

Program Announcement

U.S. Army Medical Research and Materiel Command Military Operational Medicine Research Program

Suicide Prevention and Counseling Research (SPCR)

Funding Opportunity Number: W81XWH-08-MOMRP-SPCR

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I. HELPFUL INFORMATION

A. Contacts

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.

Questions related to the submission process for this announcement should be directed to Fay Peiffer at the U.S. Army Medical Research Acquisition Activity at 301-619-4055 or fay.peiffer@us.army.mil

Questions related to the research area for this announcement ONLY should be directed to Dr. Joan Hall at 301-619-6641 or joan.hall@amedd.army.mil.

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. Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern Time
Email: support@grants.gov

Deadline for full proposal submission is 11:59 p.m. Eastern time. Therefore, there are approximate 3-hours during which the Grants.gov help desk will NOT be available. Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. *Proposals received after the deadline will not be evaluated.*

Grants.gov will notify Principal Investigators (PIs) of changes made to this Funding Opportunity 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** (https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) well before the proposal submission deadline.
- Not obtaining or confirming the organization’s registration with the **Central Contractor Registry (CCR)** (<http://www.ccr.gov/>) well before the proposal submission deadline.

- Failing to request “send me change notification emails” from [Grants.gov](http://www.grants.gov) (<http://www.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 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 full proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and Objectives

The SUPPLEMENTAL APPROPRIATIONS FOR FISCAL YEAR 2008 in the Defense Health Program appropriations provided \$273.8 M under “BATTLE CASUALTY AND PSYCHOLOGICAL HEALTH RESEARCH” to address prevention, diagnosis, treatment, and mitigation of deployment-related injuries and psychological health concerns. Of these funds, approximately \$8.5M has been allocated to the Military Operational Medicine Research Program to manage efforts directed toward Suicide Prevention and Counseling Research.

The mission of Military Operational Medicine Research Program is to develop effective medical countermeasures against combat and operational stressors to maximize Warrior health, performance, and well-being. The research program consists of four overarching areas of focus: injury prevention, psychological health and resilience, mission reset and recovery, and environmental health and well-being. The research focus is on multistressor interactions involving human tolerances, metabolic physiology, psychological processes, and brain function that span the Warfighter Deployment Lifecycle.

The MOMRP Psychological Health Research and Resilience Research Program area is dedicated to developing effective strategies and interventions that build psychological resilience and optimize psychological health and emotional well-being among Soldiers and Families.

The MOMRP anticipates the award of up to \$8.5 million (M) of the full \$273.8M FY08 Supplemental appropriation. The research projects must be tailored for use within a military milieu across levels of clinical care. Strategies that promote and sustain healthy adaptation to, and recovery from prolonged and/or adverse military operations across the deployment lifecycle are sought.

The proposals must contribute to our understanding of suicide, suicide prevention and counseling, and align with the MOMRP intramural core research program mission and objectives stated in this funding opportunity.

The aims of this funding opportunity are to: 1) facilitate development of a comprehensive approach to preventing suicide among Military Service members, 2) establish effective interventions to support first responders and loved ones of persons who completed suicide, and 3) develop effective counseling interventions to prevent suicide (including reducing nurse stress and fatigue at military treatment facilities). These efforts will assist in providing an evidence base for policy development and interventions to prevent suicide and manage Service members who present with intentional self-harming behavior, facilitate reset among providers of persons who care for those Service members and their loved ones, and assist loved ones personal recovery from their loss.

The ultimate goal of this research program is to expand our knowledge, understanding, and capacity to prevent, detect, diagnose, treat, and enhance the quality of life of persons in military communities and general public who are affected by suicide related problems.

The MOMRP research program seeks to:

- Encourage investigators to explore approaches and directions in suicide research among military populations
- Encourage development and validation of universal prevention programs that show promise in preventing suicidal behavior among military populations
- Support studies that increase understanding of causal factors of suicide and factors associated with suicide risk among military populations
- Test treatments and other interventions to prevent suicide
- Support research on the effects of suicide on loved ones and first responders
- Encourage development and validation of counseling practices to prevent suicide
- Effective interventions to reducing nurse stress and fatigue in military treatment facilities

The MOMRP is seeking proposals for military suicide prevention and counseling research across four categories: Prevention, Screening, Treatment, and Quality of Life and 10 topic areas (see the Research Proposal Topics on the next page for details). If the research is not relevant to the currently advertised MOMRP topic areas, the Government reserves the right to administratively withdraw the proposal. The Government also reserves the right to reassign the proposal's topic area if submitted under an incorrect topic area.

B. MOMRP-SPCR Award Description

1. Overview

The MOMRP will execute this extramural research program through the award of assistance agreements (grants and cooperative agreements). **The type of instrument used to reflect the business relationship between the recipient and the Government will be a matter of negotiation prior to award.** The MOMRP supporting contracting office, USAMRAA, will negotiate and award proposals selected for funding.

