# 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 Award

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524BCRPTBCCA**

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

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 14, 2024
- **Invitation to Submit an Application:** June 14, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 6, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 9, 2024
- **Peer Review:** October 2024
- **Programmatic Review, Stage 1:** December 2024
- **Invitation for Oral Presentation:** December 2024
- **Programmatic Review, Stage 2:** February 2025

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

## TABLE OF CONTENTS

# II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

## II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) 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 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 Award is designed to support collaborations and ideas that will transform the lives of individuals with, and/or at risk for, breast cancer and will significantly accelerate progress toward ending breast cancer. Applicants must bring together different perspectives to develop new paradigms that will solve fundamental yet overarching problems in breast cancer. This award requires a team-based approach by a consortium of exceptional researchers and advocates, whose collaborative efforts will make a transformative impact in breast cancer. The transformation intended by the consortium must be in people's lives, and not in the healthcare or research system.

This funding opportunity is a separate mechanism from the Transformative Breast Cancer Consortium Development Award, which 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). For FY24, investigators may be named as Consortium Director on an application submitted to either (but not both) of these mechanisms. It is not necessary to receive a development award in order to apply for the current funding opportunity or anticipated full consortium awards in the future. Detailed information on the FY24 Transformative Breast Cancer Consortium Development Award is available under a separate program announcement (HT942524BCRPTBCCDA).

For the FY24 Transformative Breast Cancer Consortium Award, the consortium should have at least four, but no more than five, project teams, each investigating different projects under a central hypothesis. No more than two project teams may be based at one institution. Each team's work must be integrated within the consortium so that every component is working toward the consortium's central hypothesis. *Note: This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts, such as the National Cancer Institute (NCI) Specialized Programs of Research Excellence (SPOREs), and it should not represent a collection of related Program Project grants or subprojects.*

The proposed consortium's overall work is expected to be innovative. In addition, the Transformative Breast Cancer Consortium Award will include funds for "seed projects" to pursue brand-new, high-risk/high-reward concepts that arise from the work, during the award period.

*The Breast Cancer Landscape* describes the reality of breast cancer and identifies overarching challenges to progress the field. ***Research funded under this award mechanism should result in answers that will fundamentally and significantly transform and disrupt the present landscape***.

Applications submitted to the Transformative Breast Cancer Consortium Award must include the following:

- Research that includes truly innovative and brand-new, paradigm-shifting work in breast cancer that will address vital issues in a unique way. The issues may be one (or more) of the FY24 BCRP Overarching Challenges or, with justification, may be a different issue that meets the intent of the award mechanism and addresses the mission of ending breast cancer. If the application identifies a different fundamental issue, it must be coupled with at least one of the FY24 BCRP Overarching Challenges.

- Research that includes different disciplines that come together to address ending breast cancer with an ecologic approach. The consortium's proposed research must look at all aspects of the disease and bring together these different perspectives into one overarching plan for a deep, definitive dive into the FY24 BCRP Overarching Challenge(s) or other fundamental issue identified in the application. The plan also should include issues related to the hypothesis that have not been previously addressed or answered.

- A plan that describes in detail the integration across the consortium in all aspects, including administration, logistics, and substance. Applications must describe the substantive integration across and among teams that are necessary for the work. The required communication plan and administrative management plan will not suffice to show integration, nor will identifying individual team members who will cross teams. A detailed explanation of the substantive research processes that will be integrated is required.

Synergistic, highly integrated, multidisciplinary, and multi-institutional research teams of leading scientists, clinicians, and consumer advocates must be assembled into a consortium to address a major problem in a way that could not be accomplished by a single investigator or group. ***While the project teams are made up of different groups, each with its own Principal Investigator (PI), the teams must be working on the major problem identified in the Transformative Breast Cancer Consortium Award application and under the leadership of the Consortium Director.*** The research proposed in Transformative Breast Cancer Consortium Award applications may include phase 1 clinical trials and collaborations with pharmaceutical or biotechnology industry scientists and/or companies, as appropriate. However, a clinical trial is not required, and the primary thrust of the application should not be a clinical trial.

