Request for Applications

The Consortium to Alleviate PTSD (CAP)

Peer Review Program
Open Announcement
(Revised 22 December 2015)
I. Request for Applications

A. Purpose: This document serves as a Request for Applications (RFA) for studies seeking funding under the Consortium to Alleviate PTSD (CAP). This RFA is intended to solicit research pre-proposals that meet the goals and objectives of the CAP and have significant potential for the alleviation of posttraumatic stress disorder (PTSD) and related conditions for a nation of active duty military and Veterans who have deployed and served in support of Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND). The application is a multi-step process which begins with the submission of a four-page pre-proposal, a quad chart, and biosketches for the principal investigator (PI) and other key investigators. Pre-proposals with the greatest potential to address the goals and objectives of the CAP will be invited to submit a full proposal directly to the CAP Consortium Scientific Review Officer (through the RFA website at rfa@ConsortiumToAlleviatePTSD.com) for review by an Independent Scientific Peer Review Committee. After Independent Peer Review, score summaries will be forwarded to the CAP Coordinating Center Leadership (Co-Chaired by Alan Peterson, PhD, and Terry Keane, PhD), who will decide on projects to be forwarded to the CAP Government Steering Committee (GSC) for consideration of funding. The current GSC is co-chaired by LTC Dennis McGurk PhD (Department of Defense Chair) and Stewart Warren, PhD (Veterans Affairs Chair). The GSC then decides upon projects to be forwarded to the VA and DoD Senior Leadership who decides which projects will be funded. The Senior Leadership includes representatives from the Office of the Assistant Secretary of Defense for Health Affairs, the Department of Veterans Affairs Office of Research and Development, and the Defense Health Agency.

The following sections (1) provide background information on the Consortium to Alleviate PTSD (CAP), (2) define the CAP goals and objectives, and (3) provide instructions on the necessary steps for the submission of pre-proposals. Selection for this funding opportunity is expected to be highly competitive and the quantity of pre-proposals received is likely to far exceed the number of awards that available funding can support. Proposals that leverage existing resources, including infrastructure and/or research funding, are encouraged. Additionally, investigators who submit pre-proposals are encouraged to consider incorporating existing infrastructure and resources (i.e., CAP research cores; see the descriptions and definitions that follow) into their research plans. If the submitting investigator has no knowledge of the CAP Cores and/or does not know how to readily integrate CAP Cores and infrastructure in the proposed research, a pre-proposal submission is still recommended. The CAP Coordinating Center may hold periodic Question and Answer (Q & A) teleconferences to provide additional details and answer questions about the research cores and the submission process. Details about these teleconferences will be advertised on our website (http://delta.uthscsa.edu/consortiumtoalleviateptsd/) within one month of scheduling. If there are questions about the RFA and no teleconference has been scheduled, these can be addressed through the Frequently Asked Questions of our website (link in Section V below) or by contacting the CAP Scientific Review Officer at rfa@ConsortiumToAlleviatePTSD.com. After CAP pre-proposal review, promising applicants will have an opportunity to meet individually with CAP Coordinating Center and
Core leadership to explore how CAP infrastructure can be meaningfully integrated for the CAP full proposal.

B. Consortium to Alleviate PTSD (CAP) Objectives: The CAP Award was originally announced through the Psychological Health and Traumatic Brain Injury Research Program (PH/TBI RP) through a joint DoD and VA collaboration under funding opportunity number W81XWH-12-PHTBI-CAP. Under this award, CAP is dedicating approximately $20.336 million (M) in DoD research funds and the Department of Veterans Affairs is dedicating an additional $5M per year for 5 years (resulting in $25M of VA funds for CAP research) for a total anticipated 5-year award of $45.336M. The original CAP announcement clarifies that VA research funds may only be used to support research at VA sites. Additionally, the U.S. Government reserves the right to increase or alter DoD and VA funds available for CAP research if additional funds become available. As outlined in the original CAP Program Announcement, the CAP objectives are as follows:

1. To significantly advance treatment strategies for PTSD including interventions for early, chronic, and latent onset cases. Studies addressing prevention strategies may also be proposed to include peri- and post-traumatic interventions designed to reverse the trajectory of initial-response stress mechanisms, obviate symptom development, and facilitate natural stress recovery processes.

