

Program Announcement

Defense Center of Excellence for Psychological Health (PH) and Traumatic Brain Injury (TBI)

Military Psychological Health Research – Complementary and Alternative Strategies

Funding Opportunity Number: W81XWH-08-PH-TBI

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I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the USAMRMC, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: (703) 696-9460

Fax: (703) 696-9478

Email: russell.shilling@tma.osd.mil

2. Grants.gov contacts: Questions related to submitting applications through the Grants.gov (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 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. Please plan ahead accordingly.

Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY 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. 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.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available 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.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the Letter of Intent submission before the mandatory deadline.
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and Objectives

The Defense Center of Excellence (DCoE) for Psychological Health (PH) and Traumatic Brain Injury (TBI) is soliciting proposals for studies on Complementary and Alternative Medicine (CAM) in service members dealing with sustainment and treatment for psychological health and promoting healing for traumatic brain injuries in service-members. The high prevalence of psychoneurological and other brain injuries associated with the current OEF/OIF war effort make it especially important to understand current use of CAM therapies by service-members, and to explore approaches that may be particularly effective in both protecting and treating the injured service-member. The DoD is dedicated to supporting evidence-based approaches to medical treatment and wants to support the use of alternative therapies if they are proven efficacious.

Specific aims of this call for proposals focus on a holistic approach for trauma spectrum disorders, including patients with TBI and/or post traumatic stress disorder (PTSD), depression, anxiety, and/or substance dependence/abuse.

B. Award Description

With the focus on a holistic approach for trauma spectrum disorders, including patients with TBI and/or post traumatic stress disorder (PTSD), depression, anxiety, and/or substance dependence/abuse, the following delineate several of the areas of interest:

1. Conducting rigorous clinical studies to determine the efficacy of alternative therapies for treating psychological health injuries using techniques such as music, animal-facilitated therapy, art, dance/movement, massage therapy, EMDR program evaluation, virtual reality, acupuncture, spiritual ministry, transcendental meditation, yoga and other novel approaches.

2. Identification of patterns of use of CAM therapies to build resilience in military populations,

3. Identification of factors and perceptions associated with use of alternative and complementary therapies by service-members,

4. Studies of mechanisms and efficacy of biologically-based treatments, botanicals, and nutritional supplements for enhancing cognitive function and mood in patients with trauma spectrum disorders, including TBI and/or PTSD, depression, anxiety, and/or substance dependence/abuse,

5. Studies that examine gender-specific implications and issues related to the use of CAM therapies,

6. Biological mechanisms and efficacy underlying acupuncture for trauma spectrum disorders, including TBI and/or PTSD, depression, anxiety, and/or substance dependence/abuse, including neuroimaging studies, and

7. Identification of the use and efficacy of therapies using bioenergies such as Qi gong, Reiki, distant healing, and acupuncture, especially new biophysical approaches involving instrumentation.

Proposals must provide a clear justification and military relevance for the choice of therapies selected for study. Collaboration with DoD medical researchers at the Defense and Veterans Brain Injury Center (DVBIC), clinical research laboratories at military medical centers and VA centers are encouraged and will be considered in the selection of awards. Studies should be designed to test pragmatic and theoretical components at once; thus, they need to include sham control to separate specific from non-specific effects. Rationale should include why the intervention should have effects across trauma spectrum and evaluate putative mechanisms. Use of primary care and community sites should be accessed and networked into participate.

It is the responsibility of the PI to clearly and explicitly articulate the project's innovation and the impact it may have on the field of Military Psychological Health Research and Traumatic Brain Injury.

C. Funding

Two types of proposals will be considered. Individual research proposals containing preliminary data are expected to average \$200,000 per year for up to four years of support; no proposal award will exceed \$1M in total funding (including indirect costs). Seedling grants proposing innovative but testable hypotheses without preliminary data, will be considered for \$300,000 in total funding (including indirect costs), with research to be completed within 18 months. A total of approximately \$4,000,000 is available for the portfolio of projects to be funded.

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

- Salary
- Research supplies
- Equipment
- Travel to scientific/technical meetings
- Travel between collaborating institutions

D. Award Administration

Refer to the Application Instructions, Appendix 5, for general award administration information.

III. TIMELINE FOR SUBMISSION AND REVIEW

Letter of Intent is required from all PIs who may be interested in submitting a proposal under this program. The Letter of Intent will not only give the Government an indication of the level of interest, but will also ensure we have adequate resources for processing the proposals through to award.

