I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Lung Cancer Research Program

Career Development Award

Announcement Type: Initial

Funding Opportunity Number: HT942524LCRPCDA

**Assistance Listing Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 28, 2024

- **Application Submission Deadline:** 11:59 p.m. ET, June 17, 2024

- **End of Application Verification Period:** 5:00 p.m. ET, June 20, 2024

- **Peer Review:** July 2024

- **Programmatic Review:** October 2024

This program announcement must be read in conjunction with the General Application Instructions, version 901. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Lung Cancer Research Program (LCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the LCRP in FY09 to promote innovative and competitive research focused on the development of integrated disciplines to identify, treat, and manage early curable lung cancer (excluding mesothelioma). Appropriations for the LCRP from FY09 through FY23 totaled $220.5 million (M). The FY24 appropriation is $25.0M.

The vision of the FY24 LCRP is to eradicate deaths and suffering from lung cancer to better the health and welfare of Service Members, Veterans, and the general public. As such, the LCRP will support and integrate research from multiple disciplines for risk assessment, prevention, early detection, diagnosis, management, and treatment for the control and cure of lung cancer.

II.A.1. LCRP Strategic Plan

The LCRP has prepared a brief synopsis, the LCRP Strategic Plan, which provides the background and an overview of the LCRP, describes the research and funding environment, and sets forth the strategic direction for the program. Applicants are strongly urged to read and consider the LCRP Strategic Plan before preparing their applications. The LCRP Strategic Plan may be found at https://cdmrp.health.mil/lcrp/pdfs/LCRP_StrategicPlan_30Aug21_FINAL.pdf.

II.A.2. FY24 LCRP Areas of Emphasis

To meet the intent of the funding opportunity, ***all applications must address at least one Area of Emphasis in a way that can lead to, or directly effect, a breakthrough and have a major impact.*** The LCRP developed a strategy to address multiple issues in lung cancer research over the cancer continuum of care spectrum that will be considered for funding under the LCRP. These Areas of Emphasis are critical gaps in cancer research, care, and/or patient outcomes that, if addressed will lead to reduced suffering from lung cancer and improved quality of life of Service Members, Veterans, and the general public. Simply identifying an Area of Emphasis is not sufficient.

- **Biology and Etiology**
    - Understand the molecular mechanisms of initiation and progression to lung cancer.
    - Understand contributors to lung cancer development other than tobacco.
    - Understand the biology of metastatic/oligometastatic disease progression.

- **Prevention**
  - Identify innovative strategies for prevention of the occurrence of lung cancer(s) or subsequent primaries.
  - Identify innovative strategies for the prevention of recurrence or metastases from lung cancer.

- **Detection, Diagnosis, and Surveillance**
  - Improve and expand approaches to screening and early detection of lung cancer.
  - Identify strategies for prompt detection and/or characterization of progressive disease.

- **Treatment and Prognosis**
  - Identify innovative strategies for the treatment of lung cancer, including overcoming resistance.
  - Develop or optimize biomarkers to assist with therapeutic decision-making.
  - Enhance the understanding, detection, and treatment of brain and leptomeningeal metastases in lung cancer.

- **Health Outcomes and Survivorship**
  - Identify and understand the long-term and cumulative effects of lung cancer and its treatment(s) on patients, families, and support systems with respect to the impact on quality of life including, but not limited to, physiological, psychosocial, cognitive, and financial effects.
  - Identify and understand impact of comorbidities on survivorship care in all stages of lung cancer.

- **Disparities**
  - Advance equity and reduce lung cancer disparities among underserved and underrepresented populations.

II.B. Award Information

The FY24 LCRP Career Development Award supports early-career, independent investigators to conduct impactful research under the mentorship of an experienced lung cancer researcher as an opportunity to obtain the funding, mentoring, and experience necessary for productive, independent careers at the forefront of lung cancer research. Research applications only in the area of mesothelioma will not be accepted. This award is intended to support impactful research projects with an emphasis on discovery.

Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.

Key elements of this award are as follows:

- **Principal Investigator (PI):** PIs must be research- or physician-scientists at an early stage of their independent research careers. PIs must be within 5 years of their first faculty appointment (or equivalent) and exhibit a strong desire to pursue a career in lung cancer research.