This funding opportunity supports rapid implementation of studies with the potential to have a significant impact on suicide prevention and counseling addressed in one of the FY08 MOMRP-SPCR topic areas. All proposed research must be responsive to the prevention, detection, diagnosis, treatment, and/or quality of life of persons affected by suicide related behavior. The study may be designed to evaluate promising products, pharmacologic agents (drugs or biologics), psychotherapeutic interventions, clinical guidance, and/or telehealth technology.

Any pharmacological agent used must be FDA approved for the intended disease/condition. This funding opportunity will not consider: (a) Proposals that suggest off-label use of pharmacological agents; (b) Research involving the use of animals; (c) Preclinical research studies; or (d) Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications.

2. Research Proposal Topics: MOMRP is seeking proposals for military suicide prevention and counseling research across four categories (Prevention, Screening, Treatment, and Quality of Life) and 10 topic areas:

Prevention

1. Effective suicide prevention strategies that focus on tactical suicide prevention across the operational spectrum and DoD that use a broad based approach designed to, but not limited to:
 - a. Reduce risk factors and enhancing protective factors
 - b. Change social norms to eliminate stigma about seeking help
 - c. Improve understanding of mental health
 - d. improve buddy-aid
2. Evidence based counseling to prevent and/or reduce nurse stress and fatigue at military treatment facilities
3. Effective peer, leader, and first responder risk assessment and management training tools and products to detect and prevent suicide

Screening

4. Test ways to effectively detect and assess the psychological impact of first responders who work on the scene with suicide completers and their survived loved ones
5. Test ways to detect the antecedents, associations (to include, but not limited to family adversities, prescribed medications, other therapies, substance misuse, and mental disorders), and other risk factors effective at predicting suicidal behavior in field and clinical environments (i.e., primary care, behavioral health) across the military operational spectrum
6. Test ways to effectively detect the psychological impact, coping mechanisms, and

psychological risks from loss to suicide among loved ones of the deceased

7. Evidence based suicide assessment scales effective at predicting suicidal behavior and evidence-based suicide assessment interventions for tactical (i.e., peer, leader, first responder) and clinical environments (i.e., primary care, behavioral health) across DoD and VA health care systems

Treatment

8. Evidence based treatment, crisis intervention, clinical post-intervention and case management for Service members identified with suicidality
9. Evidenced-based treatment of patients with co-occurring suicidality and mental and/or physical illness

Quality of Life

10. Investigations into the reactions, grief, and needs of loved ones and peers of suicide completers which lead to evidence based bereavement interventions to facilitate support and recovery from loss.

The research projects must be tailored for use within a military milieu across field, garrison, shipboard, primary care, behavioral health care, or combat settings. Other contextual factors such as, but not limited to, individual, peer, family, community, culture, and social that may affect the selection, implementation, and outcomes of empirically validated research should be addressed. Studies that focus on gender, ethnicity, individual military augmentees (IMAs), randomized controlled trials, and comparisons between Active Duty, National Guard, and Reserve service members are invited.

It is expected that research projects submitted demonstrate a) a thorough review and knowledge of the scientific literature relevant to the nature of the proposed study, b) a theoretically and hypotheses driven approach, and c) translation into clinically and operationally relevant military applications.

It is the responsibility of the PI to clearly and explicitly articulate the project's impact on Military Suicide Prevention and Counseling Research.

3. Military Populations

Military Relevance is a key feature of this award. Therefore, PIs are strongly encouraged to collaborate and integrate their projects with DoD and/or Veterans Affairs (VA) research laboratories and programs. Each PI must provide a transition plan (including funding and resources) showing how the research product will progress to the next phase and/or delivery to the military community after successful completion of this award.

PIs must describe the military population(s) to be used for the proposed study and/or the relationship of nonmilitary research participants to a military population. PIs should identify the specific research population in the research proposal and attach Letters of Support as applicable. The research projects must be tailored for use within a military milieu across levels of clinical care.

Research conducted using military populations in Iraq is conducted solely by select elements of the Multi-National Corps-Iraq (MNC-I). PIs who are outside of this system and submit a research proposal designed to recruit patients within MNC-I must be working in collaboration with an in theater military investigator,

undergo an in theater 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 an appropriate military investigator should strongly consider alternatives to conducting in theater research. DOD-supported human subjects research can only be conducted by institutions (including those in theater) with approved Federal Assurances for the protection of human research subjects.

There is no ability to conduct research using military populations in Afghanistan at present.

Department of Veterans Affairs (VA) Medical Centers' patient populations: Access to patient populations from the Department of Veterans Affairs (VA) Medical Centers or use of information from VA data systems must be coordinated by the PI. PIs who submit a research proposal designed to recruit patients from a VA Medical Center or use information from VA data systems, and those who do not have an appointment at one of the VA Medical Centers, must include a collaborator with a VA appointment. This collaborator must be willing to assume the role of PI for the VA component of the research.

Multi-institutional Studies: If the proposed study is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data obtained during the study will be handled, should be included in the appropriate sections of the proposal. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional studies.