- **Letter of Intent Deadline:** **5:00 p.m. Eastern time, April 15, 2008**
- **Proposal Submission Deadline:** **11:59 p.m. Eastern time, May 15, 2008**
- **Peer Review:** **May/June 2008**
- **Programmatic Review:** **June 2008**

Principal Investigators will be notified about funding recommendations approximately 90 days after the proposal submission deadline.

Awards will be made no later than September 30, 2008.

IV. SUBMISSION PROCESS

Proposal submission consists of a proposal submission through [Grants.gov](http://www.grants.gov) (<http://www.grants.gov/>).

Proposals that do not meet the specific intent as described herein will not be reviewed or considered.

A. Step 1: Letter of Intent Components and Submission

The Letter of Intent submission website will be available at <https://submissions.aibs.org> on or about 31 March 2008. The Letter of Intent consists of the components discussed below. Refer to the Application Instructions for detailed information.

1. Research Title
2. PI Name, email, phone number and address
3. Institutional Name & address
4. Award Mechanism: Individual Research Award or Seedling Grant
5. Keywords
6. Collaborators (Names and Institutions)
7. Conflict of Interest (Names & Institutions)
8. Letter of Intent (LOI) Narrative (one page)

B. Step 2: Proposal Components and Submission

Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

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. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

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

2. Attachments Form

- Attachment 1: Project Narrative (**10-page limit.**)

Describe the proposed project in detail using the outline below.

Background: Present the ideas and reasoning behind the proposed work. Cite relevant literature.

Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

Preliminary Data: Provide pertinent, relevant data to support the necessity, feasibility, and potentiality of the proposed project for Individual Research Proposals.

Specific Aims: Concisely explain the projects' specific aims to be funded by this proposal.

Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. A detailed plan for the recruitment of subjects or the acquisition of samples must be included.

- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publication and/or Patent Abstracts (**Five-document limit.**)
 - Letters of Institutional Support (**Two-page limit per letter.**)
 - Letters of Collaboration (if applicable) (**Two-page limit per letter.**)
 - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical and Public Abstracts (**One-page limit for each abstract.**)
- Attachment 4: Statement of Work (SOW) (**Two-page limit.**)
- Attachment 5: Impact Statement (**One-page limit.**)

Describe the impact of this study on research or patient care. Describe how the expected results of the proposal will contribute to the goals of advancing methods, concepts, diagnosis, or treatment of the disease or quality of life for patients.
- Attachment 6: Innovation Statement (**One-page limit.**)

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.
 - 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 or incremental advancement on published data is not considered innovative.

- Attachment 7: Federal Agency 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, including salary verification, DHHS rate agreement or independent audit, quotes for equipment over \$5,000, a copy of institutional policy for purchasing supplies and materials, detailed travel information and stated assurances that project personnel commitment will not exceed 100%.

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

6. R&R Subaward Budget Attachment(s) Form (if applicable)

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All proposals are evaluated 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.

The peer review and program review processes are 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 corrective actions. Correspondingly, institutional personnel and PIs 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. Violations by panelists or PIs 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 reject all proposals based on one or more of the required attachments or supporting documentation (e.g., Impact Statement, Innovation Statement, etc.).

B. Review Criteria

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

- **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.
 - How the project proposes new paradigms or challenges existing paradigms.
 - How the proposed research represents more than an incremental advance upon published data.
 - How the potential gain warrants the perceived risk.
- **Impact**
 - How the project addresses a critical problem in Military Psychological Health or patient care.
 - How the project makes an original and important contribution to advancing basic, clinical, and translational research that will improve outcomes for Military Psychological Health.
 - The difference the proposed project will make on Military Psychological Health research or patient care, if successful.
- **Research Strategy and Feasibility (Preliminary data if required.)**
 - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data and logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Personnel**
 - Whether the applicant meets the eligibility requirements.
 - Does the research team have the appropriate background and expertise to accomplish the proposed work?
 - Appropriate levels-of-effort to successfully conduct the proposed work.
- **Environment**
 - The appropriateness of the scientific environment for the proposed research.
 - Are the research requirements adequately supported by the availability of and accessibility to facilities and resources (including collaborative arrangements)?
- **Budget**
 - Is the budget appropriate and justified for the proposed research?

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

- Ratings and evaluations of the peer reviewers,
- 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 Programmatic Review members and recommended for funding to the Commanding General, DCoE.

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all Letters of Intent and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in Letter of Intent or proposal rejection. **Proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.

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.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.