the Clinical Consortium Coordinating Center. PIs should request funding for research resources for their individual Clinical Study Site. Funding for a Clinical Study Site can be requested for up to $1,500,000 for direct costs for a 5-year performance period plus indirect costs as appropriate. The submitted budget should cover baseline resources. Additional personnel, services, or material and supply costs may be added, as needed, when the clinical protocol begins.

When an applicant institution calculates its own indirect costs for subawards, it can only charge indirect costs on the first $25,000 of each subaward.

Funds can cover:

- Research resources:
  - Administrative costs
  - Data storage
  - Sample transfer
  - IT infrastructure
  - Notification procedures (e.g., adverse events, protocol changes)
  - Standardized contracts, forms, and protocols
  - Journal costs
  - Legal/Contracting fees
  - Salaries (percentages to be determined):
    - Senior Investigator
    - Clinical Coordinator
    - Clinical Nurse
    - IT personnel
    - Other personnel (as justified)
- Additional Consortium costs:
  - Attendance and support for Consortium-related meetings;
  - Computers and general software required to participate in the Consortium;

If applying for the PTSD/TBI Clinical Consortium Coordinating Center Award, requests for funds should not duplicate those covered by that award.

The nature of the PTSD/TBI Research Program does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted.

The CDMRP expects to allot approximately $60 million (M) of the $300M Fiscal Year 2007 (FY07) PTSD/TBI Research Program appropriation to fund 1 PTSD/TBI Clinical Consortium Award, depending on the quality of proposals received. Of the $60M, $37M will be allocated for infrastructure and research resources costs at the Clinical Consortium Coordinating Center and Clinical Study Sites and $23M will be allocated for clinical studies. The Clinical Consortium will be funded through the Coordinating Center Award, which will provide support for the selected Clinical Study Sites based on the budgets submitted by the Clinical Study Site applicants. Costs associated with supporting clinical studies will be projected at a Consortium pre-award meeting.

D. Award Administration

Transferring the institutional affiliation of a selected Clinical Study Site will not be permitted.

E. Timeline for Submission and Review

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

- **Pre-application Submission Deadline:** **5:00 p.m. Eastern time, October 4, 2007**
- **Invitation to Submit Proposal:** **October 9, 2007**
- **Proposal Submission Deadline:** **11:59 p.m. Eastern time, November 26, 2007**
- **Peer Review:** **January 2008**
- **Programmatic Review:** **March 2008**

The Consortium award will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2008.

Please note that Grants.gov may take at least 48 hours to process your proposal submission and to notify you of any errors. It is strongly recommended that you submit your application as early as possible to allow sufficient time for error correction.

You may be able to submit a proposal to Grants.gov after the deadline and you will receive a message that your application is being processed. You will, however, receive at a later date notification that your proposal was late and will not be accepted by Grants.gov.

III. PROGRAM HISTORY AND OBJECTIVES

The PTSD/TBI Research Program was established in FY07 to promote research that will advance the prevention, detection, diagnosis, and treatment of military-relevant PTSD and TBI. The Program focuses its funding on innovative projects that have the potential to make a significant impact on improving the function, wellness, and overall quality of life for Military Service members as well as their caregivers, families, and the American public.

The FY07 PTSD/TBI Research Program challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the fields of military-relevant PTSD- and TBI-focused research. Proposals from investigators within the Military Services and proposals involving multidisciplinary collaborations among academia, industry, the Military Services, the Department of Veterans Affairs, and other Federal Government agencies are highly encouraged. Though the Program supports groundbreaking research, all projects must demonstrate solid judgment and rationale.

The FY07 PTSD/TBI Research Program appropriation is $300M. The PTSD/TBI Clinical Consortium-Study Site program announcement is being offered for the first time in FY07.

IV. SUBMISSION PROCESS STEP 1: PRE-APPLICATION SUBMISSION

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

This section describes the process for pre-application submission. For proposal submission, see Section V. ***Proposal submission will not be accepted unless you receive a letter of invitation.*** The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or Organization after submission of the pre-application, please contact the eReceipt helpdesk at help@cdmrp.org or 301-682-5507.

For assistance, please see Helpful Information (Section I).

A. Pre-application Components and Submission

The pre-application for a Clinical Study Site consists of a Preproposal Narrative and the other components discussed below. This subsection provides a summary of the pre-application submission requirements.

All pre-application components for the PTSD/TBI Clinical Consortium- Study Site mechanism, including the Preproposal Narrative, must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. Eastern time, October 4, 2007 deadline***. Please note that pre-applications in draft status must be finalized by this deadline. Additionally, Material submitted after the pre-application submission deadline, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet this deadline shall result in pre-application rejection and subsequent proposal rejection. ***Do not submit a proposal to the FY07 PTSD/TBI Clinical Consortium-Study Site mechanism unless you receive a letter of invitation.***

1. Proposal Information: The PI must enter the Proposal Information as described in the CDMRP eReceipt system before continuing the pre-application.