- **Mentorship:** The Mentor(s) must be an experienced lung cancer researcher(s) as demonstrated by a strong record of funding and publications in lung cancer research. In addition, the Mentor(s) must demonstrate a commitment to developing the PI's career in lung cancer research.

- **Career Development:** A Career Development Plan is required and should be prepared with appropriate guidance from the Mentor(s). A clearly articulated strategy for acquiring the necessary skills, competence, and expertise to have a career at the forefront of lung cancer research should be included. The plan should outline how the PI will gain experience in lung cancer research. Because career development is the focus of this award, the PI must commit a minimum of a 25% level of time and effort during the period of performance to conduct lung cancer research under this award.

- **Impact:** Research that has high potential impact may lead to major advancements and significantly accelerate progress toward eradicating deaths and suffering from lung cancer.

- **Relevance to Military Health System (MHS) Beneficiaries:** The application should clearly articulate how the proposed research is relevant to Service Members, Veterans, and their Families.

The PI is required to attend a Department of Defense (DOD) one day in progress review meeting prior to the end of the second year of the award.

Relevance to Military Health: The LCRP seeks to support research that is relevant to the healthcare needs of military Service Members, Veterans, and their Families. ***Relevance to military health will be considered in determining relevance to the mission of the Defense Health Program (DHP) and FY24 LCRP during programmatic review.*** Investigators are ***strongly encouraged*** to consider the following characteristics as examples of how a project may demonstrate relevance to military health:

- Use of military or Veteran populations, biospecimens, data/databases, or programs in the proposed research.

- Collaboration with DOD or Department of Veterans Affairs (VA) investigators.

- Explanation of how the project addresses an aspect of lung cancer that has relevance or is unique to the military, Veterans, other MHS beneficiaries, or Family readiness of Service Members, including environmental exposures other than tobacco.

All investigators applying to FY24 LCRP funding opportunities are encouraged to consider leveraging resources from the LCRP-funded Lung Cancer Biospecimen Resource Network

(LCBRN) if retrospectively collected human anatomical substances and correlated clinical data are relevant to the proposed studies. Samples from the LCBRN are currently available through the Cooperative Human Tissue Network (CHTN). To request LCBRN samples, contact the Division Coordinator for the CHTN Mid-Atlantic division (email: CHTN-MidAtl@hscmail.mcc.virginia.edu) located at the University of Virginia.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 LCRP priorities.

Applications from investigators within the military services and applications involving multidisciplinary collaborations among academia, industry, the military services, the VA, and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families. If the proposed research relies on access to unique resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity. Investigators wishing to apply for funding to support a clinical trial should consider submitting an application to the FY24 LCRP Translational Research Award – Funding Level 2 mechanism (Funding Opportunity Number HT942524LCRPTRA).

Innovative research involving nuclear medicine and related techniques to support early diagnosis, more effective treatment, and improved health outcomes of active-duty Service Members and their Families is encouraged. Such research could improve diagnostic and targeted treatment capabilities through noninvasive techniques and may drive the development of precision imaging and advanced targeted therapies.

CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research. The standards are described in SC Landis et al., 2012, A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 490:187-191 (http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are written for preclinical studies, the basic principles of randomization, blinding,

sample-size estimation, and data handling derive from well-established best practices in clinical studies.

A clinical trial is defined in the Code of Federal Regulations (CFR), Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. *Clinical research* encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.

(2) Epidemiologic and behavioral studies that do *not* seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention.

(3) Outcomes research and health services research that do not fit under the definition of clinical trial.

Excluded from the definition of clinical research are in vitro studies that utilize human data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

The anticipated direct costs budgeted for the entire period of performance for an FY24 LCRP Career Development Award should not exceed **$375,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $1.8M to fund approximately three Career Development Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year

of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator and Mentor(s)

- **Principal Investigator**

  ○ The PI must be an independent investigator at the level of Assistant Professor, Instructor, or equivalent and be within 5 years of their first faculty appointment (or equivalent) by the time of the application submission deadline. Lapses in research time or appointments as denoted in the biographical sketch may be articulated in the application.

  ○ The PI must not have received a Career Development Award (or equivalent) previously from any program within the CDMRP.

  ○ The PI must not have received more than $300,000 in total direct costs for previous or concurrent lung cancer research as a PI of one or more federally or privately funded, non-mentored, peer-reviewed grants.