Although not all-inclusive, applications that propose the following as the primary effort(s) or central hypothesis of the consortium will ***not*** meet the intent of this award mechanism:

- NCI Program Project or SPORE grants or applications

- Conducting drug screens or testing a "cocktail" of therapeutics

- Targeting a single gene or protein

- Developing a new derivative or formulation of an old drug
- Conducting genomic landscape mapping analyses
- Seeking to improve existing technologies (e.g., mammography or magnetic resonance imaging screening)

All applications submitted to the Transformative Breast Cancer Consortium Award must address the following key features:

**1. IMPACT**

***Demonstrate potential to transform or improve the lives of individuals with, and/or at risk for, breast cancer.*** The time to the final impact may vary, but the outcomes of the effort must be transformative and significantly advance the BCRP's mission of ending breast cancer. A clear and compelling presentation of how the effort will be transformative for individuals with, and/or at risk for, breast cancer must be provided. Applications proposing research that represents an incremental advance in breast cancer do not meet the intent of this award mechanism.

**2. INNOVATION**

***Pursue innovative, high-risk/high-reward research that has the potential to change existing paradigms, or develop new paradigms.*** Innovative research may introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities. In addition to the requirement that the consortium's overall research be innovative, applications must describe a plan to support the pursuit of innovative concepts through "seed projects," i.e., the development of new concepts that emerge during the course of the award. These "seed projects" should enable the research team to explore new avenues of high-risk/high-reward ideas that were not part of the original application, but that develop during the project and are within the scope of the overall vision of the research. A portion of the total direct budget costs (no more than 5%) must be reserved to support the "seed projects," and these funds may not be used for equipment or travel.

**3. CONSORTIUM**

***Integrate project teams consisting of preeminent investigators and advocates from appropriate disciplines and institutions.*** Applications should include a robust consortium of researchers with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the proposed research. Emphasis must be placed on integrating the most highly qualified investigators and advocates to focus on the research problem, regardless of their location. These investigators must include highly accomplished scientists, clinicians, and promising young investigators in the targeted areas of research who collectively represent the best team to solve the problem(s) identified. The proposed research effort should be broad enough to require a multidisciplinary approach that is reflected in the composition of the consortium team. ***Inclusion of scientists from nontraditional disciplines is encouraged.***

The award mechanism is structured with a Consortium Director and at least three, but no more than four, Project Team PIs representing at least two institutions. ***The Consortium Director is responsible for the day-to-day management of the consortium, as well as for leading their own***

***project team.*** The Consortium Director, together with the Project Team PIs, are jointly responsible for leading and executing the proposed research projects that are integrated into a central hypothesis and will result in answers that will fundamentally and significantly transform and disrupt the present *breast cancer landscape*. Please see the top of this section, Section II.B, Award Information, for more details.

***Incorporate breast cancer consumer advocates into every aspect of the proposed consortium's activities.*** Applications are required to include consumer advocate involvement. The consortium team must include at least one breast cancer consumer advocate per project team. The consumer advocates are expected to represent the perspective of the patient population(s) that are most relevant to the consortium's proposed research. Breast cancer consumer advocates must have an active role in every aspect of the proposed consortium's work ***including consortium conception and design***, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. Consumer advocates must be integrated into and play an active role in the leadership and decision-making committees for the consortium at each participating institution. Examples of appropriate integration include membership on the advisory board(s) and steering committee(s), participation in each project team, and attendance at all consortium-related meetings. ***As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer, they should be part of a breast cancer advocacy organization, and their role in the project should be independent of their employment. They cannot be employees of any of the institutions participating in the application. They must have a high level of familiarity and training involving science and current issues in breast cancer research.***

**4. INTEGRATION**

***Provide a plan that describes in detail the integration across the consortium in all aspects, including administration, logistics, and substance.*** Applications must demonstrate the substantive integration across and among teams that are necessary for the work. The integration plan must provide a detailed explanation of the substantive research processes that will be integrated.