2. Proposal Contacts: Enter contact information for the PI and AOR.

3. Collaborators and Conflicts of Interest (COI): To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project including collaborators, consultants, and subawardees. Add all individuals outside of the proposal who may have a conflict of interest in the review of this proposal and choose "COI" from the drop-down list to indicate a conflict of interest. Inclusion of FY07 PTSD/TBI Research Program JPIP members in any capacity in the proposal, budget, or any supporting document is considered a conflict of interest and will result in administrative withdrawal of the proposal. A list of the FY07 PTSD/TBI Research Program JPIP members may be found at http://cdmrp.army.mil/prmrp/default.htm.

4. Preproposal Narrative: The Preproposal Narrative has a ***five-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the preproposal. The narrative should address the preproposal screening criteria. Internet URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the Preproposal Narrative or the pre-application components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the Preproposal Narrative are allowed.

5. Pre-Application Supporting Documentation: Submit only material specifically requested or required in this FY07 PTSDRP/TBIRP Program Announcement. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the pre-application.*** Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the pre-application.

Supporting documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. The items to be included as supporting documentation are:

a. References: Start section on a new page; one-page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

b. Biographical Sketches: Four-page limit per individual. Include biographical sketches for all key personnel including collaborating investigators. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in a lower pre-application ranking. A biographical sketch template is provided as Form 1.

c. Letters of Institutional Support: Provide letter(s) of institutional support, signed by the Department Chair or appropriate institutional official that reflects the laboratory space, equipment, and other resources available to the PI for this project. The letter should also indicate the extent to which the PI will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals.

d. Formatting Guidelines and Submission: All pre-application documents must be individual PDF files, in accordance with the formatting guidelines specified in Appendix 4, and uploaded under the "Required Files" tab of the CDMRP eReceipt system.

6. PI's Responsibility: The PI is responsible for uploading the pre-application documents as individual PDF files under the "Required Files" tab of the CDMRP eReceipt system. The electronic PDF files uploaded in the CDMRP eReceipt system comprise the official pre-application submission. After conversion of word processing documents to PDF files and

before electronic submission, the PI should review their files to ensure that the pre-application complies with the formatting guidelines.

7. AOR Approval: The pre-application does not require approval by the AOR before submission. Please see Appendix 2 for the definition of an AOR.

8. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all pre-applications in an organized and easy-to-follow manner. Reviewers expect to see a consistent, prescribed format for each pre-application. ***Failure to adhere to formatting guidelines makes pre-applications difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application rejection.*** The entire pre-application ***will*** be administratively rejected prior to screening if at the pre-application submission deadline:

- Preproposal Narrative exceeds page limit.
- Font size is less than 12 point.
- Margins are less than specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Page size is greater than specified in the formatting guidelines.
- FY07 PTSD/TBI JPIP members are included in any capacity in the pre-application process, including all supporting documentation. A list of the FY07 PTSD/TBI JPIP members may be found at http://cdmrp.army.mil/prmrp/default.htm.

For any other sections of a pre-application (including supporting documentation) with a defined page limit, any pages exceeding the specified limit will be removed from the pre-application and not forwarded for screening. Material submitted after the pre-application submission deadline, unless specifically requested by the Government, will not be forwarded for screening.

B. Pre-Application Screening

Pre-applications will be screened by the PTSD/TBI Research Program JPIP. The pre-application screening criteria are as follows:

1. Commitment to and Experience in PTSD and/or TBI Clinical Research:

- Experience of the PI in the successful conduct of ongoing or completed PTSD- and/or TBI-relevant clinical studies.
- The experience of the PI in participating in multi-institutional clinical studies.
- How the clinical research interests of the PI are consistent with one or more of the PTSD and/or TBI research gap areas identified in this announcement.
- How much experience the applicant institution has in running clinical studies.

- The applicant institution's possession of necessary resources and expertise for the collection and processing of specimens from Consortium-sponsored studies, as appropriate.
- The quality and extent of institutional commitment to using facilities and resources in the conduct of Consortium operations.

2. **Participant Recruitment and Human Subjects Protection**:

- How well the PI is able to enroll evaluable individuals with PTSD and/or TBI into Consortium-sponsored studies.

C. Notification Information

PIs will receive notification of invitation to submit a proposal for the ***Clinical Consortium-Study Site Program announcement***. PIs who are invited to submit a proposal will receive an email with instructions for downloading the completed pre-application file (in XML format) from the CDMRP eReceipt system. This file should be attached to form SF424 in Block 20 - Pre-application as part of proposal submission through Grants.gov. Do not convert this file.

Do not submit a proposal to the FY07 PTSD/TBI Clinical Consortium-Study Site Program announcement unless you receive a letter of invitation.

