Program Announcement

Defense Medical Research and Development Program (DMRDP)

Fiscal Year 2010 Basic Research Award

Funding Opportunity Number: W81XWH-10-DMRDP-BRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Assistant Secretary of Defense for Health Affairs, Defense Health Program Medical Research and Development Office is soliciting proposals for the Defense Medical Research and Development Program (DMRDP) Basic Research Award to be funded in fiscal year 2010 (FY10). The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience, and to the capability needs of the Joint Force Health Protection (JFHP) Concept of Operations (CONOPS), as delineated in the tasks described in this Program Announcement/Funding Opportunity. The objectives of the DMRDP are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of the Military Health System (MHS). The DMRDP funds research and development spanning basic research through advanced clinical development.

B. Award Description

This Program Announcement/Funding Opportunity is focused on basic research, defined as research directed towards attaining greater knowledge and understanding of fundamental principles of science and medicine. The DMRDP Basic Research Award is designed to promote new ideas that are still in the early stages of development and have the potential to yield highly impactful data and new avenues of investigation. This mechanism supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will accelerate the delivery of new medical countermeasures and information to protect military personnel from a variety of health threats inherent in the military operational environment, and to effectively diagnose and treat these personnel when they are ill or injured. These awards will also support basic research to enhance the training and education of military personnel and health care providers. Presentation of preliminary data is not required. However, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale. **Awards under this announcement will consist solely of assistance agreements.**

Innovation and Military Impact are the most important aspects of the Basic Research Award (see Section III.B for a full description of review criteria).

Awards may support human studies but may not be used to support clinical trials. Awards may not be used to support applied research or advanced technology development. Other DMRDP Program Announcements/Funding Opportunities for these areas of research have been issued or are forthcoming, and should be used for research of these types.

This announcement is intended only for extramural investigators. Other announcements will be released for intramural investigators. An ***intramural*** investigator is defined as a Department of Defense (DOD) employee working within a DOD laboratory or medical treatment facility (MTF), or a DOD activity embedded within a civilian medical center. An ***extramural*** investigator is defined as all those not included in the definition of intramural investigator. Pre-applications submitted to this announcement by an intramural investigator will be administratively withdrawn. It is permissible, however, for an intramural investigator to be named as a collaborator in a proposal submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

The DMRDP anticipates that approximately $60 million (M) will be available to support intramural and extramural basic research. The Government reserves the right to increase or decrease the approximately $60M available to support basic research.

C. FY10 Projects and Tasks

All applications for DMRDP funding must specifically and clearly address one of the projects (i.e., area of research) and tasks (i.e., specific research needs) identified below. The Government reserves the right to reassign Projects/Tasks identified in applications if submitted under an incorrect Task area.

Applications for research on Projects and Tasks (Projects/Tasks) other than those listed below should NOT be submitted in response to this Program Announcement/Funding Opportunity. ***If the proposed research project is not relevant to the advertised FY10 DMRDP Projects/ Tasks, the Government reserves the right to administratively withdraw the application.***

Research should have the potential to clarify basic mechanisms of militarily relevant disease or injury and/or enable the discovery of potential new applications relevant to one or more of the following Tasks (i.e., areas of military need), listed under their respective Projects:

Diagnosis and Treatment of Brain Injury

- **Mechanisms of TBI.** The ability to identify and characterize mechanisms of Traumatic Brain Injury (TBI), particularly mild TBI (mTBI).
- **Far Forward Diagnosis and Treatment of TBI.** Research in this task should include, but is not limited to, noninvasive diagnostic techniques to detect cellular or functional damage, pharmacologic or other agents (e.g., "neutraceuticals") for neuroprotection or treatment, and techniques to reduce structural and functional neurologic damage after TBI.
- **Epidemiology of TBI.** Epidemiology of mTBI/concussion in military operations.

