

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Lung Cancer Research Program**

### **Career Development Award**

**Funding Opportunity Number: W81XWH-13-LCRP-CDA**

**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), June 20, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 16, 2013
- **Peer Review:** December 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.*

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## **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 Career Development 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 LCRP Career Development Award mechanism is being offered for the first time in FY13.

The Career Development Award supports early-career, independent investigators to conduct innovative research under the mentorship of an experienced lung cancer researcher as an opportunity to obtain the funding, mentoring, and experience necessary for productive, independent careers at the forefront of lung cancer research. This award is intended to support novel and innovative research projects with an emphasis on discovery. 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.

***Preliminary data is not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.***

Key elements of this award are as follows:

- **Principal Investigator (PI):** PIs must be research- or physician-scientists at an early stage of their independent research careers. PIs must be within 5 years of their first faculty appointment (or equivalent), and exhibit a strong desire to pursue a career in lung cancer research.
- **Mentorship:** The mentor must be an experienced lung cancer researcher as demonstrated by a strong record of funding and publications in lung cancer research. In addition, the mentor must demonstrate a commitment to developing the PI's career in lung cancer research.
- **Career Development:** A Career Development Plan is required and should be prepared with appropriate guidance from the mentor. A clearly articulated strategy for acquiring the necessary skills, competence, and expertise to have a career at the forefront of lung cancer research should be included. The plan should outline how the PI will gain experience and training in lung cancer research. Because career development is the focus of this award, the PI's institution must demonstrate a commitment to the PI through a minimum of 50% protected time for the proposed research, though more protected time is highly desirable.
- **Innovation:** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.
- **Impact:** Research that has high potential impact may lead to major advancements and significantly accelerate progress toward eradicating deaths from lung cancer.
- **Relevance to Military Beneficiaries:** The application should clearly articulate how the proposed research is relevant to service members, their families, and other military beneficiaries.

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.*** For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP eReceipt System at [https://cdmrp.org/Program\\_Announcements\\_and\\_Forms/](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**

- **Principal Investigator**

- The PI must be an independent investigator at the level of Assistant Professor, Instructor, or equivalent; and be within 5 years of his/her first faculty appointment (or equivalent) by the time of the application submission deadline. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.
- PIs working within a laboratory team are eligible to apply for this award provided that they demonstrate their independence according to the criteria above.
- Institutional commitment to the PI's independent career should be demonstrated, including at least 50% of protected time for the proposed research.

- **Mentor**

- The mentor must hold a position at or above the level of an Associate Professor (or equivalent).
  - The mentor must have a proven publication and funding record in lung cancer research.
- It is *not* required that the PI and the mentor be located at the same institution.
  - 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 **2** years.
- The maximum allowable direct costs for the entire period of performance are **\$240,000** 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 **2** years.

- 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 as are 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 for the PI (non-governmental personnel)
- Research supplies
- Clinical research costs (other than costs for clinical trials, which are not allowed)
- Publication costs
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Mentor

*The CDMRP expects to allot approximately \$0.77M of the \$10.5M FY13 LCRP appropriation to fund approximately 2 Career Development 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-CDA.

## 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/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs, mentors, 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](mailto:help@cdmrp.org) or 301-682-5507.

No change in PI will be allowed after the pre-application deadline.

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 (COI) – 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](mailto:help@cdmrp.org) or 301-682-5507.

- **Required Files – Tab 4**

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

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

The Preproposal Narrative should include the following:

- **PI:** Describe the PI's potential for a career at the forefront of lung cancer research. Describe the PI's career goals and how they are consistent with a commitment to pursue a career in lung cancer research.
- **Mentor:** Describe the mentor's lung cancer research experience, funding history, and track record in mentoring early-career investigators.
- **Career Development:** Briefly describe the Career Development Plan and how it will contribute to the overall professional development of the PI as a productive, independent researcher at the forefront of lung cancer research.
- **Research Idea:** State the project's objectives, rationale, and specific aims.