V. SUBMISSION PROCESS STEP 2: PROPOSAL SUBMISSION

This section describes the process for submission of a proposal, once an invitation has been received. Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

Proposal submission will not be accepted unless you receive a letter of invitation. The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or Organization after submission of the pre-application, please contact the eReceipt helpdesk at help@cdmrp.org or 301-682-5507.

For complete information regarding forms and submission components, as well as general proposal preparation and submission instructions, please see Appendix 3.

Please note, submission of a proposal requires institutional registration with the Central Contractor Registry (CCR; see Appendix 2). Plan accordingly and allow several weeks for these registration processes. Grants.gov will not allow proposals to be submitted unless all of the registration steps have been completed.

A. Proposal Components Summary

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. The package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**
    - Pre-application file downloaded from the CDMRP eReceipt system
2. **Attachments Form**
    - Attachment 1: Project Narrative (30-page limit)
    - Attachment 2: Supporting Documentation
        - References Cited
        - Acronyms and Symbol Definitions
        - Facilities & Other Resources
        - Description of Existing Equipment
        - Publications and/or Patent Abstracts
        - Letters of Institutional Support
        - Letters of Collaboration (if applicable)
    - Attachment 3: Statement of Work (SOW)

3. **Research & Related Senior/Key Person Profile (Expanded Form)**
    - PI Biographical Sketch (four-page limit)
    - PI Current/Pending Support
    - Key Personnel Biographical Sketches (four-page limit each)
    - Key Personnel Current/Pending Support
4. **Research & Related Budget Form**
    - Budget Justification
5. **Research & Related Project/Performance Site Location(s) Form**
6. **R&R Subaward Budget Attachment(s) Form (if applicable)**

Grants.gov will only notify the PI of changes made to this Program Announcement and/or Application Package if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. Please note that if the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted by Grants.gov.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

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

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

Proposals that include plagiarized information will be administratively withdrawn. The institution will subsequently be requested to perform an investigation and provide those findings to the cognizant Grants Officer for a determination of the disposition of the application.

Violations by panelists or principal investigators that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation.

B. Review Criteria

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

- **Personnel**
  - The ability of the PI and other key personnel to substantially contribute to the design and conduct of Consortium clinical studies.
  - The PI's and other key personnel's level of appropriate experience in the fields of PTSD and/or TBI clinical research.
  - How the named institutional clinical coordinator is qualified to guide clinical protocols through the regulatory approval processes and interact with other Consortium clinical coordinators.

- How the participating personnel are willing to commit adequate time, resources, and subjects to Consortium studies.
- The named information technology lead's ability and experience to quickly and efficiently implement the electronic communications required by the Consortium.
- The PI's past experience with collaborative research.
- Experience of the PI in the successful conduct of ongoing or completed PTSD- and/or TBI-relevant clinical studies.

- **Participant Recruitment and Human Subjects Protection:**
  - The evidence and description of an appropriate and sufficiently large, relevant PTSD and or TBI subject population(s).
  - The commitment to addressing quality of life issues for all participants involved in Consortium studies.
- **Preliminary Study Design**
  - How the scientific rationale, including review and analysis of the literature and laboratory and preclinical evidence, support the proposed studies and their feasibility.
  - How well the aims, hypothesis or objectives, experimental design, methods, data collection procedures, and analyses are developed.
- **Clinical Impact**
  - How the proposed studies, if implemented by the Consortium, will affect the magnitude and scope of potential clinical applications (e.g., prevention, detection, diagnosis, treatment, management, and/or quality of life).
- **Intervention, Drug, or Device**
  - The appropriateness of the intervention, drug, or device to be tested in the proposed clinical studies.
- **Institutional Resources and Commitment**
  - The PI's experience in participating in multi-institutional clinical studies.
  - The evidence of appropriate expertise in the necessary disciplines within the applicant institution to enable the successful completion of the proposed study.
  - The institution's possession of the necessary resources and expertise for specimen collection and processing.
  - The institution's possession of the necessary resources and expertise for data management and maintaining security/confidentiality.
  - Evidence of adequate institutional commitment to the Consortium.
  - Evidence of willingness to resolve intellectual and material property issues with other institutions in the Consortium.

- Evidence that the institution has information technology (IT) experience in implementing multi-institutional real-time communications.
- Whether there is evidence of an intellectual and material property plan, with particular emphasis on core facilities available to support the Consortium Infrastructure.

- **Budget**
  - How the budget is appropriate for the Research Resources needed to initiate and maintain multiple PTSD and/or TBI clinical studies

2. Programmatic Review: Criteria used by the JPIP to make funding recommendations that maintain the program's broad portfolio include:

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

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by the JPIP and recommended for funding to the DOD Leadership.

