PROGRAM ANNOUNCEMENT

Defense Medical Research and Development Program

Fiscal Year 2010 Intramural Basic Research Award

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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 Concept of Operations, 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. 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 toward 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 also will 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.

Use of Human Subjects and Human Biological Substances: Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]) or are a minimal risk addendum to a current Institutional Review Board (IRB)-approved protocol. ***Studies that do not meet these criteria will be administratively withdrawn and will not be funded.*** For studies using only commercially available unidentified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the U.S. Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office web site (https://mrmc.amedd.army.mil/rodorphrpo.asp).

This announcement is intended only for intramural investigators. Other announcements were released for extramural investigators. An ***intramural*** investigator is defined as a Department of Defense (DoD) employee working within a DoD laboratory.

The DMRDP anticipates that approximately $8–$10 million (M) will be available to support intramural basic research. The government reserves the right to increase or decrease the approximately $8–$10M 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 as follows. 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 other than those listed 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 military-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:

<u>Diagnosis and Treatment of Brain Injury</u>

- **Traumatic Brain Injury (TBI).** Studies of mechanisms and systematics of the whole spectrum of TBI to include: physiologic impact of dehydration and overhydration on progression of secondary injury; characterization and comparison/contrast of cerebral spinal fluid and serum biomarkers in animal models of impact and blast-related mild TBI (mTBI); development of a valid, scalable blast and mTBI model in rodents; characterization of pupillary response and abnormalities post-blast exposure, in association with blast-related TBI; studies in valid rodent models of repeated mTBI to characterize the pathophysiology and time course of chronic traumatic encephalopathy; characterization of the hypothalamic-pituitary-adrenal axis after non-impact, blast-induced mTBI; characterization of sleep–wake cycles and behavior as well as the role of orexin/hypocretin and melatonin in mTBI in sleep-deprived and normal rodents.

<u>Polytrauma and Blast Injury</u>

- **Hemorrhage Control.** Research into changes in platelet function following trauma and the relative role of platelet dysfunction in trauma-associated coagulopathy. Research into potential methods to modulate the early post-trauma inflammatory response to traumatic hemorrhage and/or ischemia/reperfusion injury.
- **Wound Infection Prevention and Management.** Basic research directed toward identification and characterization of biomarkers associated with immune response and/or predictive of infection/wound closure or early detection of antimicrobial resistance; identification of nosocomial pathogens and mitigation of contamination in the military medical environment (e.g.,

ozone, vaporized hydrogen peroxide, phage, chitosan, and chlorine dioxide); and development of an in vivo polytrauma/blast wound infection model.

- **Antimicrobial Countermeasures.** Basic research directed toward identifying virulence factors and/or metabolic pathways associated with wound infection pathogens (e.g., *Acinetobacter*, *Pseudomonas aeruginosa*, MRSA (methicillin-resistant *Staphylococcus aureus*), ESBL (extended spectrum beta lactamase)-producing *Klebsiella pneumoniae*), including characterization and mitigation of biofilm formation. Preference will be for discoveries with applicability to polymicrobial infections to combat wound infections. Novel treatment approaches (e.g., chelators, antibody, phage, antimicrobial peptides, quorum-sensing inhibitors, lysine, and host immunoaugmentation including antibody) are encouraged. Proposals incorporating drug screening, including high-throughput screening and in silico modeling, are discouraged.

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 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.
- **Radiation Biology Modeling.** Basic research leveraging bioinformatics and computational modeling to analyze molecular and cellular signaling pathways and complex physiologic data sets in conjunction with studies aimed at advancing knowledge of molecular, cellular, tissue, and organ structure-function relationships associated with ionizing radiation, both early affects (ARS) and late affects as with fibrosis and cancer treatment. This research should lead to discovery of novel biomarkers of ionizing radiation damage and advance understanding of mechanisms both causing and involved in repairing (i.e., therapeutics) genomic and structural damage to include those involving ionizing radiation alone and complicated by the presence of additional traumas such as wounds, burns, and infection. In cases of infection from various microbial pathogens due to high-dose ionizing radiation, research will aim to advance understanding of mechanisms affecting microbial viability, antigenic characteristics, and virulence factors.
- **Research in Internal Contamination.** Basic research in the area of internal contamination to advance knowledge of the biochemical and molecular mechanisms of cells in response to exposure to military-relevant metals and metal mixtures, radioactive and nonradioactive. This research, using a variety of biochemical, molecular, and proteomic approaches, will advance understanding of mechanisms by which cells respond to and repair metal-induced damage and provide a sound scientific basis for future work on treatment of individuals with injuries from embedded metal fragment or ingested/inhaled materials.

