

Program Announcement

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

Funding Opportunity Number: W81XWH-07-PTSD-MRC

PTSD Multidisciplinary Research Consortium Award

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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](https://www.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 (PTSD) Multidisciplinary Research Consortium Award is intended to optimize research and accelerate the solution of a **major overarching problem** in post-traumatic stress disorder research within an integrated consortium of the most highly qualified investigators. Each PTSD Multidisciplinary Research Consortium Award proposal must address a single, critical question relevant to the prevention, detection, diagnosis, and/or treatment of PTSD through a synergistic, multidisciplinary research program.

The proposed PTSD Multidisciplinary Research Consortium should (1) address a major gap in basic, translational, population-based and/or clinical PTSD research; (2) develop critically needed resources (e.g., databases to address specific problems); and/or (3) create a unique, new approach or infrastructure to focus on a critical research problem. The PTSD Multidisciplinary Research Consortium may include Phase I or Phase II clinical studies, and partnerships with pharmaceutical or biotechnology industry scientists are welcome.

It is expected that the PTSD Multidisciplinary Research Consortium will be multi-institutional and will include the best scientists and clinicians as members of a synergistic, multidisciplinary team. An exceptionally compelling justification must be provided if the proposed work involves a single institution. Collaborations between academia, Historically Black Colleges and Universities/Minority Institutions, industry, the military Services, the Department of Veterans Affairs, and other Federal Government agencies are particularly encouraged in order to bring a new perspective to PTSD research and/or facilitate progress in the field by combined effort. Within the Consortium, multiple investigators can be recognized as Principal Investigators (PIs) and each will receive a separate award. ***The Multidisciplinary Research Consortium Director must be identified as the Initiating PI, and will be ultimately responsible for the majority of the administrative tasks associated with the proposal. The other members will be referred to as the Partnering PIs.*** All the investigators must collaborate to submit a single proposal addressing a central problem or question in PTSD research. It should be clear that all investigators have an equal level of intellectual input and effort. Participating institutions must be willing to resolve potential intellectual property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful establishment and maintenance of the multidisciplinary, synergistic research consortium.

All proposals submitted to the PTSD Multidisciplinary Research Consortium Award should:

- ***Focus on the solution of a critical problem in PTSD research using strategies that optimize the PTSD Multidisciplinary Research Consortium Award's comprehensive array of personnel and resources.*** The project designed for the PTSD Multidisciplinary Research Consortium must be founded on solid scientific rationale and must be critical to the prevention, detection, diagnosis, and/or treatment of PTSD. The question should be broad enough to require a multidisciplinary approach. Applicants ***must include***

published or preliminary data that supports the feasibility of their hypotheses and/or approaches and a description of the proposed team of investigators and the anticipated research in both the pre-application and the invited proposal. Preliminary data is unpublished data. If the preliminary and/or published data is generated from a source other than the applicant, appropriate acknowledgement is required. For example, if the preliminary data has been generated by a colleague, acknowledgement should be made by listing the investigator's name, institution, and a statement that the data has been obtained via personal communication. Describe previous experience most pertinent to this proposal. Cite relevant literature references for published data.

- ***Integrate a team of preeminent investigators from appropriate disciplines and institutions.*** Emphasis must be placed on integrating the most highly qualified investigators to focus on the research problem, regardless of their location. This includes highly accomplished scientists and promising young investigators in the targeted areas of research who collectively represent the best team to solve the problem(s) identified.
- ***Incorporate PTSD consumer, survivor, family member, and/or caregiver groups into the proposed consortium.*** Individuals from these groups should have active roles in the proposed PTSD Multidisciplinary Research Consortium including program conception and design, discussions, recruitment of research participants, program evaluation, and dissemination of information to the public.
- ***Optimize, facilitate, and accelerate research progress through communication.*** Communication between and among PTSD Multidisciplinary Research Consortium team members is essential to the success of the Consortium's goals. Proposals should include a strategy for sharing data in real time and using information technologies to facilitate timely and effective communication and cooperation. The PTSD Multidisciplinary Research Consortium should take full advantage of current Internet and electronic communication tools, as well as formal and informal meetings. Collaborators also must plan to meet in person two to four times per year to assess research progress, address problems, and define future directions.
- ***Provide an effective, coordinated administrative management plan that integrates and optimizes the research and collaborations.*** The PTSD Multidisciplinary Research Consortium Director, as the Initiating PI of the proposal, is responsible for the day-to-day management of the Consortium. Therefore, the Multidisciplinary Research Consortium Director is expected to commit an appropriate level of time and effort—***at least 25%***—to direct and manage an initiative of this magnitude. He or she must have the scientific ability to oversee large research programs and have a proven record of leadership, including experience in the effective use of communication tools and the management of multifaceted and multidisciplinary projects. The administrative management plan should explain how the Multidisciplinary Research Consortium will be organized and managed; it should specify the processes and tools to be used for regular and structured communication, data management, project prioritization, project meeting scheduling, reviews of research report findings, and other issues of common concern to the Consortium and its investigators. The administrative management plan also should describe procedures that maximize the use of resources and eliminate unnecessary duplication. The sharing of experimental techniques, databases, models (including