  ○ The PI must commit a minimum of a 25% level of time and effort during the period of performance to conduct lung cancer research under this award.

- **Mentor(s)**

  ○ The Mentor(s) must hold a position at or above the level of an Associate Professor (or equivalent).

  ○ The Mentor(s) must have a proven publication and funding record in lung cancer

research.

It is ***not*** required that the PI and the Mentor(s) be located at the same institution.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by or affiliated with an eligible organization.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow

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│        Step1: Submit Pre-Application           │
│   (Extramural and Intramural Submissions)      │
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        ┌──────────────────────────┐
        │    Letter of Intent      │
        │   Submitted Through      │
        │         eBRAP           │
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        │ Step 2: Submit Full Application │
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   │ Extramural Submission │ │ Intramural Submission │
   │  Submitted Through   │ │   Submitted Through   │
   │     Grants.gov       │ │        eBRAP         │
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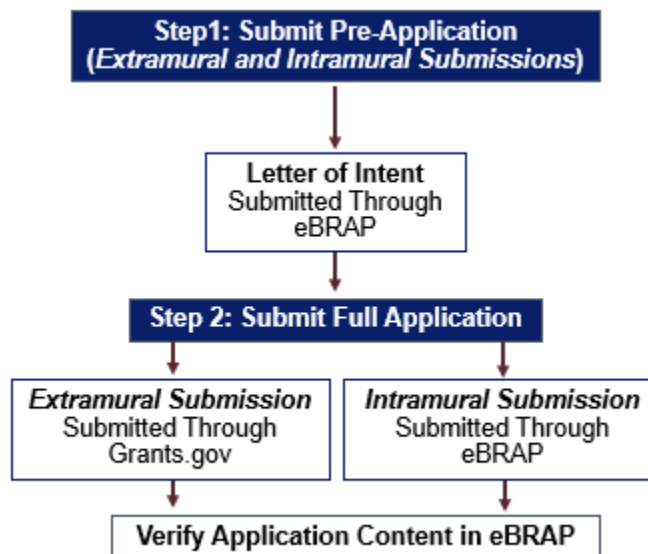
Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions.) Download application package components for HT942524LCRPCDA from Grants.gov (https://grants.gov). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524LCRPCDA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

II.D.2. Content and Form of the Application Submission

Submitting applications that 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(s).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See the CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 LCRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

II.D.2.a. Step 1: Pre-Application Submission

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI through eBRAP.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

II.D.2.a.i Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the Area of Emphasis under which the application will be submitted.

LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

○ **Pre-Application Relevance Questions:** Provide responses in appropriate eBRAP data fields for the following three questions.

1. Is the applicant currently affiliated with the military and/or VA? (Yes/No)

2. Does the proposed research include collaborations with a current military and/or VA investigator/institution? (Yes/No)

3. Does the proposed research include the use of military and/or VA resources (e.g., data, patient samples)? (Yes/No) If yes, specify the resource and how the resource will be accessed to conduct the proposed research (500-character limit, including spaces).

II.D.2.b. Step 2: Full Application Submission

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations **_must_** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components

Each application submission must include the completed full application package for this program announcement. See Section II.H.3 of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form (_Extramural Submissions Only_): Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

○ **Attachment 1: Project Narrative (eight-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators)

that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. ***Preliminary data are not required. However, logical reasoning and a sound scientific rationale for the proposed research must be demonstrated.***

– **Principal Investigator:** Describe the PI's potential for a career at the forefront of lung cancer research, including qualifications and achievements that make the PI an ideal candidate for this award. Describe the PI's career goals as a lung cancer researcher and/or clinician and how the proposed research experience will advance their career. Explain how the PI will commit a minimum of a 25% level of time and effort during the period of performance to conduct lung cancer research under this award.

– **Mentor(s):** Describe the qualifications of the Mentor(s), including record of research accomplishments, publications, patents, funding in lung cancer, committed resources, and available time to support the PI's career advancement needs. Describe the Mentor's track record for preparing early-career investigators for careers in lung cancer research and potential for successful mentorship and advancement of the PI's career in lung cancer research. If the Mentor(s) and PI are located at different organizations, describe how appropriate direction and oversight will be accomplished.