Research Involving Human Subjects. Use of human subjects and human biological substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO) in addition to local Institutional Review Boards (IRBs). 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 IRB. The PI must address pertinent issues relating to the use of human participants in the proposed research. Include the required approvals, forms and information as specified on the Human Research Protection Office (HRPO) website:

<https://mrmc.detrick.army.mil/rodorphrpo.asp>

4. Eligibility

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) will use 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. PIs must be independent investigators at any academic level.

Eligible Institutions include nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and commercial firms. Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) are encouraged to submit proposals for review and funding consideration under this announcement.

C. Funding

It is anticipated that up to \$8.5 million will be awarded. It is anticipated that no individual award will be more than \$2 million inclusive of direct and indirect costs, with a maximum period of performance of 3 years. Reasonableness of budget for the proposed research is a component of the peer review evaluation process. Strong justification must be provided to support the requested budget.

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Research-related subject costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions
- Travel to MOMRP required meetings (i.e. Programmatic Line Review (PLR) & Integrating Integrated Product Team (IIPT) Meetings)
- Indirect Costs
- Other direct costs

The MOMRP expects to allot approximately \$8.5M of the \$273.8M FY08 War supplemental appropriation to fund approximately 5-10 research proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this Funding Opportunity is contingent upon the availability of Federal funds for this program. If the funding appropriation is either increased or decreased in order to execute the program, the Government reserves the right to adjust the funding levels and number of awards accordingly.

D. Award Administration

At the Government's discretion and expense, the PI(s) and Study Coordinator(s) may be requested to participate in a pre-award meeting.

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

1. Site Visits

During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior funding and should be coordinated through the USAMRAA Contracting/Grants Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DoD personnel, are also encouraged to visit the PI during their award efforts. The visits must all be coordinated with the Contracting/Grants Officer and are intended for technical discussion and monitoring of progress of the funded project.

2. Reports, Presentations and Meetings

Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports due to the government. Reporting requirements may include the following:

- a. Monthly or quarterly reports that outline the accomplishments and progress for that period.
- b. Quarterly Standard Form Report, SF272, Federal Cash Transaction Report, used for grants and cooperative agreements that track the expenditure of funds on the project.
- c. Bi-annual reports that consist of detailed summaries of scientific issues, accomplishments and human research usage during the project.
- d. Final report that details the findings and issues of the completed project.
- e. Copies of all scientific publications and presentations as a result of this funding.
- f. Abstracts suitable for publication in relation to planned meetings.
- g. Presentation at the MOMRP Product Line Review (PLR) Meeting that details the status of a project to a panel of subject matter experts. Travel and other costs related to PLR attendance should be included in the budget submission.
- h. PI attendance at the annual MOMRP Integrating Integrated Product Team (IIPT) meeting. Travel and other costs related to IIPT attendance should be included in the budget submission.

III. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) Letter of Intent (LOI) submission and (2) proposal submission. *Letter of Intent (LOI) submission is a required first step.*

Letter of Intent Deadline:	5:00 p.m. Eastern time, October 31, 2008
Proposal Submission Deadline:	11:59 p.m. Eastern time, November 28, 2008
Scientific Peer Review:	February 2009
Programmatic Review:	March 2009

Deadline for full proposal submission is 11:59 p.m. Eastern time. Therefore, there are approximate 3-hours during which the Grants.gov help desk will NOT be available. Full Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. Please plan ahead accordingly. *Proposals received after the deadline will not be evaluated.*

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

IV. SUBMISSION PROCESS AND APPLICATION INSTRUCTIONS

Proposal submission is a two-step process consisting of (1) a Letter of Intent (LOI) submission through <https://momrp.aibs.org> and (2) a proposal submission through [Grants.gov](http://www.grants.gov) (<http://www.grants.gov/>).

PIs and Organizations identified in the proposal submitted through Grants.gov should be the same as those identified in the LOI. If there is a change in PI or organization after submission of the LOI, the PI must contact the LOI submission helpdesk at: usamraa@aibs.org or call 703-674-2500, ext. 207.

See formatting and compliance guidelines section on page 22 for additional details.

A. Step 1: Letter of Intent Submission

All LOIs components must be submitted electronically in pdf form through <https://momrp.aibs.org> by **5:00 p.m. Eastern time on the deadline.**

The LOI consists of the components discussed below. Refer to the Application Instructions for detailed information.

