

Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Clinical Exploration Award

Funding Opportunity Number: W81XWH-13-LCRP-CEA

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), July 9, 2013
- **Invitation to Submit an Application:** August 2013
- **Application Submission Deadline:** 11:59 p.m. ET, October 16, 2013
- **Peer Review:** December 2013
- **Programmatic Review:** January 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) Lung Cancer Research Program (LCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The LCRP was initiated in fiscal year 2009 (FY09) to promote innovative and competitive research focused on the development of integrated components to identify, treat, and manage early curable lung cancer. Appropriations for the LCRP from FY09 through FY12 totaled \$58 million (M). The FY13 appropriation is \$10.5M.

The goal of the FY13 LCRP is to eradicate deaths from lung cancer to better the health and welfare of the military and the American public. As such, the LCRP will support and integrate research from multiple disciplines for risk assessment, early detection, diagnosis, prevention, and treatment for the control and cure of lung cancer.

B. FY13 LCRP Areas of Emphasis

To be considered for funding, applications for the FY13 LCRP Clinical Exploration Award *must* address at least one of the seven Areas of Emphasis listed below.

- Identify or develop noninvasive or minimally invasive tools to improve the detection of the initial stages of lung cancer.
- Identify, develop, and/or build upon already existing tools for screening or early detection of lung cancer. Screening may include, but is not limited to, computed tomography scans, X-rays, imaging biomarkers, genetics/genomics/proteomics/metabolomics, and assessment of risk factors.
- Understand the molecular mechanisms of progression to clinically significant lung cancer.
- Understand the molecular mechanisms that lead to various subtypes of lung cancer.
- Identify innovative strategies for prevention and treatment of early lung cancer.
- Understand predictive and prognostic markers to identify responders and nonresponders.
- Understand susceptibility or resistance to treatment.

C. Award Information

The LCRP Clinical Exploration Award mechanism is being offered for the first time in FY13.

The intent of the LCRP Clinical Exploration Award (CEA) is to support early-phase, proof-of-principle clinical trials and correlative studies to investigate hypothesis-based, innovative interventions and/or avenues of research that have the potential to resolve current clinical barriers and result in a profound impact on the clinical management of lung cancer. While therapeutic approaches proposed for testing through the CEA must represent novel, hypothesis-based, “outside-the-box” approaches for treating lung cancer, they may include therapies already in clinical use, or undergoing clinical testing, for other diseases, provided that the proposed use

for lung cancer would lead to a major advancement for treating the disease. It is anticipated that outcomes from studies funded by this award will provide scientific rationale for subsequent development of larger, efficacy-based clinical trials of interventions that will transform lung cancer clinical care. Submissions from and partnerships with investigators at Military Medical Treatment Facilities, Military labs, and the Department of Veterans Affairs (VA) Medical Centers and research laboratories are encouraged.

Clinical Trials: The CEA will support clinical trials encompassing Phase 0, Phase I, or pilot Phase II for drug or drug combinations, Class II or III devices, or other types of trials that conduct early clinical testing of innovative approaches for lung cancer. Information on clinical trials and phases/classes of study is provided in the “Human Subject Resource Document” available for download from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/.

Correlative Studies: The CEA will also support innovative, hypothesis-based, correlative studies that derive from ongoing or completed clinical trials supported by other funding sources. These studies, if successful, will have the potential to significantly inform treatment strategies, identify subset of patients for treatment with specific therapies, provide increased understanding of biological changes resulting from the intervention in lung cancer, or provide other insight that will significantly enhance clinical management of lung cancer. Examples of correlative studies appropriate for submission to the CEA may include, but are not limited to:

- Analysis of biomarkers for prognosis and/or prediction or assessment of therapeutic response or progression;
- Investigations of the mechanism of action or the development of resistance to a drug;
- Analysis of immune response or factors associated with progression;
- Characterization of tumor antigens for the development of new improved therapies.

Funding from the CEA must support a clinical trial or correlative study associated with an ongoing or completed clinical trial and cannot be used for preclinical research studies.

