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

Patient-Centered Outcomes and Survivorship Award

Announcement Type: Initial

Funding Opportunity Number: HT942524LCRPPCOSA

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), July 17, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 7, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 12, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** December 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."

TABLE OF CONTENTS

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 of three 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. The Patient-Centered Outcomes and Survivorship Award includes three of the 13 FY24 LCRP Areas of Emphasis categorized as Disparities or Health Outcomes and Survivorship.

- **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.A.3. Award History

The LCRP Patient-Centered Outcomes and Survivorship Award mechanism was first offered in FY23. Since then, 15 Patient-Centered Outcomes and Survivorship Award applications have been received, and three have been recommended for funding.

II.B. Award Information

The Patient-Centered Outcomes and Survivorship Award supports high-risk, high-reward research studies that span the spectrum of behavioral health science, survivorship, health outcomes and comparative effectiveness research, including quality of life, symptom and side effect management, resilience, co-morbid conditions, and examining the physical, psychological, social, and economic effects of lung cancer among patients and their families.

The overall intent of the FY24 LCRP Patient-Centered Outcomes and Survivorship Award is to promote evidence-based and patient-centered approaches to improve health and lung cancer related outcomes and enhance the patient experience in defined populations. Research studies may include, but are not limited to:

- Studies to examine and improve quality of life, decision-making, and symptom and side effect management (e.g., toxicity of treatment, palliative/supportive care, psychological distress and anxiety).

- Studies to investigate the impact of prevention, diagnostics, treatment, or health care delivery approaches on health outcomes.

- Studies to assess the relationship(s) between behavioral, cognitive, and/or social functioning in relation to lung cancer detection, initiation, progression, treatment, and rehabilitation.

- Studies into the psychological health and well-being of those affected by lung cancer (e.g., patients, family members).

- Development and testing for efficacy of lifestyle interventions and symptom management approaches to minimize disease risk and maximize quality of life.

Key aspects of this award mechanism are:

- **Impact:** The Patient-Centered Outcomes and Survivorship Award is intended to support research that demonstrates the potential to have a major impact on patient outcomes. Research should challenge paradigms with respect to impact on patient care and outcomes. Proposed projects may include translational or clinical research, including ***pilot*** clinical trials. Impactful research will accelerate the movement of promising ideas into clinical applications, generate knowledge to improve clinical guidelines, or significantly advance behavioral, cognitive, and/or social functioning related to the target population.

- **Study Design:** Applications should clearly articulate the chosen design of the study. Basic studies should demonstrate research strategy, feasibility, and how the study relates to the human experience with lung cancer. Studies entailing retrospective or prospective recruitment should define the type of architecture of the study (e.g., descriptive, correlational, field experimental, meta-analyses). Study populations should be defined. The rationale should support the chosen study design with statistical evaluation to back the design. Questionnaires should be described in sufficient detail to justify interpretation of potential results.

- **Preliminary Data:** The Patient-Centered Outcomes and Survivorship Award requires preliminary data for all studies that propose the active (prospective) recruitment of human subjects. Studies not proposing active recruitment of human subjects are not required to present preliminary data but should be supported by sound reasoning and relevant literature.

- **Patient Advocate Participation:** Applications to the Patient-Centered Outcomes and Survivorship Award funding opportunity are encouraged to include a patient advocate. As part of the research team, the patient advocate would assist in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. The patient advocate will be a person with a history of lung cancer diagnosis. As a lay representative, the patient advocate should be active in a cancer advocacy organization. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. The role of the patient advocate should be focused on providing objective input on the research and its potential impact for individuals with or at risk for lung cancer.

Relevance to Military Health: The LCRP seeks to support research that is relevant to the health care 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 Department of Defense (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 Military Health System (MHS) beneficiaries, or Family readiness of Service Members, including environmental exposures other than tobacco.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

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.

Pilot clinical trials are allowed.

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.

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 Patient-Centered Outcomes and Survivorship Award should not exceed **$650,000**. 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 $2.08M to fund approximately two Patient-Centered Outcomes and Survivorship 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

The Principal Investigator (PI) must be at or above the level of Assistant Professor (or equivalent).

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.