Polytrauma and Blast Injury

- **Hemorrhage Control.** Identification of mechanisms leading to therapeutics and logistically supportable interventions to control internal hemorrhage and prevent or treat coagulopathy associated with severe trauma.
- **Bone and Soft Tissue Trauma.** Improved acute interventions that reduce complications, improve tissue salvage, and improve functional outcome including, but not limited to, limb and bone stabilization and repair, wound healing, and functional salvage.
- **First Response Diagnosis and Life Support.** Basic research that will lead to technologies for superior medical strategies and systems in far-forward areas of the battlefield.
- **Maintain Tissue Viability.** Research including but not limited to blood and blood component substitutes/expanders and improved tissue viability after wounding.
- **Wound Infection Prevention and Management.** Identifying and characterizing biomarkers associated with immune response and/or predictive of infection/wound closure or early detection of antimicrobial resistance; identifying nosocomial pathogens and discovering novel ways to mitigate contamination in the military medical environment.
- **Antimicrobial Countermeasures.** Identifying and mitigating virulence factors and/or metabolic pathways associated with wound infection pathogens (e.g., Acinetobacter, Pseudomonas aeruginosa, Methicillin-resistant Staphylococcus aureus, extended-spectrum beta-lactamases, Klebsiella pneumoniae, etc.) including characterizing and mitigating of biofilm formation. Preference will be for discoveries with applicability to polymicrobial infections resulting from combat wound infectionsand identifying novel treatment approaches for trauma-associated infections. Efforts focusing on topical treatment approaches will be given particular attention. Proposals incorporating drug screening, including high-throughput screening, and in-silico modeling are discouraged.
- **Treatment of Sensory System Traumatic Injury (Vision, Hearing, and Balance).** Basic research to advance our knowledge in support of treatments to slow/stop loss of vision and hearing following injury; treatment and mitigation of sensory system dysfunction associated with TBI and war-related injuries, and ocular drug delivery.

Operational Health and Performance

- **Operational Health and Performance.** Basic research to advance knowledge in methods to detect or assess muscle fatigue and human load capacity; possible interactions of over the counter (OTC) dietary supplements with prescription drugs; the effect of dietary supplement use on medical events (i.e., clotting factors, concussion); physiological factors of altitude illness; and fundamental physiological mechanisms of extreme environment-related illness and injury.

Rehabilitation

- **Neuromusculoskeletal Injuries.** Basic research to provide knowledge in support of novel assessment tools designed to assess limb health (i.e. blood flow, interstitial fluid swelling, early skin changes related to friction, changes in limb volume, etc.); and the prevention of heterotopic ossification. The interest is in management of neuromusculoskeletal injury associated with traumatic or war-related injuries.
- **Acute and Chronic Pain Management.** Basic research to increase knowledge and understanding in areas focusing on identifying and treating pain generators (including the pathophysiology of pain); and management of acute and chronic pain (including novel pain control methods, complementary and alternative medicine techniques, and epidemiology of incidents of pain and functional outcomes). The interest is in management of pain associated with traumatic or war-related injuries, especially using non-addictive and non-CNS depressive measures.

Psychological Health and Well-Being for Military Personnel and Families

- **Psychological Health and Well Being for Military Personnel and Families.** Basic research to advance knowledge in fundamental mechanisms of Cognitive Behavioral Intervention as a treatment for suicidality; critical aspects of Cognitive Behavioral Therapy (CBT) (specifically dismantling studies of CBT for treatment of combat-related Post-Traumatic Stress Disorder (PTSD)); factors to prevent alcohol misuse and substance abuse, and other health risk behaviors (accidents, tobacco use, etc.); the impact of co-morbid conditions on diagnosis and treatment of PTSD and other mental health problems (depression, anger, grief, guilt, etc.); novel methods to enhance psychological resilience (i.e., environmental enrichment, yoga and other "alternative" methods, positive psychology interventions, enhancement of traditional training); fundamental mechanisms of family and community resilience programs and the maintenance of strong relationships during deployment/extended separation.

Medical Simulation Training Systems

- **Role of Non-Traditional Sensory Cues in Computer-Based Simulation.** Explore the role of olfactory cues on learning, especially when incorporated into computer-based simulation. This can include understanding the interrelationship of olfaction, emotion, and learning, and it may address fundamental questions about the appropriateness and utility of using olfactory cues in applications aimed at training and psychological health treatment. The technology for producing olfactory stimuli in virtual reality medical training simulations has been investigated; the method of controlling and delivering the stimulus is not the focus of this solicitation. Examples of relevant study objectives include, but are not limited to: sensory integration issues in simulations; the effect of certain odors in evoking emotional and learning responses, including the universality of the effect from pleasant and unpleasant stimulatory odors; the effect of odors such as components of blood and burned flesh on emotion and realism in medical training

paradigms; the effect of odor on stimulating memory recall; the effect of specific odors (e.g., peppermint) on arousal, performance, and learning of fine motor tasks; and the role of specific olfactory cues in diagnostic decision making.

