I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Era of Hope Scholar Award

Announcement Type: Initial

Funding Opportunity Number: HT942524BCRPEOHS

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 23, 2024
- Application Submission Deadline: 11:59 p.m. ET, June 4, 2024
- Confidential Letters of Recommendation Submission Deadline: 5:00 p.m. ET, June 7, 2024
- End of Application Verification Period: 5:00 p.m. ET, June 7, 2024
- **Peer Review:** August 2024
- Programmatic Review, Stage 1: October 2024
- Invitation for Oral Presentation: October 2024
- Programmatic Review, Stage 2: 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."

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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) Breast Cancer Research Program (BCRP) 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. The BCRP was initiated in FY92 to support innovative, high-impact research, with a mission of ending breast cancer for Service Members and their Families, Veterans, and the general public. Appropriations for the BCRP from FY92 through FY23 totaled \$4.24 billion. The FY24 appropriation is \$150 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of ending breast cancer. Specifically, the BCRP seeks to accelerate high-impact research with clinical relevance, encourage innovation and stimulate creativity, and facilitate productive collaborations.

II.A.1. The Breast Cancer Landscape

The BCRP has prepared a brief overview, *The Breast Cancer Landscape*, that describes what is currently known about the most pertinent topics that are consistent with the BCRP's mission of ending breast cancer. Applicants are strongly urged to read and consider *The Breast Cancer Landscape* before preparing their applications. *The Breast Cancer Landscape* may be found at https://cdmrp.health.mil/bcrp/pdfs/BreastCancerLandscape2023.pdf.

II.A.2. FY24 BCRP Overarching Challenges

Considering the current <u>breast cancer landscape</u> and the BCRP's mission, all FY24 BCRP Era of Hope Scholar Award applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.*

- Prevent breast cancer (primary prevention)
- Identify determinants of breast cancer initiation, risk, or susceptibility
- Distinguish deadly from non-deadly breast cancers
- Conquer the problems of overdiagnosis and overtreatment
- Identify what drives breast cancer growth; determine how to stop it
- Identify why some breast cancers become metastatic

- Determine why/how breast cancer cells lie dormant for years and then re-emerge; determine how to prevent lethal recurrence
- Revolutionize treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival
- Eliminate the mortality associated with metastatic breast cancer
- *Alternatively, with adequate justification, applications may identify and address another overarching challenge related to the breast cancer landscape. Justification must be provided in the application.

II.B. Award Information

The Era of Hope Scholar Award supports individuals early in their careers who have demonstrated significant potential to effect meaningful change in breast cancer. These individuals should be exceptionally talented scientists who have shown that they are the "best and brightest" in their field(s) through extraordinary creativity, vision, innovation, and productivity. They should have demonstrated experience in forming effective partnerships and collaborations and must exhibit strong potential for future leadership in breast cancer research.

As the intent of the Era of Hope Scholar Award is to recognize creative and innovative individuals rather than projects, the central features of the award are the demonstrated ability of the individual named as the Principal Investigator (PI) in the application to go beyond conventional thinking in their field and the innovative contribution that the PI can make toward ending breast cancer. The application should articulate a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention.

Experience in breast cancer research is not required; however, the application must focus on breast cancer, and the PI must commit a minimum of 25% level of time and effort during the period of performance to conduct breast cancer research under this award. Individuals from other disciplines who apply novel concepts to breast cancer are encouraged to submit.

The PI is encouraged to assemble a research team that will provide the necessary expertise and collaborative efforts toward accomplishing the research goals. The PI's research team must include two or more breast cancer consumer advocates. As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer and are actively involved in a breast cancer advocacy organization. Their role should be independent of their employment, and they may not be employees of any organizations participating in the application. The consumer advocates should have a high level of knowledge of current breast cancer issues and the appropriate background and/or training in breast cancer research to contribute to the project. Their role should be focused on providing objective input *throughout* the research effort and its potential impact for individuals with, or at risk for, breast cancer.

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, 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 BCRP priorities.

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.

The proposed research must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public. Collaborations between researchers at military or Veteran institutions and non-military institutions are strongly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the partners bring to the research effort, ultimately advancing cancer research that is of significance to the Warfighter, military Families, and the American public.

