

Program Announcement

DEPARTMENT OF DEFENSE (DOD)
PEER REVIEWED CANCER RESEARCH PROGRAM (PRCRP)

*MENTOR-PREDOCTORAL FELLOW RESEARCH AWARD FOR NONINVASIVE
CANCER ABLATION RESEARCH ONLY*

Funding Opportunity Number: W81XWH-09-PRCRP-MPFR

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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 (OCRCP), 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, 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 noninvasive cancer ablation treatment research including selective targeting with nanoparticles.***

B. Award Description

The FY09 PRCRP Mentor-Predocctoral Fellow Research Award mechanism is designed to promote new ideas that are still in the early stages of development while training outstanding candidates in the topic area of noninvasive cancer ablation treatment research including selective targeting with nanoparticles. The research should have the potential to yield highly impactful data and new avenues of investigation in the PRCRP topic area of noninvasive cancer ablation treatment research including selective targeting with nanoparticles. ***No other topic areas will be allowed. Proposals must not address breast, prostate, or ovarian cancer research.*** This mechanism supports conceptually innovative research that could ultimately lead to critical discoveries or major advancements that will accelerate the field of noninvasive cancer ablation treatment including selective targeting with nanoparticles. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale. Mentored training of an outstanding Predocctoral fellow is an important aspect of this award, and inclusion of a Predocctoral Fellow is a requirement.

Preliminary data are not required. However, research projects should include a well-formulated, testable hypothesis based on a strong scientific rationale.

For FY09, the Mentor-Predocctoral Fellow Research Award will support applications that address one or more of the Focus Areas below. Applications to the FY09 PRCRP Mentor-Predocctoral Fellow Research Award will be rated on their responsiveness to these Focus Areas.

Focus Areas:

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

The PRCRP Mentor-Predocctoral Fellow Research Award supports high-impact, innovative research that will drive the field forward.

Important aspects of the Mentor-Predocctoral Fellow Research Award are as follows:

1. Innovation: Research deemed innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may be innovative in study concept, research methods or technology, clinical interventions, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

2. Impact: The proposed research should have a significant impact on the concepts or methods that drive the field of noninvasive cancer ablation treatment including selective targeting with nanoparticles research. The proposed research is expected to make original and important contributions to the goal of advancing this area of research. ***Clinical trials are not permitted under this mechanism. For the definition of a clinical trial, refer to the Application Instructions and General Information, Appendix 6.***

3. Predocctoral Fellow: A Predocctoral Fellow is a requirement. The intent of the Predocctoral Fellow is to foster the next generation of noninvasive cancer ablation treatment investigators through mentored research training of doctoral degree candidates who are committed to a career in noninvasive cancer ablation treatment including selective targeting with nanoparticles research.

- A Predocctoral Fellow is defined as a Predocctoral student who is currently enrolled full-time in an accredited doctoral program (e.g., Ph.D., M.D./Ph.D., D.Sc.) **and** who will successfully complete comprehensive examinations or otherwise meet predissertation requirements by the time of award obligation to the institute or agency.
- Only one (1) Predocctoral student can be named as a Predocctoral Fellow within a given Mentor- Predocctoral Fellowship Award application. “To be named” Predocctoral Fellows are not allowed for the application submission.
- A **Predocctoral Fellow Letter** from the proposed Fellow should:
 - Be written and signed by the Fellow
 - Identify a primary mentor (the Principal Investigator [PI] of the Mentor-Predocctoral Fellow Research Award).
 - Articulate career goals and how the proposed research training will promote a

career in noninvasive cancer ablation treatment and selective targeting with nanoparticles research.

- Supporting documentation should include a biographical sketch and three Letters of Support. One letter must be from the Predoctoral Fellow's primary mentor (the PI of the Mentor-Predoctoral Fellow Research Award).
- To qualify for the Predoctoral Fellow, all requirements described above must be included in the application.

