Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Translational Research Partnership Award

Funding Opportunity Number: W81XWH-12-LCRP-TRPA

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), May 30, 2012
- **Invitation to Submit an Application:** July 2012
- **Application Submission Deadline:** 11:59 p.m. ET, September 20, 2012
- **Peer Review:** November 2012
- **Programmatic Review:** January 2013

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the 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 fiscal year 2009 (FY09) to promote innovative and competitive research focused on the development of integrated components to identify, treat, and manage early curable lung cancer. Appropriations for the LCRP from FY09 through FY11 totaled $47.8 million (M). The FY12 appropriation is $10.2M.

The goal of the FY12 LCRP is to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the LCRP will support and integrate research from multiple disciplines for risk assessment, early detection, diagnosis, prevention, cure, and control of lung cancer.

B. Award Information

The LCRP Translational Research Partnership Award mechanism is being offered for the first time in FY12.

The key initiative of the Translational Research Partnership Award is to encourage partnerships between clinicians and laboratory scientists that will accelerate the movement of promising ideas in lung cancer into clinical applications. This award supports the development of translational research collaborations between two independent, faculty level (or equivalent) investigators to address a central problem or question in lung cancer in a manner that would be less readily achievable through separate efforts. ***One partner in the collaboration must be a laboratory scientist and the other must be a clinician, and it should be clear that both have had equal intellectual input into the design of the research project.*** Multi-institutional partnerships are encouraged but not required. At least one member of the partnership must have experience either in lung cancer research or lung cancer patient care. A proposed project in which the clinical partner merely supplies tissue samples or access to patients will not meet the intent of this award mechanism. 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 commercial organizations are encouraged.

Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's first-hand knowledge of patients and anecdotal data. While the ultimate goal of translational research is to move an observation forward into clinical application, members of the partnership should view translational research as a two-way continuum between bench and bedside. Developing the research plan must involve a reciprocal flow of ideas and information within the partnership. Developmental pathways for translational research that may be useful for designing translational research studies for support under this award mechanism may be found at http://www.cancer.gov/aboutnci/trwg/Pathways-to-Clinical-Goals.

The Translational Research Partnership Award does not support clinical trials, but may support correlative studies that are associated with an existing clinical trial and projects that develop

clinical endpoints for clinical trials. Research projects may also include preclinical studies in animal models and human subjects and human anatomical substances.

Preliminary data to support the feasibility of the research hypotheses and research approaches are required; however, these data do not necessarily need to be in lung cancer.

Areas of Emphasis: To be considered for funding, applications for the FY12 LCRP Translational Research Partnership Award must address at least one of the seven Areas of Emphasis listed below.

- Identification or development of non-invasive or minimally invasive tools to improve detection of the initial stages of lung cancer;
- Identification, development 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/ metabolomics, and assessment of risk factors;
- Understanding the molecular mechanisms of progression to clinically significant lung cancer;
- Understanding the molecular mechanisms that lead to various subtypes 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 success of the project must be supported by the unique skills and contributions of each partner. The proposed study must include clearly stated plans for interactions between the Principal Investigators (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.

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

Optional Nested Clinical Fellow or Resident Traineeship: The Translational Research Partnership Award offers opportunities for training highly motivated clinical fellows or residents interested in pursuing a research career in lung cancer. The trainee is ***not*** required to have previous lung cancer research experience. This option primarily provides salary support for the trainee. ***Only one traineeship may be requested per project. Plans for training and mentorship must be well developed and clearly described by the PI for the Translational Research Partnership Award application.***

The LCRP reserves the right to fund a submission for a Translational Research Partnership that includes a proposed Nested Clinical Fellow or Resident Traineeship, but **not fund** the traineeship.

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

C. Eligibility Information

- Each PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).
- The Clinician must be an M.D., M.D./Ph.D., or equivalent with clinical duties and/or responsibilities.
- Optional Nested Clinical Fellow or Resident Traineeship: The clinical fellow or resident trainee must be enrolled in an accredited clinical fellowship or residency program by the time of the application submission deadline. The trainee must be able to devote a minimum of 40% level of effort for the 1-year period of performance of the traineeship.
- 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 **3** years.
- A separate award will be made for each PI, even if the PIs are at the same organization.
- The maximum allowable combined total direct costs for the entire period of performance are **$900,000** plus indirect costs.
- Additional funds may be requested for the Optional Nested Clinical Fellow or Resident Traineeship for the maximum allowable total costs (direct and indirect) of **$75,000** for a period of performance of **1** year. An application requesting a higher level of funding to support this option, but that does not have the option recommended for funding during programmatic review, will have its budget reduced 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 **3** 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.
- 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. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (other than cost for clinical trials, which are not allowed)
- Travel between collaborating organizations
- Travel costs of up to $1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $4.32M of the $10.2M FY12 LCRP appropriation to fund approximately 3 Translational Research Partnership Award research projects (representing 6 individual awards), 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 Translational Research Partnership 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 partner 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. ***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 notification 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 prohibited. The Government will 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-12-LCRP-TRPA.