animal models), and biologically active agents/therapies developed by the PTSD Multidisciplinary Research Consortium with other PTSD researchers is highly encouraged.

The Consortium should include a named Research Coordinator who will coordinate the efforts of all Consortium participants. The Consortium Clinical Research Coordinator will be responsible for coordinating animal use approval(s), clinical protocol(s) approval (if applicable), and study activities across the Consortium.

Select members of the PTSD/TBI Joint Program Integration Panel (JPIP) will assume the role of an external advisory committee to the funded Consortium. The Consortium Director, Research Project PIs, and Research Core Facility PIs will be required to attend a biannual 1-day meeting in the Baltimore, MD/Washington, DC area to present the progress of their DOD-sponsored research to the JPIP and USAMRMC staff.

This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts, nor should it represent a collection of related Program Project grants or subprojects.

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. Those proposals that score favorably during the scientific peer review and require access to Military patient populations will be forwarded to the centralized DOD coordinating office for consideration and review for availability and access to military patient populations prior to being recommended 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 coordinating center only. If selected for funding you will be provided guidance on how to obtain access to the appropriate population.***

Submissions 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.

The Fiscal Year 2007 (FY07) PTSD Multidisciplinary Research Consortium Award encourages proposals that specifically address one or more of the following research gaps:

- ***Treatment and Intervention*** – Includes projects related to both the deployed and non-deployed military settings with focus on novel treatment approaches or adaptations of existing treatments across a continuum of acute through chronic care. Ultimate goals include improved functioning and well-being of affected individuals.
- ***Prevention*** – Includes projects focused on primary (pre-exposure) and secondary (immediate/early intervention) prevention. Also includes studies of post-deployment re-integration strategies.
- ***Measures in Screening, Detection, and Diagnosis*** – Includes projects focused on the development, improvement, and/or validation of resources to guide operational and clinical decision making. Also includes studies on the mechanisms of resilience and evaluation of existing interventions.
- ***Epidemiological Studies*** – Includes 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 traumatic brain injury). Emphasis placed on longitudinal studies.
- ***Families/Caregivers*** – Includes projects focused on measuring the impact of PTSD on family/caregiver function as well as projects that assess the efficacy of training and support programs.
- ***Neurobiology/Genetics*** – Includes projects focused on identifying predictors of susceptibility, exposure, or treatment response that may ultimately lead to improved prevention, detection, diagnostic, or treatment strategies.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation, its relevance to the above research gap areas, and the impact it may have on the field of PTSD research.

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

It is anticipated that a separate award will be made to each PI's institution. The combined total funding for all institutions can be requested for up to \$25,000,000 for direct costs for up to a 5-year performance period plus indirect costs as appropriate. All PIs are expected to be equal partners in the research and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified. 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:

- salary
- research supplies
- equipment
- training
- support for multidisciplinary collaborations and workshops
- consultation with scientific and/or technical experts (e.g., statisticians, editors)
- administrative and technical assistance
- clinical costs
- travel to scientific/technical meetings
- travel between collaborating institutions

The CDMRP requires attendance to biannual external advisory oversight meetings in the Baltimore, MD/Washington, DC area to present the progress of their DOD-sponsored research to the JPIP and USAMRMC staff.

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 \$25 million (M) of the \$150M FY07 PTSD appropriation to fund approximately 1 Multidisciplinary Research Consortium Award proposal, depending on the quality and number of proposals received.