Use of Military Populations: Describe the military population(s) to be used for the proposed study, if applicable. Coordination of access to various military populations is described below.

1. **Active Duty, National Guard, Reserve troops, and/or military patient populations** (not CENTCOM Area of Responsibility)**:**

   a. If the Principal Investigator (PI) ***already has*** an established Service member population, proof of access to the established Active Duty, National Guard, or Reserve troop population(s) must be documented by submission of a letter of support, signed by the lowest ranking person with approval authority for granting access to the target population (see Attachment 2., Section g. in Application Instructions/General Information).

   b. If the PI ***does not already have*** an established Service member population, access to Active Duty, National Guard, or Reserve troops must be coordinated through the Office of the Congressionally Directed Medical Research Programs (CDMRP). ***PIs who do not have a previously established study population should not contact unit Commanders at this time or during preparation of the proposal submission. If selected for funding, the PI will receive support from the CDMRP for obtaining access to the appropriate population.***

2. **CENTCOM Area of Responsibility military populations**: Access to military populations in these areas is very limited and will be coordinated through the CDMRP as described above.

   Research conducted using military populations in Iraq is conducted with oversight by the Multi-National Force-Iraq (MNF-I). PIs that are outside of this system and submit a research proposal designed to recruit patients within MNF-I must coordinate with the in-theater Joint Combat Casualty Care Research Teams charged with facilitating an in-theater review, and be approved by the MNF-I Command and the MNF-I designated Institutional Review Board (IRB). The same is true for research conducted in Afghanistan in the US Forces-Afghanistan (USFOR-A) Area of Responsibility. PIs who are outside of this system and submit a research proposal designed to recruit patients within USFOR-A must coordinate with the in-theatre Deployed Combat Casualty Research Team charged with facilitating an in-theatre review, and be approved by the USFOR-A Command and the USFOR-A designated IRB. If selected for funding, CDMRP will assist with guidance on how to obtain the required in-theater approvals.

   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 of Compliance from the Human Research Protection Office (HRPO). It is strongly suggested that proposals necessitating the use of this population involve civilian and non-deployed military populations as an alternative.

3. Department of Veterans Affairs (VA) Medical Centers patient populations: Access to patient populations from 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 who do not have an appointment at one of the VA Medical Centers, must include a collaboration with a VA investigator. This collaborator must be willing to assume the role of PI for the VA component of the research. In such situations, PIs will be required to submit a letter of collaboration (see Attachment 2., Section g. in Application Instructions/General Information) signed by the collaborating VA investigator.

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 (ORP), HRPO, in addition to local 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 review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects. Refer to the Application Instructions & General Information, Appendix 6, for detailed information.

D. Eligibility

Extramural investigators (as defined elsewhere in this Program Announcement) at any academic level (or equivalent) are eligible to apply. Young investigators including those in postdoctoral positions are strongly encouraged to apply. Refer to the Application Instructions and General Information, for general eligibility information.

E. Funding

Applications

- Maximum period of performance is **3** years.
- Maximum allowable funding for the entire period of performance is **$1,000,000** for direct costs. The applicant may request the entire maximum direct cost amount for a project that may require less than the maximum period of performance.
- Regardless of the period of performance proposed, the maximum direct cost cannot be exceeded. In addition to the direct costs, indirect costs may be proposed in accordance with your institution's negotiated rate agreement. In the event that it is determined that the FY10 Appropriations Act limits the indirect cost rate, a revised budget will be necessary prior to award.

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

- Salary
- Research supplies
- Equipment
- Clinical research costs (Clinical trials will not be supported)
- Research-related subject costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions
- Other direct costs as described in Application Instructions and General Information for the Detailed Budget and Justification.