VII. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Failure to adhere to formatting guidelines (Appendix 4) makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection. ***Proposals missing required components of the grants.gov application package (see Section V) may be administratively rejected.***

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

- Project Narrative exceeds page limit.
- Font size is less than 12 point.
- Margins are less than specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Page size is greater than specified in the formatting guidelines.
- FY07 PTSD/TBI JPIP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY07 PTSD/TBI JPIP members may be found at http://cdmrp.army.mil/prmrp/default.htm.

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

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

VIII. APPENDICES

APPENDIX 1

ELIGIBILITY INFORMATION

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The US Army Medical Research and Materiel Command (USAMRMC) uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] 25.110.)

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

Eligible Institutions: USAMRMC makes awards to institutions; eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, Historically Black Colleges and Universities/Minority Institutions, hospitals, laboratories, and companies.

HBCU/MI: A Department of Defense goal is to allocate funds for the Congressionally Directed Medical Research Programs (CDMRP) peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders 12876, 12900, and 13021. Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

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

APPENDIX 2

GRANTS.GOV INSTRUCTIONS

A. Public Law 106-107

Proposals requesting funding from the CDMRP will be submitted through the Federal Government's single entry portal, Grants.gov, in compliance with Public Law 106-107 (P.L. 106-107). The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted in November 1999. The purposes of the P.L. 106-107 are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

Individual program announcements and required forms can also be found on this website. As in previous years, award mechanisms requiring pre-applications including Letter of Intent Narratives, preproposals, nominations, and/or confidential letters will be submitted through the CDMRP eReceipt system at https://cdmrp.org.

B. Grants.gov

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between Principal Investigators (PIs) and the Federal agencies that manage grant funds. The grant community, including state, local, and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

In compliance with P.L. 106-107, the USAMRMC requires proposals submitted in response to the program announcement to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual PIs DO NOT register; however, the AOR is required to register.

The following actions are required as part of the registration process. ***The registration process can take several weeks, so please register as soon as possible.*** If you do business with the Federal Government on a continuing basis, it is likely you have already completed some of the actions, e.g., obtaining a DUNS number or registration in CCR. Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp

1. Applicant Organization Must Have a Data Universal Number System (DUNS) Number

An organization will need a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B) (http://fedgov.dnb.com/webform/displayHomePage.do). If an organization does not have a

DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/index.jsp). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

2. Applicant Organization Must be Registered with the Central Contractor Registry (CCR)

An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates institution information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. ***CCR registrations have an expiration – please verify the status of your organization's CCR registration well in advance of the proposal submission deadline.***

You can register by calling the CCR Assistance Center at 888-227-2423 or register online at http://www.ccr.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization. Allow a minimum of 5 business days to complete the entire CCR registration. If your organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service (IRS).

Foreign organizations must obtain a CAGE code prior to registering with the CCR. A CAGE code can be obtained by calling 269-961-7766 or online at http://www.dlis.dla.mil/Forms/Form_AC135.asp.

3. Authorized Organizational Representative (AOR) must be registered with Grants.gov

Before submitting a proposal, an organization representative needs to register to submit on behalf of the organization at Grants.gov - https://apply.grants.gov/OrcRegister. An organization's E-Business point of contact (POC), identified during CCR registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals without permission. The AOR's username and password serve as "electronic signatures" when an application is submitted on Grants.gov. ***Note: In some organizations, a person may serve as both an E-Business POC and an AOR.***

An AOR must first register with the Grants.gov credential provider at https://apply.grants.gov/OrcRegister to obtain a username and password. The AOR must then register with Grants.gov for an account at https://apply.grants.gov/GrantsgovRegister. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

APPENDIX 3

INFORMATION FOR PROPOSAL SUBMISSION

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/). This section describes the process for proposal submission. For pre-application submission, see Section IV. Proposal submission will not be accepted unless the PI receives an invitation to submit a proposal. This appendix outlines how to prepare a proposal application for submission through Grants.gov.

Each submission must include the completed package of forms identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. The submission of specific documents will depend upon the award mechanism for which this proposal is being submitted, as specified in Section V and described below. All attachments must be uploaded as a PDF file in accordance with the formatting guidelines except for the pre-application XML file.

Fill in the ***Application Filing Name*** on the first screen of the Grant Application Package using the CDMRP log number acquired during the pre-application process. ***Do not fill in the Competition ID.***

Click on "Help Mode" (see arrow in Figure 2 below) in the PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in this application package.

Figure 2: Grants.gov Application PureEdge Toolbar

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	Pre-application XML File	Enter the appropriate information in data fields
Attachments Form	Project Narrative (Narrative.pdf)	Upload as Attachment 1
	Supporting Documentation (Support.pdf)	Upload as Attachment 2
	Statement of Work (SOW) (SOW.pdf)	Upload as Attachment 3
Research & Related Senior/Key Person Profile (Expanded) Form	PI Biographical Sketch (Biosketch_LastName.pdf)	Attach to PI Biographical Sketch field
	PI Current/Pending Support (Support_LastName.pdf)	Attach to PI Current & Pending Support field
	Key Personnel Biographical Sketches (Biosketch_LastName.pdf)	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support (Support_LastName.pdf)	Attach to Current & Pending Support field for each senior/key person
Research & Related Budget Form	Budget Justification for entire performance period (Justification.pdf)	Attach to Section K in budget period one
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets and justifications (Justification_LastName.pdf)	Attach a separate budget with justification for each subaward

Prior to award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, and regulatory documents related to human and animal studies and other documents may be requested from the PIs. At that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the AOR.

