

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Lung Cancer Research Program

### Concept Award

Funding Opportunity Number: W81XWH-14-LCRP-CA

Catalog of Federal Domestic Assistance Number: 12.420

#### SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 29, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, August 12, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, August 15, 2014
- **Peer Review:** September 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.***

**TABLE OF CONTENTS**

- I. Funding Opportunity Description..... 3**
  - A. Program Description ..... 3
  - B. FY14 LCRP Areas of Emphasis ..... 3
  - C. Award Information..... 3
  - D. Eligibility Information ..... 5
  - E. Funding ..... 5
- II. Submission Information ..... 7**
  - A. Where to Obtain the Application Package..... 7
  - B. Pre-Application Submission and Content Form ..... 7
  - C. Application Submission Content and Forms ..... 8
  - D. Verification of Grants.gov Application in eBRAP ..... 12
  - E. Submission Dates and Times ..... 12
  - F. Other Submission Requirements..... 12
- III. Application Review Information ..... 13**
  - A. Application Review and Selection Process..... 13
  - B. Application Review Process ..... 13
  - C. Recipient Qualification ..... 14
  - D. Application Review Dates ..... 14
  - E. Notification of Application Review Results ..... 15
- IV. Administrative Actions..... 15**
  - A. Rejection ..... 15
  - B. Modification..... 15
  - C. Withdrawal..... 16
  - D. Withhold ..... 16
- V. Award Administration Information..... 16**
  - A. Award Notice ..... 16
  - B. Administrative Requirements ..... 16
  - C. National Policy Requirements ..... 17
  - D. Reporting..... 17
  - E. Award Transfers..... 17
- VI. Agency Contacts..... 17**
  - A. CDMRP Help Desk..... 17
  - B. Grants.gov Contact Center..... 17
- VII. Application Submission Checklist ..... 18**

## **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 Concept Award must address at least one of the seven Areas of Emphasis listed below.

- Identify or develop noninvasive or minimally invasive tools to improve 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 Concept Award supports the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to lung cancer. The Concept Award is not intended to support an incremental progression of an already established research project but, instead, allows Principal Investigators (PIs) the opportunity to pursue serendipitous observations. This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Applications must describe how the new idea will enhance the

existing knowledge of lung cancer or create an entirely new avenue for investigation. Submissions from and partnerships with investigators at Military Treatment Facilities (MTFs), military labs, the Department of Veterans Affairs (VA) Medical Centers and research laboratories are ***strongly encouraged***. Research completed through a Concept Award may generate sufficient preliminary data to enable the PI to prepare an application for future research.

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

**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.

Because the Concept awards are designed for preliminary investigations, projects involving human subjects or specimens must be either exempt under Title 32, Code of Federal Regulations (CFR), Part 219, Section 101(b) (32 CFR 219.101[b]) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Clinical trials are not allowed under this funding opportunity. ***Studies that do not qualify for either exempt or expedited review status will be administratively withdrawn.*** For additional information on clinical research, a Human Subject Resource Document is provided at <https://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-LCRPCEA).

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**

- All investigators at or above the level of postdoctoral fellow (or equivalent) are eligible.
- 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 **1** year.
- The maximum allowable direct costs for the entire period of performance are **\$100,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **1** year.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. *For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply 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
- Research supplies
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Clinical trial costs

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 \$1.92M of the \$10.5M FY14 LCRP appropriation to fund approximately 12 Concept Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.***

## II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the 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-CA.

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

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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 – 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 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.*

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

- **Submit Pre-Application – Tab 5**

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

### **C. Application Submission Content and Forms**

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).**

***Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s).***

Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Project Narrative, List of Abbreviations, Acronyms, and Symbols, or the Relevance Statement is prohibited and will result in administrative rejection of the application. In addition, the use of “I,” “we,” “our,” “this organization” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting the names of the PI, collaborators, or their institutions, is prohibited and will result in administrative rejection of the application.

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

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

- 1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 2. Attachments Form**
  - **Attachment 1: Project Narrative (two-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

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

    - **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.
    - **Innovation:** Describe how the proposed project is innovative and challenges accepted paradigms. Innovation should be the primary feature of the proposed study.
    - **Rationale:** Clearly articulate the rationale for the proposed research.
    - **Objectives:** State concisely the specific aims and research strategy of the study. ***Projects involving human subjects or specimens must be either exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).***

- **Methods:** Describe the experimental design, methods, and analyses including appropriate controls, if applicable. Address potential problem areas and present alternative methods and approaches.
- **Impact:** Provide a brief statement describing the impact, either short-term or long-term, of this research on lung cancer. Describe how the project will lead to an original and important contribution toward advancing basic, translational, or clinical lung cancer research, or on the quality of life of individuals with lung cancer.

*Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Project Narrative is prohibited and will result in administrative rejection of the application.*

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.*
  - References Cited(five-citation limit): List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). *Do not include URLs that identify the organization(s) of the PI or collaborators.*
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. *Do not include information that identifies the organizations(s) of the PI or collaborator(s).*
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Not required at this time. Leave Attachment 3 space blank.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” Not required at this time. Leave Attachment 4 space blank.
- **Attachment 5: Statement of Work (SOW) (one-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.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 Concept Award mechanism, use the SOW format example titled “SOW Generic Format.” The SOW must be in PDF format prior to attaching.

- **Attachment 6: Relevance Statement (one-page limit):** Upload as “Relevance.pdf.” *Do not include information that identifies the PI, collaborators, or their organization(s).*
  - **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.

*Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Relevance Statement is prohibited and will result in administrative rejection of the application.*

- **Attachment 7: 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.

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

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.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>. For this Program Announcement/Funding Opportunity, reviewers at both tiers of review will be blinded to the identity of the PI, collaborators, and their organization(s).

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

#### **B. Application Review Process**

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
  - **Innovation**
    - To what extent the proposed research is innovative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
    - To what extent exploring the concept may lead to new areas of research.
    - How the proposed research represents more than an incremental advance beyond ongoing or published research.
  - **Impact**
    - To what extent the proposed research will, whether in the short-term or long-term, lead to an original and important contribution toward advancing basic, translational, or clinical lung cancer research, or on the quality of life of individuals with lung cancer.

- **Research Strategy**

- To what degree the proposed research is supported by a sound scientific rationale.
- To what degree the experimental design and methodology are appropriate to address the stated objectives.

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

- **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.

- **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 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 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 applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI, collaborators, or their organization(s) are identified or referenced in the Project Narrative, List of Abbreviations, Acronyms, and Symbols, or the Relevance Statement.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting (and therefore revealing) the names of the PI, collaborators, or their institutions.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the 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 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**

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

Grants.gov Application Components	Action	Completed
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: Not required; leave Attachment 3 blank.	
	Lay Abstract: Not required; leave Attachment 4 blank.	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Relevance Statement: Upload as attachment 6 with file name "Relevance.pdf."	
	Letters Confirming Access to Military or VA Patient Populations or Human/Animal Anatomical Substances, Databases: Upload as Attachment 7 with file name "Access.pdf," if applicable.	
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.	