2. To identify and confirm clinically relevant biomarkers as diagnostic and prognostic indicators of PTSD and co-occurring disorders. Proposed studies could address ways to effectively use specimens to develop effective diagnostics or indicators of treatment response. Studies could include focus on biomarkers as a method for guiding treatment, determining effectiveness of treatment, assessing recovery from chronic PTSD, and informing treatment response (i.e., to inform return to duty). Studies must focus primarily on the clinical application of biomarker-based research (diagnostic, prognostic, and treatment-focused).

C. CAP Focus Areas: As outlined in the original CAP Program Announcement, the CAP research activities must be focused on PTSD and common co-occurring psychiatric or medical conditions such as:

- Behavioral health disorders (suicide, substance abuse, risky behaviors, etc.),
- Mood and anxiety disorders,
- Sexual dysfunction,
- Neurologic disorders (including memory, autonomic system, and sleep),
- Pain (including headache),
- Cognitive deficits, and
- Neuroendocrine deficits.
D. **Military and Veteran Focus:** In addition to the Objectives and Focus Areas noted above, applications are required to address topics with a focus on active duty Service Members and Veterans. Applications that do not demonstrate a military and/or Veteran focus will be less likely to receive a positive review. Department of Defense or Department (DoD) of Veterans Affairs (VA) investigators are strongly encouraged to apply. However, applications will be accepted from all U.S. based investigators. Alignment and collaboration with already established military and VA investigators, research teams, research institutions, and treatment facilities is encouraged.

E. **Award Information:** The CAP Request for Applications (RFA) is intended to support studies that have the potential to make an important contribution to PTSD research and/or patient care. Projects are expected to be innovative, address both an Objective and Focus Area, and impact the health care needs of active duty Service Members and Veterans. Successful submissions will describe a meaningful advancement of current research or novel research that innovatively expands the extant body of PTSD research without overlapping current research. Collaboration with military and VA researchers and clinicians is encouraged. Proposed studies may focus on any phase of research from basic through translational, including preclinical studies in animal models or human subjects, as well as correlative studies associated with an existing clinical trial. Any study proposed must be completed by 30 September 2020 (the CAP period of performance end date).

F. **Submission Deadlines:** This is an open RFA, so there are no deadlines for the CAP preproposal submission. However, due to the limited time available to complete studies, it is strongly recommended that pre-proposals be submitted as soon as possible. A description of the pre-proposal review process can be found in Section II of this document. CAP full proposal submission will be guided by the CAP Consortium Coordinating Center if the pre-proposal is selected for full submission. Only those preproposals with the highest scientific and programmatic merit will be invited for a full proposal submission. There is a separate review process for CAP Pre-Proposals and Full Proposals. The CAP Consortium reviews full submissions using an ad hoc Independent Peer Review Committee (IPRC) comprised of subject matter experts and overseen by an Independent Chair who is separate from CAP with no conflict of interest. The Independent Chair (IC) is responsible for guiding the all phases of the full proposal review process, summarizing feedback from the review for the PI and CAP Coordinating Center, and transmitting the feedback to the full proposal PI. The CAP Independent Peer Review Committee will meet as needed based on the frequency and merit of submitted full proposals. Submitting investigators are reminded that all proposed research must be
planned and budgeted with an end-date of 30 September 2020. In order to ensure timely submission of full proposals for independent peer review, the following timeline is recommended for submission of pre-proposals to the CAP Coordinating Center for review:

G. Submission for CAP Scientific Review Committee

The deadline for full proposal submissions is variable and approval for full submission is dependent upon availability of CAP funds. The CAP Coordinating Center will inform approved pre-proposal PIs about full submission deadlines directly through email and/or through an approved update of this RFA. See Section V of this document for most recent approved deadlines for full proposal submission.

Because this is an open RFA, the CAP Independent Peer Review Committee will be convened as needed to address submissions for this RFA. The CAP Coordinating Center will inform submitting PIs of the dates for Independent Peer Review as it is scheduled.

*Pre-proposals invited for full submission may require substantial revisions or collaborative work with the CAP Coordinating Center and Core Directors to allow the proposed projects to better integrate with the CAP infrastructure. As a result, proposing investigators are strongly encouraged to submit their preproposal at least 3 months prior to their desired Full Submission Independent Peer Review date. It is also recommended that submitting investigators take time to discuss their submission with relevant CAP Core Directors (listed in Section IV below). The CAP Coordinating Center can help arrange a conversation if it is desired.