Rehabilitation

- **Sensory System Traumatic Injury (Vision, Hearing, and Balance).** Basic research to advance our knowledge on the mechanism of tinnitus, the effect of blast on vestibular structures and dysfunction, and to understand visual dysfunction and photophobia following TBI.

- **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 discovery of pain biomarkers.

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, and enhancement of traditional training); and fundamental mechanisms of family and community resilience programs and the maintenance of strong relationships during deployment/extended separation.

D. Eligibility

Intramural investigators (defined as a DoD employee working within a DoD facility) at any academic level (or equivalent) are eligible to apply. Young investigators including those in postdoctoral positions are strongly encouraged to apply.

E. Funding

The maximum period of performance must end 30 September 2011.

The maximum allowable funding for the entire period of performance is **$500,000**, including direct and indirect costs. The applicant may request the entire maximum cost amount for a project that may require less than the maximum period of performance.

Regardless of the period of performance proposed, the maximum cost cannot be exceeded. Note: Section 8115 of the FY08 DoD Appropriations Act prohibits the use of DoD basic research appropriations provided in the Act for any contract, grant, or cooperative agreement with negotiated indirect cost rates in excess of 35%. This same restriction is expected to be enacted with the National Defense Authorization Act for FY10.

Proposal funding in response to this announcement is contingent on the availability of federal funds. Additionally, amounts in this announcement are approximate and subject to realignment. The number of intramural proposals that will be funded will be determined based on the quality and number of intramural proposals received.

Principal Investigators (PIs) awarded funding through this announcement must ensure that funds are obligated by 30 September 2011 per this announcement. Because funds may not be received until at least June 2010, and possibly as late as July 2010, PIs should plan the activities to be performed in such a way that funds can be effectively utilized by 30 September

2011. Any funding that is not obligated by 30 September 2011 may be withdrawn by the issuing comptroller. The *Budget Sections* of the research proposal require the PI to fully articulate, *by year and cumulatively*, the budgetary requirements to obligate the total amount of funding requested throughout the entire period of performance. The reasonableness of the budget and plan to obligate the funds, if awarded, are part of the proposal submission and review process.

Multi-Institutional Studies

If the proposed study is multi-institutional (i.e., involving several DoD institutions), 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 will be required for multi-institutional studies if the PI is awarded funding. Proposals involving collaboration with a non-DoD institution must be submitted under a separate DMRDP announcement for extramural research.

The DMRDP expects to fund approximately 16–20 intramural Basic Research Awards, depending upon the quality and number of proposals received. This announcement is intended for intramural investigators. A separate announcement was released for extramural investigators. Funding of proposals received in response to this Program Announcement/ Funding Opportunity is contingent on the availability of federal funds for this program.

II. TIME LINE FOR SUBMISSION AND REVIEW

Proposal Submission Deadline:	4 May 2010, 5:00 PM eastern time
Peer and Programmatic Review:	June 2010

III. SUBMISSION PROCESS

Overview of Proposal Approval Process

The proposal submission and approval process is sequential in nature and consists of the following:

1. Proposal submission
2. Compliance review
3. Combined scientific peer and programmatic reviews by the Joint Program Committees (JPCs) that culminate in funding recommendations to the Director, DMRDP
4. Written notification to PI of proposal funding recommendation

PIs will be notified electronically as to whether their proposal was approved or disapproved for funding through this intramural announcement. Formal notification will occur by letter from the Commanding General, USAMRMC, to the PI's Commander/Commanding Officer or Officer-in-Charge.