C. Eligibility

Mentor: Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications for the mentor position. The PI must be the mentor of the designated Predoctoral Fellow.

Predoctoral Fellow: A predoctoral student currently enrolled full-time in an accredited doctoral program (e.g., Ph.D., M.D./Ph.D., D.Sc.) and who has successfully completed comprehensive examinations or otherwise met predissertation requirements by the time of award obligation to the institute or agency.

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

Funding for the Mentor-Predoctoral Fellow Research Award:

- The maximum period of performance is 3 years.
- The maximum allowable direct cost amount for the entire period of performance is \$475,000 (\$375,000 for research plus \$100,000 for the Predoctoral Fellow to cover stipend or salary and tuition).
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

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

- Salary
- Stipend
- Tuition
- Research supplies
- Equipment
- Clinical costs (*Clinical trials are not permitted under this mechanism*)

- Travel to scientific/technical meetings
- Travel between collaborating institutions

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot \$1.4M of the \$16 M FY09 appropriation to fund approximately two Mentor-Predoctoral Fellow Research Awards in noninvasive cancer ablation research including selective targeting with nanoparticles applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/ Funding Opportunity is contingent on 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:** August 5, 2009, 5:00 p.m. Eastern time (ET)
- **Invitation to Submit an Application:** October 19, 2009
- **Application Submission Deadline:** December 9, 2009, 11:59 p.m. ET
- **Scientific Peer Review:** January 2010
- **Programmatic Review:** March 2010

Awards will be made approximately 4 to 6 months after receiving a 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 \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/). *Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.*

PIs and organizations identified in the application 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.

A. Step 1 - Pre-Application Components, Submission, and Screening

1. 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. ET on the pre-application deadline**. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- **Preproposal Narrative:** The Preproposal Narrative has a **three-page limit** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the pre-application. The preproposal narrative should address the following:
 - **Innovation:** Describe how the research represents more than an incremental advance on published data.
 - **Impact:** Briefly state how the proposed research will significantly impact the concepts and methods that drive the field of noninvasive cancer ablation treatment including selective targeting with nanoparticles research.
 - **Research Aims:** Concisely state the project's objective and specific aims. Describe the role of the Predoctoral Fellow in the proposed project. ***This award may not be used to conduct clinical trials.***
 - **Mentor-Predocutorial Training Research Plan:** State the training plan for the predoctoral candidate and how the research will prepare the trainee for a career in the areas of noninvasive cancer ablation treatment including selective targeting with nanoparticles research.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are:
 - **References:** List up to five relevant journal references.
 - **Biographical Sketches:** Include biographical sketches for the PI, key collaborators, and the Predoctoral Fellow.

2. **Pre-Application Screening:** Pre-applications will be screened by the PRCRP Integration Panel, composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Innovation:** How the proposed research represents more than an incremental advance on published data.
- **Impact:** What impact these studies will have on the concepts or methods that drive the field.
- **Responsiveness to Intent:** How well the proposed research addresses one or more of the FY09 Focus Areas for noninvasive cancer ablation treatment including

selective targeting with nanoparticles research. How the Predoctoral Fellowship is critical to the research implementation.

- **Mentor-Predoctoral Training Research Plan:** How well the plan delineates the preparation of the predoctoral candidate for a career in noninvasive cancer ablation treatment research including selective targeting with nanoparticles.

B. Step 2 - Application Components and Submission

Principal Investigators will receive notification of invitation to submit an application for the PRCRP Mentor-Predoctoral Fellow Research Award. Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted. Each application submission must include the completed Grants.gov 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.

Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or focus area(s).