Because the CEA seeks to support clinical trials and correlative studies that may deliver groundbreaking ideas, it is the responsibility of the PI to clearly articulate how the proposed study represents research that is beyond conventional therapeutic approaches for lung cancer. Studies in a broad range of areas related to lung cancer clinical management will be considered under the CEA, including but not limited to evaluation of drugs, biologics, devices, surgical procedures, behavior modifications, or other types of therapeutic approaches.

Key elements of this award are as follows:

- The application should clearly specify the type of clinical study, including phase or class designation (if applicable), that is being proposed.
- ***The application must include documentation of an existing Investigational New Drug (IND) or Investigational Device Exemption (IDE), if applicable.***
- The proposed intervention or correlative study must be based on sound scientific rationale that is established through logical reasoning, critical review and analysis of the literature, and preliminary data.

- The application should demonstrate availability and accessibility of suitable human subject population that will support a meaningful outcome for the study (if applicable).
- ***The application must demonstrate documented availability and accessibility of the drug/compound, device, and/or other materials needed, e.g., a letter from the manufacturer assuring an adequate supply of the agent (and placebo if necessary).***
- The proposed study should include clearly defined and appropriate endpoints.
- The application should include a detailed statistical analysis plan, including a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- The proposed study is expected to begin no later than 12 months after the award date.
- The application should include a Transition Plan that describes a clear path for further development of research.
- **Relevance to Military Beneficiaries:** The application should clearly articulate how the proposed research is relevant to service members, their families, and other military beneficiaries.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the Institutional Review Board (IRB) of record. IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

All investigators applying to FY13 LCRP funding opportunities are encouraged to consider leveraging resources available through the LCRP-funded Lung Cancer Biorepository Resource Network (LCBRN) (<http://www.lcbrn.org/>) if retrospectively collected human anatomical substances or correlated data are relevant to the proposed studies.

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

D. Eligibility Information

- The PI must be an independent investigator at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.

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

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are **\$450,000** 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 **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.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Shall not be requested for:

- Preclinical research studies

The CDMRP expects to allot approximately \$0.72M of the \$10.5M FY13 LCRP appropriation to fund approximately 1 Clinical Exploration Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

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

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-13-LCRP-CEA.

B. Pre-Application Submission Content and Form

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

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

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the USAMRAA Contracting/Grants Officer.

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

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

FY13 LCRP Integration Panel (IP) members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP [Help Desk](mailto:help@cdmrp.org) at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

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

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

The Preproposal Narrative should include the following:

- **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research; include relevant literature citations and preliminary studies that led to the development of the proposed clinical trial and/or correlative study. For a clinical trial, clearly describe the intervention and its target and mechanism of action in lung cancer. If the proposed study is correlative to an ongoing or completed clinical trial, describe the relationship between the intervention and the question(s) to be studied.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Study Design:** Describe the design of the clinical trial or research approach for correlative studies. The description should include:
 - The type of study to be performed (e.g., Phase/Class, prospective, randomized, controlled, correlative, etc.) and proposed methodology.
 - The study variables and proposed measurement.
 - The research team’s capabilities in conducting clinical trials, including discussion of key coordinating activities.
 - The feasibility of initiating the clinical trial or correlative study within 12 months of the award date. **Note: Invited applications must provide proof of an existing IND/IDE, if applicable.**
- **Innovation:** Describe how the proposed study is an innovative, unconventional approach for the clinical management of lung cancer.
- **Clinical Impact:** Describe how the proposed study, if successful, will have a major impact toward improving lung cancer management and contribute to the eradication of deaths from lung cancer. Briefly describe how the proposed study is responsive 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 the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- PI and 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 DHP and the LCRP, pre-applications will be screened by the LCRP IP based on the following criteria:

- **Intent of the Award Mechanism:** To what degree the proposed study represents hypothesis-based, innovative clinical research that has the potential to resolve current clinical barriers in lung cancer.
- **Research Approach:** To what degree the experimental approach for accomplishing the specific aims is feasible, will accomplish the objectives, and is based on sound rationale.
- **Impact:** To what degree the proposed study may lead to a profound impact on the clinical management of lung cancer. How well the study addresses one or more of the LCRP Areas of Emphasis.

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

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

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

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the Clinical Exploration 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 (15-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.

