

# 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-14-LCRP-CDA

Catalog of Federal Domestic Assistance Number: 12.420

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 3, 2014
- **Invitation to Submit an Application:** July 2014
- **Application Submission Deadline:** 11:59 p.m. ET, September 17, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, September 22, 2014
- **Peer Review:** November 2014
- **Programmatic Review:** January 2015

***Change for Fiscal Year 2014:*** *The CDMRP eReceipt System has been replaced with the Electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

***This Program Announcement/Funding Opportunity 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 2014 (FY14) 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 disciplines to identify, treat, and manage early curable lung cancer. Appropriations for the LCRP from FY09 through FY13 totaled \$68.5 million (M). The FY14 appropriation is \$10.5M.

The goal of the FY14 LCRP is to eradicate deaths from lung cancer to better the health and welfare of military service members, Veterans, their families, other military beneficiaries, and the American public. As such, the LCRP will support and integrate research from multiple disciplines for risk assessment, prevention, early detection, diagnosis, and treatment for the control and cure of lung cancer.

### **B. FY14 LCRP Areas of Emphasis**

To be considered for funding, applications for the FY14 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 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/transcriptomics, 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 and/or localized lung cancer.
- Understand predictive and prognostic markers to identify responders and nonresponders.
- Understand susceptibility or resistance to treatment.

### **C. Award Information**

The Career Development Award supports early-career, independent investigators to conduct impactful 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 impactful research projects with an emphasis on discovery. Submissions from and partnerships with investigators at Military Treatment Facilities (MTFs), military labs, the Department of Veterans Affairs (VA) Medical Centers and research laboratories are *strongly 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 40% protected time for the proposed research, though more protected time is highly desirable.
- **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, Veterans, their families, and other military beneficiaries.

**Military Relevance:** The LCRP seeks to support research that is relevant to the health care needs of military service members, Veterans, their families, and other military beneficiaries.

***Military relevance will be considered in determining relevance to the mission of the DHP and FY14 LCRP during programmatic review.*** Investigators are ***strongly encouraged*** to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Use of military or Veteran populations or data in the proposed research
- Collaboration with DoD or VA investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area
- Explanation of how the project addresses an aspect of lung cancer that has direct relevance to military service members, Veterans, or other military health system beneficiaries

**Use of Active Duty Military and VA Populations:** If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for establishing and demonstrating such access. If possible, access to target active duty military and/or VA patient populations/resources should be confirmed at the time of application

submission by inclusion of a letter of support, signed by the lowest ranking person with approval authority, for studies involving active duty military service members, Veterans, military and/or VA controlled study materials, and military and/or VA databases. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources. Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research, or by advertising to the general public.

***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 electronic Biomedical Research Application Portal (eBRAP) at <https://ebrap.org/eBRAP/public/Program> Investigators wishing to apply for funding for a clinical trial should consider submitting an application to the FY14 LCRP Clinical Exploration Award mechanism (Funding Opportunity Number: W81XWH-14-LCRP-CEA).

All investigators applying to FY14 LCRP funding opportunities are encouraged to consider leveraging resources available through the LCRP-funded Lung Cancer Biospecimen 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 L.***

#### **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 biosketch 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 40% of protected time for the proposed research.
- The PI must not have received a Career Development Award previously from any program within the CDMRP.
- The PI must not have received more than \$300,000 in total direct costs for previous or concurrent lung cancer research as a PI of one or more federally or privately funded, non-mentored, peer-reviewed grants.

- **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.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- 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.***

For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary for the PI
- 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:

- Clinical trial costs
- Salary for the mentor

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or an MTF, or working in a DoD activity embedded within a civilian medical center. Extramural investigators are defined as all those not included in the definition of intramural investigators. As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.*** Refer to Appendix 4 of the General Application Instructions for additional information.

***The CDMRP expects to allot approximately \$1.152M of the \$10.5M FY14 LCRP appropriation to fund approximately 3 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 electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

**New for FY14:** ***The CDMRP has replaced its eReceipt System with eBRAP.*** Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and

affiliated to the organization in eBRAP (see *eBRAP User Guide* at <https://ebrap.org/eBRAP/public/UserGuide.pdf>). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

**Note:** Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. *Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.* If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see [Section IV.A., Rejection](#)).

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-14-LCRP-CDA.

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

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.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@eBRAP.org](mailto:help@eBRAP.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 eBRAP 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**
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 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@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

- **Required Files – Tab 4**

*Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

**Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit 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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Relevance:** Clearly articulate how the application is relevant to at least one of the LCRP Areas of Emphasis, as well as its relevance to military service members, Veterans, their families, and other military beneficiaries.
- **Principal Investigator:** 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:** 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:** State the project's hypothesis/objective, rationale, specific aims, and study design. This award cannot be used to conduct clinical trials.
- **Impact:** Describe the applicability of the research on lung cancer patients and describe how the proposed project will have an impact toward eradicating deaths from lung cancer.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and 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).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - Key Personnel Biographical Sketches (two-page limit per individual): Biosketches 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.