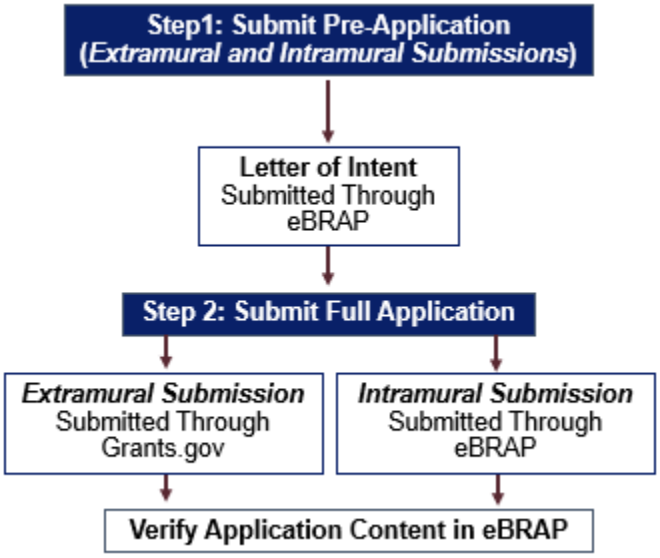
The CDMRP uses two portal systems to accept pre- and full application submissions.

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 the CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



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 HT942524LCRPPCOSA 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 HT942524LCRPPCOSA 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.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
No pilot clinical trial	Patient-Centered Outcomes and Survivorship
Pilot clinical trial	Patient-Centered Outcomes and Survivorship – Clinical Trial Option

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 (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) 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. ***Applications proposing a pilot clinical trial must include preliminary data***.

  - **Background:** Present the scientific rationale behind the proposed research with relevant literature citations, sound rationale, and/or preliminary data (if applicable) in support of the idea. Describe the need or gap in understanding survivorship, including how the proposed research may have a major impact on patient outcomes. Articulate how the study will assess the relationship(s) between behavioral and social functioning in at least one of the areas of lung cancer initiation, progression, detection, treatment, and rehabilitation. State the area of behavioral health science to be studied (e.g., basic behavioral, quality of life, decision-making and/or cognitive function, educational interventions, symptom management).

  - **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.

  - **Research Strategy and Feasibility:** Describe the study design, methods, and analyses in sufficient detail for evaluation including availability of resources (if applicable). Studies entailing retrospective or prospective recruitment should define the type of study (e.g., descriptive, correlational, field experimental, meta-analyses). Study populations should be defined. Address potential problem areas and pitfalls and present alternative methods and approaches. If using psychometric measures, describe their reliability and validity. If use of a biorepository, patient medical files, or meta-analysis is proposed, describe the data to be collected and the process or methodology to collect the samples (i.e., for biorepositories, the standardization of procedures for collection). 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) or an international regulatory agency, if applicable. If human subjects or human anatomical samples will be used, include a plan for the

recruitment of subjects or the acquisition of samples and document the experience of the PI and/or key collaborators in recruiting human subjects for similar projects. Basic studies should demonstrate the research strategy and feasibility and how the study relates to the human experience with cancer.

- If animal use is proposed, then provide a strong justification on how the animal research and outcomes will translate to human behavior and support the intent of the Patient-Centered Outcomes and Survivorship Award**.**

- Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. If women and minorities are excluded, to what extent the application provides a rational justification.

If funds for a pilot clinical trial are requested, details regarding the Clinical Trial Strategy must be described in Attachment 9.

- **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:** 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.

- **Letter of Patient Advocate Commitment (if applicable):** Provide a letter from the patient advocate confirming their commitment to the research project.

- **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.

- **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.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the ideas and scientific rationale behind the proposed research project.

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

  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Provide evidence or scientific rationale that supports the hypothesis and/or objective(s).

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

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

  - **Impact:** Summarize the potential impact of the proposed project toward the goal of reducing suffering from lung cancer. State explicitly how the research will ultimately accelerate the movement of promising ideas toward clinical applications.

  - **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.

  - State the FY24 LCRP Area(s) of Emphasis the project addresses.
  - Describe the ultimate applicability of the research.
  - What population will the research help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks of the anticipated outcomes? If the research is too basic for clinical applicability, describe the interim outcomes expected and their applicability to the field.
  - What are the likely contributions of the proposed research project to advancing research, patient care, and/or quality of life?
  - 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 Patient-Centered Outcomes and Survivorship Award, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

- **Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf".** Describe, in layman's terms, the behavioral health aspects of the proposed research that may lead to a potential major impact on patient outcomes. Articulate how the research will accelerate promising findings toward clinical applicability and leverage results to maximize impact on near term patient outcomes. Describe how the proposed research is relevant to at least one of the FY24 LCRP Areas of Emphasis. ***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 accelerate progress towards reducing suffering from lung cancer.

