# 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

## Transformative Breast Cancer Consortium Development Award

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524BCRPTBCCDA**

**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 16, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, May 30, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, June 4, 2024
- **Peer Review:** July 2024
- **Programmatic Review:** September 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 *breast cancer landscape* and the BCRP's mission, all FY24 BCRP Transformative Breast Cancer Consortium Development 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 FY24 Transformative Breast Cancer Consortium Development Award is intended to provide successful applicants the time and resources needed to bring investigators and breast cancer advocates together to establish a consortium framework and conduct preliminary research to support application to a future, full Transformative Breast Cancer Consortium Award (pending availability of funds). This is a development award and is a separate mechanism from the full consortium award. Recipients of the FY24 Transformative Breast Cancer Consortium Development Award are expected to submit an application to compete for the full Transformative Breast Cancer Consortium Award anticipated to be offered in a future fiscal year(s). However, it is not necessary to receive a development award in order to apply for a full consortium award in the future. For FY24, investigators may be named as Consortium Director on an application submitted to either (but not both) of these mechanisms. Detailed information on the FY24 Transformative Breast Cancer Consortium Award is available under a separate program announcement (HT942524BCRPTBCCA).

The FY24 Transformative Breast Cancer Consortium Development Award provides support to:

- Develop the infrastructure of a multi-institutional research team inclusive of scientists, clinicians, and breast cancer advocates (e.g., building appropriate collaborations, outlining integration, research management, administrative management, and communication plans, and devising an intellectual property plan)
- Generate necessary preliminary data to serve as proof of concept or for project integration
- Acquire research resources
- Develop a framework of necessary statistical analyses

***Breast cancer consumer advocates must be active participants in the development and execution of the Transformative Breast Cancer Consortium Development Award.***

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.

***Research involving human subjects and research involving human anatomical substances and data is permitted; however, clinical trials are not allowed under this funding opportunity.***

***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 BCRP Transformative Breast Cancer Consortium Development Award should not exceed **$100,000**. 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 $0.16M to fund approximately one Transformative Breast Cancer Consortium Development 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

Independent investigators at all academic levels (or equivalent) are eligible to be named as the Consortium Director on an application.

***Investigators named as Consortium Director on a pre-application or full application submitted under funding opportunity HT942524BCRPTBCCA are not eligible to be named as the Principal Investigator (PI) under the current funding opportunity.***

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

### II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

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

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

## II.D. Application and Submission Information

### II.D.1. Location of Application Package

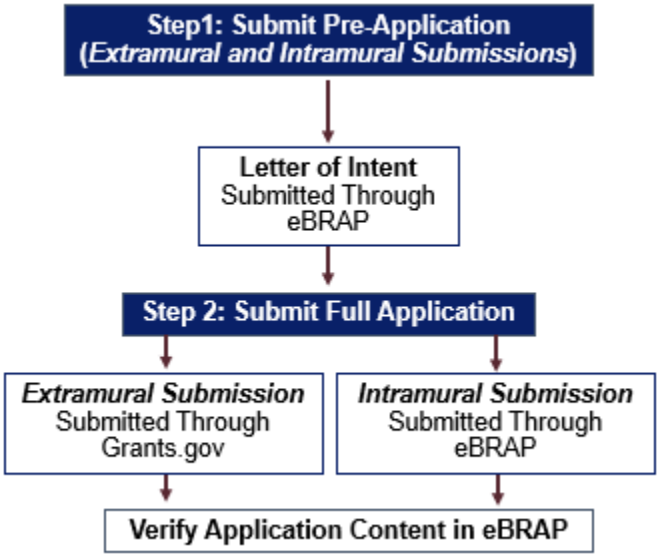
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the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

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

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

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

*Application Submission Workflow*




**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 HT942524BCRPTBCCDA 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 HT942524BCRPTBCCDA 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 topic area 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.***

### 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 CMDRP 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 (three-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 overall goals of the proposed consortium using the outline below.

- **Overarching Challenge:** State explicitly which FY24 BCRP Overarching Challenge(s) or other fundamental issue(s) in breast cancer the proposed consortium will address.

- **Central Hypothesis:** Describe the hypothesis that will form the basis of the future, full Transformative Breast Cancer Consortium Award.

- **Background and Experience:** Briefly describe the Consortium Director's research experience and leadership skills that make them well-qualified for the role. Identify and provide the rationale for selecting the project team members and explain why these individuals collectively represent the best team to solve the problem(s) identified.

- **Structure of the Consortium and Integration:** Discuss the consortium's overall approach to address the central hypothesis with a description of the research that will be proposed through application to a future, full Transformative Breast Cancer Consortium Award.

    - Briefly identify the projects that will each be led by the Consortium Director and Project Team PIs.

    - Describe the critical research objectives, the team leaders, and the project they oversee.

    - Identify the key points of interaction between the projects and how such interaction will create synergy to address the overarching challenge(s) or other fundamental issue(s) more effectively than if the projects were conducted independently.

- **Preliminary Research:** Describe the preliminary research to be conducted under the development award that is needed to finalize proof of concept or to increase synergy/integration under the future, full Transformative Breast Cancer Consortium Award. Briefly describe the methods and analyses, including appropriate controls. Describe the availability of necessary research resources and, if appropriate, include a brief summary of the plan for acquiring these resources. If applicable for the preliminary research to be conducted under the development 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, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. Describe the anticipated outcomes of the preliminary research project and explain how the data generated will serve as proof of concept or project integration to support application to a future, full Transformative Breast Cancer Consortium Award.

- **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:** 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."

  - Provide a plan for the development of an intellectual and material property agreement and a process for resolving intellectual and material property issues among participating organizations.