**5. IMPLEMENTATION**

***Provide a strategy for implementation.*** Projects must demonstrate solid scientific rationale, and applications ***must*** include published and/or preliminary data that support the feasibility of their hypotheses and/or approaches. The application must include a detailed research management plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the milestones, and explains how these solutions will ultimately be translated to individuals with, and/or at risk for, breast cancer. It is expected that the proposed plan will present an exceptional level of innovation and creativity.

***Accelerate research progress through communication.*** Communication between and among consortium team members is essential to the success of the consortium. Applications must include a strategy for sharing data in real time and using information technologies to facilitate timely and effective communication and cooperation. The communication plan should specify the processes and tools to be used for regular and structured communication. The consortium should take full advantage of state-of-the-art communication and data sharing tools in addition to

formal and informal meetings. The framework for the communication plan must be part of the application and the individual(s) who will maintain the data sharing and communications technologies must be identified.

***Provide an effective, coordinated administrative management plan that integrates and optimizes the research and collaborations.*** The Consortium Director is required to commit a minimum level of time and effort of 25% to direct and manage an initiative of this magnitude, as well as lead their own project team. The Consortium Director must have the scientific ability and proven administrative ability to oversee large research programs and a proven record of leadership, including experience in the effective use of communication tools and the management of multifaceted and multidisciplinary projects. The administrative management plan must explain how the consortium will be organized and managed, and specify the processes and tools to be used for project meeting scheduling, reviews of research findings, ensuring multidisciplinary authorship of all publications arising from the consortium's work, and other issues of common concern to the consortium and its investigators. The administrative management plan also must describe procedures and processes that will be used to maximize the resources (e.g., databases, animal models) and products (e.g., antibodies) generated by the consortium and how these resources and products will be made available to the scientific community. A portion of the total direct budget costs must be reserved for a program manager.

**Award Structure:** The Transformative Breast Cancer Consortium Award is structured to accommodate up to five PIs (the Consortium Director and three or four Project Team PIs). ***The Consortium Director will be responsible for the majority of the administrative tasks associated with application submission and the day-to-day management of the consortium. In addition, the Consortium Director will be responsible for leading their own project team.*** The Consortium Director and Project Team PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named on separate awards to the recipient organizations. For individual submission requirements for the Consortium Director and Project Team PIs, refer to Section II.D.2, Content and Form of the Application Submission.

The Consortium Director, Project Team PIs, and consumer advocates will be required to present an update on progress toward accomplishing research milestones and goals of the consortium and each project at an annual In-Progress Review (IPR) Meeting for the Transformative Breast Cancer Consortium Award. The intent of the IPR Meeting is to assess research progress, address problems, and define future directions. Annual IPR Meetings will be held at the conclusion of year 1 and every subsequent year in the period of performance and will be attended by members of the BCRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer to facilitate oversight and provide feedback to the consortium. IPR Meetings will either be held in person in the National Capital Region or virtually, at the discretion of the government. Continued funding may be contingent upon the successful completion of specific research milestones and goals. Research milestones from the approved SOW will be determined during the award negotiation process.

In addition to IPR Meetings, each consortium must hold biannual workshops, which may be held at the PIs' institutions or virtually, to facilitate ongoing communication and exchange of

information within the consortium, as well as with advisory board(s) and/or steering committee(s).

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY24 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 (e.g., up to and including phase 1 or equivalent) 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 types of awards made under the program announcement will be cooperative agreements (31 USC 6305) based on anticipated "substantial involvement" on the part of CDMRP. Substantial involvement includes assistance, guidance, coordination, and/or participation in project activities, including but not limited to, IPR Meetings wherein recommendations for continued funding will be made based on overall study progress.

The anticipated direct costs budgeted for the entire period of performance for an FY24 BCRP TBCCA] Award should not exceed **$25M**. 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 $38.75M to fund approximately one Transformative Breast Cancer Consortium 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 a Consortium Director or Project Team PI on an application.

The Consortium Director is required to commit and maintain a minimum level of time and effort of 25% during the period of performance to direct and manage the consortium and to lead their own project team.