The package includes:

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

2. Attachments Form

- **Attachment 1: Project Narrative (8 page limit).**

Describe the proposed project in detail using the outline below. *The presentation of preliminary data is not required.* However, PIs must demonstrate logical reasoning and sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive. Throughout the Project Narrative, describe how the proposed research is innovative, and the potential impact it will have on the topic area and Focus Area:

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous studies most pertinent to this application.
- **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 supported by this application.
- **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. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award may not be used to conduct clinical trials.***

- **Attachment 2: Supporting Documentation**

- References Cited
- Acronyms & Symbol Definitions
- Facilities & Other Resources
- Description of Existing Equipment
- Publication URLs and/or Patent Abstracts (five-document limit)
- Letters of Institutional Support
- Letters of Collaboration (if applicable)
- Three Letters of Support for the Predoctoral Fellow: Three Letters of Support should be provided, including one letter from the primary mentor (the PI on the Mentor-Predoctoral Fellow Research Award). Each letter of support should include the qualifications and achievements that qualify the Predoctoral student as an ideal candidate. Describe the proposed Predoctoral Fellow's commitment to noninvasive cancer ablation and selective targeting with nanoparticles research.

- **Attachment 3: Technical Abstract**

- **Attachment 4: Public Abstract**

- **Attachment 5: Statement of Work (SOW; three-page limit)**

- **Attachment 6: Detailed Budget and Justification**

- **Attachment 7: Impact Statement (one-page limit)**

Explain how the proposed research will have an impact on the concepts or methods that drive the field of noninvasive cancer ablation treatment and selective targeting with nanoparticles research. Describe how the proposed research will provide original and important contributions to the goal of advancing research in this field.

- **Attachment 8: Innovation Statement (one-page limit)**

Summarize how the proposed research is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.

- **Attachment 9: Predoctoral Fellow Letter (two-page limit)**

The Predoctoral Fellow letter should be written and signed by the candidate, and it should articulate the candidate's career goals and how the proposed research training will promote a career in noninvasive cancer ablation treatment including selective targeting with nanoparticles research. Describe the qualifications and achievements that make the predoctoral student the ideal candidate for the Predoctoral Fellow. Describe the potential for a successful career in noninvasive cancer ablation treatment including selective targeting with nanoparticles.

- **Attachment 10: Predoctoral Fellow Biosketch (four-page limit)**

Suggested format is provided in Appendix 9.

- **Attachment 11: 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 12-15: 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. 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, 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>

The peer review and program 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 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 correcting 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 this prohibition 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 program 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 (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

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

- **Innovation**
 - How the project 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, or other ways.
 - How the proposed research represents more than an incremental advance to published data.
- **Impact**
 - If successful, how the proposed research will have an impact on the concepts or methods that drive the field.
 - How the proposed research will provide original and important contributions to the goal of advancing noninvasive cancer ablation treatment including selective targeting with nanoparticles research.
- **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 by the presentation of preliminary data relevant to the project and logical reasoning.
 - How well the hypotheses or objectives, experimental design, methods, and analyses are developed, and how well these support completion of the aims.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Personnel**
 - The research team's background, experience, and expertise with respect to the proposed work.
 - The appropriateness of the levels of effort by the PI and other key personnel (including the Predoctoral Fellow) to ensure success of the proposed work.
 - How the Predoctoral Fellow's career goals and plans, and the proposed research training will promote a career in noninvasive cancer ablation and selective targeting with nanoparticles research.

The following criteria 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 (including collaborative arrangements).
 - How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **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,
- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact and innovation,
- Responsiveness to Focus Areas, and
- Program portfolio balance.

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 Integration Panel members and recommended for funding to the Commanding General, U.S. Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding.

V. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Predoctoral Fellow Statement is missing.
- Budget is missing.
- 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.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by CDMRP via email 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>
- 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 maximum allowed by award mechanism.
- Inclusion of URLs with the exception of links to published references.

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 U.S. Army Medical Research Acquisition Activity (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 submitting applications through the [Grants.gov](http://www.grants.gov) (<http://www.grants.gov>) portal should be directed to Grants.gov help desk, which is available Monday to 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. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan accordingly, as 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 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.