- **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 how data and resources generated from the preliminary research conducted under the development award 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.

- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **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 reasoning behind the overall goals of the proposed consortium.

  - **Overarching Challenge:** State the overarching challenge(s) in breast cancer the proposed consortium will address.

- **Central Hypothesis:** State the hypothesis that will form the basis of the future, full Transformative Breast Cancer Consortium Award.

- **Consortium Structure and Integration:** Briefly explain the consortium's overall approach to address the central hypothesis with a description of the proposed projects and objectives to be reached. Discuss how the projects will synergize to address the overarching challenge(s) or other fundamental issues more effectively than if the projects were conducted independently.

- **Preliminary Research:** Briefly describe the preliminary research and explain how the anticipated outcomes of this research will serve as proof of concept or project integration.

- **Impact:** Explain how the proposed consortium will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer and will significantly advance and accelerate progress toward the BCRP's mission of ending breast cancer.

- **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 of scientific jargon, acronyms, and abbreviations.

  - Present the ideas and reasoning behind the proposed effort.

  - Describe the ultimate applicability and impact of the research.

    - Which overarching challenge(s) in breast cancer will this research address?

    - What types of patients or at-risk individuals will the outcomes of the consortium help and how will it help them?

    - What are the potential clinical applications, benefits, and risks?

    - What is the projected time it may take to achieve a patient-related outcome?

    - What is the potential transformative impact of the proposed effort on individuals with, and/or at risk for, breast cancer?

- **Attachment 5: Statement of Work (SOW) (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 SOW format and recommended strategies for assembling the SOW.

For the Transformative Breast Cancer Consortium Development 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.

- **Attachment 6: Impact Statement (300 words or less recommended; one-page limit): Upload as "Impact.pdf".** ***Do not restate the research strategy as part of the Impact Statement.*** In a manner readily understood by readers without a background in science or medicine, articulate how the consortium's research will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer and will significantly advance and accelerate progress toward the BCRP's mission of ending breast cancer. Applications proposing research that represents an incremental advance in breast cancer do not meet the intent of this award mechanism.

- **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.

- **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.

- **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".
  - 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 "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 8.

### 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 **1** year.

The application's direct costs budgeted for the entire period of performance should not exceed **$100,000**. 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 **1** year.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Consortium-related meetings and teleconferences between/among participating investigators.
- Costs related to identifying and acquiring research resources.
- Other costs associated with planning and developing the consortium collaborations, communications, and resources.

### 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:

- **Impact**

  ***Note:*** Reviewers will evaluate how the proposed research will have an impact on the overarching challenge(s), assuming the objective/goals are realized.

  - To what degree the proposed consortium's research will have a major impact on at least one of the overarching challenges.
  - To what degree the proposed consortium's research will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer.
  - To what degree the proposed consortium's research will significantly advance and accelerate progress toward the BCRP's mission of ending breast cancer.

- **Consortium Team**

  - To what degree the Consortium Director's research experience and leadership skills make them well-qualified for the role.
  - Whether the project team members are identified and to what degree the rationale for selecting these individuals is appropriate.
  - To what degree the application explains why the project team members collectively represent the best team to solve the problem(s) identified.

- **Consortium Structure and Integration**

  - To what degree the consortium's proposed overall approach to address the central hypothesis through research that will be proposed through application to a future, full Transformative Breast Cancer Consortium Award is appropriate and feasible.
  - Whether the application identifies the projects that will each be led by the Consortium Director and Project Team PIs.
  - How well the critical research objectives are developed and whether the team leaders and the projects they oversee are appropriately described.
  - To what degree the application identifies the key points of interaction between the projects and demonstrates that such interaction will create synergy to address the

overarching challenge more effectively than if the projects were conducted independently.

- **Preliminary Research**
    - To what degree the preliminary research needed to finalize proof of concept or to increase synergy/integration is appropriate and feasible.
    - How well the methods and analyses, including appropriate controls, are developed.
    - Whether the availability of necessary research resources and, if appropriate, the plan for acquiring these resources is described.
    - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
    - To what degree the anticipated outcomes of the preliminary research project and data generated will demonstrate proof of concept or project integration to support application to a future, full Transformative Breast Cancer Consortium Award.

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.
- **Environment**
    - Whether the research environment is appropriate for the proposed research.
    - Whether the quality and extent of institutional support are appropriate for the proposed research.
    - 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 Defense Health Program and FY24 BCRP, as evidenced by the following:
    - Adherence to the intent of the funding opportunity
    - Program portfolio composition
    - Relative impact

### 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 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.

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, IRB, 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.

PHS Inclusion Enrollment Reporting Requirement ***(only required for clinical research studies)***: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the

"Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $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: 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 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/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 funding cycle.
- The application does not address at least one of the FY24 BCRP Overarching Challenges and adequate justification for exception was not provided.
- The PI does not meet the eligibility criteria.

**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" | ☐ |
| Representations *(Extramural submissions only)* – Attachment 7, upload as "RequiredReps.pdf" | ☐ |
| Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – 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)*<br>Include budget justification | ☐ |
| **Budget** *(Intramural submissions only)*<br>Include budget justification | ☐ |
| **Project/Performance Site Location(s) Form** | ☐ |
| **Research & Related Subaward Budget Attachment(s) Form** *(if applicable)* | ☐ |

## APPENDIX 1: ACRONYM LIST

| | |
|---|---|
| BCRP | Beast 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 |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FY | Fiscal Year |
| IRB | Institutional Review Board |
| 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 |
| TBCCA | Transformative Breast Cancer Consortium Award |
| TBCCDA | Transformative Breast Cancer Consortium Development Award |
| 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 |