Program Announcement

Defense Health Program

Department of Defense Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Early Investigator Synergistic Idea Award

Funding Opportunity Number: W81XWH-11-LCRP-EISIA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), August 3, 2011
- **Invitation to Submit an Application:** September 2011
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** March 2012

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

TABLE OF CONTENTS

I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

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

The vision of the FY11 LCRP is to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the LCRP will support and integrate research from multiple disciplines for early detection, diagnosis, prevention, cure, and control of lung cancer.

B.   Award Information

The LCRP Early Investigator Synergistic Idea Award mechanism is being offered for the first time in FY11.

The Early Investigator Synergistic Idea Award supports collaborations between two independent investigators early in their careers who address an innovative and high impact lung cancer research question from synergistic and complementary perspectives. This award is designed specifically to promote collaborations between a clinician and laboratory scientist. Multi-institutional applications are encouraged but not required. ***To be eligible for this award, the Principal Investigators (PIs) must both be independent investigators at or below the level of Assistant Professor (or equivalent) and within the first 5 years of his/her first faculty position (either tenure or non-tenure track), or equivalent.*** Submissions from and partnerships with investigators at Military Medical Treatment Facilities**,** military labs, the Department of Veterans Affairs (VA) Medical Centers and research laboratories, and industry are encouraged.

Areas of Emphasis: The FY11 LCRP only accepts Early Investigator Synergistic Idea Award applications that address at least one of the seven Areas of Emphasis listed below:

- Identification or development of non-invasive or minimally invasive tools to improve the detection of the initial stages of lung cancer.

- Identification and development of new tools and/or building upon already existing tools for screening or early detection of lung cancer. Screening may include, but is not limited to, computed tomography scans, X-rays, other imaging biomarkers, genetics/ genomics/proteomics, and assessment of risk factors.

- Understanding the molecular mechanisms that lead to clinically significant lung cancer.

- Identification of the mechanisms that lead to the development of the various types of lung cancer.

- Identification of innovative strategies for prevention and treatment of early lung cancer.

- Understanding predictive and prognostic markers to identify responders and non-responders.
- Understanding acquired resistance to treatment.

The Early Investigator Synergistic Idea Award requires that two investigators jointly design a single project. However, each partner will be recognized as a PI, submit a separate application, and receive an individual award. The research project must be supported by the unique expertise, experience, and abilities of each PI, and it must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts. Each proposed study must include clearly stated plans for interactions between the PIs and institutions involved. The plans must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues, and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

Although groundbreaking research often involves a degree of risk, applications should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature. Due to this award's emphasis on innovation, presentation of preliminary data relevant to lung cancer and the proposed project is encouraged but not required.

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

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DOD)-funded research projects (new and ongoing) involving human subjects and human anatomical substances must be reviewed and approved by the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), and the local Institutional Review Board of record. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. Refer to the General Application Instructions, Appendix 5, for more information.

C.   **Eligibility Information**

- *Clinician:*
  - Must be an M.D., M.D./Ph.D., or equivalent with clinical duties and/or responsibilities.

- ○ Must be an independent investigator *at or below* the level of Assistant Professor (or equivalent) and within the first five years of his/her first faculty position (either tenure or non-tenure track), or equivalent, at the time of application submission.

- *Laboratory Scientist:*
  - ○ Must be an independent investigator *at or below* the level of Assistant Professor (or equivalent) and within the first 5 years of his/her first faculty position (either tenure or non-tenure track), or equivalent, at the time of application submission.

- Please note that graduate students, postdoctoral fellows, and other "mentored" researchers are not eligible for this award.

- Cost sharing/matching is not an eligibility requirement.

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

D. Funding

- The maximum period of performance is **2** years.

- The maximum allowable direct costs for the entire period of performance is **$400,000** plus indirect costs**.**

  - ○ The combined total funding for the Initiating PI and the Partnering PI may not exceed **$400,000** for direct costs for up to a **2**-year period of performance, plus indirect costs as appropriate.

- 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.

- A separate award will be made to each PI's organization.

- The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

May be requested for (not all-inclusive):

- Salary

- Research supplies

- Equipment

- Clinical research costs (no clinical trials allowed)

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

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $2.556M of the $12.8M FY11 LCRP appropriation to fund approximately 4 Early Investigator Synergistic Idea Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II.   SUBMISSION INFORMATION

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

The Early Investigator Synergistic Idea Award mechanism is structured to accommodate two PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, both PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified separately by email. **Please note that the Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.** If an application is invited, only the Initiating PI will receive a letter of invitation via email from CDMRP. The letter will provide the information necessary to begin application submission through Grants.gov.