A. SF-424 (R&R), Application for Federal Assistance Form.

This form is required for each application. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this application package. The form is self-explanatory, with the following exceptions:

- **Applicant Identifier** box should be filled in with the submitting Institution's Control Number.

- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions the "Application" box should be chosen. For substantial changes that must be made after the original submission, the complete application package must be resubmitted. In these cases, the "Changed/Corrected Application" box must be checked and the Grants.gov tracking number must be entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable
- **Block 4 – Federal Identifier Box.** This box will be populated by Grants.gov for an original application, but the Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application) must be manually entered for changed or corrected applications.
- **Block 13 – Proposed Project.** The start date should be 9 months to a year from the deadline for proposal submission for this award mechanism.
- **Block 14 – Congressional Districts Of.** If applying from a foreign institution enter "00-000" for both applicant and project.
- **Block 17 – Is Application Subject to Review by State Executive Order 12372 Process?** Choose option, b. NO, program is not covered by E.O.12372.
- **Block 19 – Authorized Representative.** The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. ***Hard copies of applications will not be accepted.***
- **Block 20 – Pre-application** box and attachment should be used to attach the pre-application file associated with this proposal. This pre-application file must be downloaded from the CDMRP eReceipt system. ***Please do not convert this XML file to PDF.***

B. Attachments Form

The following information must be included as attachments to this form in accordance with the formatting guidelines:

Attachment 1: Project Narrative: 30-page limit. The Project Narrative is the main body of the proposal. The Project Narrative must be submitted as a single PDF file named "Narrative.pdf," in accordance with the formatting guidelines. Describe the qualifications of the group, the available resources and clinical study experience using the following general outline:

Commitment to and Experience in PTSD and/or TBI Clinical Research: Describe ongoing or completed PTSD and/or TBI-relevant clinical studies. Reference relevant publications (no limit) and submit reprints (5-document limit) with the proposal supporting documentation (Attachment 2). Describe how the PI possesses commitment to PTSD and/or TBI clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups. Include examples of multi-institutional clinical studies. Describe the specific areas of clinical research interest such as novel drugs, combinatorial therapy schedules, interventions, education interventions, and

imaging techniques. Include the overall scope of the program and a demonstration of integration of basic and/or correlative science into the program. Describe the procedures for ensuring compliance with FDA requirements for investigational agents.

Proposed Clinical Studies: Describe the scientific rationale and feasibility of the clinical studies that will be proposed to the Clinical Consortium Committee for consideration. Describe the aims, hypothesis or objectives, experimental design, methods, data collection procedures, and analyses. Describe how being a part of this Consortium will facilitate the successful conduct of these studies. Describe how these and other future clinical studies proposed to the Consortium will improve the function, wellness, and overall quality of life for Service members as well as their caregivers and families who are affected by TBI, PTSD, and/or PTSD and TBI.

Consortium Resources: Provide the name for the institutional Clinical Research Coordinator that has the necessary experience to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites. Also include evidence of successful multi-center clinical study collaborations.

Institutional Resources and Commitment: Describe the available expertise within each institutional department relevant to the development and conduct of potential PTSD and or TBI clinical studies: Include any additional clinical and/or laboratory expertise that could serve as the basis for the development of future clinical protocols by the Consortium. Describe the resources and expertise available for the collection and processing of specimens from Consortium-sponsored studies, as applicable. Describe the resources and expertise for data management and maintenance of data security/confidentiality exist. Provide evidence of commitment to entering eligible participants into Consortium-sponsored studies and acknowledgment that the Consortium studies have the highest priority. Describe institutional commitment to resolving intellectual and material property issues.

IT Resources: Since the Consortium will rely heavily on information technology, provide the name of the individual who will be responsible for database and information infrastructure. Describe relevant personnel and institutional experience with implementing multi-institutional real-time communications.

Personnel: Describe how the PI and other key personnel have the ability to substantially contribute to the writing, design, and conduct of Consortium clinical studies. Describe how all participating personnel are willing to commit adequate time, resources, and subjects to Consortium studies. Describe the experience of the PI and the team's understanding of and experience with the local IRB approval process. Provide details of training in human subjects research ethics. Describe past experience with collaborative research projects.

Participant Recruitment , Human Subjects Research Experience, and Human Subjects Protection: Describe the PTSD and/or TBI population (including size, age range, and clinical manifestations) and provide evidence of ability to enroll at least 35 evaluable individuals with PTSD and/or TBI per year. Provide evidence of commitment to addressing quality of life issues for all participants enrolled in Consortium studies.