If you have any additional questions about the proposal submission process or encounter any difficulties in navigating the web site, please contact the web team via e-mail at webteam@amedd.army.mil or by phone 301-619-9832.

Proposal

The proposal will be created within the new DMRDP web site and it will consist of the components described below. All proposal components must be submitted electronically through the DMRDP web site (https://dmrdp.amedd.army.mil/ login.jsp) by ***5:00P.M. eastern time on the deadline***. Users first entering the DMRDP web site will be required to complete a user registration form. Follow the on-screen instructions. Users who have a valid .mil e-mail address will receive an auto-generated e-mail message containing their user ID and password.

To initiate a proposal, follow these instructions:

- Go to the DMRDP web site home page and log in.
- Click on the link to the Proposal Template document and download the document to your computer. Also click on the Quad Chart template and download the PowerPoint document to your computer. Please fill these documents out in their entirety before proceeding. Click on the [View Topics and Submit Proposal] button **(THIS FEATURE WILL NOT BE AVAILIBLE UNTIL MONDAY, APRIL 12, 2010.)**
- Use the drop-down menu to select the appropriate project of interest (e.g., Polytrauma and Blast Injury)
- A list of the relevant tasks for the selected project will be displayed. Under the task of interest, select [Create Proposal] button.
    - The submission of your proposal will take place in four steps which include: proposal data, organizational data, budget data, and the upload of the proposal document and the Quad Chart PowerPoint document.
    - On the main page (https://dmrdp.amedd.army.mil/home.jsp) you can click on the PowerPoint document (Submission screen captures.ppt), so that you can print out the document. This document will give you an idea of what information will be captured during the web form data collection process.
- **Step 1**: Displayed is a web form that collects information about your proposal. You will notice an auto-generated proposal number. Please include this number in your proposal document before uploading (step 4). Data will be validated as you are filling in information. Please note that you must enter this data directly into the on-line form - you cannot upload as a separate document. At the bottom of the page you will see 2 buttons [SAVE] and [SAVE AND CONTINUE]. The [SAVE] button will allow you to save the information that you have filled in on the entire page to the system. This will allow you to complete the entire process in stages. The [SAVE AND CONTINUE] button will allow you to save the information that you have filled in on the entire page to the website and then continue to step 2.
- **Step 2**: Displayed is a form to capture organization information. Please input all primary and secondary organizations that pertain to your proposal. For further information please see the on screen instructions. At the bottom of the page you will see 2 buttons [SAVE] and [SAVE

AND CONTINUE]. The [SAVE] button will allow you to save the information that you have filled in on the entire page to the website. This will allow you to complete the entire process in stages. The [SAVE AND CONTINUE] button will allow you to save the information that you have filled in on the entire page to the website and then continue to step 3.

- **Step 3**: Displayed is a form to capture all budget information. Please input all relevant budget information into this web form. For further information please see the on screen instructions. At the bottom of the page you will see 2 buttons [SAVE] and [SAVE AND CONTINUE]. The [SAVE] button will allow you to save the information that you have filled in on the entire page to the website. This will allow you to complete the entire process in stages. The [SAVE AND CONTINUE] button will allow you to save the information that you have filled in on the entire page to the website and then continue to step 4.
- **Step 4**: This page allows the user to upload supporting documents, quad chart, and the proposal document (MS Word saved as PDF) that has been previously filled out. ***Please remember to include the proposal id that was auto generated in step 1 in the quad chart and proposal document as well as within any supporting document.*** To complete the submission of your DMRDP proposal please click the [COMPLETE] button.

  Please Note: Once you have clicked the [COMPLETE] button, you cannot make any changes to your proposal.

Step 1 Breakdown

Section I – Proposal Information

- Complete each required field for the Proposal
  - The Proposal Title: The Title should be brief and should reflect the content of the Proposal.
  - Project Start Date and Project End Date: The dates that the project will begin and end.
  - Keywords: Enter at least three and up to eight keywords of your choice that describe the content of the proposal. Please, separate each keyword with a comma.