Note: For clinical trials, the Project Narrative is NOT the formal clinical trial protocol. Instead, all elements of the proposed clinical trial necessary for peer review must be described as indicated below.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations, preliminary data, and/or preclinical data that led to the development of the proposed clinical trial and/or correlative study. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.

If the proposed study is correlative to an ongoing or completed clinical trial, explain the history and background of the clinical trial and declare the source of funding.

Clearly articulate how the proposed study represents research that is beyond conventional therapeutic approaches for lung cancer.

- **Hypotheses/Objective:** State the hypotheses/study questions and overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Study Design:** Describe the type of study to be performed (e.g., Phase/Class, prospective, randomized, controlled, correlative, etc.) and outline the proposed methodology in sufficient detail to show a clear course of action.
 - Identify and describe the hypothesis/intervention to be studied and how it will be applied.
 - Describe the projected outcomes of the study.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (i.e., convenience, simple random, stratified random). Address any potential barriers to accrual and plans for addressing potential delays. Describe how the subject-to-group assignments process will be conducted (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Include a discussion of risk/benefit considerations. Include a clear and detailed description of the potential ethical issues raised by the proposed

study and provide a detailed plan for how the ethical issues will be addressed.

- Document the availability and accessibility of the drug/compound, device, or other materials needed.
- Describe in detail the laboratory evaluations (correlative studies) to be conducted.
- **Data and Statistical Analysis Plan:** Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Specify the approximate number of human subjects/samples that will be accrued. If multiple study sites are involved, state the approximate number to be enrolled at each site.
- **Study Personnel:** Identify the key members of the study team and describe their roles on the project. If applicable, a medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested may result in the removal of those items or administrative withdrawal of the application.***
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
 - Background and Proprietary Information (if applicable): All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project. Identify any proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, for more information about the CDMRP expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
 Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects.
 - Background: Present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design including appropriate controls.
 - Clinical Impact: Briefly describe how the proposed project may lead to a major impact on lung cancer clinical management.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”
 Lay abstracts should be written using the outline below. ***Do not duplicate the technical abstract.*** Minimize the use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer advocate community.
 - Describe the scientific objective and rationale for the proposed project in a manner that will be readily understood by readers without a background in science or medicine.
 - 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 an impact on the standard of care for lung cancer?
- What are the likely contributions of this study to advancing the field of lung cancer research?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

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

Explain in detail why the proposed research project is important, as follows:

- **Areas of Emphasis:** Describe how the proposed research is relevant to at least one of the LCRP Areas of Emphasis.
- **Describe the short-term impact:** Detail the anticipated outcomes that will be directly attributed to the results of the proposed research, including a description of the target population. Explain how these results/outcome(s)/product(s) will have the potential to transform lung cancer management and change clinical practice.
- **Describe the long-term impact:** Explain the long-term gains from the proposed research, including how the outcomes or products will ultimately contribute to eradicating deaths from lung cancer.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.”

Describe how the proposed work is innovative, representing a novel, hypothesis-based, “outside-the-box” approach for treating lung cancer. Research that represents an incremental advancement on published data is not considered innovative.

- **Attachment 8: Transition Plan (two-page limit):** Upload as “Transition.pdf.”

Provide information on the methods and strategies proposed to move the product to the next level of clinical research or use after successful completion of the award. The transition plan may include the components listed below:

- Details of the funding strategy that will be used to bring the outcomes to clinical testing or the next level of clinical trial (e.g., specific potential commercial partners, specific funding opportunities to be applied for, etc.).
- A description of collaborations and other resources that will be used to provide continuity of development.
- **Attachment 9: IND/IDE Documentation Form (if applicable):** Upload as “IND.IDE.pdf.”

If applicable, complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.

- **Attachment 10: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as “MilBen.pdf.”

Describe the impact, either short-term or long-term, of the proposed research on the health and welfare of service members, their families, and other military beneficiaries. Describe how the study design will replicate field conditions, if appropriate. If active duty military, military families, or U.S. Veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. Veteran population).

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*

- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
- 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., for detailed information.