- **Innovation:** Describe how the proposed study is innovative and represents more than an incremental advance on published data.
- **Impact:** Describe how the proposed research is relevant to at least one of the LCRP Areas of Emphasis, the impact of the proposed project on lung cancer research and/or patient care, and its relevance to military beneficiaries.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal 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).
- Key Personnel Biographical Sketches (two-page limit per individual): Biographical sketches will be reviewed administratively to confirm eligibility.
- Key Personnel Previous/Current/Pending Support (no page limit).
- **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.

### Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the LCRP, pre-applications will be screened by the LCRP IP based on the following criteria:

- **PI:** Whether the PI demonstrates potential for contributing to the field of lung cancer research. How the PI's career goals are consistent with a commitment to advance an independent research career as a lung cancer researcher.
- **Mentor:** How the mentor's research experience, funding history, and track record in mentoring early-career investigators indicates the potential for successful mentorship.
- **Career Development:** How the Career Development Plan will contribute to the overall professional development of the PI. How the mentor will contribute to the PI's career development.
- **Research Idea:** How the rationale and specific aims support the project's objectives.
- **Innovation:** To what degree the proposed research is highly creative and represents more than an incremental advance upon published data.

- **Impact:** What impact the proposed studies will have on at least one of the LCRP Areas of Emphasis and their relevance to lung cancer research, patient care and military beneficiaries.
- **Notification of Pre-Application Screening Results**  
Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### C. Application Submission Content and Form

*Applications will not be accepted unless the PI has received notification of invitation.*

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/>).

**Grants.gov application package components:** For the Career Development 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 (eight-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. *Preliminary data is not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.*

- **Principal Investigator:** Describe the PI’s potential for a career at the forefront of lung cancer research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI’s career goals as a lung cancer researcher and/or clinician and how the proposed training will advance his or her career. Discuss the appropriateness of the level of effort of the PI for successful conduct of the proposed research.

- **Mentor:** Describe the qualifications of the mentor including record of research accomplishments, publications, patents, and funding in lung cancer. Describe the mentor’s track record for training early-career investigators. If the mentor and PI are located at different organizations, describe how appropriate direction and oversight will be accomplished.
- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations and preliminary data (if applicable) that led to the development of the proposed study. Any preliminary data provided should be from the laboratory of the PI, mentor, or member(s) of the collaborating team.
- **Hypotheses/Objectives:** State the hypotheses/study questions and overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award cannot be used to conduct clinical trials.***
- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- **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: 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).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government

award under which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. **Additionally, the letter(s) must demonstrate a commitment to allow at least a 50% effort on the project by the PI.**
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.

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

Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects.

- **Personnel:** Describe the PI’s career goals and his/her potential for a career at the forefront of lung cancer research. Describe the mentor’s background and experience in lung cancer research.
- **Career Development:** Describe how the award will provide the PI with the opportunity to advance an independent career at the forefront of lung cancer research.

- **Research**
  - Background: Present the ideas and reasoning behind the proposed project. State the area of emphasis the project addresses.
  - Hypotheses/Objectives: State the hypotheses/study questions and overall objective(s) to be reached.
  - Specific Aims: State the specific aims of this study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Innovation: Briefly describe how the proposed project is innovative.
  - Impact: Summarize the potential impact of the proposed project toward the goal of eradicating deaths from lung cancer and its relevance to military beneficiaries.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”

Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.

- Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine. State the area of emphasis the project addresses.
- Describe the PI’s career goals in lung cancer research.
  - How will the award advance the PI’s career in lung cancer research?
  - How does the research and career development plan support the PI in attaining these goals?
- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
  - What is the projected time it may take to achieve a clinically relevant outcome?
  - What are the likely contributions of this study to advancing the field of lung cancer research?
- **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, including guidance on appropriate SOW formats.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Describe how the proposed research addresses at least one of the LCRP Areas of Emphasis. Articulate the project’s impact to both lung cancer research and to lung cancer patient care, even if clinical impact is not an immediate outcome. Describe how the proposed project, if successful, will lead to major advancements and significantly accelerate progress toward eradicating deaths from lung cancer.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

Describe how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. The following examples of ways in which research may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their applications:

  - Study concept – Investigation of a novel idea and/or research question that could have a significant impact on lung cancer.
  - Research method or technology – Use of novel research methods or new technologies to address a research question.
  - Novel method or technology – Development of a novel method or technology for prevention, detection, diagnosis, or treatment of lung cancer.
  - Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- **Attachment 8: Career Development Plan (one-page limit):** Upload as “CareerDev.pdf.”

