

Program Announcement

Department of Defense (DOD)

Congressionally Directed Medical Research Programs (CDMRP)

Lung Cancer Research Program (LCRP)

Lung Cancer Promising Clinician Research Award

Funding Opportunity Number: W81XWH-09-LCRP-LCPCRA

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Lung Cancer Research Program (LCRP) was established in fiscal year 2009 (FY09) to promote innovative and competitive research focused on the development of integrated components to identify, treat, and manage early curable lung cancer and the establishment of a tissue bank. The FY09 appropriation is \$20 million (M).

The goal of the FY09 LCRP is to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the LCRP will support and integrate research from multiple disciplines for early detection, diagnosis, prevention, cure, and control of lung cancer.

B. Award Description

The Lung Cancer Promising Clinician Research Award (LCPCRA) supports a research project performed by promising physician-researchers. This award is intended to prepare physicians with clinical duties and/or responsibilities for an independent and active career in lung cancer research. Previous experience in lung cancer research is allowed, but not required. However, Principal Investigators (PIs) with a limited background in lung cancer research are strongly encouraged to have a collaborator(s) who is experienced in the lung cancer field.

To be eligible for this award, PIs must be in his/her first faculty appointment (either non-tenure or tenured track). PIs must demonstrate a commitment to a career in lung cancer research and clinical practice. As such, the PI is expected to commit 40% of his/her time for research. ***The Department of Defense (DOD) LCRP strongly encourages submissions from and partnerships with investigators at Military Treatment Facilities, Military Research Institutions, and the Department of Veterans Affairs (VA) Medical Centers and research laboratories.***

Areas of Emphasis: The FY09 LCPCRA mechanism ONLY accepts applications that address at least one of the seven Areas of Emphasis listed below.

- Identification or development of non-invasive or minimally invasive tools to improve the detection of the initial stages of lung cancer
- Identification and development of tools for screening or early detection of lung cancer. Screening may include, but is not limited to, computed tomography scans, X-rays, other imaging, biomarkers, genetics/genomics/proteomics, and assessment of risk factors
- Understanding the molecular mechanisms that lead to clinically significant lung cancer
- Identification of the mechanisms that lead to the development of the various types of lung cancer
- Identification of innovative strategies for prevention and treatment of early lung cancer
- Understanding predictive and prognostic markers to identify responders and non-responders

- Understanding acquired resistance to treatment

The inclusion of preliminary data relevant to lung cancer and the proposed project is encouraged, but not required. Any preliminary data presented should be from the laboratory of either the PI or any of the named collaborators.

Clinical trials are not allowed under this mechanism. PIs wishing to apply for funding for a clinical trial should utilize the Collaborative Translational Research Award mechanism.

C. Eligibility

To be eligible for this award mechanism, PIs must meet the following criteria:

- Must be an M.D., M.D./Ph.D., or D.O.
- Must be within the first five years of his/her first faculty position (or equivalent) at the time of award. The first faculty position (or equivalent) may be either tenure-track or non-tenure track.
- Must not have received more than \$300,000 in direct costs for lung cancer research as a PI of a federally funded, non-mentored peer reviewed grant.

Please note that graduate students, postdoctoral fellows, and other “mentored” researchers are not eligible for these awards. *Additionally, Ph.D.s are not eligible for this award.* Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is **\$375,000** in direct costs.
- The PI 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 PI may not exceed the maximum direct cost. In addition to the 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
- Research supplies
- Equipment
- Clinical research costs (no clinical trials allowed)

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

Institutional commitment must demonstrate that the salary support requested by the PI provides at least 40% protection of the PI's time for research.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.2M of the \$20M FY09 LCRP appropriation to fund approximately 2 LCPCRA applications, depending upon the quality and number received. 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

A change in PI is not allowed for the LCPCRA mechanism, except under extreme circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met. Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

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:	November 19, 2009, 5:00 p.m. Eastern time (ET)
Application Submission Deadline:	December 3, 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

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/).

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 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. 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 (one-page limit)
 - State which of the seven Areas of Emphasis that this application addresses

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) by 11:59 p.m. ET on the deadline date.

Each application submission must include the completed application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

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

- **Attachment 1: Project Narrative (10-page limit)**

Describe the proposed project in detail using the outline below. ***The inclusion of preliminary data relevant to lung cancer and the proposed project is encouraged, but not required. Any preliminary data presented should be from the laboratory of either the PI or any of the named collaborators.***

Background of Research Project: Present the ideas and reasoning behind the proposed work. Cite relevant literature. Describe previous experience 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 funded by this application. If this proposal is part of a larger study, present only tasks that the DOD award would fund.

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. Describe the statistical plan if appropriate for the research proposed. *This award may not be used to conduct clinical trials.*

PI's Career Goals: Describe the PI's career goals as a researcher and clinician, and how the proposed research will promote an independent and active career in lung cancer research. Explain how the proposed project will integrate the PI's research goals and clinical practice.

- **Attachment 2: Supporting Documentation**

- Journal References Cited
- Acronyms and Symbol Definitions
- Facilities & Other Resources
- Description of Existing Equipment
- Publications and/or Patent Abstracts (five-document limit)
- Letters of Institutional Support

The letter(s) should indicate the level of institutional commitment to fostering the PI's research and clinical career, as reflected by (1) the extent to which the PI will be relieved of clinical or other responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for interactions with colleagues.

- Letter of Eligibility

This letter should be signed by the Department Chair, Dean, or equivalent official and should verify the PI meets the eligibility requirements outlined in section I.C.

- Intellectual and Material Property Plan (if applicable)

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

Explain how the expected results of the study will make an original and important contribution to the goal of advancing lung cancer research for one of the Areas of

Emphasis and its impact on patient care. Describe how the award will facilitate an independent and active career in lung cancer research.

- **Attachment 8: Approval for Access to Military Populations (if applicable), (1-page limit)**

If studies include active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities) a letter of support, signed by the lowest ranking person with approval authority, should be provided.

- **Attachment 9: Federal Agency Financial Plan (if applicable)**
- **Attachment 10-15: 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. P 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>

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 (e.g., Impact Statement).

B. Review Criteria

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

- **Research Strategy and Feasibility (preliminary data relevant to lung cancer and the proposed project is encouraged, but not required)**
 - How well the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, lung cancer-relevant preliminary data, and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
 - How well the research project will allow the PI to enhance his/her lung cancer expertise.
- **Principal Investigator**
 - How the PI's potential for a productive and sustained career in lung cancer is demonstrated by his/her background, experience, and the quality of the proposed application.
 - How the proposed project will integrate the PI's research goals and clinical practice as a way to facilitate an active and independent career in lung cancer research.
 - How well the PI demonstrates an understanding of the disease and clearly articulates the studies to be conducted through the proposal.
 - Appropriateness of the levels of effort by the PI and other key personnel to ensure the success of this research effort.
 - Whether the PI meets the eligibility requirements.
- **Impact**
 - How the proposed work addresses a critical problem in lung cancer research or patient care.
 - How well the proposed research project responds to one or more of the FY09 LCRP emphasis areas towards the goal of advancing lung cancer 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 and the development of an independent and active career in lung cancer 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 and the PI's career development.
- **Budget**
 - How the budget is appropriate for the proposed research.
- **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:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact,
- Program portfolio balance, with consideration of the Areas of Emphasis,
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. 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 Emphasis 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.
- 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.
- Following the application deadline, the applicant 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/09lcrppanel>
- 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.
- PI does not meet the eligibility requirements for the award mechanism.

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) ([http://www.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. The deadline for application submission is 11:59 p.m. ET on the deadline date. Please note that 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.