- 1. Proposal Information:** Enter the Proposal Information as described in <https://momrp.aibs.org> before continuing the LOI.
- 2. Proposal Contacts:** Enter contact information for the PI and Contract Representative (CR). The CR is the organization's business official responsible for sponsored program administration (or equivalent). This is the individual listed as the person to be contacted on matters involving this application in Block 5 of the Grants.gov SF424 form.
- 3. Collaborators and Conflicts of Interest (COI):** To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project including collaborators, consultants, and subawardees. Add all individuals outside of the proposal who may have a COI in the review of this proposal. Applicants will be prompted to input their first name, last name, and institution (one per line) in a text field on the <https://momrp.aibs.org> LOI web site. Inclusion of the program's fiscal year 2008 (FY08) Joint Program Committee (JPC) members in any capacity in the proposal, budget, or supporting documentation, with the exception of references cited, is considered a COI and will result in administrative withdrawal of the proposal. A list of the FY08 JPC members may be found at <https://momrp.aibs.org> and <https://www.momrp.org/>
- 4. The LOI Narrative: Three-page limit.** The LOI Narrative page limit is inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. LOI Narratives are used for program planning purposes and will not be reviewed during scientific peer, military relevance, or programmatic review. The following content is required in the LOI:
 - a. Program Announcement Proposal Topic.
 - b. Background: Present the ideas and rationale behind the proposed study.
 - c. Objective/Hypothesis: State the objective/hypothesis to be tested.
 - d. Specific Aims: State the specific aims of the study to include how your proposed research applies to one of the topic areas of scientific interest stated in the solicitation.
 - e. Study Design: Briefly describe the study design including appropriate controls.
 - f. Anticipated Outcomes: The expected results of the project should be presented as a timeline of specific outcomes. Describe how the outcomes will be measured.

- g. Military Impact: Summarize how the proposed project will impact the deployment-related topic area to be studied.
- h. Total Estimated Budget Amount.
- i. Printed name of PI, signature, date, email address, telephone number.

The LOI must be submitted in pdf form with appropriate signatures using the PIs Letterhead form. A Log Number will be assigned to each LOI that must be used when submitting the full proposal through Grants.gov.

- 5. **Submission:** All LOI documents must be submitted at <https://momrp.aibs.org>.
- 6. **PI Responsibilities:** The PI is responsible for completing the LOI submission at <https://momrp.aibs.org> and reviewing the submission to ensure compliance with the program announcement requirements.
- 7. **CR/Authorized Organizational Representative (AOR) Responsibility:** The LOI does not require approval by either the CR or AOR of the organization before submission
- 8. **LOI submission Deadline:** Full proposals will not be accepted if an LOI was not submitted by the stated deadline.

B. Step 2: Full Proposal Components and Submission

Proposal submission will not be accepted unless a Letter of Intent was submitted by the LOI deadline. Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

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. Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. Please plan ahead accordingly.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the U.S. Army Medical Research Acquisition Activity (USAMRAA) Program Announcement.

Click on “Help Mode” in the Grants.gov PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in the application package (Figure 2).

Figure 2. Grants.gov Pure Edge Tool Bar.



Proposal Submission Components:

1. 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 changes that must be made after the original submission, the complete application package must be resubmitted, with the “Changed/Corrected Application” box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable.
- **Block 4 – Federal Identifier Box.** Populated by Grants.gov for an original application. If “Changed/Corrected Application” is entered in Block 1, then manually enter the Grants.gov tracking number (i.e., the Grant ID Number assigned to the original application).
- **Block 5 – Applicant Information.** This is the information for the Applicant Organization, not an individual. The “Person to be contacted on matters involving this application” is the CR or Business Official. This is not the Project Director (PD)/Principal Investigator (PI).
- **Block 6 – Employer Identification.** Enter the EIN or TIN as assigned by the Internal Revenue service. If applying from a foreign institution, enter 44-4444444.
- **Block 7 – Type of Applicant.** This is for the Applicant Organization, not an individual. This is not the PD or PI.
- **Block 8 – Type of Application.** For all submissions, the “New” box must be chosen.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.
- **Block 11 – Descriptive Title of Applicant's Project.** Enter a brief descriptive title of the project.
- **Block 12 – Areas Affected by Project.** List the largest political entities affected by the project (e.g., state, county, city). Enter N/A for not applicable.
- **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 15 – Project Director/Principal Investigator Contact Information.** Enter information for the individual (PI) responsible for the overall scientific and technical direction of this application.
- **Block 16 – Estimated Project Funding.** Enter the total funds (direct + indirect costs) requested for the entire performance period of the 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 18 – Complete Certification.** Check “I agree” box to provide the required certifications and assurances.
- **Block 19 – Authorized Organizational Representative (AOR).** The AOR is the individual with the organizational authority to sign for an application. 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.** Ensure the LOI log number is listed in block 20. No other information is required.

2. Attachment Forms

Attachment 1: Project Narrative (not to exceed 20 pages) Named “Narrative.pdf.”

- Proposal Abstract
- Background and Literature Review
 - An overview of the subject, issue and/or problem
 - Rationale for the proposed research
 - Objectives: State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study
 - Theory under consideration
 - Thorough description and evaluation of the work done on the subject matter and argument to support position under review
- Research Design and Methods
 - Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.
 - If recruiting human participants, describe the recruitment process:
 - Methods for identification of potential volunteers (e.g., medical record review, obtaining sampling lists, health care provider identification, etc.).
 - Description of compensation plan (should be fair and not provide undue inducement; if the study requires multiple visits, a plan for pro-rating payments in the event of volunteer withdrawal should be considered).
 - Type of consent to be used (informed, waived, or surrogate).
 - List the major inclusion and exclusion criteria of the study.