D. Award Administration

Changes in PI, institution, and/or Statement of Work will only be allowed in extenuating circumstances and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

Transferring an award that includes a clinical trial 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, September 6, 2007
- **Invitation to Submit Proposal:** September 20, 2007
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, November 26, 2007
- **Peer Review:** January 2008

- **Programmatic Review:**

March 2008

Awards 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 appropriation is \$150M. The PTSD Multidisciplinary Research Consortium Award mechanism 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 \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

To foster collaborations and to optimize partnerships, the Multidisciplinary Research Consortium Award is structured to accommodate multiple PIs. The Initiating PI is responsible for completing the pre-application process and for ensuring that all requirements of the proposal submission process are met. Initiating and Partnering PIs each have different proposal submission requirements. Each PI must complete his or her respective proposal submission requirements.

Please note that each PI is equally responsible for the conduct and success of the project.

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 PIs and Organizations 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 Multidisciplinary Research Consortium Award 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 Multidisciplinary Research Consortium Award mechanism, including the Preproposal Narrative, must be submitted electronically through the [CDMRP eReceipt system](#) by **5:00 p.m. Eastern time, August 30, 2007 deadline**. 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 Multidisciplinary Research Consortium Award mechanism unless you receive a letter of invitation.***

- 1. Proposal Information:** The Initiating 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 Initiating PI and AOR. The contact information for each Partnering PI must be entered under the Collaborators and Conflicts of Interest tab.

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 for each PI. The Initiating PI must enter the name, email, and title of each Partnering PI and choose “Partnering PI” from the drop-down list to indicate his or her role in the project. 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 Joint Program Integration Panel (JPIP) members in any capacity in the proposal, budgets, 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 JPIP members may be found at <http://cdmrp.army.mil/prmrp/default>

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 PTSD 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 preapplication.* 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](#).

6. 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](#).

7. PI Responsibilities:

a. Initiating PI Responsibility: The Initiating PI is responsible for uploading the preapplication 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 Initiating PI should review his or her files to ensure that the pre-application complies with the [formatting guidelines](#).

b. Partnering PI(s) Responsibility: The Partnering PI(s) have no responsibility in the pre-application process.

8. AOR Approval: The pre-application does not require approval by the AOR before submission. Please see [Appendix 2](#) for the definition of an AOR.

9. 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>

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 JPIP. The pre-application screening criteria are as follows:

1. Objectives, Impact, and Research Strategy:

- How clearly the PI states the overarching problem.
- The rationale provided for addressing this problem in a multidisciplinary, multi-institutional consortium and its relevance to one or more of the research gap areas identified for PTSD.
- If the proposed Consortium is not multi-institutional, whether a single institution is well-justified.
- The probability that the interactions and collaborations established through the Consortium will result in a synergistic effort that will substantively accelerate the research needed to resolve the central problem.
- How well the PI describes the interdependence among participants in completing each aim of the study.
- How well the PI outlines a plan for center and project management, including an outline of a plan for communications.
- How well the PI outlines an experimental strategy to address the identified problem, including a timeline for completing the proposed research.

2. Innovation

- How the proposed research is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.

3. PIs and Key Personnel:

- How well the multidisciplinary, multi-institutional team of investigators who will address the major, overarching problem is described, including names and locations of all scientific collaborators.
- The qualifications of the Consortium Director, including his or her ability to organize, administer, and manage an expert team of multidisciplinary, highly integrated, multi-institutional researchers in a consortium to solve a critical problem in PTSD research.

Do not submit a proposal to the FY07 PTSD Multidisciplinary Research Consortium Award mechanism unless you receive a letter of invitation.

C. Notification Information

PIs will receive notification of invitation to submit a proposal for the ***Multidisciplinary Research Consortium Award***. 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.

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 PIs and Organizations 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.

For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. Each PI must submit an individualized SF-424 (R&R) Application for Federal Assistance Form, Attachments Form, Research & Related Budget Form, Research & Related Project/Performance Site Location(s) Form, and R&R Subaward Budget Attachment(s) Form (if applicable). Each PI must also submit an identical copy of a joint Statement of Work (SOW).