PLEASE NOTE: Full submissions will only be accepted for those pre-proposals invited for the full submission to the CAP Independent Peer Review Committee. A letter of endorsement from the CAP Director will be required at the time of the full submission. CAP Coordinating Center can help the approved PI secure this letter. PIs of approved pre-proposals are strongly encouraged to seek this letter as soon as possible due to high demands on CAP leadership. However, it should be noted that the CAP Government Steering Committee requires that the CAP Coordinating Center leadership review and approve all components of the research proposal prior to providing the CAP Director’s letter. Therefore, all portions of the research proposal must be completed with adequate time for review and approval, especially when there are multiple proposals being reviewed and submitted simultaneously. The full proposal submission will be prepared using an abbreviated format similar to the standard SF424 (R&R) application forms used in accordance with the VA Application Guide SF424 (which can be found at http://vaww.research.va.gov/funding/electronic-submission.cfm).

H. Eligibility Information:

• Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
• Organizations eligible to apply include national, for-profit, non-profit, public, and private organizations.
• There must be an eligible investigator at a Department of Veterans Affairs Medical Center or a VA Approved Site to be eligible for any funding available from the VA.

I. Budget: CAP funding will be available through both the DoD and VA, and proposals seeking joint DoD and VA funding are particularly encouraged. Any well-justified budget will be considered. VA funding for CAP projects will support VA investigators at VA medical centers (VAMCs) or VA-approved sites. Funds added by the VA will only be utilized to support research at VA sites. Pre-proposals selected by the CAP Coordinating Center for a full proposal submission will have an opportunity to discuss their budget in depth with CAP leadership and budget advisors to explore how DoD and VA funds can be utilized for the proposed research.

II. Pre-Proposal Submission Information

A. Pre-Proposal Submission Overview: The CAP proposal submission is a multi-step process modeled after recent DoD Program Announcements and Requests for Applications. It involves the initial submission of a CAP pre-proposal. Those pre-proposals deemed to have the highest scientific and programmatic merit will be invited to submit a CAP full proposal for review by the Independent Peer Review Committee (See Section III for an explanation of this process). This process will allow investigators invited to submit full proposals to work closely with the CAP Coordinating Center to refine the goals, objectives, and aims of the proposed study (including ways to maximize integration of the established CAP infrastructure, which is strongly encouraged). The pre-proposal process includes (1) submission of a 4-page pre-proposal and related documents, (2) review of the pre-proposals by the CAP Coordinating Center, and (3) selection of the most promising pre-proposals for full proposal submission to CAP Independent Peer Review (submitted through the CAP RFA email at rfa@ConsortiumToAlleviatePTSD.com)

B. Pre-Proposal Formatting Guidelines: All 4-page pre-proposals narratives and related documents should be sent as a single PDF file directly to the CAP Coordinating Center as an e-mail attachment to rfa@ConsortiumToAlleviatePTSD.com. Submission questions should be emailed to info@ConsortiumToAlleviatePTSD.com. Pre-proposals may not be any longer than 4 pages, excluding references, in a 12 point font (Times New Roman preferred) with no less than ½ inch margins on all sides.

C. Pre-Proposal Submission Documents: Submit a PDF of the following documents in the order listed below to the CAP Coordinating Center as an e-mail attachment to rfa@ConsortiumToAlleviatePTSD.com.

• Pre-Proposal Cover Sheet: Complete the required information for the PreProposal Cover Sheet. The most recently approved cover sheet can be found at: http://tango.uthscsa.edu/consortiumtoalleviateptsd/pdf/CAP-RFA-
The Cover Sheet should be the first document included in the PDF pre-proposal file.

- **4-Page Pre-Proposal Narrative.** There is no standard format for the preproposal narrative, but it must contain all required information as described in Section [IV.D] below.

- **References Cited.** List the references cited. The references are not counted as part of the 4-page maximum for the pre-proposal narrative. Use a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, publisher, etc., as appropriate).

- **Quad Chart.** All pre-proposals and full proposals must include a quad chart (separate from the 4-page pre-proposal) briefly describing the study including rationale, population to be studied, sample size, study sites, methods, total budget, and a picture or other graphic describing the study. An example of a CDMRP-compliant quad chart can be found at: https://cdmrp.org/Program_Announcements_and_Forms/


### D. Pre-Proposal Narrative Content Requirements:

All submitted 4-page pre-proposals must include the following:

- **Title.** Provide the title of the proposed project.