- The number of participants that must be enrolled to properly power the proposed study, the number of participants that must be screened to meet the enrollment target number, and the plan for replacing participants who choose to drop out.
- Describe plans for military populations use for the proposed research project.
- Describe the study intervention. Briefly describe the data collection procedures and interaction(s) with the participants, detailing how frequently and for what duration the investigator will interact with the participant (e.g., initial interview, followed by weekly group psychotherapy sessions, each 50 minutes in duration, for 10 weeks).

The Project Narrative must be submitted in pdf form and will available for peer, military relevance, and programmatic review.

Attachment 2: Supporting Documentation: Single PDF file named “Support.pdf.”

Support documentation is limited to the items listed below.

- **References Cited: No page limit.** List all cited references using the American Psychological Association Publication Manual, 5th edition. The inclusion of Internet URLs to references is encouraged.
- **Acronyms and Symbol Definitions: No page limit.** Starting on a new page titled “Acronyms and Symbol Definitions,” provide a glossary of acronyms and symbols.
- **Letters of Institutional Support: (Three-page limit per letter.)**
- If the PI is a practicing clinician, the institution must clearly demonstrate a commitment to the clinician’s research.
- **Intellectual and Material Property Plan (if applicable)**
- **Letters of Collaboration (if applicable) (no page limit)**
- **Letters of Support (if applicable) (no page limit)**

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. ***The Supporting Documentation attachment is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal. These materials should be included as part of Attachment 1.***

Attachment 3: Statement of Work (SOW): Two-page limit, named “SOW.pdf.”

The SOW is a concise restatement of the research proposal that outlines and establishes the PI’s performance expectations and timeline during the period of performance of the award. Although some allowance is made for problems encountered and uncertainties that are part of research, the PI is expected to meet the provisions and milestones in the SOW. Failure to meet deliverables as defined by tasks may result in withdrawal of funds.

The SOW should be a series of relatively short statements that outline step-by-step how each of the major goals or objectives of the proposed research/services will be accomplished. The SOW should only describe work for which funding is being requested by this proposal.

As appropriate, the SOW should:

- Describe the work to be accomplished and deliverables as tasks that relate to one another, to the proposal specific aims, and to the period of performance.
 - Indicate the number of research subjects (animal or human) and/or anatomical samples projected or required for each task.
 - Identify methods, outcomes, products, and deliverables for each phase of the project.
- Identify the timeline and milestones for the work over the period of the proposed effort;
 - Allow at least 6 months for regulatory review and approval processes for studies involving human participants.
- Indicate time required for human use approval
- Include the following information for each study site/subaward site that will be actively participating in the study:
 - Collaborator, consultant, and/or subawardee name
 - Institution
 - Institution address
 - human use at this site

The SOW should include a list of tasks that relate to the specific aims with a brief description of each task and subtask to include the items requested above and a concise timeline. There is no limit to the number of tasks and subtasks that are described within the two-page SOW length limit. Below is a suggested format:

Task 1. Brief overview description of this task (timeframe, e.g., months 1-18):

1a. Description of subtask 1a (timeframe, e.g., months 1-4).

1b. Description of subtask 1b (timeframe, e.g., months 6-12).

1c. Description of subtask 1c (timeframe, e.g., months 1-18).

Task 2. Brief overview description of this task (timeframe, e.g., months 4-36):

2a. Description of subtask 2a (timeframe, e.g., months 4-12).

2b. Description of subtask 2b (timeframe, e.g., months 13-25).

2c. Description of subtask 2c (timeframe, e.g., months 25-30).

2d. Description of subtask 2d (timeframe, e.g., months 25-36).

The concise timeline should account for the duration by quarter (Q) or year and scheduling relationships of the major tasks identified in the descriptive SOW above.

Attachment 4: Military Relevance Statement Two-page limit Named “MilRel.pdf.”

Demonstrate how the proposed study is responsive to the health care needs and quality of life of members of the Armed Forces who are deployed and/or other populations of interest as appropriate for this solicitation. If a military population(s) will be used in the proposed project, describe the population(s), the appropriateness of the population for the proposed research, and the feasibility of using the population. Explain how the proposed research study is aligned with the military research gap(s) appropriate for the topic area address. Describe

how the study design will replicate clinical/field conditions for the selected topic area. Discuss how the product, pharmacologic agent (drug or biologic), psychotherapeutic intervention, clinical guidance, or telehealth technology is suitable for operation in a field or clinical environment.

Attachment 5: Impact Statement (One-page limit.) Named “Impact. Pdf”

State explicitly how the proposed study will have an impact on the prevention, detection, diagnosis, or treatment of the specified disease/condition, if successful. Explain the potential clinical and operational applications, benefits, and risks.