A. Proposal Components Summary for the Initiating PI

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 (40-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 Collaboration
 - Intellectual and Material Property Plan (if applicable)
 - Letters of Institutional Support
 - Attachment 3: Technical and Public Abstracts
 - Attachment 4: SOW
 - Attachment 5: Innovation Statement
 - Attachment 6: Impact Statement
 - Attachment 7: Synergy Statement
 - Attachment 8: Federal Entity Financial Plan (if applicable)
- 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)**

B. Proposal Components Summary for each Partnering PI

The proposal submission process for each Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov. In order to complete the proposal submission process, each Partnering PI must first obtain a pre-application XML file (do not convert to PDF) from eReceipt. Directions for downloading this file will be contained in an email from eReceipt. 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 4: SOW
 - Attachment 8: Federal Entity Financial Plan (if applicable)
- 3. Research & Related Budget Form**
- Budget Justification

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

5. 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 and clinicians 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>

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 principle 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 (e.g., Innovation Statement, Impact Statement, or Synergy Statement).

B. Review Criteria

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

- **Impact**
 - How the Consortium addresses a critical overarching problem in PTSD research.
 - How the project makes an original and important contribution to the goal of advancing research on the prevention, detection, diagnosis, and/or treatment of PTSD or enhancing the quality of life of affected individuals, family members, and/or caregivers.
- **Innovation**
 - How the proposed research and/or collaborations are innovative in one or more of

the following areas: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.

- How the proposed research represents more than an extension or an incremental advance upon published data.
- **Research Strategy**
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How the conceptual framework, rationale, design, methods, and analyses work together to support the feasibility and promise of the approach.
 - How well the applicant acknowledges potential problem areas and considers alternative approaches.
 - Whether required statistical support services are included in the Consortium design.
 - Whether the proposal describes the interdependence among participants in completing each aim of the study.
- **Center Structure**
 - How the research problem provides a real basis for a unified focus that will facilitate and accelerate progress.
 - Whether the overarching problem can be solved only through a multidisciplinary, multi-institutional approach.
 - How the proposed management plan integrates and optimizes research and collaborations and results in a synergistic research effort.
 - How well the Consortium plans to maximize use of resources and avoid unnecessary duplication of effort.
 - Whether the Consortium Director (i.e., Initiating PI) has a clear strategy and plan to ensure cross-Consortium participation and to facilitate communication of results, issues, problems, and progress.
 - How well the proposal describes the use of state-of-the-art communication tools and a plan for data management and statistical support.
 - Whether there is evidence of an intellectual and material property plan.
- **Synergy**
 - How the proposed collaboration between independent investigators is likely to facilitate or greatly accelerate a significant achievement in PTSD research.
 - Whether the proposal describes a unified effort that addresses a major overarching research question rather than an additive set of loosely-related subprojects.
 - Whether the proposal provides a clear and balanced plan outlining the contributions of each investigator to the overall synergy of the project.

- **Personnel**

- How the research team’s background and expertise are appropriate to accomplish the proposed work, including whether the Consortium Director (Initiating PI) has the appropriate qualifications and experience to oversee the research and manage the proposed Center.
- Whether the team assembled in the Multidisciplinary Research Consortium Award proposal represents the “critical mass” of talent required to solve the proposed problem.
- Whether the named Research Coordinator has experience in guiding the animal use regulatory process, guiding clinical protocols through the regulatory approval processes, and coordinating studies across multiple sites.
- How well the Consortium unites and integrates the most highly qualified individuals to contribute to the project.
- How well the Consortium involves consumers, survivors, family members, and/or caregivers.
- How the team includes members who will provide new perspectives and fresh insights.
- Appropriateness of the levels of effort for successful conduct of the proposed work, including whether the Consortium Director will dedicate at least 25% effort to this award.
- Whether the contribution of each investigator is clear.

- **Environment**

- The appropriateness of the scientific environment for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- The quality and extent of institutional support at each participating institution.
- Whether the different institutions/organizations involved in this project strengthen the proposed Consortium.
- Whether the appropriate support staff is available for administering all functions of the Consortium (e.g., communications infrastructure, informatics, access to required databases).

- **Budget**

- How the budgets are appropriate for the proposed research.

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 innovation and 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 Commanding General, USAMRMC.

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>

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 (HBCU/MIs), hospitals, laboratories, and companies.

HBCU/MIs: 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/MIs. 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](https://www.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 \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](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 PIs receive 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 1 below) in the PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in this application package.