The 30-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

Attachment 2: Supporting Documentation. Upload these sections as a single PDF file named "Support.pdf," in accordance with the formatting guidelines.

a. References Cited: No page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

b. Acronyms and Symbol Definitions: No page limit. Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.

c. Facilities & Other Resources: No page limit. Describe the facilities 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 facility or equipment is 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.

d. Description of Existing Equipment: No Page Limit. Include a description of existing equipment to be used for the proposed research project.

e. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. Extra items will not be reviewed.

f. Letters of Institutional Support: Provide letter(s) of institutional support, signed by the Department Chair or appropriate institutional official, that reflects the laboratory space, equipment, and other resources available to the PI for this project. The letter should also indicate the extent to which the PI will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals. Additionally, indicate the institution's commitment to resolving IP and material property issues.

g. Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or institution.

Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.***

Attachment 3: Statement of Work (SOW): Three-page limit. The SOW must be uploaded as a single PDF file named "SOW.pdf" in accordance with the formatting

guidelines. The Statement of Work is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's Statement of Work must include aims to be funded by this proposal. The Statement of Work should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Include the following information for each clinical study site/subcontract site (collaborative site and consultant) that will be actively participating in the study:
  - Institution name
  - Institution address
  - Collaborator, consultant, and/or subawardee name
  - Human use at this site
- Identify the timeline and milestones for the work over the performance period for the proposed effort;
  - Allow at least 6 months for regulatory review and approval processes for studies involving human subjects;
- Indicate time required for human use approval and FDA submission of applicable documents (i.e., IND and IDE);
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

The SOW will be updated at the Consortium pre-award planning meeting.

C. Research & Related Senior/Key Person Profile (Expanded Form)

Include the requested information for each senior/key person proposed on the project. Each attachment must be a single PDF file, in accordance with the formatting guidelines.

1. PI Biographical Sketch: Four-page limit. Suggested format is provided as Form 1. The biosketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the PI.

2. PI Current/Pending Support: No page limit. Current/Pending Support for the PI must be submitted as a PDF file in accordance with the formatting guidelines. This file must be named "Support_LastName.pdf," where "LastName" is the last name of the PI.

Proposals submitted under this program announcement should not duplicate other funded research projects.

For all existing and pending research projects involving the PI include:

- Title
- Time commitments
- Supporting agency
- Name and address of the Funding Agency's Procuring Contracting/Grants Officer
- Performance period
- Level of funding
- Brief description of the project's goals
- List of the specific aims

Provide justification for the requested support and identify where the projects overlap or parallel. If no current support exists, enter "None." Updated current and pending support will be required during award negotiations.

3. Key Personnel Biographical Sketches: Four-page limit per individual. Suggested format is provided as Form 1. Each biosketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the appropriate individual.

4. Key Personnel Current/Pending Support: No page limit. Current/Pending Support for each individual must be submitted as a PDF file in accordance with the formatting guidelines. Each file must be named "Support_LastName.pdf," where "LastName" is the last name for the individual. Refer to "PI's Current/Pending Support" above for content of this document, except substituting individual information for that of the PI.

D. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. All costs must be entered in US dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.

The following cost regulations and principles must be adhered to budget calculations:

- **Subcontracting Indirect Costs:** When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.
- **Maximum Obligation:** The USAMRMC does not amend grants to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the following regulations and principles:
    - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.

- **Educational Institutions:** OMB Circular A-21, Cost Principles for Educational Institutions.
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments.
- **Cost of Preparing Proposals:** The cost of preparing proposals in response to this program announcement is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and OMB Circulars A-21 and A-122.

Section A & B – Senior/Key Person and Other Personnel: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period of performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K).

The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

Section C – Equipment Description: It is DOD policy that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 2 years and an acquisition cost of $5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification (Section K) to include:

- Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
- Historical Cost: Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
- Estimate: Include rationale for estimate and reasons for not soliciting current quotes.
- Special test equipment to be fabricated by the contractor for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.

- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.
- Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.
- Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

Section D – Travel

- **Travel costs to attend one scientific/technical meeting per year.** Costs should not exceed $1,800.
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the United States, including between foreign countries, requires prior approval from USAMRAA 90 days before travel.
- **Travel to CDMRP-required meetings** (if applicable) (Section II.C). Costs should be reasonable.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F – Other Direct Costs (as applicable)

Section F.1 – Materials and Supplies (Consumables): The justification (to be included in Section K) supporting material and supply (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

Section F.2 – Publication Costs: This section is self-explanatory.

Section F.3 – Consultant Services: Regardless of whether funds are requested, the justification (to be included in Section K) should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

Section F.4 – ADP/Computer Services: This section is self-explanatory.