***An investigator may be named as Consortium Director on only one pre-application or full application under this funding opportunity.***

***Investigators named as the PI on a pre-application or full application submitted under funding opportunity HT9425-24-BCRP-TBCCDA are not eligible to be named as Consortium Director under the current funding opportunity.***

***There are no limits on the number of pre-applications for which an investigator may be named as a Project Team PI for this 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

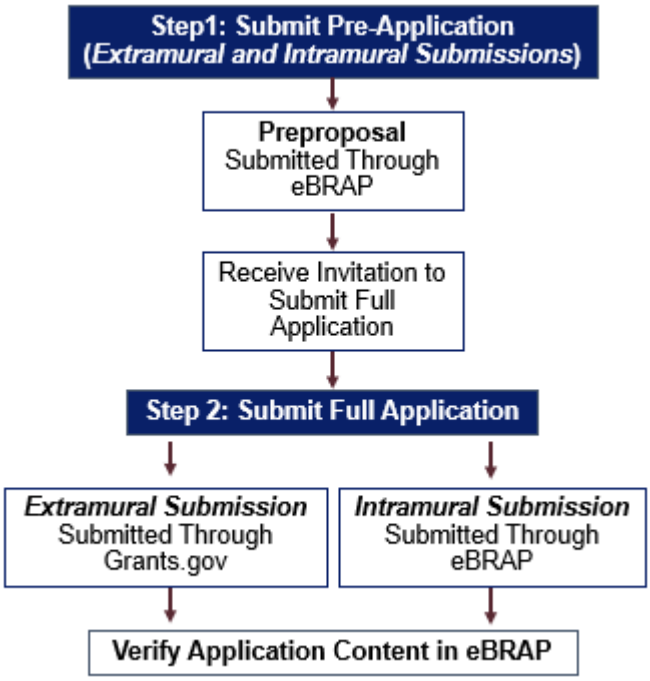
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the 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 HT942524BCRPTBCCA 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 HT942524BCRPTBCCA 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 Consortium Director through eBRAP (https://eBRAP.org/), including the submission of contact information for each Project Team PI.

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 each PI, the Business Official(s), performing organization(s), and contracting organization(s) must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

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

| Application Includes: | Select Option: |
|---|---|
| No Clinical Trial | No Option |
| Clinical Trial | Clinical Trial |

After the Consortium Director confirms submission of the pre-application, the Project Team PIs will be notified of the pre-application submission via an email from eBRAP. ***The Project Team PIs must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Project Team PIs must register in eBRAP.

After associating the pre-application with their eBRAP account, the Project Team PIs should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

***Project Team PIs should not initiate a new pre-application based on the same research project submitted by the Consortium Director.*** Project Team PIs are urged to complete these steps as soon as possible. If they are not completed:

- The Project Team PIs will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Project Team PI will not be able to submit their full application package components to eBRAP.

**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 additional information on pre-application submission):

***Note: Upload documents as individual PDF files unless otherwise noted.***

- **Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit 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 that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - How will the proposed research fundamentally and significantly transform and disrupt the present *breast cancer landscape*?

- How does the consortium bring different disciplines together with one overarching plan to address breast cancer with an ecologic approach?

- How will the proposed research be innovative and introduce brand-new paradigms in breast cancer?

- How will a deep, definitive dive into one (or more) of the FY24 BCRP Overarching Challenges or other fundamental issue(s) be asked, answered, or addressed by the consortium in a manner that has not yet been attempted? Explain how and/or why this fundamental issue has not yet been asked or answered.

- How will the proposed research make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer? How will the outcomes of the proposed research significantly accelerate progress toward ending breast cancer?

- What is the overall organization of key personnel, including consumer advocates, and what will be each team member's role in the consortium? How will the consortium team be integrated to address an overarching problem in breast cancer in a way that could not be accomplished by a single investigator or group?

- How will the consortium be integrated in all aspects, including administration, logistics, and substance?

- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:

  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).

  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

  - **Key Personnel Biographical Sketches (five-page limit per individual):** ***All biographical sketches should be uploaded as a single combined file.*** Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

  - **Additional Information:** One page for additional information that the PI can use, at their discretion, to provide supporting data or rationale for the pre-application.