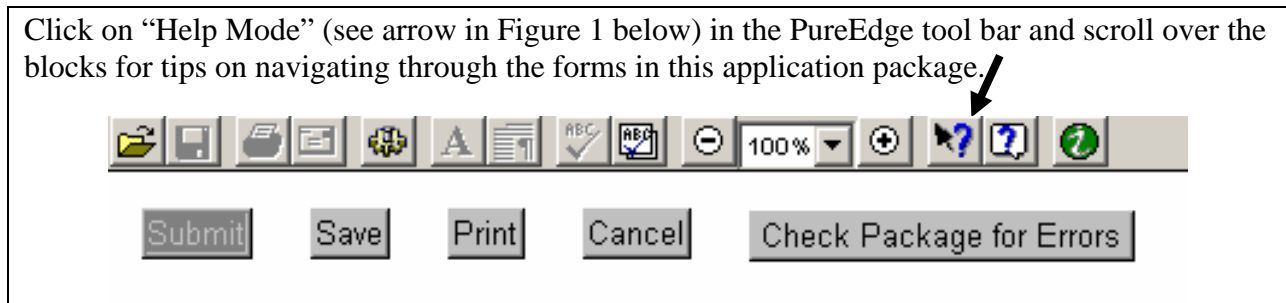


Figure 1: Grants.gov Application PureEdge Toolbar

A. Proposal Submission Components for the Initiating PI

For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. The Initiating PI must submit individualized forms identified in the table below. The Research & Related Senior/Key Person Profile (Expanded) Form must include information for each Partnering PI and all key personnel. The joint SOW attached to the Attachments Form must be an identical copy to that submitted by each Partnering PI.

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
	Technical and Public Abstracts (Abstracts.pdf)	Upload as Attachment 3
	Statement of Work (SOW) (SOW.pdf)	Upload as Attachment 4
	Innovation Statement (Innovation.pdf)	Upload as Attachment 5
	Impact Statement (Impact.pdf)	Upload as Attachment 6
	Synergy Statement (Synergy.pdf)	Upload as Attachment 7
	Federal Entity Financial Plan (if applicable) (FedFin.pdf)	Upload as Attachment 8
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.

B. Proposal Submission Components for each Partnering PI

For administrative reasons, the CDMRP requires separate application package submissions for Initiating and Partnering PIs. Each Partnering PI must submit individualized forms identified in the table below, with the exception that an identical copy of the joint SOW is uploaded through the Attachments Form.

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)	Submitted by Initiating PI
	Supporting Documentation (Support.pdf)	Submitted by Initiating PI
	Technical and Public Abstracts (Abstracts.pdf)	Submitted by Initiating PI
	Statement of Work (SOW) (SOW.pdf)	Upload as Attachment 4
	Innovation Statement (Innovation.pdf)	Submitted by Initiating PI
	Impact Statement (Impact.pdf)	Submitted by Initiating PI
	Synergy Statement (Synergy.pdf)	Submitted by Initiating PI
	Federal Entity Financial Plan (if applicable) (FedFin.pdf)	Upload as Attachment 8
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.

C. 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.*

D. Attachments Form

The following information must be included as attachments to this form in accordance with the [formatting guidelines](#):

Attachment 1: Project Narrative: 40-page limit. The Project Narrative is the main body of the proposal. The Project Narrative must be submitted by the Initiating PI as a single PDF file named "Narrative.pdf," in accordance with the [formatting guidelines](#).

Incorporate into the Project Narrative details of how the proposed Consortium is innovative, synergistic, and the impact it will have on PTSD. Presentation of preliminary and or

published data is required. Preliminary data is unpublished data. If the preliminary data is generated from a source other than the applicant, appropriate acknowledgement is required. For example, if the preliminary data has been generated by a colleague, acknowledgement should be made by listing the investigator's name, institution, and a statement that the data has been obtained via personal communication. Cite relevant literature references for published data.