- **Study Personnel.** Demonstrate that the PIs, collaborators, and other researchers are well suited to the project and have an ongoing record of accomplishments. Describe any collaboration between civilian, DoD, and/or VA personnel. Describe any collaboration with CAP Investigator(s) and Research Cores. State whether the proposed investigators have DoD or VA appointments.

- **Research Aims & Objectives.** Research aims and objectives should be clearly defined and sensibly tied to a definite research question. A clear endpoint should be tied to each objective.

- **Study Rationale/Research Gap.** Projects should address an important problem or a critical barrier to progress in the field. The study should address a targeted Consortium area of need. All projects must be in line with CAP objectives and focus areas. These goals and priorities may change based upon feedback from the Government Steering Committee. The rationale should also clearly describe how the proposed study will align with one or more areas outlined in the PTSD Joint Integrated Research Approach.
(Figure 1) and build on existing VA and DoD research and clinical goals to maximally benefit Service Members and Veterans.

- **Research Methods.** The overall strategy, methodology, statistical plan, and analyses should be well-reasoned and appropriate to accomplish the specific aims of the project. A sample size estimate should be included. If the proposed research includes human subjects or human anatomical samples, there should be a clear plan for the recruitment of human subjects or acquisition of human samples. Potential problems, alternative strategies, and benchmarks for success should be presented. The proposed research needs to show feasibility for a military or VA setting.

- **Research Performance Sites.** Applicants should describe how the project benefits from unique features of the scientific environment, subject populations, or collaborative arrangements. A description of the study population and location should also be provided.

- **Collaboration with Cores.** When applicable, CAP research cores and existing military and VA infrastructure should be meaningfully integrated into the research. The applicant should describe how the PI will integrate the proposed project with the existing CAP infrastructure. Use of PTSD common data elements should be considered (if applicable). Priority will be given to studies that integrate CAP Research Cores into proposed research. See below for description of CAP Cores and Core Directors. If the pre-proposal PI is unfamiliar with the CAP infrastructure and/or has difficulty with the logistics of integrating CAP resources into the proposed research, a pre-proposal should still be submitted. If the CAP Coordinating Center supports a full proposal submission for CAP VA-DoD Scientific Review, the pre-proposal PI will have an opportunity to speak with CAP and Core leadership to explore how CAP infrastructure can be leveraged for the proposed research.

- **Innovation.** State how the project has the potential to significantly inform military and/or VA healthcare and practice. A successful proposal will also describe how the proposed research meaningfully expands on existing research without overlapping current studies OR the unique contribution of the project to the research community and how it will not replicate current studies, but moves beyond with an innovative approach and/or objectives.

- **Pre-Proposal Estimated Budget.** Describe the estimated budget and costs necessary to complete the project. The budget should reflect yearly costs, including the total direct and indirect costs (if applicable) for each year over the entire period of performance with an end date no later than 29 September 2020. CAP project funding will be available through both the DoD and VA; proposals seeking joint DoD and VA funding are particularly encouraged. Any well-justified budget will be considered. VA funding for CAP projects will support VA investigators at VA medical centers (VAMCs) or VA-approved sites. In some cases, Intergovernmental Personnel Agreements (IPAs) may be used to support non-VA investigators at institutions with an
official VA affiliation. The PIs for projects invited for full proposal submissions must
work closely with CAP leadership in budget formation for both the VA and DoD proportions of the budget. All awarded funds will be subject to policies and restrictions based on the source of that funding (VA-ORD and/or DoD).

III. Pre-Proposal Review Process and Screening Criteria:

A. Pre-Proposal Screening Process: Pre-proposals are screened by the CAP Coordinating Center to ensure that submitted pre-proposals meet the basic criteria (described below) for a CAP study and to ensure that the proposed research is a good programmatic fit with the rest of the CAP research portfolio. The CAP Coordinating Center will contact all submitting investigators by phone or email after pre-proposal review to inform them of the Coordinating Center’s decision to move forward with a full proposal (or to decline a full proposal). Pre-proposals will be reviewed as they are submitted. Although the CAP Coordinating Center will try to review pre-proposals as quickly as possible, we cannot specify the timeline for this stage of the review.