Attachment 6: Transition Plan (One-page limit.) Named “Transition.pdf”

Provide information on the methods and strategies proposed to move the product, pharmacologic agent, psychotherapeutic intervention, clinical guidance, and/or telehealth technology to the phase and/or military field deployment after the successful completion of the award. The plan should include details of potential funding sources, collaborations, other resources that will be used to provide this continuity of development, and a potential timeline for field deployment.

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches including partnering PIs (four-page limit each)
- Key Personnel Current/Pending Support including partnering PIs

PI Biographical Sketch: Four-page limit. Named “Biosketch_LastName.pdf” in which “LastName” is the last name of the PI.

4. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. Refer to the Program Announcement/Funding Opportunity for limits on funding and period of performance.

The program does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted. The maximum funding amount may be requested for less than the maximum performance period if addressed adequately in the Budget Justification.

All costs must be entered in US dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.

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

- **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 regulations and principles:
 - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31, Contract Cost Principles and Procedures (<http://farsite.hill.af.mil>).
 - **Educational Institutions:** 2 CFR Part 220, Cost Principles for Educational Institutions (<http://www.gpoaccess.gov/cfr/index.html>).
 - **Nonprofit Organizations:** 2 CFR Part 230, Cost Principles for Nonprofit Organizations (<http://www.gpoaccess.gov/cfr/index.html>). OMB Circular A-133, Audits of States, Local Governments, and Nonprofit Organizations (<http://www.whitehouse.gov/OMB/circulars/index.html>).
 - **State, Local, and Tribal Governments:** 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (<http://www.gpoaccess.gov/cfr/index.html>).
 - **Cost of Preparing Proposals:** The cost of preparing proposals in response to this Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant award. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and 2 CFR Parts 220 and 230.

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).

Qualifications of the PI and other professional personnel and the amount of time that they will devote to the research are important factors in selecting proposals for funding. For all personnel identified on the budget form, list the percentage of each appointment to be dedicated to this project.

Section C – Equipment Description: It is Department of Defense 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 will be separately negotiated.

An itemized list of proposed 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 one year 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.** Costs should not exceed \$5,400 per year during the performance period.
- **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 the grant officer 60 days before travel, unless identified in the proposal that is part of the award.
- **Travel to MOMRP-required meetings.** Funds for the PI to attend two Department of Defense military research-related meeting to be determined by the MOMRP during the performance period. Justification must be provided if additional personnel are included in the travel budget. Costs should not exceed \$3,600 for travel to these meetings.

Section E – Participant/Trainee Support Costs: This section is self-explanatory; follow the instruction in the form.

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.

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 – Additional Direct Costs (if applicable):

a. 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.

b. Miscellaneous Costs: 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 CFR 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. As a minimum, justification for indirect costs should identify: (1) All individual cost elements included in each forecast rate, (2) the basis used to prorate indirect expenses to cost pools, if any, (3) how each rate was calculated, and (4) 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.

Section K – Budget Justification: The Budget Justification for the entire performance period must be attached as a PDF file named “**Justification.pdf**” to the Research & Related Budget – Section K (under budget period one). Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.

NOTE: *While the budget justification must include information for all budget periods, this file must be uploaded for budget period one before access will be granted to subsequent budget periods.*

5. 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.

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

Files 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 a 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 access will be granted to 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:

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

C. Formatting Guidelines

Full Proposals should be submitted no later than 28 November 2008. An award decision should be rendered by the Government within 180 days after submission. Forms and information supporting the submission of a full proposal are located at www.grants.gov.

The proposal must be clear and legible. Attachments must conform to the following guidelines:

1. **Type Font:** 12 point, 10 pitch (Times New Roman)

2. **Spacing:** Single-spacing between lines of text

3. **Margins:** 1.0 inches on all sides

4. **Color, 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 megabytes (MB). Since some reviewers work from black and white printed copies, applicants 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, etc. must be submitted in JPEG format only (no bitmaps or TIFF).

5. **Acronyms:** Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations and symbols.

6. **Language:** English

7. **Format:** PDF

D. Compliance Guidelines

Compliance guidelines are designed to ensure the presentation of all LOIs and proposals are organized and easy-to-follow. Scientific peer and military relevance 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 LOI or proposal rejection. LOIs or proposals missing required components as specified in the Funding Opportunity will 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 is missing.
- Scientific Peer and/or Military Relevance Reviewer(s) have not declared a COI but are found to have involvement with the applicant prior to or during the review.
- FY08 JPC member(s) are named in the proposal.

- FY08 JPC member(s) are found to be involved in any capacity in the LOI and proposal processes including but not limited to concept design, proposal development, budget preparation, and the development of any supporting document.
- FY08 JPC member(s) communicated program priorities prior to the deadline for proposal submission listed in this program announcement.

For any other sections of the LOI or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for scientific peer review or military relevance review. Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for scientific peer review or military relevance 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 an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All proposals are evaluated by scientists and clinicians using a two-tier review process. The first tier includes a scientific peer review of proposals against established criteria for determining scientific merit. The second tier consists of a military relevance review of proposals against established criteria and a programmatic review that compares submissions to each other and then recommends proposals for funding based on scientific merit, military relevance, and the overall goals of the program.