– **Background:** Present the scientific rationale behind the proposed research; include relevant literature citations and preliminary data (if applicable) that led to the development of the proposed study. Any preliminary data provided should be from the laboratory of the PI, Mentor(s), or member(s) of the collaborating team.

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

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

– **Research Strategy and Feasibility:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines 2.0 (https://arriveguidelines.org/arrive-guidelines) to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. For clinical research, describe the strategy for the inclusion of women and minorities in the clinical research appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms

of sex/gender, race, and/or ethnicity, and an accompanying rationale for the selection of subjects. ***This award cannot be used to conduct clinical trials.***

– **Statistical Analysis Plan:** Describe the statistical analysis plan for the resulting outcomes. If applicable, include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the application.

– **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

– **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 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 Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

– **Letters of Organizational Support (if applicable):** 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 support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

– **Letters of Collaboration (if applicable):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural

DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- ▪ Availability of and access to research resources (to include proprietary material for the purpose/duration of the proposed research) and/or

- ▪ Availability of and access to appropriate populations (and/or access to available samples/data or databases), if applicable

- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."

  - ▪ **Intellectual and Material Property Plan (*if applicable*):** Provide a plan for resolving intellectual and material property issues among participating organizations.

  - ▪ **Commercialization Strategy (*if applicable*):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Inclusion of Women and Minorities:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research community. Include the name of the repository(ies) where scientific data and resources arising from the project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities

and/or research participants. Refer to the CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about the CDMRP's expectations for making data and research resources publicly available.

– **Use of DOD Resources (*if applicable*):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active-duty military populations and/or DOD resources or databases.

– **Use of VA Resources (*if applicable*):** Provide a letter of support signed by the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. If the VA-affiliated non-profit corporation is not identified as the applicant organization for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important. Technical abstracts should be written using the outline below.

– **Personnel:** Describe the PI's career goals and their potential for a career at the forefront of lung cancer research. Describe the Mentor's background and experience in lung cancer research. Describe the degree to which the Mentor(s) has planned interactions with the PI for the proposed work and will be involved in guidance, intellectual collaboration, and support of the PI.

– **Career Development:** Describe how the award will provide the PI with the opportunity to effectively advance an independent career in lung cancer research.

– **Background Research:**

▪ Background: Present the scientific reasoning behind the proposed project.

▪ Area(s) of Emphasis: State the FY24 LCRP Area(s) of Emphasis that will be addressed.

▪ Objective/Hypothesis: State the objective to be reached/hypothesis to be tested. Provide evidence or scientific rationale that supports the objective/hypothesis.

- Specific Aims: State the specific aims of this study.

- Study Design: Briefly describe the study design, including appropriate controls.

- Impact: Summarize the potential impact of the proposed project toward the goal of eradicating deaths and suffering from lung cancer.

- Relevance to Military Health: Describe how the proposed project is relevant to military Service Members, Veterans, and their Families.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine***. Avoid overuse use of scientific jargon, acronyms, and abbreviations. Lay abstracts should be written using the outline below.

  – Describe the scientific objective and rationale for the proposed project in a manner that will be ***readily understood by readers without a background in science or medicine.***

    - State the FY24 LCRP Area(s) of Emphasis the project addresses.

    - Describe the PI's career goals in lung cancer research.

    - How will the award advance the PI's career in lung cancer research?

    - How do the proposed research project and Career Development Plan support the PI in attaining these goals?

  – Describe the ultimate applicability of the research.

    - What types of patients will it help and how will it help them?

    - What are the potential clinical applications, benefits, and risks? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.

    - What is the projected time anticipated to achieve a clinically relevant outcome?

    - What are the likely contributions of this study to advancing the field of lung cancer research?

- How is the project relevant to military Service Members, Veterans, and their Families?

○ **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested Statement of Work (SOW) format and recommended strategies for assembling the SOW.

For the Career Development Award, refer to the "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

The SOW should indicate a feasible plan and timeline to conduct the research. The SOW must include specific research milestones to be accomplished by the end of each year in the period of performance.

○ **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** *The Impact Statement should be written in plain language for lay persons.* Describe how the proposed research is relevant to at least one of the FY24 LCRP Areas of Emphasis and describe how the research will make an impact. *The relevance of all research, including basic, should relate to patient outcomes and how it benefits those affected by lung cancer.* Describe how the proposed research will lead to major advancements with a significant impact on lung cancer research and/or patient care, including its potential to accelerate progress toward eradicating deaths and suffering from lung cancer.