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

A.   Where to Obtain the Application Package

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

B.   Pre-Application Submission Content and Form

All pre-application components must be submitted by the Initiating PI through the CDMRP eReceipt System (https://cdmrp.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

The Initiating PI is responsible for submission of all pre-application components.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

    The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section**.**

- **Required Files – Tab 4**

    Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

    The Preproposal Narrative should include the following:

    ○ **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning behind the proposed research; include relevant literature citations.

    ○ **Research Strategy:** State the project's specific aims. State which of the Areas of Emphasis the proposed project will address. *Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.*

    ○ **Synergy:** Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently. Describe how the combined efforts are centered on a unified objective, and how the PIs will work together to achieve that objective from different perspectives.

    ○ **Innovation:** Describe how the proposed research project is innovative, and how the research represents more than an incremental advance on published data.

    ○ **Impact:** Explain the potential impact of the proposed research project and how it will, if successful, move the research field toward achieving the LCRP's vision of eradicating deaths from lung cancer to better the health and welfare of the military and the American public.

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

    ○ References Cited (one-page limit): List relevant references 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). The inclusion of Internet URLs to references is encouraged.

- ○ Key Personnel Biographical Sketches (four-page limit per individual)

- **Submit Pre-Application – Tab 5**

- **Other Documents Tab**

No additional documents are required**.**

Pre-Application Screening

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DOD and CDMRP, pre-applications will be screened based on the following criteria:

- ○ **Synergy:** How well the proposed study represents a synergistic collaboration that will produce results greater than those of the PIs working independently. To what degree it is evident that all PIs have provided comparable levels of intellectual input into the proposed project.

- ○ **Research Idea:** How well the application addresses the intent of the award and at least one of the Areas of Emphasis.

- ○ **Innovation:** How well the research proposes new paradigms, challenges existing paradigms, looks at existing problems from new perspectives, or exhibits other uniquely creative qualities.

- ○ **Impact:** To what degree the proposed research, if successful, will make an important contribution that significantly advances current methods and concepts toward the vision of eradicating deaths from lung cancer.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, Initiating PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the title page of this Program Announcement Funding Opportunity.

C.   Application Submission Content and Form

Applications will not be accepted unless the Initiating PI has received a letter 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 (AOR) through the Grants.gov portal (http://www.grants.gov/). For the Early Investigator Synergistic Idea Award, additional application components are also required and should be submitted as directed below.

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.

Application Components for the Initiating PI:

Grants.gov application package components: For the Early Investigator Synergistic Idea 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):

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

- **Attachments Form**
  - ○ **Attachment 1: Project Narrative (10-page limit):** Upload as "ProjectNarrative.pdf."

    Describe the proposed project in detail using the outline below. The inclusion of preliminary data relevant to lung cancer and the proposed project is encouraged, but not required. Any preliminary data presented should be from the laboratory of either the PI or any of the named collaborators.

    - – **Background of Research Project:** Present the ideas and reasoning behind the proposed work, and cite relevant literature. Describe previous experience most pertinent to this application.

    - – **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

    - – **Specific Aims:** Concisely explain the project's specific aims to be funded by this application. If this proposal is part of a larger study, present only tasks that this DOD award would fund.

    - – **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. Describe the statistical plan if appropriate for the research proposed. ***This award may not be used to conduct clinical trials.***

    - – **Project Coordination and Communication:** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and institutions participating in the project.

  - ○ **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are

scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***Each component has no page limit unless otherwise noted.***

– References Cited: 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. 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, reflecting the laboratory space, equipment, and other resources available for the project.

– Letter of Eligibility: This letter should be signed by the Department Chair, Dean, or equivalent official, and should verify that the PI meets the eligibility requirements outlined in Section I.C.

– 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 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 (if applicable): Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about CDMRP's expectations for making data and research resources publicly available.

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

Describe the proposed research project, including the following elements: Background, Objective/Hypothesis, Study Design and Specific Aims, Synergy, Innovation, and Impact. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

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

Public abstracts should be written using the outline below.

– Clearly describe, in a manner readily understood by lay persons, the rationale and objective for the proposed work.

▪ Do not duplicate the technical abstract.

– 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?

▪ What is the projected time it may take to achieve a clinically relevant outcome?