The scientific peer, military relevance, and programmatic review processes are conducted confidentially 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 corrective actions. 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. Likewise persons involved in the proposal review process are prohibited from communicating the program priorities, other than what is listed in this program announcement, to PIs and/or being involved in the proposal development (including the LOI process, concept design, budget, and supporting documentation). Violations of these prohibitions will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality of the scientific peer, military relevance, and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Military Relevance Statement).

B. Review Criteria:

The Scientific Peer Review and the Military Relevance and Programmatic Review are of relatively equal importance.

1. First Tier Review

Scientific peer review: All proposals will be evaluated according to the following criteria, which are of equal importance:

- **Study Design**
 - How the scientific rationale and preliminary data, including critical review and analysis of the literature, and clinical evidence support the proposed study and its feasibility.
 - The theoretical or conceptual framework from which the study is premised
 - How the aims, hypotheses, experimental design, methods, data collection procedures, and analyses are developed.
 - How the logistical aspects of the proposed study (e.g., communication plan, data transfer and management, and standardization of procedures) meet the needs of the proposed study.
 - How the recruitment, informed consent, and screening processes for volunteers will be conducted to meet the needs of the proposed study.
 - How the inclusion, exclusion, and randomization criteria meet the needs of the proposed study.
- **Impact**
 - How the results of the proposed study will affect the magnitude and scope of potential clinical applications related to suicide prevention and counseling (e.g., prevention, detection, diagnosis, treatment, management, and/or quality of life).
 - How the proposed study addresses one of the funding opportunity topic areas.
- **Intervention, Drug, or Device/Product**
 - How the intervention, drug, or device/product to be tested is appropriate for the proposed study.
 - How the availability and purity of the substance to be used in the study is appropriate for the proposed study.
- **Feasibility**
 - Evidence of the feasibility of the proposed study
 - How the plan for addressing unanticipated delays (e.g., slow accrual) is likely to lead to success in completing the proposed study within the performance period.
 - How the proposal addresses the availability of volunteers for the study, the prospect of their participation, and the consideration of likelihood of volunteer attrition.
 - Evidence the PI will have access to any military populations required for the study, if applicable.
- **Statistical Plan**
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
 - How the data analysis plan is consistent with the study objectives.

- **Personnel**
 - How the study team’s background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease/condition, and clinical studies).
 - How the levels of effort of the clinical team are appropriate for successful conduct of the proposed study.
- **Environment**
 - How the evidence indicates an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the study at each participating center (including collaborative arrangements).
 - Evidence for appropriate institutional commitment from each participating institution.
 - How the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed study.
- **Ethics and/or Regulatory Issues**
 - How the ethical considerations, information privacy, and assessment of risks and benefits of participation in the study will be addressed.
 - Evidence that an appropriate plan for dealing with adverse events, which should include named agencies or offices to be notified in this event, and point of contact information has been prepared.
 - How plans for data disposition during and after the study are appropriate for the proposed study.
 - How the procedures for protocol modifications during the course of the study have been addressed.
 - How the plans for data and safety monitoring are appropriate for the proposed study.
- **Transition Plan**
 - How the transition plan describes field or clinical deployment of the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology.
 - Whether there is evidence that the PI has or can secure additional funding, or whether the PI clearly described potential options to secure the additional funding needed to bring the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology to the next study phase and/or field deployment.
 - How the proposed resources will be used to provide continuity of development/deployment and support the likelihood of success.
- **Budget**
 - How the budget is appropriate for the proposed research.

2. Second Tier Review:

Military relevance and programmatic review by JPC: All proposals will be evaluated according to the following criteria, which are of equal importance:

- **Alignment with gaps**
 - How the proposed study aligns with identified gap(s) in the topic area addressed.
- **Military benefit**
 - How the proposed study may benefit the identified military population, if successful.
- **Field Deployability**
 - How the transition plan addresses the deployability of the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology.
 - Whether the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology may be suitable for operation in the field environment.
 - How well the transition plan addresses a timeline for field deployment of the product, pharmacologic agent, behavioral intervention, device, clinical guidance, and/or emerging approach and technology.
- **Study Population**
 - How well the research design will replicate field conditions for the selected topic area.
 - How the plan to study military populations, if applicable, is appropriate and feasible.
- **Overall Program Review:**
 - Responsiveness to funding opportunity topic areas,
 - Ratings and evaluations of the scientific peer and military relevance reviewers,
 - Programmatic relevance,
 - 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 JPC members and recommended for funding to the Commanding General, USAMRMC.

VI. GRANTS.GOV INFORMATION

A. Public Law 106-107

Proposal submission is a two-step process consisting of (1) a Letter of Intent (LOI) submission through <https://momrp.aibs.org> and (2) a proposal submission through the Federal Government's entry portal [Grants.gov](http://www.grants.gov/) (<http://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.