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

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

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

D. Submission Dates and Times

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

E. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the

Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DHP and LCRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

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

B. Application Review Criteria

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

- **Clinical Impact**

- To what degree the proposed study could ultimately transform lung cancer clinical management, far beyond current clinical practice, including its potential contribution to the eradication of deaths from lung cancer.
- How well the sample population represents the targeted patient population that might benefit from the proposed or potential intervention.
- To what degree an appropriate plan for transitioning the study outcomes into further development is present, including:
 - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
 - Whether the funding strategy described to bring the outcome(s) to clinical testing or the next level of clinical trial is appropriate.

- How well the proposed research addresses at least one of the LCRP Areas of Emphasis.
- **Innovation**
 - How well the research proposes to use a new intervention and/or existing intervention in a unique or creative way (e.g., first in lung cancer, new and unconventional therapeutic approach, etc.).
 - To what degree the concept or research question is groundbreaking.
 - How the proposed research represents more than an incremental advance upon published data.
- **Study Design**
 - How well the scientific rationale for the proposed study is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory and/or preclinical evidence.
 - To what extent the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the clinical objective.
 - To what degree the statistical plan, including sample size projections and power analysis, as applicable, is appropriate and adequate for the study and all proposed correlative studies.
 - ***For applications proposing clinical trials:***
 - How well the inclusion, exclusion, and randomization criteria meet the needs of the proposed clinical trial, and how well the level of risk to the human subjects is minimized.
 - To what degree the intervention addresses the clinical need(s) described.
 - Whether there is sufficient evidence of an existing IND/IDE (if applicable).
 - Whether there is sufficient evidence of availability and accessibility of the drug/compound, device, and/or materials needed.
- **Recruitment, Accrual, and Feasibility**
 - How well the PI addresses the availability, accessibility, and interest of human subjects for the clinical trial, or how well the PI has justified the availability and accessibility of human samples for correlative studies.
 - Whether there is evidence that a plan to address potential ethical issues raised by the proposed study has been appropriately considered and developed (if applicable).
 - How well the recruitment processes for human subjects, or the collection processes for human samples, are designed to meet the needs of the proposed study.
 - Whether there is evidence of an adequate contingency plan to resolve potential delays (e.g., slow accrual, attrition).

- **Personnel**

- Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
- To what degree the PI's and study team's backgrounds and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical trial experience).
- Appropriateness of the levels of effort by the PI and other key personnel to ensure the success of this research effort.

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

- **Environment**

- To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial/study (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Military Relevance**

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

- **Budget**

- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influenced the review.

2. Programmatic Review: To make funding recommendations, the following equally considered criteria are used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and FY13 LCRP, as evidenced by the following:

- Adherence to the intent of the award mechanism
- Program portfolio composition including consideration of relevance to military beneficiaries
- Relative impact and innovation

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY13 LCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY13 LCRP IP members can be found at <http://cdmrp.army.mil/lcrp/panels/panels13.shtml>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is, or is requesting funding for, a preclinical study.
- No evidence of an existing IND/IDE for the intervention, if applicable.
- The PI does not meet the eligibility criteria.
- The application does not address at least one of the LCRP Areas of Emphasis.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

For all awards including prospective accrual of human subjects, quarterly technical progress reports will be required.

D. Award Transfers

The institutional transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

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 Form | Complete form as instructed. | |
| Attachments Form | Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1. | |
| | Upload Supporting Documentation (Support.pdf) as Attachment 2. | |
| | Upload Technical Abstract (TechAbs.pdf) as Attachment 3. | |
| | Upload Lay Abstract (LayAbs.pdf) as Attachment 4. | |
| | Upload Statement of Work (SOW.pdf) as Attachment 5. | |
| | Upload Impact Statement (Impact.pdf) as Attachment 6. | |
| | Upload Innovation Statement (Innovation.pdf) as Attachment 7. | |
| | Upload Transition Plan (Transition.pdf) as Attachment 8. | |
| | Upload IND/IDE Documentation Form (IND.IDE.pdf), if applicable, as Attachment 9. | |
| | Upload Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 10. | |
| Research & Related Senior/Key Person Profile (Expanded) | Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field. | |
| | Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field. | |
| | Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field. | |
| | Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Project/Performance Site Location(s) Form | Complete form as instructed. | |
| R & R Subaward Budget Attachment(s) Form | Complete form as instructed. | |