Clinical trials are allowed. A clinical trial is defined in the Code of Federal Regulations, 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 Era of Hope Scholar Award should not exceed \$3.5M. 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 \$5.4M to fund approximately one Era of Hope Scholar Award application. 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-Department of Defense (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 PI must be an independent and non-mentored investigator within 6 years of their last training position as of the application submission deadline (excluding time spent on family medical leave). Lapses in research time or appointments denoted in the biographical sketch may be articulated in the application. Examples of training positions include postdoctoral fellowship,

medical residency, and clinical fellowship. Postdoctoral fellows, clinical fellows (including residents and interns), and other researchers currently in training positions are not eligible.

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

An investigator may be named as the PI on only one FY24 Era of Hope Scholar Award application under this program announcement.

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 <u>Section II.H.2</u>, <u>Administrative Actions</u>, 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.

Step1: Submit Pre-Application (Extramural and Intramural Submissions) Letter of Intent Submitted Through eBRAP Step 2: Submit Full Application Submitted Through Grants.gov Intramural Submission Submitted Through eBRAP Verify Application Content in eBRAP

Application Submission Workflow

Extramural Submission: An application submitted by an <u>extramural organization</u> 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 HT942524BCRPEOHS from Grants.gov (https://grants.gov). Full applications from extramural organizations *must* be submitted through Grants.gov.

Intramural Submission: An application submitted by an <u>intramural DOD organization</u> for an investigator employed by that organization. Intramural DOD organizations <u>may</u> submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524BCRPEOHS 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 funding cycle 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 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 BCRP 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 overarching challenge under which the application will be submitted.
- List of Individuals Providing Confidential Letters of Recommendation: Enter contact information for three individuals who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload their letter.

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.

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 <u>Section II.H.3</u> 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 (six-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.

The Project Narrative should clearly state the applicant's *vision for ending breast cancer* and *why this application meets the objectives of this unique program description.* As the intent of the Era of Hope Scholar Award is to recognize creative and innovative individuals, rather than projects, the central feature of the award is the innovative and meaningful contributions that the named PI can make toward ending breast cancer.

The following items should be addressed specifically by the PI:

- Vision: Clearly state your vision of the future of breast cancer. Describe your views of the major problems or barriers in breast cancer that must be solved to accelerate progress toward ending breast cancer. Describe what you foresee as the critical approaches that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems or barriers.
- Accomplishments: Describe what you have accomplished that demonstrates your extraordinary creativity, vision, and productivity. Describe how these accomplishments have had an impact beyond your own laboratory or research setting into the broader scientific, clinical, and/or patient community.
- Leadership: Describe the experience you have that suggests a strong potential for leadership in breast cancer. Describe your plans for leadership as an Era of Hope Scholar within the broader breast cancer community, beyond your own laboratory or institution.
- Research Goals: State explicitly which BCRP Overarching Challenge(s) your research will address. If addressing another Overarching Challenge related to the breast cancer landscape, provide justification. Without describing specific research methodology, list the key research goals you propose to pursue. Describe what you hope to accomplish during the award period. Explain why/how your goals are innovative and distinct within your field and within the broader field of breast cancer research.
- **Research Barriers:** Aside from funding, what barriers exist that could inhibit your research goals, and what strategies will you employ to overcome these barriers?
- Commitment: Explain how you will commit a minimum of 25% level of time and effort during the period of performance to conduct breast cancer research under this award.
- Research Environment: Describe the environment in which you work. How will this environment facilitate your development as an innovator and leader in breast cancer research?
- 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 and the extent to which the PI will be relieved of academic or administrative responsibilities and allowed to pursue their own goals. 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.
- Consumer Advocate Letters of Commitment: Provide a letter signed by each consumer advocate confirming their commitment to participate in the proposed 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, <u>DoD Instructions</u> 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. Refer to 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 CDMRP's expectations for making data and research resources publicly available.
- 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.
 - Not required at time of submission. Leave Attachment 3 space blank.
- 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.
 - Not required at time of submission. Leave Attachment 4 space blank.
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf". Refer to the eBRAP "Funding Opportunities & Forms" web page

(<u>https://ebrap.org/eBRAP/public/Program.htm</u>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Era of Hope Scholar Award mechanism, 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.