Each PI must request travel funds to attend one program review per year during the award period of performance. For planning purposes, it may be assumed that program reviews will be held in the Washington, DC – Baltimore, Maryland, metropolitan area.

Funding in response to this Program Announcement/Funding Opportunity is contingent on the availability of federal funds. Dollar amounts in this Program Announcement/Funding Opportunity are approximate and subject to realignment. Finally, the Government expects to award a portion of the total amount through this extramural Program Announcement/Funding Opportunity; the remaining funds will be awarded through a companion intramural Program Announcement/Funding Opportunity. The number of extramural applications that will be funded will be determined based on the quality and number of intramural and extramural applications received.

Resultant awards will be funded in accordance with the availability of funds.

The DMRDP expects to fund approximately 40-50 intramural and extramural Basic Research Awards, depending upon the quality and number of proposals received. This announcement is intended for extramural investigators. A separate announcement will be released for intramural investigators. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

F. Award Administration

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

II. TIMELINE FOR SUBMISSION AND REVIEW

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

Pre-application Submission Deadline:	**December 10, 2009, 5:00 p.m. Eastern time**
Invitation to Submit Full Proposal:	**By January 15, 2010**
Proposal Submission Deadline:	**February 17, 2010, 11:59 p.m. Eastern time**
Scientific peer review:	**April 2010**
Programmatic Review:	**June 2010**

Awards will be made approximately 4 to 6 months after receiving the funding notification letter.

III. SUBMISSION PROCESS

The proposal process for the DMRDP Basic Research Award is being administered by the USAMRMC CDMRP. Proposal submission is a two-step process consisting of (1) a pre-application submission through the US Army Medical Research Acquisition Activity (USAMRAA) website at http://www.usamraa.army.mil/dmrdp.cfm and (2) a proposal submission through Grants.gov (http://www.grants.gov/). Applications will be invited based on pre-application screening.

PIs and organizations identified in the proposal submitted through Grants.gov must be the same as those identified in the pre-application. If there are extenuating circumstances that lead to a change in PI or organization after submission of the pre-application, the PI must contact the help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative proposals submitted to different award mechanisms within the DMRDP.

A. Step 1: Pre-application Components, Submission, and Screening

Pre-application submission is the required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the USAMRAA website at http://www.usamraa.army.mil/dmrdp.cfm by ***5:00 p.m. Eastern time on the deadline***. Refer to the Application Instructions and General Information for detailed information.

As the pre-application package for this award mechanism uses Adobe Acrobat forms, you must have a version of Adobe Acrobat that is compatible with our pre-application receipt system.

Currently, Adobe Acrobat versions 9.0, 9.1, 9.11, 9.12, and 9.2 are not compatible for the submission of the pre-application package. FAILURE TO USE ONE OF THE COMPATIBLE VERSIONS (EXCLUDING ADOBE ACROBAT VERSIONS 9.0, 9.1, 9.11, 9.12, and 9.2) FROM THE LINK AT http://www.grants.gov/help/download_software.jsp WILL RESULT IN REJECTION OF YOUR PRE-APPLICATION.

If you collaborate on the pre-application package with your peers, you must ensure they also have a compatible version of Adobe Acrobat.

Compatible versions of Adobe Acrobat are available for downloading at no cost on the Grants.gov website however it should again be noted that Adobe Acrobat versions 9.0, 9.1, 9.11, 9.12 and 9.2 are not compatible for submission of the pre-application.

http://www.grants.gov/help/download_software.jsp

- **Proposal Information:** Because the invitation to submit an application is based on the contents of the pre-application, investigators must not change the title, research objectives, personnel, or the FY10 DMRDP Project/Task in the pre-application submission after the pre-application is submitted. However, if extenuating circumstances make changes after the submission of the pre-application necessary, the PI must contact the help desk at help@cdmrp.org or 301-682-5507. Such requests will be evaluated on a case-by-case basis and at the discretion of the US Army Medical Research and Materiel Command (USAMRMC) Contracting Office.
- **Proposal Contacts:** Refer to the Application Instructions and General Information for details.
- **Conflicts of Interest (COI):** To avoid COI during the pre-application screening and review processes, list the names of all scientific participants, including collaborators, consultants and subawardees.
- **Preproposal Form**: The preproposal data will be reported on the Preproposal Form. This data collection form is a PDF file that can be edited and saved using Adobe Acrobat Reader. The form consists of Sections 1-8. Details on each section are provided below:
    - **Section 1 – Proposal Information**

    Enter the name of the PI (i.e., the individual responsible for the overall scientific and technical direction), the preproposal title, and the log number assigned by the eReceipt system. Enter the DMRDP Project and Task (from Section I.C.) that this application addresses.