Describe the proposed Multidisciplinary Research Consortium using the following outline:

- **Background:** Present the ideas and reasoning behind the proposed Consortium research. Cite relevant literature. Include data to support the feasibility of the hypotheses and/or approaches. Provide information on the multidisciplinary, multi-institutional team of highly qualified researchers and clinicians participating in the project and how the expertise of each will contribute to the success of the Consortium as a whole. Describe the qualifications of the Consortium Director and his or her ability to organize, administer, and manage the proposed Consortium.
- **Hypothesis or Objective:** State the purpose of the Consortium and the expected results and outcomes. Describe how the Consortium is a synergistic effort to solve the overarching problem, as opposed to being a collection of individual investigators pursuing loosely related projects.
- **Specific Aims:** Concisely explain the projects' specific aims to be funded by this proposal.
- **Research Strategy:** Describe the integrated research plan for addressing the overarching problem. Describe the experimental design, methods, and analyses for components of the Consortium in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Explain how the Consortium will maximize the use of resources and minimize unnecessary duplication, including sharing of experimental techniques, databases, models, and key reagents. Describe the statistical support services that will be utilized by the Consortium.
- **Center Structure:** Describe how the team will be organized, administered, and managed. Specify the processes and tools to be used for regular and structured communication, data management, project meeting scheduling, reviews of research report findings, and other issues of common concern to the Consortium and its participants. Address the features of this plan that facilitate and encourage the expedited exchange of research findings. Include a named research coordinator who will guide the animal use review process, guide clinical protocols through the regulatory approval processes, and coordinate study activities across the Consortium participants.

The 40-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. Supporting Documentation is inclusive of information for each PI. The Initiating PI must upload Supporting Documentation 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 to each PI 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 available to each PI to be used for the proposed research project.
- e. Publications and/or Patent Abstracts: Five-document limit per PI.** Include up to five relevant publication reprints and/or patent abstracts per PI. A patent abstract should provide a non-proprietary description of the patent application. Extra items will not be reviewed.
- f. Letters of Collaboration:** Provide a signed letter from each collaborating individual or institution.
- g. Intellectual and Material Property Plan: No page limit.** Provide a plan for resolving intellectual and material property issues among participating institutions.
- h. Letters of Institutional Support:** Provide letters of institutional support, signed by the Department Chair or appropriate institutional official, that reflect the laboratory space, equipment, and other resources available to each PI for this project. The letters should also indicate the extent to which each PI will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals.

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: Technical and Public Abstracts. The technical and public abstracts must be submitted by the Initiating PI as a single PDF file named “Abstracts.pdf,” in accordance with the [formatting guidelines](#). Abstracts of all funded proposals will be posted on the CDMRP

website at <http://cdmrp.army.mil>. Proprietary or confidential information should *not* be included in either the technical or the public abstract.

Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed in either abstract.

Technical Abstract: One-page limit. Use the outline below.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.

Public Abstract: One-page limit. Start on a new page. The public abstract is an important component of the proposal review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposal in a manner readily understandable by non-scientists.
 - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a consumer-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study?

Attachment 4: Statement of Work (SOW): Five-page limit. The Initiating and Partnering PIs must create a joint SOW. For administrative purposes, an identical copy of the joint SOW must be submitted by each PI, 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 study site/subcontract site (collaborative site and consultant) that will be actively participating in the study:
 - Institution name
 - Institution address

- Collaborator, consultant, or subawardee name
- Animal or 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 if the work involves animal, human subjects or anatomical samples note the number of research subjects (animal or human) and/or anatomical samples required for each task;
- Indicate time required for human use approval and FDA submission of applicable documents (i.e., IND and IDE).
- For animal and human studies (including tissue, anatomical, or biological substances), indicate the sample size projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

Attachment 5: Innovation Statement: One-page limit. The Innovation Statement must be submitted by the Initiating PI as a single PDF file named “Innovation.pdf,” in accordance with the [formatting guidelines](#). Summarize how the proposal is innovative. The following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- Study concept - Investigation of a novel idea and/or research question.
- Research method or technology - Use of novel research methods or new technologies, including technology development, to address a research question.
- Clinical interventions - Use of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies - Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

Investigating the next logical step as an extension of previous work or incremental advancement on published data is not considered innovative.

The Innovation Statement will be available for both peer and programmatic review.

Attachment 6: Impact Statement: One-page limit. The Impact Statement must be submitted by the Initiating PI as a single PDF file named “Impact.pdf,” in accordance with the [formatting guidelines](#). State explicitly how the proposed work will have an impact on research or patient care. Describe how the combination of innovation and the expected results of the proposal will improve the function, wellness, and overall quality of life for service members as well as their caregivers and families.

The Impact Statement will be available for both peer and programmatic review.