- O Attachment 6: Research Team Statement (one-page limit): Upload as "Team.pdf". Describe how the PI's and research team's combined backgrounds and breast cancerrelated technical and administrative expertise will contribute to accomplishing the research goals and/or ability to manage this award. Provide the names of at least two consumer advocates and their affiliation with a breast cancer advocacy organization(s). Describe how the consumer advocates' knowledge of current breast cancer issues and how their background and/or training in breast cancer research will contribute to the proposed research. Explain how the consumer advocates will be integrated into the planning, design, implementation, and evaluation of the research.
- Attachment 7: 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.
- o Attachment 8: 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.

- o PI Biographical Sketch (no-page limit): Upload as "Biosketch LastName.pdf".
 - Include the following: products, patents, or licenses; presentations at international scientific meetings; awards or other forms of acknowledgment for the PI's achievements.
 - Highlight any publications in high-impact journals.
- o **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 biographical sketches for team members, including consumer advocates.
- **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 "<u>Suggested</u>
 <u>Intragovernmental/Intramural Budget Form</u>" for each intramural DOD subaward and
 upload as a single document titled **IGBudget.pdf** to Grants.gov as <u>Attachment 8</u>.

II.D.2.b.iii. Additional Application Components

In addition to the complete application package, Era of Hope Scholar Award applications also require the following components:

(a) Three Confidential Letters of Recommendations (two-page limit per letter suggested):

Submission of *three confidential letters of recommendation* from the three individuals named during the pre-application process is required. The three letters of recommendation should be written on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the application verification deadline. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the "Pre-Application Files" tab of the pre-application. The PI will not be able to view the letters. If confidential letters of recommendation cannot be submitted by any of the individuals named in the pre-application, the PI should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

Each letter should describe the PI's unique qualifications and accomplishments that highlight their potential for success in pursuing highly innovative research avenues. Specifically, each letter should offer the writer's perspective on the PI's:

- Creative and original accomplishments
- Likelihood of continued innovation and productivity
- Potential for leadership in the breast cancer community
- o Likelihood of establishing a successful career at the forefront of breast cancer research
- o Ability to manage the technical and administrative aspects of this award
- **(b) Oral Presentation:** PIs named in applications selected for Programmatic Review, Stage 2, will be required to give an oral presentation (see <u>Section II.E.1.b</u>, <u>Programmatic Review</u>) that will be held in the National Capital area or virtually, at the discretion of the government, and is tentatively scheduled for December 2024.

Each presentation will include a 10-minute talk by the PI, followed by a 20-minute questionand-answer session with Programmatic Panel members. The questions below will be the topics for discussion during the PI's talk and the question-and-answer session. PIs who are selected must prepare a presentation consisting of no more than four slides that specifically address the following four questions (one question per slide):

- What conceptual or intellectual barriers do you consider the most urgent to overcome in order to end breast cancer?
- How does your vision for breast cancer research challenge current dogma within the broader field of breast cancer research?
- Without addressing any specifics of the project, how do you envision your research contributing to the next leap forward toward ending breast cancer?
- How will you use your leadership skills to develop your vision for preventing and treating breast cancer beyond your laboratory and institution?

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 4 years.

The application's direct costs budgeted for the entire period of performance should not exceed **\$3.5M**. 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 4 years.

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

• Travel to attend a DOD-required meeting in Years 1 and 3. For planning purposes, it should be assumed that the meetings 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 three investigators to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 BCRP Era of Hope Scholar Award.

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**, (the Principal Investigator and Research Goals criteria are of equal importance, followed by Research Team and Environment):

• Principal Investigator

- How the PI's record of accomplishments demonstrates their extraordinary creativity, vision, and productivity.
- How the application provides sufficient evidence to suggest that the PI will become a leader in breast cancer, including a plan for leadership within the broader breast cancer community, beyond their own laboratory or institution.
- How the PI's accomplishments have had an impact beyond their own laboratory or research setting into the broader scientific, clinical, and/or patient communities.
- Whether any products, patents, or licenses have resulted from the PI's work.
- Whether the PI's work has resulted in publications in high-impact journals and/or presentations at international scientific meetings.
- Whether the PI has received awards or other forms of acknowledgment for their achievements.