    - **Section 2 – Specific Hypothesis/Aims (Problem to be studied; limited to 2,300 characters, including spaces)**

    Clearly state the specific objectives of the work proposed, including the hypothesis to be evaluated and an explanation of the military relevance of the work; that is, how the work addresses the selected project and task identified in the Program Announcement/Funding Opportunity.

    - **Section 3 – Scientific Rationale (limited to 2,300 characters, including spaces)**

    Describe the scientific rationale for the research project, including a brief description of previous studies or preliminary data (if available) that support the feasibility of the proposed work.

- **Section 4 – Approach/Methods (limited to 2,300 characters, including spaces)**

  Briefly describe the experimental design, methods, and materials that are planned to accomplish the proposed research. For human studies, this should include a description of the size and characteristics of the subject population that will be employed.

- **Section 5 – Duration of Project to Be Studied**

  Enter the total duration of the proposed work in years and months (e.g., 2 years and 4 months).

- **Section 6 – Personnel and Budget Information**

  - Participating Personnel and Effort – List the PI, all associate investigators and collaborators (if any), their titles, organizations (institution or company name), role in the project (i.e., PI , associate investigator, collaborator), and planned annualized percent of effort over the duration of the award.
  - Estimated Budget by Fiscal Year – Enter the total direct costs planned for each year of work that is proposed, to include pay and benefits for individuals contributing toward the project, equipment purchases, and any other direct costs such as supplies and materials , purchased services, and travel.

- **Section 7 – Animal and Human Use**

  Check the appropriate boxes to indicate whether the proposed work involves animal and/or human studies. The USAMRMC ORP must review all research involving animals, human anatomical substances, and human subjects as described later in this announcement.

- Section 8 – Quad Chart (note details following Section)

Pre-Application Supporting Documentation

Quad Chart: This data collection form is a PDF file that can be edited and saved using Adobe Acrobat Reader. Details on each section are provided below:

- Problem and Military Relevance – Provide a bulleted summary of the problem addressed and its relation to the Project and Task described in the Program Announcement/Funding Opportunity, based on Section 2 of the preproposal.
- Proposed Solution – Provide a bulleted summary of the objectives of the work based on Section 4 of the preproposal.
- Picture – Insert a picture or other graphic that is representative of the work to be performed; this may, for example, show some aspect of the research to be performed, the expected technology outcome of the work, or the military problem that is being addressed.
- Timeline and Cost – Identify at a high level the major planned activities or phases of the work and their duration on the chart provided, and provide the estimated direct costs by year.

- Include the Project and Task titles as a subtitle on the quad chart.

Pre-Application Screening: Pre-applications will be screened by one of five Expanded Joint Technology Coordinating Groups (EJTCGs) that span the various areas of DMRDP interest, composed of research program managers, scientists, clinicians, and representatives of the military user community. The pre-application screening criteria are as follows:

- **Specific Hypothesis/Aims:** Whether the hypothesis/aims address a military-relevant health problem responsive to one of the Projects and Tasks outlined in the Program Announcement/Funding Opportunity and the potential contribution that the study could make, if successful.
- **Scientific Rationale:** Whether the scientific rationale logically supports the Project and its feasibility.
- **Approach/Methods:** Whether the experimental design, methods, subject populations, data collection procedures, and analytical methods are appropriate for the specific hypothesis/aims of the study.
- **Estimated Budget:** Whether the estimated direct costs are consistent with the funding limits for awards and appears consistent with the scope of work to be performed.

B. Step 2: Application Components and Submission

Application submission will not be accepted unless a pre-application was submitted by the pre-application deadline and the PI was invited to submit a full proposal. Applications must be submitted electronically by the Authorized Organizational Representative through Grants.gov (www.grants.gov).