Applicant Information

- Complete each required field for the Applicant, the individual responsible for adding the proposal to the website.

Primary Contact Information

- Complete each required field for the organization - the individual to contact concerning this proposal.

Principal Investigator Information

1. Complete each required field for the organization - the individual responsible for the overall scientific and technical direction

Section II – Questions

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

Section III – Proposal Summary/Abstract

– The summary/abstract is to be no longer than 250 words and must briefly capture the essence of the proposal.

Step 2 Breakdown –

Section IV – Project/Performance Site Location(s)

– Include organization of the primary and any secondary site locations.

Step 3 Breakdown –

Section V – Budget

- Use the on-line budget pages to enter your proposal budget information.
  - Estimated Budget by Fiscal Year – Provide a breakdown of the planned budget for each year proposed as follows:
    - Civilian Pay and Benefits (U.S. Government Employees/Foreign Service Nationals): Based on the percent of effort an individual is contributing toward the project multiplied by the sum of his/her base salary and benefits.
    - Equipment: Include all planned equipment purchases.
    - Other: Enter the total for any other costs not included in the above two categories. Such costs may include supplies and materials, institutional overhead costs, purchased services, and travel.
    - Use of Purchased Services *[limited to 1,000 characters]* – If the proposed work will require the use of purchased services, provide a description of the services that will be purchased and list the contract number(s) for each contract that will be employed. If no purchased services will be required, enter "None." **Note: See Section I.D, Eligibility: services purchased from non-DoD organizations may only be obtained through existing contracts.**

Step 4 Breakdown –

Include the following in the Proposal Document to be uploaded as a PDF file. Please include the Proposal number, the Proposal Title and the PI at the top of this document for reference purposes.

Section VI

– *Specific Hypothesis/Aims (Problem to Be Studied) [***1-page limit***]*

– 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.

– *Scientific Rationale* **[1-page limit]**

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

– *Approach/Methods* [**1-page limit**]

– Briefly describe the experimental design, methods, and materials that are planned to accomplish the proposed research.

Section VI - Bibliography and References Cited (No page limit)

– List all cited references. The inclusion of Internet URLs to references is encouraged.

Section VII Facilities & Other Resources (No page limit)

Section VIII Equipment (No page limit)

Section IX Acronyms And Symbol Definitions (As Applicable) (No page limit)

Section X Statement of Work (Not to exceed 3 pages)

Section XI Identification Of Senior/Key Personnel And Biographical Sketch (Not To Exceed 4 Pages Per Individual)

Section XII Pi Current/Pending Support (No Page Limit)

- Provide the following information for each individual identified as a Senior/Key Person in Section XI.

Section XIII – Quad Chart (Use the template contained in Step 4 PowerPoint file)

– Using the provided template, enter the title of your proposal, enter a subtitle consisting of the task title from Section I.C., and complete the following four sections of the quad chart:

- 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 based on Section 7 of the proposal.
- Proposed Solution – Provide a bulleted summary of the objectives of the work based on Section 7 of the proposal.
- Picture – Insert a picture or other graphic that is representative of the work to be performed; for example, this may show some aspect of the research to be performed, the expected technology outcome of the work, or the military problem that is being addressed.
- Time Line 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 total (direct plus indirect) budget by year.

IV. INFORMATION FOR APPLICATION REVIEW

A. Proposal Review and Selection Overview

All proposals will be evaluated for both scientific excellence and programmatic/relevance by the JPC. The first review consists of a scientific peer review of applications against established criteria for determining scientific merit. The second review 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 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 corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to influence the evaluation process. Actions by panelists or PIs that compromise the confidentiality of the scientific peer and programmatic review processes also may 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.

B. Review Criteria

Review Criteria for Proposals

The 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 costs are consistent with the funding limits for award and appear consistent with the scope of work to be performed.