- Whether the PI has the necessary technical and administrative expertise and/or ability to manage this award.
- Whether the application demonstrates that the PI will commit a minimum of 25% level of time and effort during the period of performance to conduct breast cancer research under this award.

Research Goals

- How well the application clearly states the PI's vision for the future of breast cancer.
- o To what degree the proposed research will likely produce a breakthrough and discoveries to ultimately solve the major problems or identified barriers.
- o To what degree the proposed research goals suggest innovative, creative thinking that will make progress toward ending breast cancer.
- o To what degree the proposed research goals are distinct within the PI's field and within the broader field of breast cancer research.
- How well the application identifies barriers that could inhibit the research goals and proposes appropriate strategies to overcome these barriers.
- Whether the application explicitly states which overarching challenge(s) the research will address.

Research Team and Environment

- How well the combined backgrounds and breast cancer-related technical and administrative expertise of the research team will contribute to accomplishing the research goals and/or ability to manage this award.
- Whether two or more consumer advocates are named in the application and meet the criteria according to the program announcement.
- How well the consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
- How well the consumer advocates' knowledge of current breast cancer issues, and how their background and/or training in breast cancer research, will contribute to the proposed research.
- Whether the environment will facilitate the PI's growth as an emerging innovator and leader.

- Whether appropriate documentation of institutional support is provided that reflects the
 extent to which the PI will be relieved of academic or administrative responsibilities and
 allowed to pursue their goals.
- o If applicable, to what degree the intellectual and material property plan is appropriate.

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**:

• Budget

- Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
- Whether the budget is appropriate for the proposed research.

• Application Presentation

o 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 Defense Health Program and FY24 BCRP, as evidenced by the following:
 - **Stage 1:** During the first stage of programmatic review, the application will be selected for the second stage using the following criteria:
 - Relative innovation
 - Adherence to the intent of the award mechanism
 - Stage 2 (Oral Presentation): During the second stage of programmatic review, the following criteria will be used:
 - Understanding of barriers in breast cancer
 - Articulation of a realistic vision with a high potential to impact breast cancer
 - Leadership skills to develop a vision for preventing and treating breast cancer beyond the PI's laboratory and institution

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 <u>Section II.E.1.b</u>, <u>Programmatic Review</u>. 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 BCRP 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.

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.

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 <u>DoD R&D Terms and Conditions</u> and the <u>USAMRAA Research</u> <u>Terms and Conditions</u>: <u>Addendum to the DoD R&D Terms and Conditions</u> 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.

Public Health Service (PHS) Inclusion Enrollment Reporting Requirement (only required for clinical research studies and clinical trials): 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 \$10M 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: <u>help@eBRAP.org</u>

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.

- More than one application is received in which the same investigator is named as the PI.
 Only the first application received will be accepted; additional applications will be administratively rejected.
- 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 BCRP 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 BCRP Programmatic Panel members can be found at https://cdmrp.health.mil/bcrp/panels/panels/24.
- 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.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. 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). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Submission of the same research project to different funding opportunities within the same program and funding cycle.
- The application does not address at least one of the <u>FY24 BCRP Overarching Challenges</u> and adequate justification for exception was not provided.
- The PI does not meet the eligibility criteria.
- Application fails to include two consumer advocates on the research team as required by this program announcement.
- Three confidential letters of recommendation as required by this program announcement were not submitted.

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 | П |
| (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" | |
| Research Team Statement – Attachment 6, upload as "Team.pdf" | |
| Representations (Extramural submissions only) – Attachment 7, upload as "RequiredReps.pdf" | |
| Suggested Intragovernmental/Intramural Budget Form (<i>if applicable</i>) — Attachment 8, 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) | |
| Additional Application Components | |
| Confidential Letters of Recommendation | |

APPENDIX 1: ACRONYM LIST

BCRP Breast Cancer Research Program

CDMRP Congressionally Directed Medical Research Programs

CFR Code of Federal Regulations

DOD Department of Defense

DoDGARs Department of Defense Grant and Agreement Regulations

eBRAP Electronic Biomedical Research Application Portal

EOHS Era of Hope Scholar Award

ET Eastern Time

FAD Funding Authorization Document

FY Fiscal Year

LOI Letter of Intent

M Million

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

STEM Science, Technology, Engineering, and/or Mathematics

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