## 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 Integration Panel based on the following criteria:

- **Relevance:** To what degree the proposed project is relevant to at least one of the LCRP Areas of Emphasis; to what degree the proposed project is relevant to military service members, Veterans, their families, and other military beneficiaries.
  - **Principal Investigator:** To what degree 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 well the mentor's research experience, funding history, and track record in mentoring early-career investigators indicate the potential for successful mentorship.
  - **Career Development:** How well 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:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the hypothesis or objective.
  - **Impact:** Whether the proposed project has the potential to lead to critical discoveries or major advancements that will accelerate progress toward eradicating deaths from lung cancer.
  - **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 weakness) 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 Forms

*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/>).

**New for FY14:** *Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.* The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

**Note:** *Changes to either the Project Narrative or Budget are not allowed in eBRAP;* if such changes are required, the entire application package must be submitted through Grants.gov as a “Changed/Corrected Application” with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period).*

**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.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective 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. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. Address potential problem areas and present alternative methods and approaches. If animals are to be used, explain how and why the animal species and model(s) being used can address the scientific objectives. 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. As appropriate, provide a statistical plan and sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
- **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 40% 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: 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. If applicable, state and identify the 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, Section L, 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.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of this study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Summarize the potential impact of the proposed project toward the goal of eradicating deaths from lung cancer.
  - Relevance: Summarize how the proposed research addresses at least one of the LCRP Areas of Emphasis. Clearly articulate how the proposed project is relevant to military service members, Veterans, their families, and other 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(s) 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?
  - How is the project relevant to military service members, Veterans, their families, and other military beneficiaries?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Program Announcement and Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Career Development Award mechanism, use the SOW format example titled “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”  
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: Career Development Plan (one-page limit):** Upload as “CareerDev.pdf.”
  - Clearly describe and outline the individualized career development plan.
  - 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 8: 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 9: Relevance Statement (one-page limit):** Upload as “Relevance.pdf.”
  - **Areas of Emphasis:** Describe how the proposed research is relevant to at least one of the LCRP Areas of Emphasis in a way that is consistent with the program’s goals.

- **Military Relevance:** Describe how the proposed research is relevant to the health care needs and welfare of military service members, Veterans, their families, and other military beneficiaries in a way that is consistent with the program’s goals. 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). If applicable, show how the proposed research project aligns with DoD and/or VA areas of research interest.
  - **Attachment 10: Letters Confirming Access to Target Military or VA Patient Population(s) or Human/Animal Anatomical Substances, Databases, if applicable:** Upload as “Access.pdf.” If applicable, provide a letter(s) of support, signed by the lowest ranking person with approval authority, for studies involving active duty military and/or Veteran populations, military and/or VA-controlled study materials, and military and/or VA databases.
  - **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.3., 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.4., 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.5., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

#### **D. Verification of Grants.gov Application in eBRAP**

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. *The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*

#### **E. 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 either of these deadlines will result in application rejection.

#### **F. 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 applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is 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 (a) technical merit and (b) the relevance to the mission of the DHP and LCRP and to the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

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 Process**

- 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 well 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 well 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 well 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 (and if applicable, the statistical plan, rationale for the statistical methodology, and power analysis) are developed.
  - Whether 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.
- **Impact**
  - How well the research, if successful, will 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.

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

- **Relevance**
  - How well the proposed research addresses at least one of the LCRP Areas of Emphasis.
  - How the proposed project is relevant to military service members, Veterans, their families, and other military beneficiaries in a way that is consistent with the program's goals.
- **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 40% of the PI's time for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
  - **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 influence 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 FY14 LCRP, as evidenced by the following:**
    - Adherence to the intent of the award mechanism
    - Programmatic relevance in relation to the LCRP Areas of Emphasis and military relevance
    - Program portfolio composition
    - Relative impact

### **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 email notification of posting of the funding recommendation in eBRAP. 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 eBRAP 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 exceeds page limit.
- 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 specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in [Section IV.A., Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- A FY14 LCRP Integration Panel (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 documentation. A list of the FY14 LCRP IP members can be found at <http://cdmrp.army.mil/lcrp/panels/panels14>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

#### **D. Reporting**

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

#### **E. 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 M, 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 eBRAP 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@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through 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	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Career Development Plan: Upload as Attachment 7 with file name "CareerDev.pdf."	
	Letter from Mentor: Upload as Attachment 8 with file name "MentorLetter.pdf."	
	Relevance Statement: Upload as Attachment 9 with file name "Relevance.pdf."	
	Letters Confirming Access to Military or VA Patient Populations or Human/Animal Anatomical Substances, Databases: Upload as Attachment 10 with file name "Access.pdf," if applicable.	
	Eligibility Statement: Upload as Attachment 11 with file name "Eligibility.pdf."	
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_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.	