### II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) and the BCRP, pre-applications will be screened based on the following criteria:

- To what degree the proposed research will fundamentally and significantly transform and disrupt the present *breast cancer landscape*.

- To what degree the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach.

- To what degree the proposed research is innovative and introduces brand new paradigms in breast cancer.

- Whether the pre-application proposes a deep, *definitive* dive into one (or more) of the FY24 BCRP Overarching Challenges or other fundamental issue(s) to be asked, answered, or addressed by the consortium in a manner that has not yet been asked or answered.

- To what degree the proposed research will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer.

- Whether the proposed research will significantly accelerate progress toward ending breast cancer.

- To what degree the consortium team is integrated to address an overarching problem in breast cancer in a way that could not be accomplished by a single investigator or group.

- To what degree the proposed consortium will be integrated in all aspects, including administration, logistics, and substance.

### II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, the Consortium Director will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

The CDMRP requires separate full application package submissions for the Consortium Director and each Project Team PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Consortium Director and Project Team PIs during pre-application submission. ***All associated applications (the Consortium Director's and each Project Team PI's) must be submitted by the full application submission deadline.***

### 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 for the Consortium Director

Each application submission must include the completed full application package for this program announcement. See Section II.H.3, Full Application Submission Checklist, 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 (45-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

  Describe the proposed consortium in detail using the outline below.

  - **Overarching Challenge:** State explicitly which overarching challenge(s) in breast cancer the proposed research will address. Describe how a deep, ***definitive*** dive into the overarching challenge(s) or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will

fundamentally and significantly transform and disrupt the current *breast cancer landscape*.

- **Central Hypothesis:** State the consortium's central hypothesis to be tested.

- **Projects and Objectives:** Briefly explain the consortium's proposed projects that will each be led by the Consortium Director and Project Team PIs and explain the objective(s) to be reached by each project. Explain how the projects form a coherent plan to address the consortium's central hypothesis. Identify the key points of interaction between the projects and how such interaction will create synergy to address the overarching challenge more effectively than if the projects were conducted independently.

***Consortia should have at least four, but no more than five, project teams, each investigating different projects. One project team will be led by the Consortium Director and the remaining three or four project teams will be led by Project Team PIs. For each proposed project (either four or five total with one led by the Consortium Director), provide the following details using this outline. Start each project on a separate page:***

- **Title:** Provide a title for each project.

- **Project Leader:** Identify the project leader (either the Consortium Director or one of the Project Team PIs) and any key personnel, as appropriate.

- **Background:** Describe in detail the rationale for the study and reasoning on which the proposed research is based. Provide sufficient preliminary data to support the feasibility of the work proposed. The application must demonstrate logical reasoning and provide a sound scientific rationale as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.

- **Hypothesis/Objective:** State the hypothesis to be tested and/or the objective(s) to be reached.

- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.

- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Where relevant, describe the accessibility to the data, cohort(s), and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the project. If applicable, describe resources available for the development of sufficient quantities of critical reagents under Good Manufacturing Practice (GMP). Address potential pitfalls and problem areas and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed

research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be supported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable. For clinical research, see Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

- **Clinical Strategy *(if applicable)*: *Only small-scale (e.g., up to and including phase 1 or equivalent) clinical trials are allowed.*** Provide detailed plans for initiating and conducting the clinical trial during the course of the award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other FDA approvals). If an IND or IDE is required, the IND/IDE application must be submitted to the FDA within 12 months of the award start date. Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover).

  - Provide a description of the clinical trial design, including all study variables, controls, and end points that will be used and/or assessed.

  - Identify the intervention to be tested and describe the projected outcomes. Describe how the proposed intervention compares with currently available interventions and/or standards of care. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as appropriate). Provide preclinical and/or clinical evidence to support the safety of the intervention.

  - Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from who the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site and describe the efforts that will be made to achieve accrual goals. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.

  - List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/ exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide justification for exclusions.

    ***Inclusion of Women and Minorities in Study:*** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women

and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. See Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

- Describe the process for obtaining informed consent and any screening procedures required to determine eligibility for study participation.

- Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific action to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). If multiple site studies are involved, state the approximate number of subjects to be enrolled at each site.

- Outline the timing and procedures planned during the follow-up period. Estimate the potential for subject loss to follow-up, and how such loss will be handled/ mitigated.

- Provide evidence to document the availability of, and access to, all critical reagents, including the intervention itself, if applicable, for the duration of the proposed trial.

- Describe how quality control will be addressed. Describe how compliance with current Good Laboratory Practice (GLP), GMP, and Good Clinical Practice (GCP) guidelines will be established, monitored, and maintained, as applicable.

- Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, and statistician) possesses the appropriate expertise in conducting clinical trials.

– **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the number of human subjects that will be enrolled. If multiple sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

○ **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 letters signed by each project's breast cancer consumer advocate confirming their commitment to participate on the project team.

- **Commercial Entity Letters of Commitment *(if applicable)*:** If the proposed study involves the use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

- **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.

- **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.

- **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 proposed research.

  - **Overarching Challenge:** State the overarching challenge(s) in breast cancer the proposed research will address. Describe how a deep, ***definitive*** dive into the overarching challenge(s) or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will fundamentally and significantly transform and disrupt the current *breast cancer landscape*.

  - **Central Hypothesis:** State the consortium's central hypothesis to be tested.

  - **Projects and Objective:** Briefly explain the consortium's proposed projects that will each be led by the Consortium Director and Project Team PIs and explain the objective(s) to be reached by each project. Explain how the projects will support the consortium's central hypothesis.

  - **Innovation:** Briefly describe how the consortium will change existing paradigms, or develop new paradigms.

  - **Impact:** Explain how the consortium will make a transformative impact on the lives of individuals with, and/or at risk for, 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.

- Clearly describe the rationale, objectives, and aims of the application.
- Describe the ultimate applicability and impact of the research.
  - What overarching challenge(s) in breast cancer will this research address?
  - How will the consortium change existing paradigms or develop new paradigms?
  - 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 this study on individuals with, and/or at risk for, breast cancer?

- **Attachment 5: Statement of Work (eight-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 Award mechanism, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

  The SOW should include a feasible plan and timeline to conduct the research. The SOW must include specific research milestones, including "seed project" initiation, to be accomplished by the end of each year in the period of performance.

  ***Each PI must submit an identical copy of a jointly created SOW. The contributions of the Consortium Director and each Project Team PI should be noted for each task.***

- **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.*** Articulate how the proposed 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: Innovation Statement (one-page limit): Upload as "Innovation.pdf".**
  - Describe how the proposed consortium's research will introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities.
  - Describe the innovations and technical solutions that will be implemented to accomplish the consortium's overall research goals.
  - To support the pursuit of innovative ideas, describe the plan for potential "seed projects" that may emerge over the course of the award that will allow the consortium teams to pursue high-risk/high-reward ideas.
- **Attachment 8: Consortium Plan (eight-page limit): Upload as "ConsortiumPlan.pdf".**
  - **Consortium Team and Environment:** Describe how the consortium is composed of an integrated team of preeminent investigators and advocates from appropriate disciplines and institutions. Explain how the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach. Describe how the Consortium Director's research experience and leadership skills make them well qualified to be the Consortium Director. In addition, describe how each Project Team PI will bring a different strength and/or expertise to the application. Describe how the combined expertise of the Consortium Director, each Project Team PI, and consumer advocates in the consortium will better address the research question and explain why the work should be done together rather than through separate efforts. Explain how the consumer advocates will represent the perspective of the patient population(s) most relevant to the consortium's proposed work. Include an organizational chart identifying the roles of all team members, including consumer advocates. Describe the research environments and how each of the facilities and resources at all of the institutions will support the research requirements and the projects.
  - **Integration Plan:** Present a detailed integration plan that describes the integration across the consortium in all aspects, administration, logistics, and substance. Describe the substantive integration across and among teams that are necessary to the work. Provide a detailed explanation of the substantive research processes that will integrate.
  - **Research Management Plan:** Present a detailed research management plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the research goals, and explains how these solutions will be translated to individuals with, and/or at risk for, breast cancer.