- **Attachment 7: Patient Advocate Involvement Statement, if applicable (2-page limit): Upload as "Advocate.pdf".** The Patient Advocate Involvement Statement should be written by the PI. Provide the name of a patient advocate and their affiliation to a cancer advocacy organization(s). Describe the integral roles that the patient advocate will play in the planning, design, implementation, and evaluation of the research. Describe how the patient advocate's knowledge of current lung cancer issues and how their background will contribute to the project.

- **Attachment 8: Statistical Analysis (no page limit): Upload as "StatsData.pdf".** Describe the statistical methodology and plan, including how it supports the stated hypothesis or objective. If an existing dataset is to be used, describe the dataset and how it supports the aims of the project. State the inclusion and exclusion criteria for the subjects with sound rationale for the criteria, if applicable. Describe the power analysis and whether it determined population numbers; if not, justify why the power analysis is not essential to the statistical evaluation. State whether the study will include univariate, bivariate, or multivariate analyses. State the variables to be used in the main analysis; include covariates and how the data will be adjusted to account for covariates, if applicable. Stratification of data (if applicable) should be described and justified. For data management, describe methods for data collection (e.g., identifiers, confidentiality). Describe how the study will conform to the 1996 Health Insurance Portability and Accountability Act, if applicable. Explain data capture, verification, and disposition, if applicable. Describe how data will be evaluated for reproducibility and adjusted for confounding variables. Articulate how large datasets will be evaluated, if applicable.

- **Attachment 9: Clinical Trial Strategy, *if applicable* (no page limit): Upload as "Clinical.pdf".** ***If funds for a clinical trial are requested, this attachment is required.***

  - Describe the rationale for the proposed clinical trial. Provide a description of the intervention and the endpoints to be measured. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically, identify the portions of the study that would be supported with funds from this award.

  - Provide detailed plans for initiating the clinical study within the first year, including FDA Investigational New Drug/Investigational Device Exemption (IND/IDE) application submission plans within 60 days of the award, if applicable. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

  - Indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria. Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the

proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

- **Attachment 10: Questionnaires and Other Data Collection Instruments, if applicable (no page limit): Upload as "Question.pdf".** The Questionnaires and Other Data Collection Instruments attachment should include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study. Describe how and when the instrument(s) will be administered. Describe how the instrument(s) will be adapted to the subject population, if applicable.

- **Attachment 11: 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 by 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(s). If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., the Armed Forces, their Family members, and/or the Veteran population).

- **Attachment 12: 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 13: 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".
- **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".
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(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.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.
- **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 13.

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 **$650,000**. 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 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. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY24 LCRP Patient-Centered Outcomes and Survivorship Award.

Must not be requested for:

- Clinical trial costs beyond pilot studies

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:

- **Research Strategy and Feasibility**
    - Whether the stated hypothesis or the objective is relevant to an FY24 LCRP Area of Emphasis.
    - To what degree the study design, proposed methods, and analyses are appropriate to test the hypothesis and/or reach the final objective.
    - To what degree the application demonstrated the research is relevant to the intent of the Patient-Centered Outcomes and Survivorship Award.
    - If applicable, for retrospective or prospective recruitment studies, whether the application defines the type of study (e.g., descriptive, correlational, field experimental, meta-analyses).
    - If applicable, whether study populations are defined.
    - To what degree the application addresses potential problem areas and potential pitfalls and presents alternative methods and approaches.
    - If applicable, how well the application describes the reliability and validity of psychometric measures.

- If a biorepository, patient medical files, and/or meta-analysis is proposed, to what degree the description of the data to be collected and the process or the methodology to collect the samples will support the planned evaluation of the study (e.g., for biorepositories, standardization of procedures for collection).

- If applicable, how well the application describes how the data will be reported and how it will fulfill a regulatory documentation requirement of the FDA or an international regulatory agency.

- If applicable, how well the research plan documents the recruitment of human subjects or acquisition of human anatomical samples.

- Whether the application describes the strategy for the inclusion of women and minorities that is appropriate for the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group and an accompanying rationale for the selection of subjects.

- If animal use is proposed, to what extent a strong justification demonstrates how animal research and outcomes will translate to human behavior and support the intent of the Patient-Centered Outcomes and Survivorship Award.

- **Impact**

  - Whether the behavioral health aspects of the proposed research are clearly articulated and demonstrate a potential to lead to a major impact on patient outcomes.

  - 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 a potential to accelerate progress toward reducing suffering from lung cancer.