Because the invitation to submit an application is based on the contents of the pre-application, investigators must not change the title, research objectives, personnel, or the FY10 DMRDP Project/Task in the pre-application submission after the pre-application is submitted. However, if extenuating circumstances make changes after the submission of the pre-application necessary, the PI must contact the help desk at help@cdmrp.org or 301-682-5507. Such requests will be evaluated on a case-by-case basis and at the discretion of the US Army Medical Research and Materiel Command (USAMRMC) Contracting Office.

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. Extramural submitters must provide a letter from all collaborating investigators who are named in the proposal and the Commander or Commanding Officer of any intramural collaborator (as defined elsewhere in this announcement) that authorizes the collaborator's participation in the research effort.

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition

Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (6-page limit.)**

     Throughout the Project Narrative, describe how the proposed research is innovative and the potential impact it may have on protection or sustainment of military health. Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. Describe the proposed project using the following outline:

     - **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims to be funded by this proposal.
     - **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Describe the statistical plan, if appropriate, for the research proposed. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples and statistical plan.

   - **Attachment 2: Supporting Documentation**
     - References Cited
     - Acronyms and Symbol Definitions
     - Facilities & Other Resources
     - Description of Existing Equipment
     - Publications and/or Patent Abstracts (Five-document limit)
     - Letters of Institutional Support (Three-page limit per letter)
     - Letters of Collaboration (if applicable) (two- page limit per letter)

       Provide a signed letter from each collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed work.

If the collaborator is a DOD intramural investigator, as defined in section 1.B. Award Description, a letter from the Commander or Commanding Officer of the intramural collaborator, that authorizes the intramural collaborator to participate in the research, is required.

- Conflicts of Interest
- Intellectual and Material Property Plan (if applicable)

- **Attachment 3: Technical Abstract (One-page limit)**
- **Attachment 4: Public Abstract: (One-page limit)**
- **Attachment 5: Statement of Work (SOW) (Three-page limit)**
- **Attachment 6: Detailed Budget and Justification**
- **Attachment 7: Impact and Innovation Statement (One-page limit)**

Describe the ultimate vision for how the proposed work, if successful, will accelerate the delivery of new solutions for the military operational community to prevent and treat military-relevant injuries and diseases, or new information technologies to improve patient care and the training of military healthcare providers.

Describe how the proposal is innovative**.** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. The following list, although not all-inclusive, provides examples of research that is ***not*** innovative:

- Proposing a project whose scope is primarily small molecule or genomic/ proteomic screening.
- Exploring a previously tested hypothesis in a different cell line or in a new population.
- Using a published series of in vitro assays to further characterize a model system.
- Investigating the next logical step or continuation of a previous research project.
- Proposing work that is an incremental advancement of published data.

- **Attachment 8: Federal Agency Financial Plan (if applicable).** Refer to Application Instructions and General Information for detailed information**.**
- **Attachment 9: Request for Information on Study Population (if applicable; four-page limit).** Refer to Application Instructions and General Information for detailed information.
- **Attachments 10-14: Subaward Detailed Budget and Justification (if applicable)**

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

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

- Key Personnel Current/Pending Support

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

IV. INFORMATION FOR APPLICATION REVIEW

A. Preproposal and Proposal Review, and Selection Overview

All preproposals will be reviewed for programmatic and basic scientific relevance by one of five EJTCGs that span the various areas of DMRDP interest. This review will be used to determine which investigators will be invited to submit full proposals. Invited full applications will be evaluated for both scientific excellence and programmatic/relevance using a two-tiered review process. The first review (conducted by independent contract scientists) consists of a scientific peer review of applications against established criteria for determining scientific merit. The second review (conducted by the EJTCGs) is a programmatic review that compares submissions to each other and recommends proposals for funding based on military need, scientific merit, and overall goals of the research program.

The scientific peer 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 corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to influence the evaluation process . Violation of these prohibitions will result in the administrative withdrawal of the application. Actions by panelists or PIs that compromise the confidentiality of the scientific peer 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., Innovation and Impact Statement).

B. Review Criteria

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

- **Innovation**
  - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.
  - How the proposed research is a new research idea and not the next logical step or continuation of a previous research project.