○ **Attachment 7: Career Development Plan (one-page limit): Upload as "CareerDev.pdf".**

 – Clearly describe and outline the individualized Career Development Plan.

 – Highlight the unique features of this Career Development Plan as it pertains specifically to lung cancer research (workshops, seminars, etc.).

 – Indicate specifically how the individualized Career Development Plan will provide the PI with an opportunity to advance their independent career in lung cancer research.

 – Describe how the Career Development Plan is supported by the research environment and mentorship, including a description of ongoing lung cancer research at the institution. Include information on collaborations with other investigators.

○ **Attachment 8: Letter from Mentor (two-page limit): Upload as "MentorLetter.pdf".** Provide a signed letter from the Mentor indicating recommendation, support, and planned interactions with the PI for the proposed work. Include information on the Mentor's record of preparing early-career investigators for careers in lung cancer research.

- ○ **Attachment 9: Relevance to Military Health Statement (one-page limit): Upload as "MilRelevance.pdf".** *The Relevance to Military Health Statement will be evaluated by the FY24 LCRP Programmatic Panel during programmatic review only*. Identify how the proposed research will support mission readiness through filling a gap in cancer prevention, early detection/diagnosis, prognosis, treatment, quality of life, and/or survivorship that may have a profound impact on the health and well-being of Service Members, their Families, Veterans, or other beneficiaries. Articulate how the proposed research will advance the knowledge and understanding of cancer, patient care, and/or treatment options in the MHS for the benefit of active-duty Service Members, Veterans, and other military beneficiaries. Describe the anticipated short- and/or long-term outcomes of the proposed research and their potential impact on the basic health, welfare, and/or psychosocial wellness of active-duty Service Members, Veterans, and other military beneficiaries. If active-duty military, military Families, and/or 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 Veteran population).

- ○ **Attachment 10: Letter of Eligibility Statement (one-page limit): Upload as "Eligibility.pdf".** Provide a letter signed by the PI and the Department Chair, Dean, or equivalent official verifying that the eligibility requirements will be met by the application submission deadline. The letter should verify that the PI is an independent, early-career investigator within 5 years of their first faculty appointment (or equivalent), including the date the PI began their first faculty appointment (month/year); that the PI has not received a Career Development Award previously from any program within the CDMRP; and that the PI has not received more than $300,000 in total direct costs for previous or concurrent lung cancer research as a PI of one or more federally or privately funded, non-mentored, peer-reviewed grants.

- ○ **Attachment 11: Representations** *(Extramural Submissions Only)***: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- ○ **Attachment 12: Suggested Intragovernmental/Intramural Budget Form** *(if applicable)***: Upload as "IGBudget.pdf".** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The *total* costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- ○ **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

    – Include examples of accomplishments such as products, patents, or licenses; presentations at international scientific meetings; and awards or other forms of acknowledgment for the PI's achievements.

    – Highlight any publications in high-impact journals.

- ○ **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- ○ **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

    – Include mentor's biographical sketch.

- ○ **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

    – Include mentor's previous/current/pending support.

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- ○ **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- o **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- o **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 12.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

II.D.3. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The application's direct costs budgeted for the entire period of performance should not exceed **$375,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the 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.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI to present project information or disseminate project results at one DOD LCRP meeting during the period of performance in Year 2 or beyond should be requested. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.

- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 LCRP Career Development Award.

Must not be requested for:

- Clinical trial costs

- Mentor(s) salary

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Principal Investigator**

  ○ How well the PI's potential for a career at the forefront of lung cancer research is supported by their qualifications and achievements.

- The degree to which the PI's career goals as a lung cancer researcher and/or clinician and the proposed research experience will advance their career.

- Whether the application demonstrates that the PI will commit a minimum of a 25% level of time and effort during the period of performance to conduct lung cancer research under this award.

- **Mentor(s)**

  - How well the Mentor's qualifications, record of research accomplishments, committed resources, and available time support the PI's career advancement needs.

  - Whether the Mentor is an independent, established lung cancer researcher as demonstrated by publications, patents, and/or funding history.

  - The degree to which the Mentor's track record in preparing early-career investigators for careers in lung cancer research indicates the potential for successful mentorship and advancement of the PI's career in lung cancer research.