- **Statistical Analysis and Data Management**

  - To what extent the statistical methodology and plan supports the stated hypothesis or objective.

  - If applicable, how well the described dataset supports the aims of the project.

  - If applicable, whether the inclusion and exclusion criteria for the subjects is sound and rationale for the criteria.

  - How well the application describes the power analysis and whether it determined population numbers. If applicable, how well the application justifies why a power analysis is not essential to the statistical evaluation.

- Whether the application states whether the analyses will be univariate, bivariate, or multivariate.
- How well the variables are described and any covariates identified (if applicable). How well the application accounted for covariates and whether the adjustment is justified (if applicable).
- If applicable, how well the stratification of data is described and whether it is justified.
- How well the data management is described and justified, including all methods for data collection (e.g., identifiers, confidentiality).
- To what extent the data management plans support the generation, analyses, standardization, and storage of data.
- How well the application explained the data capture, verification, disposition, if applicable.
- If applicable for laboratory projects, to what extent evaluations to be made, storage of samples, and organization and maintenance of large datasets are described and justified.
- To what extent the data have been evaluated for reproducibility and adjusted for confounding variables.
- Whether there is a plan to evaluate large datasets, if applicable.
- Whether the application describes plans to conform to the 1996 Health Insurance Portability and Accountability Act, if applicable.

- **Clinical Strategy** ***(if a pilot clinical trial is proposed)***
  - To what extent the application justifies the rationale for the proposed clinical trial.
  - To what degree the proposed clinical trial and proposed intervention are supported by strong preliminary data and relevant literature citations.
  - How well the endpoints to be measured are justified for the described clinical trial.
  - Whether the proposed type of clinical trial to be performed (e.g., randomized, cohort, case-control, cross-sectional) is supported by the methodology to be used.
  - Whether there are detailed plans for initiating the clinical study within the first year, including FDA IND/IDE application submission plans within 60 days of the award, if applicable.
  - Whether the study population is clearly defined and whether access to the study population, recruitment plans, and inclusion/exclusion criteria including justification for the plans and alternatives strategies if issues arise. Whether the informed consent process is clearly articulated.

- Whether the application describes the strategy for the inclusion of women and minorities that is appropriate for the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects.

- Whether an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity is included.

- If applicable, whether the application shows how the data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA.

- To what degree potential challenges and alternative strategies are addressed.

- How well the clinical trial will inform correlative clinical research, if applicable.

If questionnaires and/or other data collection instruments are included in the application:

- **Questionnaires and/or Other Data Collection Instruments:**

  - Whether the application includes a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides, or other instruments.

  - For each instrument, to what extent the application describes how the information collected is related to the objectives of the study.

  - Whether the application describes how and when the instrument(s) will be administered.

  - If applicable, whether the application describes how the instrument(s) will be adapted to the subject population

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**:

- **Personnel**

  - How appropriate the levels of effort are for successful conduct of the proposed work.

- **Budget**

  - Whether the budget is appropriate for the proposed research.

- **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 (including collaborative arrangements).

- 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.

- **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 balance and 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

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met.

The organizational 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.

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 (IRB), or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219). Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

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.

For all awards including prospective accrual of human subjects, quarterly technical progress reports may be 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: ***(only required for clinical research studies and pilot clinical trials)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity using the PHS Inclusion Enrollment Report 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 full 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 application does not address an FY24 LCRP Area of Emphasis.

- The PI does not meet the eligibility criteria.

- An application proposing a clinical trial where Attachment 9: Clinical Trial Strategy is missing.

- 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"	☐
Patient Advocate Involvement Statement *(if applicable)* – Attachment 7, upload as "Advocate.pdf"	☐
Statistical Analysis – Attachment 8, upload as "StatsData.pdf"	☐
Clinical Strategy Statement *(if applicable)* – Attachment 9, upload as "Clinical.pdf"	☐
Questionnaires and Other Data Collection Instruments *(if applicable)* – Attachment 10, upload as "Question.pdf"	☐
Relevance to Military Health Statement – Attachment 11, upload as "MilRelevance.pdf"	☐
Representations *(Extramural submissions only)* – Attachment 12, upload as "RequiredReps.pdf"	☐
Suggested Intragovernmental/Intramural Budget Form (*if applicable)* – Attachment 13, 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	☐

Full Application Components	Uploaded
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
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
FY	Fiscal Year
IDE	Investigational Device Exemption
IND	Investigational New Drug
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