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 any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

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**

  FY12 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 (help@cdmrp.org or 1-301-682-5507).

  The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section. This Program Announcement/Funding Opportunity allows a ***maximum of one*** Partnering PI.

- **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 needed to support the proposed study. ***The inclusion of preliminary data relevant to the proposed project, but not necessarily in lung cancer, is required.***

The Preproposal Narrative should describe the proposed project using the outline below:

- **Rationale:** Clearly articulate the rationale for the project by presenting the ideas and reasoning that support it; include relevant literature citations.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Approach:** State the project's specific aims and briefly describe the experimental approach to be used for accomplishing the aims. ***This award may not be used to conduct clinical trials.***
- **Partnership:** Describe how the combined efforts of the PIs will result in a level of productivity that will be 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. Briefly describe the PIs' histories of collaborative study with each other or with other investigators, including the PIs' abilities to function synergistically in a project among equals.
- **Impact:** Describe the potential short-term and long-term impact of this study on lung cancer research and/or patient care. Research that has high impact will, if successful, significantly accelerate progress toward the eradication of deaths from lung cancer.
- **Areas of Emphasis:** Briefly describe how the proposed research is relevant to at least one of the LCRP Areas of Emphasis.

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

- **Submit Pre-Application – Tab 5**

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

- **Other Documents Tab**

  No additional documents are required**.**

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the Department of Defense (DoD) and LCRP, pre-applications will be screened by the LCRP Integration Panel based on the following criteria:

  - **Partnership:** 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.
  - **Impact:** To what degree the proposed study could, whether short-term or long-term, make a significant impact on lung cancer research and/or patient care, including its potential contribution to the eradication of deaths from lung cancer.
  - **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible and addresses the hypothesis or objective.
  - **Responsiveness to the Areas of Emphasis:** To what degree the proposed research is responsive to at least one of the LCRP Areas of Emphasis.

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

  Following the pre-application screening, Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The Invitation to Submit an Application date is indicated on the title page of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the Initiating PI has received an invitation to submit an application.

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/).

The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI. Initiating and Partnering PIs will each be assigned unique 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 Translational Research Partnership 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 (12-page limit):** Upload as "ProjectNarrative.pdf."

     The 12-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the application.

     Describe the proposed project in detail using the outline below. ***The inclusion of preliminary data relevant to the proposed project, but not necessarily in lung cancer, is required.*** Any preliminary data provided should be from the laboratory of the PI(s) or member(s) of the collaborating team named on the application.

     - **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application, including each PI's history of synergistic and collaborative study with one another and/or with other investigators.
     - **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. Include specific examples of synergistic elements incorporated into the research design. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***This award cannot be used to conduct clinical trials.***
     - **Project Coordination and Communication:** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among both 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. ***There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information. ***Provide this information for both the Initiating and Partnering PI.***
- 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, ensuring the availability of laboratory space, equipment, and other resources for the project. ***Provide a letter from each PI's organization.***
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PIs have the support or resources necessary for the proposed work.
- Letter of Eligibility (required if requesting Optional Nested Clinical Fellow or Resident Traineeship): Provide a Statement of Eligibility form signed by the Program Director, Chair, or equivalent that verifies that the trainee is enrolled in an accredited clinical fellowship or residency training program or will be by the time of the application submission deadline, and is able to participate at a minimum of 40% level of effort for the 1-year period of performance.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

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

  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.

  - Background: Present the ideas and reasoning behind the proposed project.
  - Objective: State the objective to be reached. Provide evidence or rationale that supports the objective.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design.
  - Impact: Summarize the potential impact of the proposed project toward the goal of eradicating deaths from lung cancer.

- **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.*** The lay abstract is used by consumer peer reviewers along with other components of the application package.

  - 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***.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
    - What is the projected time it may take to achieve a clinically relevant outcome?
  - What are the likely contributions of this study to advancing the field of lung cancer research?

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

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

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

  Explain in detail why the proposed research project is important.

  Describe the short-term impact: Detail the anticipated outcome(s)/product(s) that will be directly attributed to the results of the proposed research.

