

Program Announcement

Department of Defense (DOD)

Congressionally Directed Medical Research Programs (CDMRP)

Lung Cancer Research Program (LCRP)

Clinical Fellow Research Award

Funding Opportunity Number: W81XWH-09-LCRP-CFRA

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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 LCRP Clinical Fellow Research Award (CFRA) supports a research project performed by a clinical fellow under the guidance of a designated mentor having an established lung cancer research program. This award is intended to prepare fellows with clinical duties and/or responsibilities for a career in lung cancer research. The Principal Investigator (PI) must be in either an accredited medical residency or medical fellowship program. ***The 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.***

Funds from this award are intended to provide aggressive protection, of at least 40%, of the clinical fellow's time for research. The clinical fellow must demonstrate a strong commitment to a career in lung cancer research and clinical practice.

Areas of Emphasis: The FY09 LCRP CFRA 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 the PI, the designated mentor, 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 a physician (M.D., M.D./Ph.D. or D.O.) with clinical duties and/or responsibilities.
- Must be in an accredited medical residency or medical fellowship program.

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

D. Funding

- The period of performance is **2** years.
- The maximum allowable funding for the entire period of performance is **\$200,000** in direct costs.
- The applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs will not exceed 8% of the direct costs for these applications. The maximum indirect cost rate of 8% will be applied to the Modified Total Direct Costs in accordance with the institution's negotiated rate agreement.

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

- Salary support for the PI
- Reductions in institutionally obligated clinical time
- Salary for key support persons (e.g., laboratory technician, research nurse, or data manager)
- Up to \$20,000 per year for research supplies and equipment
- 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 \$0.65M of the \$20M FY09 LCRP appropriation to fund approximately 3 Clinical Fellow Research Award 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 CFRA 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 information on changes in award personnel or institution.

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
 - State which of the seven Areas of Emphasis that this application addresses

B. Step 2 – Application Components and Submission

Applications 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 (6-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 provided should be from the laboratory of the PI, designated mentor or member(s) of the collaborating team.***

- **Research Project:** Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the application to be competitive. Discuss the relevance of this research to lung cancer. ***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 clinical fellowship will promote his/her career in lung cancer research and patient care. Discuss the PI's career plans after the completion of this award.
- **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 critical professional interaction with senior colleagues with establish research careers. The letter(s) must demonstrate a commitment to allow at least a 40% effort by the PI on this award.
 - Letter from Designated Mentor (three-page limit)

The Letter should describe:

 - The fellow's potential for a career in lung cancer research.
 - The mentor's commitment to the career development and mentorship of the clinical fellow's career as a lung cancer researcher and clinician.
 - The mentor's lung cancer research experience, lung cancer research program, committed resources, and level of effort for advising the clinical fellow.
 - The mentor's training achievements, as reflected by his/her previous trainees' career achievements, and indicate the potential for successful training of the PI in lung cancer research.
 - The scientific environment, including critical professional interaction with established senior research colleagues, that will support successful completion of the proposed project and transition the clinical fellow into a career into lung cancer research and patient care.
 - Letters of Collaboration (if applicable)
 - Intellectual and Material Property Plan (if applicable)
- **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**

State explicitly how the proposed research will, if successful, have an impact on human lung cancer. Describe how the award will facilitate a 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)**

- **Attachments 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)

A biographical sketch of the PI's mentor is required.

- Key Personnel Current/Pending Support

Current/Pending Support for the PI's mentor is required.

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 (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 Project (preliminary data is not required)**
 - How the research project is appropriate to prepare the PI for a successful career in lung cancer research and clinical medicine.
 - 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.
- **Principal Investigator**
 - Whether the PI meets the appropriate eligibility requirements.
 - How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for a successful career in lung cancer research and patient care.
 - How the mentor's letter of support provides evidence for the PI's potential for a career in lung cancer research.
 - How the PI's stated career goals demonstrate a commitment to pursuing a career as a lung cancer researcher and clinician.
- **Mentor**
 - How the mentor's training achievements, as reflected by his or her previous trainees' career achievements indicate the potential for successful training of the PI in lung cancer research.
 - How the mentor's research experience, research program, committed resources, and level of effort are appropriate for the proposed mentoring and conduct of the research project.

- Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.
- **Research Environment**
 - How the research requirements are supported adequately by the scientific environment, necessary resources, and critical professional interaction with established senior research colleagues.
 - Whether there is a clear institutional commitment to allow at least 40% protection of the PI's time for research.
 - How the quality and extent of other institutional support is appropriate.
- **Impact**
 - How the project, if successful, will have an impact on human lung cancer.
 - How the award will facilitate a career in lung cancer research.

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

- **Budget**
 - How 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:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative impact,
- Program portfolio balance, with consideration of the Areas of Emphasis, and
- 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, USAMRMC.

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, 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 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.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.

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/>) portal should be directed to the Grants.gov help desk. 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, Monday through Friday, 7:00 a.m. to 9:00 p.m. ET
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.