# Program Announcement

## Defense Health Program

**Department of Defense Congressionally Directed Medical Research Programs**

# Lung Cancer Research Program
## Concept Award

**Funding Opportunity Number:  W81XWH-11-LCRP-CA**

**Catalog of Federal Domestic Assistance Number:  12.420**

### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:**  5:00 p.m. Eastern time (ET)**,** October 19, 2011
- **Application Submission Deadline:**  11:59 p.m. ET, November 9, 2011
- **Scientific Peer Review:**  January 2012
- **Programmatic Review:**  March 2012

*New for fiscal year 2011 (FY11):  The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.*

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# I. FUNDING OPPORTUNITY DESCRIPTION

## A. Program Description

Applications for the FY11 Lung Cancer Research Program (LCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The LCRP was established in FY09 to promote innovative and competitive research focused on the development of integrated components to identify, treat, and manage early curable lung cancer, to include the establishment of a tissue bank. Appropriations for the LCRP from FY09 through FY10 totaled $35 million (M). The FY11 appropriation is $12.8M.

The vision of the FY11 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 Information

The LCRP Concept Award mechanism was first offered in FY09. The Concept Award supports the exploration of highly innovative, untested, potentially high-gain concepts, theories, paradigms, and/or methods that address an important problem in 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 and new ideas. This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Applications 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 laboratories, the Department of Veterans Affairs (VA) Medical Centers, and research laboratories and industry are encouraged. Research completed through a Concept Award may generate sufficient preliminary data to enable the PI to prepare an application 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 FY11 LCRP accepts only those Concept Award 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 new tools and/or building upon already existing 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.

***Research involving human subjects and human anatomical substances is permitted; however, studies must be exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Clinical trials are not allowed under this funding opportunity.*** A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. For more information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms.

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

C.  **Eligibility Information**

- Investigators at all levels are eligible to submit applications.

- Cost sharing/matching is not an eligibility requirement.

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

D.  **Funding**

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

- The maximum allowable direct costs for the entire period of performance is **$75,000** plus indirect costs**.**

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **1** year.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Travel between collaborating institutions
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

***The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $1.68M of the $12.8M FY11 LCRP appropriation to fund approximately 14 Concept Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

### A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-11-LCRP-CA.

### B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.org/).

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

- **Collaborators and Conflicts of Interest – Tab 3**

- **Required Files – Tab 4**

  **Letter of Intent (LOI) (one-page limit):**  Provide a brief description of the research to be conducted.  Include the Area of Emphasis under which the application will be submitted.  LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Submit Pre-Application – Tab 5**

- **Other Documents Tab**

  No additional documents are required.

### C.    Application Submission Content and Form

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity.  The application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (http://www.grants.gov/).

***Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).***
Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Project Narrative or Abbreviations list is prohibited and will result in administrative rejection of the application.  In addition, the use of "I," "our," "this organization," or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed will result in administrative rejection of the application.

Although required, the Statement of Work, Research & Related Budget form, R & R Subaward Budget Attachments(s) Form (if applicable), Biographical Sketch(es), current/pending support, and Project/Performance Site Location(s) Form will not be forwarded for peer or programmatic review.  These documents will be used for administrative purposes only.

**Grants.gov application package components:**  For the Concept Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:**  Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

- **Attachment 1: Project Narrative (two-page limit):** Upload as "ProjectNarrative.pdf."

  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 application.

  Clearly explain how the proposed research is innovative and relevant to lung cancer research. Investigators must indicate which of the FY11 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 a primary feature of this award mechanism. Describe how the proposed project represents a new concept or question, research methods or technologies, adaptations of existing methods or technologies, or challenges existing paradigms.

  - **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.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*

  - References Cited (five-citation limit): List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). **Do not include URLs that identify the organization(s) of the PI or collaborators.**

  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. **Do not include information that will identify the organization(s) of the PI or collaborators.**

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Not required at this time. Leave Attachment 3 space blank.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."

  Not required at this time. Leave Attachment 4 space blank.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
- PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

## D. Submission Dates and Times

All submission dates and times are indicated on the title page of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

## E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

## III. APPLICATION REVIEW INFORMATION

## A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares

applications to each other and makes recommendations for funding to the Commanding General, USAMRMC), based on technical merit, the relevance to the mission of the Department of Defense (DOD) and CDMRP, and the specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess. **Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).**

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level 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. Organizational personnel and PIs are prohibited from contacting persons involved in the 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 organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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).

**B.  Application Review Criteria**

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following criteria, which are of equal importance:

- **Innovation**
  - How well the research proposes new paradigms or challenges existing paradigms 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 exploring the concept may lead to new areas of research.
  - How the proposed research represents more than an incremental advance beyond ongoing or published research.

- **Impact**
  - How well this research addresses at least one of the Areas of Emphasis.
  - To what degree the proposed work is important to the identification, treatment, and/or management of lung cancer.
  - What impact the proposed research will have on the concepts or methods that drive the field of lung cancer research.

- **Research Strategy**
  - How the scientific rationale and logical reasoning support the project and its feasibility.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

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

## C.    Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

## D.    Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

## E.    Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation.  PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

## IV.  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.
    - The PI, collaborators, or their organization(s) are identified or referenced in the Project Narrative or in the List of Abbreviations, Acronyms, and Symbols.
    - Use of "I," "our," "this organization," or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed.
    - Pre-application is not submitted.

### B.  Modification

- Pages exceeding the specified limits will be removed prior to review 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 in Section IV.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 as submitted.

### C.  Withdrawal

The following may result in administrative withdrawal of the application:

- FY11 LCRP Integration Panel (IP) member is found to be involved in the preapplication 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 FY11 LCRP IP members may be found at http://cdmrp.army.mil/lcrp/panels/panels11.
- The application does not address at least one of the Areas of Emphasis.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.

- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- 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 required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

## V. AWARD ADMINISTRATION INFORMATION

### A. Award Notice

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

### B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section C, for general information regarding administrative and national policy requirements.

### C. Reporting

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

### D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes.

## VI.   AGENCY CONTACTS

### A.   CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.  Response times may vary depending upon the volume of inquiries.

> Phone:    1-301-682-5507
>
> Email:    help@cdmrp.org

### B.   Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays).  Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

> Phone:    1-800-518-4726
>
> Email:    support@grants.gov

***Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity.  If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII.  APPLICATION SUBMISSION CHECKLIST

| Grants.gov Application Components | Action | Completed |
|---|---|---|
| SF-424 (R&R) Application for Federal Assistance Form | Complete form as instructed. | |
| Attachments Form | Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1. | |
| | Upload Supporting Documentation (Support.pdf) as Attachment 2. | |
| | The Technical Abstract is not required with application submission.  Leave Attachment 3 space blank. | |
| | The Public Abstract is not required with application submission.  Leave Attachment 4 space blank. | |
| | Upload Statement of Work (SOW.pdf) as Attachment 5. | |
| Research & Related Senior/Key Person Profile (Expanded) | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. | |
| | Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field. | |
| | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. | |
| | Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | Complete form as instructed.  Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Project/Performance Site Location(s) Form | Complete form as instructed. | |
| R & R Subaward Budget Attachment(s) Form | Complete form as instructed. | |