Describe the long-term impact: Explain the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the proposed work will have on accelerating the movement of a promising idea in lung cancer into clinical applications.

LCRP Areas of Emphasis: Summarize how the proposed project addresses at least one of the LCRP Areas of Emphasis.

- **Attachment 7: Partnership Statement (one-page limit):** Upload as "Partnership.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 how the proposed partnership involves a substantial contribution by each partner and the reciprocal flow of ideas and information. 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 8: Statement of Traineeship (*required if requesting an Optional Nested Clinical Fellow or Resident Traineeship;* two-page limit)*:*** Upload as "Traineeship.pdf."

  Clearly describe the lung cancer research training program for the trainee, incorporating consideration of the candidate's goals and prior experience. This should include a plan to obtain any necessary background, in addition to the research experience and skills, necessary to support the trainee during the 1-year period of performance of the traineeship. Describe the availability of courses, such as research design, biostatistics, and epidemiology at the institution, and how they will be integrated into the training plan. A timeline of key activities and planned attendance at conferences and seminars should be provided. Include information to describe the mentor's research support related to the candidate's research plan, and nature of the supervision that will occur during the proposed award period. The sponsoring institution must demonstrate a research and training program related to the candidate's area of interest, including a high-quality research environment with staff capable of productive collaboration with the trainee.

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

   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI 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 biographical sketches for both the Initiating and Partnering PI.
     - Include a biographical sketch for the clinical fellow or resident trainee (if applicable).

- Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
    - Include current/pending support for both the Initiating and Partnering PI.

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

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

    The Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed $900,000 (without the Optional Nested Clinical Fellow or Resident Traineeship).

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

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

Application Components for the Partnering PI(s):

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 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 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."

The Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs' budgets cannot exceed $900,000 (without the Optional Nested Clinical Fellow or Resident Traineeship).

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 will result in application rejection.

E. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Numbering 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 LCRP, and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. 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, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance.

   - **Partnership**
     - Whether both PIs meet the eligibility requirements.
     - To what degree the proposed partnership between the PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
     - How the partners' expertise and levels of effort support the proposed project.
     - To what degree the proposed project is centered on a unified theme that addresses a central problem or 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 all participating PIs and institutions.
   - **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, and 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.
   - **Impact**
     - To what degree the project could, whether short-term or long-term, make a significant impact on lung cancer research and/or patient care.

- If successful, how the partnership and the aims of the study project will eventually move from a clinical observation, a laboratory discovery, or population-based study into clinical applications.
- How well the proposed research addresses at least one of the LCRP Areas of Emphasis.

- **Clinical Fellow or Resident Traineeship (if applicable)**
  - Whether the clinical fellow or resident is an appropriate candidate for this traineeship, and whether he/she is able to participate at a minimum of 40% level of effort over the 1-year period of performance.
  - Whether the PI and other scientific personnel are well qualified to conduct training for the trainee, and whether there is a senior staff member who is identified and responsible for the trainee.
  - How well the research training is structured and balanced to ensure that the trainee will acquire the knowledge and necessary skills relevant to the area of lung cancer being studied.

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.
  - If multi-institutional, the quality and completeness of the Intellectual and Material Property Plan.

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether the resources are divided appropriately among all PIs.

- **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 LCRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

- Adherence to the intent of the award mechanism
- Programmatic relevance in relation to the LCRP Areas of Emphasis
- Ratings and evaluations of the peer reviewers
- Relative impact
- Program portfolio composition

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. Each PI 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:

- Submission of an application for which a letter of invitation was not received.
- All associated (Initiating and Partnering PI) applications are not submitted by the deadline.
- Project Narrative exceeds page limit.
- Project Narrative is missing.

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

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.
- If included, the Optional Nested Clinical Fellow or Resident Traineeship will be administratively removed if the trainee does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

C. Withdrawal

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

- A FY12 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 document. A list of the FY12 LCRP IP members can be found at http://cdmrp.army.mil/lcrp/panels/panels12.shtml.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The application does not address at least one of the Areas of Emphasis.
- The proposed research is, or requests funding for, a clinical trial.
- The Initiating and/or Partnering PI does/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 U.S. 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, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

For the transfer of an award that includes a Nested Clinical Fellow or Resident Traineeship, but where the trainee will not be transferring along with the PI, funds associated with the traineeship may be removed.

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 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
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Impact Statement (Impact.pdf) as Attachment 6.		
	Upload Partnership Statement (Partnership.pdf) as Attachment 7.		
	Upload Statement of Traineeship (Traineeship.pdf) as Attachment 8 (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.		