Attachment 7: Synergy Statement: One-page limit. The Synergy Statement must be submitted by the Initiating PI as a single PDF file named “Synergy.pdf,” in accordance with the [formatting guidelines](#). Discuss in detail the advantages of addressing this problem through the combined expertise of the investigators and how this contributes to the synergy of the proposal. Describe the elements of interdependence in the proposed work. Discuss how this collaboration will create an entity that is greater than the sum of each individual component. Describe each investigator’s history of synergistic and collaborative study.

The Synergy Statement will be available for both peer and programmatic review.

Attachment 8: Federal Entity Financial Plan (if applicable). Proposals from Federal entities must provide a plan delineating how all funds provided directly to them by USAMRAA will be obligated by September 30, 2008, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities.

A suggested plan would include having a foundation, non-Federal institution, or university act as the Awardee/Recipient of a Cooperative Agreement from USAMRAA. The Recipient may then provide personnel, equipment, and supplies (but not funds) to carry out the collaborative research. The Cooperative Agreement will define the relationship between the Government (to include the Federal entity) and the non-government entities.

The Federal Entity Financial Plan should be submitted as a single PDF file named “FedFin.pdf,” in accordance with the [formatting guidelines](#) by the proposal submission deadline. If the plan cannot be included with your proposal submission through grants.gov, The PI or Contract Representative should upload the plan as a PDF file under the "Regulatory and Other Documents" tab of the CDMRP eReceipt system by February 18, 2008. Failure to submit such a plan will result in proposal rejection prior to programmatic review.

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

The Initiating PI must include the requested information for each senior/key person proposed on the project. Partnering PI information should be uploaded with Key Personnel information. 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 Initiating PI.

2. PI Current/Pending Support: No page limit. Current/Pending Support for the Initiating 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 Initiating PI.

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

For all existing and pending research projects involving the Initiating 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 Initiating PI.

F. 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. ***Each PI must upload an individual budget and budget justification.***

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 each 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: Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject’s participation in the research study.

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/forminfo2192.html) must be submitted with the proposal.

Section K – Budget Justification: The Budget Justification for the entire performance period must be attached by each PI 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.

G. 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.

H. 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; and
- The proposed acquisition price.
- 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 Animal Use

Specific documents relating to the use of animals in the proposed research will be requested by the Congressionally Directed Medical Research Programs (CDMRP) if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP; formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. PIs must complete and submit the animal use

appendix titled “Research Involving Animals”, which can be found on the ACURO website <https://mrmc-www.army.mil/rodorpaurd.asp>). Allow 2 to 4 months for regulatory review and approval processes for animal studies. Specific requirements for research involving animals can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

D. 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, anatomical substances, and/or data 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, anatomical substances, and/or data, 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, anatomical substances, and/or data, 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.

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. Clinical Trial Registry: Initiating PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: CDMRP-CDMRP Log Number-A, B, C, etc. *Clinical trials must be registered prior to enrollment of the first patient.* All trials that meet the definition on the NIH database (see <http://prsinfo.clinicaltrials.gov/>, click on "Data Element Definitions," see section 6, "Study Phase" and "Study Type") including all Phase I-IV clinical trials and trials that do not fit into one or more phases, but that are clearly interventional or observational (e.g., some epidemiological or behavioral studies), are required to register.

5. 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. Additional reporting may be required as stipulated during award negotiations. Projects involving clinical studies will be required to submit quarterly reports outlining accrual and retention statistics and any problems with study execution. 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

MPEGMoving Picture Experts Group
NIHNational Institutes of Health
NFRP.....Neurofibromatosis Research Program
OCRPOvarian Cancer Research Program
OMBOffice of Management and Budget
ORP.....Office of Research Protections
PCRP.....Prostate Cancer Research Program
PDFPortable Document Format
PI.....Principal Investigator
P.L.....Public Law
POC.....Point of Contact
PRMRPPeer Reviewed Medical Research Program
PTSD.....Post-Traumatic Stress Disorder
R&R OPI.....Research & Related Other Project Information
SOW.....Statement of Work
SPORESpecialized Programs of Research Excellence
TBITraumatic Brain Injury
TIFFTagged Image File Format
TIN.....Tax Identification Number
TSCRPTuberous Sclerosis Complex Research Program
URL.....Uniform Resource Locator
USAMRAA.....US Army Medical Research Acquisition Activity
USAMRMCUS Army Medical Research and Materiel Command
USC.....United States Code
WAVWaveform 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.