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 United States Army Medical and Materiel Command 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 Authorized Organizational Representative (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 business is conducted with the Federal Government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a Data Universal Number System (DUNS) number or registration in the Central Contractor Registry (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](http://fedgov.dnb.com/webform/displayHomePage.do) (<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. ***As CCR registrations do expire; PIs should verify the status of their organization's CCR registration well in advance of the proposal submission deadline.***

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. With the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of

the organization. Allow a minimum of 5 business days to complete the entire CCR registration. If the 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. 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

VII. ADMINISTRATIVE INFORMATION

A. Excluded Parties List

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The 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 DODGAR 25.1125).

B. Administrative Requirements

A recipient organization should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circulars at www.whitehouse.gov/omb). Investigators are cautioned that awards are made to organizations, not individuals. The principal investigator (PI) must submit a proposal through an organization and be employed an organization to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017). Should the PI of a funded project leave the recipient institution, both the PI and institution must contact USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify USAMRAA prior to the PI leaving the institution.

By submitting a proposal and accepting an award, the recipient organization is certifying the investigators' credentials were examined and verify the investigators are qualified to conduct the proposed study and use human research participants.

C. J-1 VISA Waiver

Organizations located outside of the U.S. may submit in response to this Program Announcement; however, it is the organizations' responsibility to ensure 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. **In addition, the Government will not provide funds to support scientists from terrorist countries.** Additional information on J-1 VISA Waivers can be located at the following Department of State web site: travel.state.gov/visa/temp.

D. Disclosure of Information outside the Government

Proposals will only be disclosed outside of the Government for the sole purpose of technical evaluation. The USAMRMC obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

E. Government Obligation

Only a warranted Contracting/Grants Officer may obligate the Government to the expenditure of funds for awards under this Program Announcement. The Government does not fund preparation of proposals or support research that is inferred from discussions with technical project officers.

F. Integrity of Review Process

The scientific peer review, military relevance review, and programmatic review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel.

Violations of the nondisclosure statement can result in the dissolving of a panel(s) and other correcting 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 scientific peer review, military relevance review, and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards.

G. Disclosure of Proprietary Information Included in a Proposal

Proprietary information submitted in a proposal 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.

H. Award Negotiation

Prior to award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, and regulatory documents related to human studies and other documents, will be requested from the PI. Also at that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the Contracting Representative or Authorized Organizational Representative (AOR) at the organization.

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract or Grant 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 also be required.

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.

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009. The award start date will be determined during the negotiation process.

I. 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. Instructions in the assistance agreement concerning license agreements and patents must be followed.

J. Contracted Fundamental Research

Any awards under this PA to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meets the DOD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the contract or grant.

VIII. INSTRUCTIONS AND GUIDELINES FOR REGULATORY REQUIREMENTS

Principal Investigators (PIs) may not use, employ, or subcontract for the use of any human subjects, including the use of human anatomical substances and/or human data, 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 will 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 will 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.amedd.army.mil/docs/rcq/FY02FSPAppendix.pdf>.

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

C. Research Involving Human Subjects or Human Data

During the regulatory review process for research involving human subjects, the recommendations of the second tier Human Research Protection Office (HRPO) must be considered by the local Institutional Review Board (IRB). It is strongly recommended that investigators carefully read the "Guidelines for Investigators" found at

<https://mrmc.amedd.army.mil/docs/rcq/GuidelinesforInvestigators.pdf> (specifically, pages 28-47 for protocol and consent guidance). The time to approval depends greatly on adherence to these guidelines in a clear and comprehensive manner. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission. An initial review by the HRPO before local IRB approval will be considered on a case-by-case basis.

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

The following are reporting requirements and responsibilities of the Principal Investigator to the USAMRMC Office of Research Protections ORP, HRPO, and should be reflected in the protocol:

1. Requirements: Personnel involved in human subjects research must have appropriate training in the protection of human subjects. Documentation confirming that this training 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.amedd.army.mil/rodorphrpo.asp>.

2. Informed Consent Form: Elements to include in the informed consent form can be found at <https://mrmc.amedd.army.mil/docs/rcq/GuidelinesForInvestigators.doc#p41SecF>, and an informed consent form template is located at https://mrmc.amedd.army.mil/docs/rcq/consentform_template.pdf.

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. PIs 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: PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of: MOMRP- Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: MOMRP-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 National Institutes of Health (NIH) database (see <http://prsinfo.clinicaltrials.gov/>, click on “Data Element Definitions”) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per the U.S. Public Law 110-85.

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.

6. Research Involving the Use of Animals will not be considered.

IX. INSTRUCTIONS FOR REPORTS

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 assistance agreement. Report 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.*

A. Research Progress Reports

Reporting requirements consist of quarterly and annual reports (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 reports may be required as stipulated during award negotiations. Copies of all scientific publications and patent applications resulting from the Military Operational Medicine Suicide Prevention and Counseling Research funding should be included in the progress report. The Government reserves the right to request additional reports.

B. 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.

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.