  - If the Mentor and PI are located at different organizations, how well will appropriate direction and oversight be accomplished.

- **Career Development Plan**

  - How well the applicant has outlined a detailed, individualized Career Development Plan that will effectively advance the applicant's independent career as a lung cancer researcher.

  - Whether the proposed plan (workshops, seminars, etc.) is appropriate and will prepare the PI for a successful independent career at the forefront of lung cancer research.

  - The degree to which the Mentor(s) has described planned interactions with the PI for the proposed work and will be involved in guidance, intellectual collaboration, and support of the PI.

- **Research Strategy and Feasibility**

  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if applicable), and logical reasoning.

  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses (and if applicable, the statistical analysis plan, rationale for the statistical methodology, and power analysis) are developed.

  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

- If animal studies are included, how well they are designed in accordance with the ARRIVE 2.0 guidelines (https://arriveguidelines.org/arrive-guidelines) to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.

- If human subjects or human anatomical samples will be used, how well the plan for the recruitment of subjects or the acquisition of samples is justified and appropriate to accomplish the proposed work.

- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- Whether the research project is appropriate for advancing the PI's career to the forefront of lung cancer research and/or patient care.

- Appropriateness of the levels of effort by the PI, Mentor, and other key personnel to ensure the successful conduct of the proposed research.

- How well the applicant acknowledges potential problems and addresses alternative approaches.

- **Impact**

  - Whether the proposed research addresses at least one of the FY24 LCRP Areas of Emphasis and describes how the research will make an impact.

  - Whether the proposed research project describes how it will lead to major advancements with a significant impact on lung cancer research and/or patient care.

  - How well the proposed research project demonstrates potential to accelerate progress toward eradicating deaths and suffering from lung cancer.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Environment**

  - To what extent the scientific environment is appropriate for the proposed research project.

  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.

  - To what extent the quality and level of institutional support are appropriate for the proposed research project.

  - If applicable, to what degree the Intellectual and Material Property Plan is appropriate.

- **Budget**

  - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the DHP and FY24 LCRP, as evidenced by the following:

  - Adherence to the intent of the funding opportunity

  - Program portfolio composition

  - Relative impact and relevance to military health

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section II.E.1.b, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at https://cdmrp.health.mil/about/2tierRevProcess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution 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 and approval 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 and approval process may also

result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. The federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the LCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. No commitment on the part of the government should be inferred from discussions with any other individual. ***The award document signed by the Grants Officer is the official authorizing document (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of

funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 7, Section F, for general information on organization or PI changes.

II.F.3. Administrative and National Policy Requirements

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this program announcement.

Refer to the General Application Instructions, Appendix 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D Terms and Conditions](#) and the [USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions](#) for further information.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, Institutional Review Board, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

II.F.4. Reporting

Annual technical progress reports as well as a final technical progress report will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether additional and/or more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline whether and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement *(only required for clinical research studies):* Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10.0M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.

- Project Narrative exceeds page limit.

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

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

- Documents not requested will be removed.

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY24 LCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation.

A list of the FY24 LCRP Programmatic Panel members can be found at https://cdmrp.health.mil/lcrp/panels/panels24.

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

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

- The PI does not meet the eligibility criteria.

- A clinical trial is proposed.

- The mentor does not meet the eligibility criteria.

- An application does not address at least one of the FY24 LCRP Areas of Emphasis.

- An application proposes only mesothelioma research.

II.H.2.d. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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.

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐
Attachments	
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐
Career Development Plan – Attachment 7, upload as "CareerDev.pdf"	☐
Letter from Mentor – Attachment 8, upload as "MentorLetter.pdf"	☐
Relevance to Military Health Statement – Attachment 9, upload as "MilRelevance.pdf"	☐
Letter of Eligibility – Attachment 10, upload as "Eligibility.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐
Research & Related Personal Data	☐
Research & Related Senior/Key Person Profile (Expanded)	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐
Budget *(Intramural submissions only)* Include budget justification	☐
Project/Performance Site Location(s) Form	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CHTN	Cooperative Human Tissue Network
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
LCBRN	Lung Cancer Biospecimen Resource Network
LCRP	Lung Cancer Research Program
LOI	Letter of Intent
M	Million
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs