

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Concept Award

Funding Opportunity Number: W81XWH-09-LCRP-CA

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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 Concept Award mechanism supports the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to lung cancer. The Concept Award is not intended to support a logical progression of an already established research project but, instead, allows Principal Investigators (PIs) the opportunity to pursue serendipitous observations. This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Proposals must describe how the new idea will enhance the existing knowledge of lung cancer or create an entirely new avenue for investigation. Submissions from and partnerships with investigators at Military Medical Treatment Facilities, Military labs, and the Department of Veterans Affairs (VA) Medical Centers and research laboratories are encouraged. Research completed through a Concept Award may generate sufficient preliminary data to enable the PI to prepare a proposal for future research.

***Presentation of preliminary data is not consistent with the intent of the Concept Award mechanism and is discouraged. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.***

**Areas of Emphasis:** The FY09 LCRP Concept Award 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

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

All investigators, including postdoctoral fellows (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 your institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Travel to scientific/technical meetings
- Travel between collaborating institutions

***The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1.2M of the \$20.0M FY09 LCRP appropriation to fund approximately 10 Concept Award applications, depending upon the quality and number of proposals received.***

### 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.*

<b>Pre-application Submission Deadline:</b>	<b>August 20, 2009, 5:00 p.m. Eastern Time</b>
<b>Application Submission Deadline:</b>	<b>September 3, 2009, 11:59 p.m. Eastern Time</b>
<b>Scientific Peer Review:</b>	<b>October 2009</b>
<b>Programmatic Review:</b>	<b>November 2009</b>

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 \(https://cdmrp.org/\)](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](mailto:help@cdmrp.org) or 301-682-5507.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

### 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](https://cdmrp.org/) 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
  - State which of the seven FY09 LCRP Areas of Emphasis the proposal 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](http://www.grants.gov)).

Each application submission must include the completed application package of forms and attachments identified in [www.grants.gov](http://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 proposal. 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 proposal.*

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

Clearly explain how the proposed research is innovative and relevant to lung cancer research. *Investigators must indicate which of the FY09 LCRP Areas of Emphasis are addressed by the proposed research.* Preliminary data are not consistent with this award mechanism, and are discouraged. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.

- **Innovation:** Innovation is the primary feature of this award mechanism. Describe what is innovative about the proposed research.
- **Rationale:** State the rationale for the proposed research.
- **Objectives:** State concisely the specific aims and research strategy of the study.
- **Methods:** Describe the experimental design, methods, and analyses including appropriate controls, if applicable.
- **Impact:** Provide a brief statement, in nontechnical terms, describing the importance of this research to lung cancer. Briefly describe the potential impact of the proposed research on the concepts or methods that drive the field.

The two-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 (Limited to 5 references)
  - Acronyms and Symbol Definitions
- **Attachment 3: Statement of Work (SOW) (Three-page limit)**
- **Attachment 4: Detailed Budget and Justification**
- **Attachment 5: Federal Agency Financial Plan (if applicable)**
- **Attachments 6-15: Subaward Detailed Budget and Justification (if applicable)**

### **3. 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 proposals 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 proposal. 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 proposal.***

## **B. Review Criteria**

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

- **Innovation**
  - How the proposed concept is innovative.
  - Evidence that the concept is new or in an early stage of development.
  - How exploring the concept may lead to new areas of research.
- **Impact**
  - How this research addresses one or more of the FY09 LCRP Areas of Emphasis.
  - How the proposed work is important to lung cancer.
  - What impact the proposed research will have on the concepts or methods that drive the field of lung cancer.
- **Research Strategy**
  - How the scientific rationale and logical reasoning support the project and its feasibility.

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

- **Application Presentation**
    - How the writing and components of the application influenced the review.
  - **Budget**
    - How the budget is appropriate for the proposed research
- 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 the LCRP 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 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.
- 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 e-mail 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.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 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](mailto: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](mailto: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. 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](mailto: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.***