  - Clearly describe and outline the individualized career development plan that focuses on at least one of the LCRP Areas of Emphasis.
  - Highlight the unique features of this career development plan as it pertains specifically to lung cancer research.
  - Indicate specifically how the individualized career development plan will provide the PI with an opportunity to advance his/her independent career in lung cancer research.
  - Describe how the career development plan is supported by the research environment and mentorship, including a description of ongoing lung cancer research at the institution. Include information on collaborations with other investigators.
- **Attachment 9: Letter from Mentor (two-page limit):** Upload as “MentorLetter.pdf.” Provide a signed letter from the designated mentor indicating recommendation, support, and planned interactions with the PI for the proposed work. Include information on the mentor’s record of preparing early-career investigators for careers in lung cancer research.

- **Attachment 10: 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. Describe how the study design will replicate field conditions, if appropriate. If active duty military, military families, or U.S. Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. Veteran population).
  - **Attachment 11: Eligibility Statement:** Upload as “Eligibility.pdf.”  
Use the Eligibility Statement form (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official verifying that the eligibility requirements will be met by the application submission deadline.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
- 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.”
    - Include mentor’s (and co-mentor’s, if applicable) biographical sketch.
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support.
- 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, 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.shtml>.

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:

- **Principal Investigator**
  - How the PI's career goals demonstrate a strong personal commitment to advancing an independent career at the forefront of lung cancer research.
  - To what degree the PI's record of accomplishments and letters of support demonstrates his/her potential for advancement as a productive, independent investigator in lung cancer research.
- **Mentor**
  - How the mentor's background, qualifications, lung cancer research program, committed resources, and available time support the PI's career advancement needs.
  - Whether the designated mentor is an independent, established lung cancer researcher as demonstrated by publications, patents, and/or funding history.
  - To what degree the mentor's track record in preparing early-career investigators indicates the potential for successful mentorship and advancement of the PI's career in lung cancer research.
- **Career Development Plan**
  - How well the PI has outlined a detailed, individualized career development plan that will effectively advance the PI's independent career as a lung cancer researcher.
  - Whether the proposed training (such as workshops, seminars, etc.) is appropriate and will prepare the PI for a successful independent career at the forefront of lung cancer research.
  - To what degree the mentor will be involved in guidance and intellectual collaboration and support of the PI.
- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if applicable), and logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How the research project is appropriate for advancing the PI's career to the forefront of lung cancer research and/or patient care.
  - Appropriateness of the levels of effort by the PI, mentor, and other key personnel to ensure the success of this research effort.
  - How well the PI acknowledges potential problems and address alternative approaches.
- **Innovation**
  - How well the research proposes new paradigms, challenges existing paradigms, or is otherwise highly creative 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 the proposed research represents more than an incremental advance upon published data.

- **Impact**

- How the research, if successful, may lead to critical discoveries or major advancements in lung cancer research and/or patient care, including the potential to accelerate progress toward eradicating deaths from lung cancer.
- How the proposed research addresses at least one of the LCRP Areas of Emphasis.

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

- **Environment**

- To what degree the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- To what degree the quality and extent of organizational support are appropriate.
- Whether there is a clear organizational commitment to allow protection of at least 50% of the PI's time for the proposed research.

- **Military Relevance**

- How the proposed research is relevant to service members, their families, and other military beneficiaries.

- **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 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 pre-applications from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal 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 pre-application or 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.shtml>.
- 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 PI and/or mentor do not meet the eligibility criteria.
- 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**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

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](mailto: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](mailto: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

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Completed</b>
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.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload Career Development Plan (CareerDev.pdf) as Attachment 8.	
	Upload Letter from Mentor (MentorLetter.pdf) as Attachment 9.	
	Upload Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 10.	
	Upload Eligibility Statement (Eligibility.pdf) as Attachment 11.	
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.	