Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Concept Award for Genetic Cancer Research or Non-invasive Cancer Ablation Research only

Funding Opportunity Number: W81XWH-09-PRCRP-CA

Table of Contents

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Peer Reviewed Cancer Research Program (PRCRP) is new for fiscal year 2009 (FY09). Congress appropriated funds for research into cancers not addressed by the Breast Cancer Research Program (BCRP), the Prostate Cancer Research Program (PCRP), or the Ovarian Cancer Research Program (OCRP), which are executed and managed by the Congressionally Directed Medical Research Programs (CDMRP). The total FY09 appropriation for the PRCRP is $16 million (M).

The goal of the PRCRP is to improve quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. The PRCRP fosters groundbreaking research, team science, and partnerships for the development of better prevention against, earlier detection of, and more effective treatments for cancer. PRCRP funds appropriated by Congress are directed for research in the following areas:

- $4M for research of melanoma and other skin cancers as related to deployments of service members to areas of high exposure;
- $2M for research of pediatric brain tumors within the field of childhood cancer;
- ***$8M for genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle;***
- ***$2M for non-invasive cancer ablation treatment research, including selective targeting with nanoparticles.***

B. Award Description

The PRCRP Concept Award supports the exploration of a highly innovative new concept or untested theory. The Concept Award is not intended to support a logical progression of an already established research project but, instead, supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Research completed through a Concept Award may provide sufficient preliminary data to enable the Principal Investigator (PI) to prepare a proposal for future research.

Presentation of preliminary data is not allowed. However, a rationale for the work must be provided.

For FY09, the Concept Award is being offered in two congressionally directed topic areas: (1) Noninvasive cancer ablation research including selective targeting with nano-particles, and (2) genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle. ***No other topic areas will be allowed***. ***Proposals must not address breast, prostate, or ovarian cancer research.*** Focus Areas for each of the two topic areas are provided in this Program Announcement/Funding Opportunity. ***Applications to the FY09 PRCRP Concept Award will be rated on their responsiveness to the following Focus Areas for each of the two topic areas***.

Focus Areas for Genetic Cancer Research:

- Identification and characterization of changes in gene structure and/or gene expression resulting from physical, biological, or chemical exposures and stressful environments that, alone or in concert, are known or suspected to increase cancer risk. Although not all inclusive, hazards encountered by the military population include:
  - Radiation (UV and other radiation sources)
  - Biological Agents
  - Chemicals
  - Physical and Psychological Stress
  - Other Environmental Conditions (e.g., noise, heat, altitude)
- Investigation of biological pathways involved in carcinogenic mechanisms which are affected by military exposures
- Investigation of the trans-generational cancer risk of military exposures
- Evaluation of differences in genetic susceptibility to cancer among ethnic groups affected by military exposures

Focus Areas for Noninvasive Cancer Ablation:

- Development of approaches for deep organ access for ablation technologies
- Validation of nanoparticle targeting

For applications in the topic area of Genetic Cancer Research, it is the responsibility of the applicant to clearly and explicitly articulate the project's military relevance.

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 either exempt under Title 32, Code of Federal Regulations (CFR), Part 219, Section 101(b) (32 CFR 219.101[b]) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Studies that do not qualify for either exempt or expedited status during review at any level will be administratively withdrawn and will not be funded. For studies using only commercially available or de-identified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (https://mrmc.amedd.army.mil/rodorphrpo.asp).

C. Eligibility

Investigators at all academic levels (or equivalent) are eligible to submit applications. Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **1** year.

- The maximum allowable funding for the entire period of performance is **$75,000** in direct costs.
- The applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the negotiated rate agreement of the applicant's institution.

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

- Salary
- Research supplies
- Clinical research costs ***(Clinical Trials are not permitted under this award mechanism)***
- Travel to scientific/technical meetings
- Travel between collaborating institutions

The PRCRP expects to allot approximately $1.3M of the $16.0M FY09 PRCRP appropriation to fund 11 Concept Awards applications, depending on the quality and number of applications received. Approximately 9 Concept Award applications in the topic area of genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle will be funded, for a total investment of $1.08M. Approximately 2 Concept Award applications in the topic area of noninvasive cancer ablation research including selective targeting with nanoparticles will be funded, for a total investment of $225,000. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

E. 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) application submission. ***Pre-application submission is a required first step***.