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

Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

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

Explain how the proposed research, if successful, will have an impact on the concepts or methods that drive the field of lung cancer research and its impact on patient care. Describe how the proposed research will make original and important contributions towards the goal of eradicating deaths from lung cancer to better the health and welfare of the military and the American public.

○ **Attachment 7: Innovation Statement (one-page limit):** Upload as "Innovation.pdf."

Describe how the proposed project represents new paradigms or challenges existing paradigms, or is otherwise uniquely creative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways. Proposing research that represents an incremental advancement on published data is not considered innovative.

○ **Attachment 8: Synergy Statement (one-page limit):** Upload as "Synergy.pdf."

Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the application. Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

- ○ **Attachment 9: Approval for Access to Military Populations (if applicable), (one-page limit):** Upload as "Access.pdf."

  If studies include active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities), a letter of support, signed by the lowest ranking person with approval authority, should be provided.

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

  - ○ PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
    - ▪ Include biosketches for both the Initiating PI and Partnering PI.
  - ○ PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - ▪ Include current/pending support for both the Initiating PI and Partnering PI.
  - ○ Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
  - ○ Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

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

  Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PI, even if they are at the same organization.

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

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

Application Components for the Partnering PI:

The Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.

The application submission process for the Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. **SF 424 (R&R) Application for Federal Assistance Form**

2. **Attachments Form**

   - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.*

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

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

   Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget form for the Initiating PI should not include budget information for the Partnering PI, even if they are at the same organization.

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

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

D. Submission Dates and Times

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

E. Other Submission Requirements

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

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

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

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B.   Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria. Of these criteria, Synergy, Innovation, and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance:

- **Synergy**
    - To what degree the proposed partnership between PIs is likely to facilitate or greatly accelerate a significant achievement in lung cancer research that could not otherwise be accomplished by each PI working independently.
    - To what degree the contributions of each PI to the overall synergy of the project are appropriately balanced.
    - To what degree the proposed project is centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
    - How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among both PIs and institutions.

- **Innovation**
    - To what degree the research proposes new paradigms or challenges existing paradigms, or is otherwise uniquely creative in one or more of the following ways: Concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.

- ○ To what degree the proposed research represents more than an incremental advance upon published data.
- **Impact**
  - ○ How the proposed work addresses a critical problem in lung cancer research or patient care.
  - ○ How the proposed research, if successful, will make original and important contributions towards the LCRP's vision of eradicating deaths from lung cancer to better the health and welfare of the military and the American public.
- **Research Strategy and Feasibility**
  - ○ How well the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, lung cancer-relevant preliminary data (if provided, though not required), and/or logical reasoning.
  - ○ How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - ○ How well the PIs acknowledge potential problems and address alternative approaches.
  - ○ How well the proposed project addresses at least one of the Areas of Emphasis.
- **Personnel**
  - ○ How the research team's background and lung cancer-related expertise are appropriate with respect to its ability to perform the proposed work.
  - ○ To what degree the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Environment**
  - ○ To what degree the scientific environment is appropriate for the proposed research.
  - ○ How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - ○ To what degree the quality and extent of organizational support are appropriate.
- **Budget**
  - ○ Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - ○ To what extent the writing, clarity, and presentation of the application components influenced the review.

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

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

C.   Recipient Qualification

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

D.   Application Review Dates

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

E.   Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt 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:
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

- Submission of an application for which a letter of invitation was not received.
- All associated applications (from Initiating and Partnering PIs) are not submitted by the deadline.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.

- Documents not requested will be removed.

- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- FY11 LCRP Integration Panel (IP) member is found to be involved in the preapplication or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 LCRP IP members may be found at http://cdmrp.army.mil/lcrp/panels/panels11.

- The application does not address at least one of the Areas of Emphasis.

- Submission of the same research project to different funding opportunities within the same program and fiscal year.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.

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

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

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

- The proposed research is or includes a clinical trial.

- The Initiating and/or Partnering PI do not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity

(USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V.   AWARD ADMINISTRATION INFORMATION

A.   Award Notice

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

B.   Administrative and National Policy Requirements

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

C.   Reporting

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

D.   Award Transfers

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

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.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 1-800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Initiating PI Completed	Partnering PI Completed
F-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Innovation Statement (Innovation.pdf) as Attachment 7.		
	Upload Synergy Statement (Synergy.pdf) as Attachment 8.		
	Upload Approval for Access to Military Populations (Access.pdf) as Attachment 9 (if applicable).		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.		