B. Pre-Proposal Screening Criteria: To determine the technical merits of the pre application and the relevance to the CAP mission, pre-applications will be screened based on the following criteria:

- **Scientific Merit.** Are the research aims and objectives clearly defined and sensibly tied to a definite research question?
- **Research Gap.** Does the project address an important problem or a critical barrier to progress in the field with specific Military or VA benefit?
- **Fit with CAP Portfolio.** Does the study address a targeted CAP area of need?
- **Collaboration with Consortium Cores.** Are CAP research cores and existing infrastructure meaningfully integrated into the research?
- **Innovation.** Does the project have the potential to significantly inform military and/or VA healthcare/practice?
- **Budget.** Is this project’s budget appropriate?

IV. CAP Research Cores:

As noted above, CAP pre-proposal submissions should include some description of how the proposed research will capitalize on the existing CAP infrastructure. As a research consortium, CAP is designed to strongly support all component studies and the CAP Cores are a vital part of that support. Questions about cores should be directed to the CAP Coordinating Center at: info@ConsortiumToAlleviatePTSD.com.

**CAP Cores and Core Directors are listed in the table below:**

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<tr>
<th>Core Director and Co-Director</th>
<th>Core Title</th>
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<td>Alan Peterson &amp; Terry Keane</td>
<td>Coordinating Center</td>
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**Coordinating Center:** The CAP Coordinating Center assumes a “Sponsor” role in study management. This role requires centralized oversight and direction at all levels of study design, development, implementation, and dissemination to assure compliance with the DoD and VA regulations and expectations. Operations require a direct working relationship with individual project teams through real-time communications, assurance and implementation of standardized operating procedures (SOPs), automated systems for accountability and regulatory reporting, and quality control monitoring of studies and study processes. The Coordinating Center works closely with PIs to develop a protocol that addresses DoD, VA, and academic center regulatory issues and that consistently incorporates the Consortium cores and services to produce an integrated project executed to the highest scientific and human use regulatory standards.

**Assessment Core:** The Assessment Core has four main objectives that support proposed and future clinical trials and epidemiological studies: (1) to create uniformity of instrumentation and measurement and to employ state-of-the-art measures with sound psychometric properties; (2) to ensure measurement of outcome and predictor variables that are relevant and sensitive to the active duty military ethos and culture as well as Veterans’ experiences; (3) to train and to provide oversight and supervision of Independent Evaluators (IEs), to adjudicate diagnostic decisions for clinical trials when necessary, to conduct interrater reliability evaluations of taped PTSD interviews, and to shape IEs over time to obviate drift; and (4) to work with the Data Management and Biostatistics Core to create a data dictionary and to manage and leverage the omnibus multi-study dataset including the use of Common Data Elements across studies.

**Biomarkers and Genomics Core:** The primary objectives of the Biomarkers and Genomics Core are to (1) support the efforts of CAP studies with biomarker or genomic components involving the collection and analysis of biological and physiological specimens; (2) to centralize the collection, processing, storage, and analysis of samples; and (3) to maintain a biospecimen repository linkable with clinical data through the overall Consortium data repository; (4) facilitate the collection of human postmortem tissue in order to accelerate PTSD biomarker discovery; and (5) link with expertise to facilitate the translation of biomarker discovery into diagnostic and prognostic panels.

**Neuroimaging Core:** The overall objective of the Neuroimaging Core is to foster the use of advanced neuroimaging methods in the study of PTSD and related conditions for the purposes of (1) investigating the underlying pathology (using structural imaging) and pathophysiology (using functional imaging); (2) assessing and enhancing the diagnostic sensitivity of imaging methods; (3) investigating the neurophysiology of treatment response (image-based response assessment); and (4) ensuring comparability of imaging data
acquisition and pre-processing between sites. Neuroimaging methods utilized include structural and functional magnetic resonance imaging (MRI and fMRI), magnetic resonance spectroscopy (MRS), and position emission tomography (PET).

**Data Management and Biostatistics Core:** The objectives of the Data Management and Biostatistics Core are to facilitate high-quality research by (1) organizing and maintaining the Consortium, Repository, and project databases to maximize accessibility while maintaining strict confidentiality; (2) developing and maintaining on-line data entry systems and other computer-based tools that facilitate the entry, storage, manipulation, and retrieval of data generated by each project as well as project management; (3) developing and applying modern statistical methods for the analysis of Consortium data (4) providing methodological consultation in research design and biostatistical planning, (5) administering the STRONG STAR Data Repository.