Section F.5 – Subaward/Consortium/Contractual Costs: On the project's Research and Related Budget Form, enter the total funds requested for (1) all subaward/consortium

organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

Section F.6 – Equipment or Facility Rental/User Fees: This section is self-explanatory.

Section F.7 – Alterations and Renovations: Not allowable.

Sections F.8–F.10 – Research-Related Subject Costs: Not applicable for this mechanism. Research related subject costs will be awarded by the Clinical Consortium Coordinating Center.

Sections F.8–F.10 – Other Direct Costs (if applicable): Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified in Section K.

Section G – Direct Costs: This section is self-explanatory. All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

Section H – Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. If negotiated forecast rates do not exist, provide sufficient detail in the budget justification (Section K) regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions. Commercial firms can also visit www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established. When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.

As a minimum, justification for indirect costs should identify:

- All individual cost elements included in each forecast rate;
- The basis used to prorate indirect expenses to cost pools, if any;
- How each rate was calculated; and
- The distribution basis of each developed rate.

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

Section J – Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a profit/fee is negotiated, a contract will be awarded. Any fixed fee applied to the research project must be listed and any claimed Facilities Capital Cost of Money supported by **DD Form 1861** (www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html) must be submitted with the proposal.

Section K – Budget Justification: The Budget Justification for the entire performance period must be attached as a PDF file named "Justification.pdf" to the Research & Related

Budget – Section K (under budget period one). Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.

The budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods.

E. Research & Related Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Please note that each additional research site requesting funds will require a subcontract budget.

F. R&R Subaward Budget Attachment(s) Form (optional form; use if applicable)

Please note that the files to be attached to the R&R Subaward Budget Attachment(s) Form must be PureEdge documents. Extract an R&R Subaward Budget Attachment for each subaward, using the button provided on this form. Save each attachment to your computer and complete the form(s).

The Budget Justification for each subaward must be attached as a PDF file named "Justification_LastName.pdf" (where "LastName is the investigator of the subaward) to the Research & Related Budget – Section K for that subaward. Each subaward budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods for the subaward. Once all subaward budget files are completed, attach all subaward budget file(s) for this application to the R&R Subaward Budget Attachment(s) Form.

The DUNS number for each subaward site should be included on this form.

A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. The following information must be provided on subawards totaling $10,000 or more:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;
- The proposed acquisition price; and
- The applicant's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $500,000 and the applicant is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the applicant is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

APPENDIX 4

FORMATTING GUIDELINES

The proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF, except for the pre-application file (XML file) attached to block 20 of SF-424.
- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Proposals may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, Principal Investigators may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are encouraged.
- **Language:** English.
- **Headers and Footers:** Should not be used.
- **Page Numbering:** Should not be used.

All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded as a PDF file.

APPENDIX 5

AWARD ADMINISTRATION INFORMATION

A. Award Notices

Each Principal Investigator (PI) will receive notification of the award status of his or her proposal. A copy of the peer review summary statement, if applicable, will be posted to the Congressionally Directed Medical Research Programs (CDMRP) eReceipt system. PIs can expect to receive this notification approximately 4 weeks after programmatic review.

B. Administrative Requirements

Awards are made to organizations, not individuals. Each PI must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including Military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and Department of Defense [DOD] Grant and Agreement Regulations) to be eligible for an award. Any organization requesting receipt of an award through this program announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

If allowed, a change in institutional affiliation will require the investigator to resubmit the entire proposal packet through his or her new institution to include any regulatory documentation that may require protocols, etc., to be approved for the new institution. The investigator's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting and regulatory review and a subsequent delay in resuming work on the project.

C. Award Negotiation

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the US Army Medical Research Acquisition Activity (USAMRAA). A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the PI's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

D. Disclosure of Proprietary Information outside the Government

By submitting a proposal, each PI understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The US Army Medical Research and Materiel Command (USAMRMC) will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes

and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

E. Government Obligation

PIs are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. PIs who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

F. Information Service

PIs may use the technical reference facilities of the National Technical Information Service (www.ntis.gov), for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

G. Inquiry Review Panel

PIs may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

H. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

I. J-1 Visa Waiver

It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

APPENDIX 6

REGULATORY REQUIREMENTS AND REVIEWS

Principal Investigators (PIs) may not use, employ, or subcontract for the use of any human subjects, human biological substances, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the US Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (DOD) regulations are met.

Concurrent with the US Army Medical Research Acquisition Activity (USAMRAA) negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form to be submitted upon request.

A. Certificate of Environmental Compliance

The Certificate of Environmental Compliance may be requested prior to award negotiations. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

B. Safety Program Documents

The Principal Investigator Safety Program Assurance form may be requested prior to award negotiations.