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 a JPC, 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 JPC 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 the 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. FORMATTING GUIDELINES

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 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

VI. ADMINISTRATIVE ACTIONS

After receipt, the applications 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. Application (Proposal)

- Rejection: The following **WILL** result in administrative rejection of the application:
  - Project narrative exceeds page limit.
  - Project narrative is missing.
  - Budget is missing.
  - Quad chart is blank or missing.
  - Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
  - 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 e-mail 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 e-mail 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 in this Program Announcement/Funding Opportunity.
  - The application is submitted by an extramural investigator.
  - The proposed research project is or contains a clinical trial.

B. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation.

VII. CONTACT INFORMATION

Applicants should 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.

Program Announcement, Proposal Format, or Required Documentation: If you have questions about the Program Announcement, proposal, or required documentation, please contact Dr. Farrukh Rizvi.

Phone: 301-619-8361
E-mail: Farrukh.Rizvi@amedd.army.mil

Proposal Submission Process or Difficulties in Navigating the Web Site: If you have any questions about the proposal submission process or encounter any difficulties in navigating the web site, please contact the DMRDP web team.

Phone: 301-619-9832
E-mail: webteam@amedd.army.mil

APPENDIX 1

RESEARCH PROGRESS REPORTS

Reporting requirements may consist of quarterly, biannual, and final reports. These reports will present a detailed summary of scientific issues and accomplishments toward stated milestones. A final report will be submitted within 30 days of the end of the award period and will detail the findings, their potential impact to the Warfighter, and other issues for the entire project. Copies of all scientific publications, presentations, and reports resulting from this funding mechanism shall be submitted when published or completed even if beyond the period of performance to allow reporting to Congress on the accomplishments of the program. Funds must be obligated by Principal Investigators no later than 30 September 2011. Investigators whose research efforts extend beyond the approved period of performance should request a no-cost extension of the effort. The reporting requirement will remain in place as needed.

APPENDIX 2

RESEARCH INVOLVING THE USE OF ANIMALS, HUMAN SUBJECTS, OR HUMAN ANATOMICAL SUBSTANCES/HUMAN DATA

Principal Investigators (PIs) and partnering organizations may not use, employ, or subcontract for the use of any human participants, 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 U.S. Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense regulations are met.

Additionally, ***studies involving animals and studies that meet the definition of non-exempt human subjects research (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances)***, must be approved through a regulatory review process by the PI's local Institutional Animal Care and Use Committee and/or Institutional Review Board (IRB) **and** by the Office of Research Protections (ORP) at USAMRMC. For animal research, the ORP office responsible is the Animal Care and Use Review Office (ACURO), and for all research involving human subjects the Director, ORP will designate either the ORP Clinical Investigations Regulatory Office or ORP Human Research Protection Office as the responsible office. ***Exempt human subjects research*** needs a determination from the PI's local IRB **as well as** the ORP at USAMRMC.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the proposal is selected for funding (these documents should not be submitted with the proposal). The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must complete and submit the animal use appendix entitled "Research Involving Animals," which can be found on the ACURO web site (https://mrmc-www.army.mil/rodorpaurd.asp). PIs should allow 2 to 4 months for regulatory review and approval processes for animal studies.

Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

2. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

All DoD-funded research involving human subjects and human biological substances must receive a headquarters-level administrative review (HLAR) and be approved by the USAMRMC ORP in addition to local IRBs. The ORP 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 may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the recommendations of HLAR must be addressed and approved by the local 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.

Documents related to the use of human subjects or human anatomical substances will be requested if the proposal is selected for funding (these documents should not be submitted with the proposal). ***PIs should allow at least 6 months for regulatory review and approval processes for studies involving human subjects.***

a. Requirements: Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/rodorptoolkit.asp.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at https://mrmc.detrick.army.mil/rodorphrpo.asp.

b. Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

c. Intent to Benefit: PIs must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; http://www.dtic.mil/biosys/downloads/title10.pdf. 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."

Note: This statute is only applicable to certain intervention studies. 10 USC 980 does not apply to retrospective studies, observational studies, blood draws, and tissue collections. Contact ORP for further clarification regarding applicability of 10 USC 980 to your specific protocol.

All questions relating to research involving both animals and human subjects should be directed to Dr. Laura Brosch, R.N., Ph.D., Director, ORP, at 301-619-7802.