- How the proposed research represents more than an incremental advance upon published data.

- **Military Impact**
  - How the research, if successful, might make a significant contribution toward the resolution of a military health or performance problem.
  - How the potential gain warrants the perceived risk.
- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and/or by logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed work.
  - How the levels of effort are appropriate for successful conduct of the proposed work.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources.
  - How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
  - How the budget is appropriate for the proposed research.
- **Application Presentation**
  - How the writing and components of the application influenced the review.

Programmatic Review: Scientifically sound proposals that best fulfill the following criteria and most effectively address the projects and tasks listed in this funding opportunity will be identified by an EJTCG, and the group's recommendations for funding will be forwarded to the Director of the DMRDP for approval. Criteria 1-4 are listed in order of descending importance with Criteria 1 and 2 of equal importance.

Criteria used by the EJTCG members to make funding recommendations include:

1. **Responsiveness to Research Projects and Tasks**
   - How well the proposed study meets the DMRDP's identified tasks within the project addressed, if successful.
   - How well the proposed study advances scientific knowledge within the tasks identified in the program announcement.
   - Whether the proposed research is a duplication of effort funded by DOD or other agencies.

2. **Programmatic Relevance in Terms of Military Impact**
   - The potential impact of the results of the proposed project, if successful, on understanding or solving a military problem.

3. **Ratings and Evaluations of the Scientific Peer Reviewers**
   - Scientific merit of the proposed project will be considered in the context of the programmatic review and compared to all eligible proposals under consideration.

4. **Portfolio Balance**
   - How well the proposed study contributes to ensuring an overall balance of research and development efforts.

V. ADMINISTRATIVE ACTIONS

After receipt of the pre-applications from the USAMRAA website and the applications from Grants.gov, they will be administratively reviewed for inclusion of appropriate components in accordance with this Program Announcement/Funding Opportunity. If components are missing or not appropriate, the following administrative actions may occur. These administrative actions are taken to ensure fairness to all submitting investigators and to provide the same information to scientific peer and programmatic reviewers for all submitted applications.

A. Pre-Application (Pre-proposal)

- **Rejection**: The following **WILL** result in administrative rejection of the pre-applications:
  - Any of Sections 1-4 of the 8-part Preproposal Form are missing
  - Budget information is missing
  - QUAD chart is blank or not submitted
  - Inclusion of URLs, with the exception of links to published references.

- **Modifications:**
    - Documents not requested will be removed.
    - Following the pre-application deadline, you may be contacted via email with a request to provide certain missing information (excluding those listed directly above in "Rejection"). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the pre-application will be reviewed without the missing information.
- **Withdrawal**: The following **WILL** result in administrative withdrawal
    - Pre-application is submitted by an intramural investigator

B. Application (Proposal)

- **Rejection:** The following **WILL** result in administrative rejection of the entire application:
    - Project Narrative exceeds page limit.
    - Project Narrative is missing.
    - Budget is missing.
    - Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59cm x 27.94cm).
    - Submission of an application for which invitation was not received.
    - Direct costs as shown on the detailed budget form exceed the maximum allowed by this award mechanism.
    - Inclusion of URLs, with the exception of links to published references.
- **Modifications**
    - Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
    - Documents not requested will be removed.
    - Following the application deadline, you may be contacted via email with a request to provide certain missing supporting documents (excluding those listed directly above in "Rejection"). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.
- **Withdrawal:** The following WILL result in administrative withdrawal of the application:
    - The proposed research project is not relevant to the FY10 DMRDP Projects/Tasks advertised this Program Announcement/Funding Opportunity.
    - The application is submitted by an intramural investigator.

- The proposed research project is or contains a clinical trial.
- Following the application deadline, you may be contacted via email with a request to provide the Commander's/Commanding Officer's letter (for intramural collaborator). If this letter is not submitted within 30 days of the date and time the email was sent, the application will not be forwarded for review.

C. Withhold

Applications that appear to involve 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 USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement, proposal format, or required documentation: Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

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

B. Pre-application Questions: Issues related to pre-applications should be directed to the help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507
Website: https://cdmrp.org
Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the help desk is unable to answer questions about Grants.gov submissions.

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

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link 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.