V. Full Proposal Submission Information

If a pre-proposal submission is approved by the CAP Coordinating Center, the submitting investigator will be invited by the CAP Coordinating Center to submit a full proposal. Because this is an open RFA, there are no hard deadlines for full proposal submission. The Full proposal review process can be time-consuming, so Investigators (if invited) are strongly encouraged to submit full proposals for CAP Independent Peer Review as soon as possible. The most recently approved submission deadlines are as follows:

- **Initial Rough Draft due to CAP Coordinating Center:** 25 January 2016*
  *Note: The CAP Coordinating Center will provide input and assist in finalizing the proposal. Please copy all materials to Ms. Elisabeth Buel at BUELE@UTHSCSA.

- **Final Proposal due to Independent Scientific Peer Review:** 26 February 2016

- **Independent Scientific Peer Review:** March 2016

- **Scientific Review Feedback to PI:** April 2016

**A. Full Proposal Submission Overview:** The full CAP proposal was designed to be similar to most federal grant proposal formats. Content of the full proposal must meet CAP requirements described below. Submitted full proposals will be reviewed by a CAP Independent Peer Review panel where each proposal will be reviewed by subject matter experts and scored using a standardized scoring rubric. The result of the full proposal review will be a standardized review score (similar to scoring in VA grant review) ranging from 100 (high technical and programmatic merit with few minor flaws) up to 900 (low technical and programmatic merit with several major flaws).

**B. Full Proposal Formatting Guidelines:** A 10-page full proposal and all supporting documents should be sent a single PDF file directly to the CAP Coordinating Center.
as an e-mail attachment to rfa@ConsortiumToAlleviatePTSD.com. Submission questions should be emailed to info@ConsortiumToAlleviatePTSD.com. The body of full proposals for this RFA should be no longer than 10 single-spaced pages using a 12 point font (Times New Roman preferred) with no less than ½ inch margins on all sides.

C. Full Proposal Submission Documents: Submit a PDF of the following documents in the order listed below to the CAP Coordinating Center as an e-mail attachment to: rfa@ConsortiumToAlleviatePTSD.com.

• Proposal Cover Sheet: Complete the same Cover Sheet used for the PreProposal submission. The most recently approved cover sheet can be found at: http://tango.uthscsa.edu/consortiumtoalleviateptsd/pdf/CAP-RFA-Coversheet-9OCT-2015.doc. The Cover Sheet should be the first document included in the PDF full proposal file.

• 10-Page Full Proposal Narrative. There is no standard format for the full proposal narrative, but it must contain all required information as described in Section [V.D] below.

• References Cited. List the references cited. The references are not counted as part of the 10-page maximum for the pre-proposal narrative. Use a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, publisher, etc., as appropriate).

• Quad Chart. All pre-proposals and full proposals must include a quad chart (separate from the 10-page full proposal) briefly describing the study including rationale, population to be studied, sample size, study sites, methods, total budget, and a picture or other graphic describing the study. An example of a CDMRP-compliant quad chart can be found at: https://cdmrp.org/Program_Announcements_and_Forms/


• Study Budget and Budget Justification. All full proposals must include an itemized budget reflecting both direct and indirect study costs. Please note that CAP studies may utilize both Department of Defense (DoD) and VA funds, and the allowable indirect costs associated with DoD funds. Research costs should be explained using a budget justification document giving a brief rationale for each cost category. CAP budgets must be provided in the approved standard format as shown in the budget sample found at: http://tango.uthscsa.edu/consortiumtoalleviateptsd/.
• There is no standard format for the budget justification document, but the budget justification should briefly describe the scope and rationale for costs in all cost categories in the budget document. Questions about the budget format and budget justification document should be directed to Elizabeth Buel at buele@uthscsa.edu.

D. Full proposal Narrative Content Requirements: All submitted 10-page full proposal narratives should include the following:

- **Title.** Provide the title of the proposed project.

- **Background/Significance.** Briefly describe the scope of the proposed research problem and highlight gaps in the existing treatment/knowledge base for this problem.

- **Study Overview.** Provide a brief overview and rationale for the proposed research project including a description of any treatments/treatment arms.

- **Aims and Hypotheses.** Provide a brief description of the aims and hypotheses of the proposed research. Study aims should specify the ways in which the proposed research will address a cohesive research question and should be linked with hypotheses that describe how the research will test each aim.

- **Investigators.** This section should include a brief description of the research team and the team is suited to the proposed study.

- **Preliminary Studies (if applicable).** Briefly describe any previous research or pilot study outcomes that inform the design and potential impact of the proposed research.