Pre-application Submission Deadline	**July 15, 2009, 5:00 p.m. Eastern Time (ET)**
Application Submission Deadline:	**July 30, 2009, 11:59 p.m. ET**
Scientific Peer Review:	**August/September 2009**
Programmatic Review:	**October 2009**

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through 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 pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1: Pre-Application Components and Submission

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 CDMRP eReceipt system by ***5:00 p.m. Eastern time (ET) on the deadline date***. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2: Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

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**

   Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, references to the PI or the institution in the project narrative are prohibited and will result in administrative withdrawal of the application. In addition, the use of "I," "our," "this institution," or similar phrases that make it

possible to identify the PI and/or institution through the references listed will result in administrative withdrawal of the application.

- **Attachment 1: Project Narrative (One-page limit)**

Describe the proposed project in detail using the outline below. ***Presentation of preliminary data is not consistent with the intent of this award mechanism and, therefore, is not allowed.*** However, PIs must demonstrate logical reasoning, and a rationale for the work must be provided. Proposals must describe how the new concept could create an entirely new avenue for investigation and how it is relevant to cancer.

Innovation: Innovation should be the primary feature of the proposed study.

Hypothesis and Rationale: State the hypothesis to be tested and rationale for the proposed research. Do not include preliminary data.

Objectives: State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study.

Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches.

Impact: Provide a brief statement in nontechnical terms regarding the potential impact of this work on cancer. Describe how the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical cancer research, or on the quality of life of individuals with cancer. ***Studies that do not qualify for exempt or expedited status during review at any level will be administratively withdrawn and will not be funded.***

References: Cite relevant literature references using Attachment 2.

The one-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

- **Attachment 2: Supporting Documentation**
  - References Cited
  - Acronyms and Symbol Definitions
- **Attachment 3: Statement of Work (SOW) (Three-page limit)**
- **Attachment 4: Detailed Budget and Justification**
- **Attachment 5: Military Relevance Statement (For *Genetic Cancer topic area applications only*, One-page limit)**

  Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces and their family members. If active duty military, military families, or veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the

feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. Veteran population). Describe how the study design will replicate field conditions, if appropriate. Explain how the proposed research study is aligned with the military research gap(s) appropriate for the topic area.

- **Attachment 6: Approval for Access to Military Populations (if applicable): One-page limit**

  A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities). ***Studies that do not qualify for exempt or expedited status during review at any level will be administratively withdrawn and will not be funded. The Approval for Access to Military Populations letter of support will not be forwarded for peer or programmatic review and will be used for administrative purposes only.***

- **Attachment 7: Federal Financial Plan (if applicable). No page limit, named "FedFin.pdf."** Proposals from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

  (1) The Recipient can show that such funds will not originate from the USAMRMC award, or

  (2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or

  (3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

  Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) facility after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

- **Attachments 8-17: Subaward Detailed Budget and Justification (if applicable)**

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

- PI Biographical Sketch

  Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. The biographical sketch will be used for administrative purposes only.

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

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess.htm.

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application 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 application review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review 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 applications based on one or more of the required attachments or supporting documentation.

> ***Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, identifying or making references to the PI or the institution within the project narrative is prohibited and will result in administrative withdrawal of the application. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed, will result in administrative withdrawal of the application.***

B. Review Criteria

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

   - **Innovation**
     - How the research proposes new paradigms or challenges existing paradigms.
     - How the proposed research is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, clinical interventions, or other ways.
     - Whether the concept is untested (no preliminary data exists).

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

- **Impact**
  - How the study addresses a critical problem in cancer research or care.
  - How the project will lead to an original and important contribution to the goal of advancement of basic, translational, or clinical cancer research, or on the quality of life of individuals with cancer.
  - What impact this study will have on the concepts or methods that drive the field.
- **Research Strategy**
  - How the rationale supports the project.
  - How the proposed research will lay the ground work for further hypothesis-driven research if successful.

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

- **Application Presentation**
  - How the writing and components of the application influenced the review.

2. **Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Adherence to the intent of the award mechanism,
- Program portfolio balance with consideration of the each topic's Focus Areas,
- Programmatic relevance,
- Ratings and evaluations of the peer reviewers,
- Relative innovation and impact.

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 PRCRP Integration Panel (IP) and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command (USAMRMC). The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- PI's name or institution is included in the Project Narrative.
- Use of "I," "our," "this institution," or similar phrases in the Project Narrative that make it possible to identify the PI and/or institution through the references listed.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- PI's name or institution included as footer or header will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at http://cdmrp.army.mil/09prcrppanel.htm.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.

- Inclusion of URLs, with the exception of links to published references.
- Inclusion of preliminary data in the Project Narrative.
- Inclusion of studies that do not qualify for either exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]) or expedited review (32 CFR 219.110 or 21 CFR 56.110).

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

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

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

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

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 the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726
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.