A Facility Safety Plan from each PI's Institution is required; it will be requested at award negotiations. A Facility Safety Plan from the PI's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/docs/rcq/sohd/Facility_Safety_Plan_Approved_Institutions.pdf. If the PI's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

C. Research Involving Human Subjects, Including the Use of Human Anatomical Substances and/or Human Data

For all other studies, documents related to the use of human subjects or substances will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the proposal).

In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects or biological substances, a second tier of human subjects regulatory review and approval is required by the DOD, which is conducted by the USAMRMC ORP, Human Research Protection Office (HRPO). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. The recommendations of the second-tier HRPO review must be considered by the local IRB; therefore, to expedite the review of research involving human subjects or biological substances, PIs should not submit documentation to their local IRB until they have received an initial review by HRPO.

Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.

1. Requirements: Specific requirements for research involving human subjects, anatomical substances, and/or data can be found at https://mrmc.amedd.army.mil/rodorptoolkit.asp.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

It is expected that there will be timely resolutions of human subjects protocols submitted to the investigator's local IRB.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.detrick.army.mil/rodorphrpo.asp.

2. Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

3. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; http://www.dtic.mil/biosys/downloads/title10.pdf) applicable to DOD-sponsored research before writing a research protocol. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement

whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

4. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells: Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g 2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

APPENDIX 7

REPORTING REQUIREMENTS

The Government requires reports to be submitted by each Principal Investigator for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full US Army Medical Research and Materiel Command reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

1. Research Progress Reports. Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. The Clinical Study Sites will be required to submit quarterly written reports that outline accrual and retention statistics as well as any problems with study execution. Additional reporting may be required as stipulated during award negotiations. Copies of all scientific publications and patent applications resulting from Congressionally Directed Medical Research Programs funding should be included in the progress report. The Government reserves the right to request additional reports.

2. Fiscal Reports. Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

3. Non-Exempt Human Studies Reports. For non-exempt human subjects research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

4. Animal Use Reports. Principal Investigators are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

APPENDIX 8

ACRONYM LIST

ACURO.....Animal Care and Use Office
ADP.....Automated Data Processing
AOR .....Authorized Organizational Representative
ASDRP.....Autism Spectrum Disorder Research Program
AVI .....Audio Video Interleave
BCRP .....Breast Cancer Research Program
CCR.....Central Contractor Registration
CDMRP.....Congressionally Directed Medical Research Programs
CFDA.....Catalog of Federal Domestic Assistance
CFR.....Code of Federal Regulations
cGMP .....Current Good Manufacturing Practices
CAGE.....Commercial and Government Entity
COI.....Conflicts of Interest
CMLRP .....Chronic Myelogenous Leukemia Research Program
CR .....Contract Representative
DFARS.....Department of Defense Federal Acquisition Supplement
DOD.....Department of Defense
DODGAR .....Department of Defense Grant and Agreement Regulations
DUNS.....Data Universal Number System
EIN.....Employer Identification Number
EPLS .....Excluded Parties List System
FAR.....Federal Acquisition Regulation
FDA.....Food and Drug Administration
FY .....Fiscal Year
GCP.....Good Clinical Practice
GLP .....Good Laboratory Practice
GWVIRP.....Gulf War Veterans' Illnesses Research Program
HBCU/MI .....Historically Black Colleges and Universities/Minority Institutions
HIPAA .....Health Insurance Portability and Accountability Act
hES.....Human Embryonic Stem
HRPO.....Human Research Protection Office
HSRRB .....Human Subjects Research Review Board
IDE.....Investigational Device Exemption
IND .....Investigational New Drug
IP.....Integration Panel
IRB.....Institutional Review Board
IRS .....Internal Revenue Service
JPEG .....Joint Photographic Experts Group
LAR.....Legally Authorized Representative
LOI.....Letter of Intent
M.....Million
MB .....Megabyte

MPEG .....Moving Picture Experts Group
NIH .....National Institutes of Health
NFRP.....Neurofibromatosis Research Program
OCRP .....Ovarian Cancer Research Program
OMB .....Office of Management and Budget
ORP.....Office of Research Protections
PCRP.....Prostate Cancer Research Program
PDF .....Portable Document Format
PI.....Principal Investigator
P.L. .....Public Law
POC.....Point of Contact
PRMRP .....Peer Reviewed Medical Research Program
PTSD.....Post-traumatic Stress Disorder
R&R OPI.....Research & Related Other Project Information
SOW.....Statement of Work
SPORE .....Specialized Programs of Research Excellence
TBI .....Traumatic Brain Injury
TIFF .....Tagged Image File Format
TIN.....Tax Identification Number
TSCRP .....Tuberous Sclerosis Complex Research Program
URL.....Uniform Resource Locator
USAMRAA.....US Army Medical Research Acquisition Activity
USAMRMC .....US Army Medical Research and Materiel Command
USC.....United States Code
WAV .....Waveform Audio
XML.....Extensible Markup Language

IX. CDMRP-SPECIFIC FORMS

FORM 1

BIOGRAPHICAL SKETCH

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

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

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.