- **Innovation and Impact.** Provide a description of how the proposed research will address gaps in the extant knowledge and/or offers an innovative approach to the designated research question.

- **Research Procedures.** Provide a description of the research procedures including (if applicable): chosen research outcomes, recruitment strategy, associated measures for each aim, power analysis.

- **Military Relevance and Access to Military/VA Populations.** Provide a brief description of how the aims and objectives of the proposed research apply to military service and/or VA care.

- **Data Analytic Strategy.** Provide a brief description of how data will be analyzed to validly address the specific aims of the research. This section can also include procedures for managing missing data.
VI. Full Proposal Review Process and Scoring Criteria:

A. Full Proposal Review Panel: Full proposal submissions will undergo Independent Peer Review on an ad hoc basis. The Independent Peer Review Committee (IPRC) will be assembled and directed independently from the CAP Consortium. IPRC Members will include field experts who are not affiliated with CAP in the subject matter described in the proposals (a perfect match in reviewer expertise cannot be guaranteed, but every effort will be made to ensure that appropriate expertise is available to judge scientific merit). To aid in assembling an Independent Review Panel, **all PIs submitting a full proposal must convey at least 3 names of suggested, non-conflicted reviewers to the CAP Coordinating Center.** Suggested reviewers will be conveyed to the IPRC Independent Chair for recruitment onto the Independent Review Committee. If a submitting PI wishes to also indicate individuals they believe are in conflict and should be excluded from review, they may communicate those names as well (though this is not required).

B. Full Proposal Review Scoring: The IPRC uses a standardized scoring rubric rating overall merit of each submission on a 100 to 500 scale, similar to that used by the VA for grant review. Total scores can generally be interpreted as follows:

100 to 150 (EXCELLENT): strong scientific merit addressing an important problem or critical knowledge gap with a few (if any) minor problems in research design or methods.

160 to 220 (VERY GOOD): solid scientific merit addressing an important scientific area with several minor significant flaws in scientific design.

230 to 280 (GOOD): good scientific merit addressing a valid area of investigation using a research design with key flaws and/or limited impact.

290 to 340 (FAIR): unclear scientific merit, often in need of additional preliminary data to adequately address the concern; impact and/or innovation are unclear.

350 to 500 (POOR): poor scientific merit and/or a failure to address an important scientific question; may also include studies with poor feasibility.

**NOTE:** A good scientific review score does not guarantee funding through CAP. The CAP Coordinating Center will review all scientific review scores and recommend for funding those studies that represent good scientific merit and a good programmatic fit with the rest of the CAP research portfolio. Final approval for funding requires the approval from the CAP Government Steering Committee and Senior Leaders, as described previously in this RFA.

C. Full Proposal Screening Criteria: The IPRC will consider the following qualities of research proposals in determining overall scientific merit:

- **Study Rationale/Significance.** Does the project address an important problem or a critical barrier to progress in the field? Does the study address a targeted Consortium area of need?
- **Impact.** Does the project have the potential to significantly inform military and/or VA healthcare/practice?
- **Innovation.** Does the proposed research explore a new direction in PTSD and PTSD-related research or show a novel extension/expansion of a current direction?
- **Study Personnel.** Are the PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments? Is there evidence of appropriate collaboration between academic and DoD and/or VA personnel? Is there collaboration with CAP Investigator(s)?
- **Research Methods.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? If applicable, is the research proposed feasible for a military or VA setting?
- **Research Performance Sites.** Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Should the investigators consider a different study site? Is there a study site more appropriate for this research?
- **Collaboration with Cores.** Are CAP Cores meaningfully integrated into the research?
- **Estimated Budget.** Is this project’s budget appropriate? Can this study be conducted with a lower budget? Can this study accomplish all stated goals on the projected budget? Are all expenses necessary? If applicable, is this budget balanced based upon the amount of work being accomplished with DoD and VA support?

**D. Resubmission:** Generally, proposals receiving an overall review score of 350 to 500 are dissuaded from resubmission. However, some poorly scored proposals may include good programmatic fit and may be approached by the CAP Coordinating Center about resubmission. Proposals that scored well but were turned down for funding, should discuss resubmission with the CAP Coordinating Center if they wish to submit again.

**VII. Questions:**

Questions regarding the pre-proposal should be emailed to info@ConsortiumToAlleviatePTSD.com. A list of Frequently Asked Questions from investigators will be compiled and posted on the CAP website at www.ConsortiumToAlleviatePTSD.com.