

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Concept Award

Funding Opportunity Number: W81XWH-13-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), July 17, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, July 31, 2013
- **Peer Review:** October 2013
- **Programmatic Review:** January 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

TABLE OF CONTENTS

- I. Funding Opportunity Description 3**
 - A. Program Description 3
 - B. FY13 LCRP Areas of Emphasis 3
 - C. Award Information..... 3
 - D. Eligibility Information 4
 - E. Funding 4
- II. Submission Information 5**
 - A. Where to Obtain the Application Package..... 6
 - B. Pre-Application Submission Content and Form 6
 - C. Application Submission Content and Form 7
 - D. Submission Dates and Times 9
 - E. Other Submission Requirements..... 9
- III. Application Review Information..... 9**
 - A. Application Review and Selection Process..... 9
 - B. Application Review Criteria 10
 - C. Recipient Qualification 11
 - D. Application Review Dates 11
 - E. Notification of Application Review Results 11
- IV. Administrative Actions 11**
 - A. Rejection 11
 - B. Modification..... 12
 - C. Withdrawal..... 12
 - D. Withhold 13
- V. Award Administration Information 13**
 - A. Award Notice 13
 - B. Administrative and National Policy Requirements..... 13
 - C. Reporting..... 13
 - D. Award Transfers..... 13
- VI. Agency Contacts 14**
 - A. CDMRP Help Desk..... 14
 - B. Grants.gov Contact Center..... 14
- VII. Application Submission Checklist 15**

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Lung Cancer Research Program (LCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The LCRP was initiated 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. Appropriations for the LCRP from FY09 through FY12 totaled \$58 million (M). The FY13 appropriation is \$10.5M.

The goal of the FY13 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 risk assessment, early detection, diagnosis, prevention, and treatment for the control and cure of lung cancer.

B. FY13 LCRP Areas of Emphasis

To be considered for funding, applications for the FY13 LCRP Concept Award *must* address at least one of the seven Areas of Emphasis listed below.

- Identify or develop noninvasive or minimally invasive tools to improve the detection of the initial stages of lung cancer.
- Identify, develop, and/or build 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, imaging biomarkers, genetics/genomics/proteomics/metabolomics, and assessment of risk factors.
- Understand the molecular mechanisms of progression to clinically significant lung cancer.
- Understand the molecular mechanisms that lead to various subtypes of lung cancer.
- Identify innovative strategies for prevention and treatment of early lung cancer.
- Understand predictive and prognostic markers to identify responders and nonresponders.
- Understand susceptibility or resistance to treatment.

C. Award Information

The Concept Award 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. 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 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 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.

Because these awards are designed for preliminary investigations, projects involving human subjects or specimens must be 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). Clinical trials are not allowed under this funding opportunity. ***Studies that do not qualify for either exempt or expedited review status will be administratively withdrawn.*** For additional information on clinical research, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/. Investigators wishing to apply for funding for a clinical trial should consider submitting an application to the FY13 LCRP Clinical Exploration Award mechanism (Funding Opportunity Number: W81XWH-13-LCRP-CEA).

All investigators applying to FY13 LCRP funding opportunities are encouraged to consider leveraging resources available through the LCRP-funded Lung Cancer Biorepository Resource Network (LCBRN) (<http://www.lcbrn.org/>) if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- Investigators at all levels are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **1** year.
- The maximum allowable direct costs for the entire period of performance are **\$100,000** 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.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply and are so noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

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

Shall not be requested for:

- Clinical trial costs

The CDMRP expects to allot approximately \$1.92M of the \$10.5M FY13 LCRP appropriation to fund approximately 12 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 two-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 applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

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-13-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 pre-application should be the same as those intended for the subsequent application submission. If any changes are 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**

FY13 LCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the LCRP Area(s) 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.

Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

- **Submit Pre-Application – Tab 5**

This tab must be completed for the pre-application to be accepted and processed by CDMRP.

- **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 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 List of Abbreviations, Acronyms, and Symbols is prohibited and will result in administrative rejection of the application and preclude invitation to submit a full application. In addition, the use of “I,” “we,” “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 and preclude invitation to submit a full application.

Although required, the Statement of Work, Research & Related Budget, R & R Subaward Budget Attachment(s) Form (if applicable), PI/Key Personnel Biographical Sketches and Previous/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 page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. ***Presentation of preliminary data is not consistent with the intent of this award mechanism and is discouraged. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.***

- **Innovation:** Describe how the proposed project is innovative and challenges accepted paradigms. Innovation should be the primary feature of the proposed study.
- **Rationale:** Clearly articulate the rationale for the proposed research.

- **Objectives:** State concisely the specific aims and research strategy of the study. *Projects involving human subjects or specimens must be either exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).*
- **Methods:** Describe the experimental design, methods, and analyses including appropriate controls, if applicable. Address potential problem areas and present alternative methods and approaches.
- **Impact:** Provide a brief statement describing the impact, either short-term or long-term, of this research to lung cancer and how it addresses at least one of the Areas of Emphasis. It is the responsibility of the applicant to clearly and explicitly articulate the project’s impact on service members, their families, and other military beneficiaries. Describe how the project will lead to an original and important contribution toward advancing basic, translational, or clinical lung cancer research, or on the quality of life of individuals with lung cancer.
- **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. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.*
 - 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 collaborator.
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Not required at this time. Leave Attachment 3 space blank.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” Not required at this time. Leave Attachment 4 space blank.
- **Attachment 5: Statement of Work (SOW) (one-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.
- **Attachment 6: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as “MilBen.pdf.”
Describe the impact, either short-term or long-term, of the proposed research on the health and welfare of service members, their families, and other military beneficiaries.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Previous/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 Previous/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 will 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. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status 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 makes

recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), based on technical merit, the relevance to the mission of the DHP and LCRP 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>. For this Program Announcement/Funding Opportunity, reviewers at both tiers of review 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. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations 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 panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 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 scored criteria, which are of equal importance:
 - **Innovation**
 - To what extent 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 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**
 - To what extent the proposed research addresses at least one of the LCRP Areas of Emphasis.
 - To what extent the proposed research will, whether in the short-term or long-term, lead to an original and important contribution toward advancing basic, translational, or clinical lung cancer research, or on the quality of life of individuals with lung cancer.
 - **Research Strategy**
 - To what degree the proposed research is supported by a sound scientific rationale.

- To what degree the experimental design and methodology are appropriate to address the stated objectives.

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

- **Application Presentation**

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

2. Programmatic Review: To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- a. Ratings and evaluations of the peer reviewers**

- b. Relevance to the mission of the DHP and FY13 LCRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio composition including consideration of relevance to military beneficiaries
- Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

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. Each PI will receive a 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:

- No LOI was submitted.

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI, collaborators, or their organization(s) are identified or referenced in the Project Narrative, Relevance to Military Beneficiaries Statement or Abbreviations list.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed.

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, the PI 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:

- A FY13 LCRP IP member is named as being involved in the research proposed or is found to have assisted 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 FY13 LCRP IP members can be found at <http://cdmrp.army.mil/lcrp/panels/panels13>.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or requests funding for, a clinical trial.
- The application does not address at least one of the LCRP Areas of Emphasis.

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 USAMRAA 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, 2014. 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 D, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

Refer to the General Application Instructions, Appendix 4, Section F, 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 as well as 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: 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: 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 or by responding to the prompt provided by Grants.gov when first downloading the application package. 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.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3. Leave Attachment 3 space blank.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4. Leave attachment 4 space blank.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 6.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/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 Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete 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.	