- **Consortium Management Plan:** Present an overall management plan to facilitate group interactions, adherence to regulatory requirements, administrative interactions, and oversight by advisory board(s) and/or steering committee(s). Provide an effective and coordinated administrative management plan that describes how the consortium will be organized and managed. Specify the processes and tools to be used for project meeting scheduling, reviews of research findings, authorship of publications arising from the consortium's work, and other issues of common concern to the consortium and its investigators. The administrative management plan must also describe procedures that maximize the use of resources and eliminate unnecessary duplication of efforts. The application should include a program manager who will guide the overall administrative management of the consortium.

- **Communication Plan:** Provide a detailed communication plan that describes how communication between and among consortium team members and their institutions will be accomplished. Provide a strategy for how data will be shared in real time and use information technologies that facilitate timely and effective communication and cooperation among consortium members. Identify the individual(s) who will maintain the data sharing and communications technologies.

- **Attachment 9: Consumer Advocate Statement (two-page limit): Upload as "ConsumerAdvocate.pdf".** The Consumer Advocate Statement should be written by the Consortium Director. Provide the name(s) of at least one consumer advocate for each project team and their affiliation with a breast cancer advocacy organization(s). Explain how the consumer advocates contributed to the consortium conception and design. Describe the integral roles they will play in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. 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 consortium. Explain how the consumer advocates' experience and expertise will be integrated into the research projects and management of the consortium.

- **Attachment 10: Data and Research Resources Sharing Plan (two-page limit): Upload as "Sharing.pdf".** Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Specifically describe a plan to make animal models, tissue samples, and other resources developed as a part of the proposed research projects available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resources sharing plan. Refer to CDMRP's Policy on Data & Resources 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 11: Transition Plan and Regulatory Strategy (three-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to move the consortium's findings to the next phases of development and/or clinical use following the successful completion of the award. Articulate this information for the overall effort as well as the individual projects. Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Provide the components listed below, as appropriate:

  - A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable and should include the intended user.

  - Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care (e.g., specific potential industry partners, specific funding opportunities to be applied for).

  - For knowledge products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A "knowledge product" is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)

  - For knowledge outcomes, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical/patient care or distributed to the breast cancer community.

  - If applicable, details of the development plan and FDA regulatory strategy that will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.

  - A description of collaborations and other resources that will be used to provide continuity of development.

  - A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA). If the application does not include a clinical trial, provide a realistic timeline for near-term clinical investigation.

- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- **Attachment 12: Inclusion of Women and Minorities (six-page limit): Upload as "Inclusion.pdf".** ***(Attachment 12 is only applicable and required for applications that propose clinical research and/or clinical trials.)*** 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. Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. 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 Institutional Review Board [IRB] review) are exempt from this requirement.

- **Attachment 13: 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 14: 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 all 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.

  ***The Consortium Director and Project Team PIs must each have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Consortium Director should not include budget information for Project Team PIs even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.***

**(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 14.

### II.D.2.b.iii. Full Application Submission Components for the Project Team PIs

The application submission process for each Project Team PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

**(b) Attachments:**

- **Attachment 5: Statement of Work (eight-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 13: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

**(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 information.

**(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 information.

- **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 all 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 information.

- **Budget Justification (no page limit):** Upload as "BudgetJustification.pdf".

***The Consortium Director and Project Team PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Project Team PIs should not include budget information for the Consortium Director, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.***

**(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 General Application Instructions, Section V.A.(f), for detailed information.

**(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 information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

### II.D.2.b.iv. Additional Application Components

In addition to the complete application package, Transformative Breast Cancer Consortium Award applications also require the following components:

- **Oral Presentation:** PIs named in Transformative Breast Cancer Consortium Award applications that are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation (see Section II.E.1.b, Programmatic Review) that will be held in the National Capital Area or virtually, at the discretion of the government, and is tentatively scheduled for February 2025. ***Only the invited PIs (the Consortium Director and the three or four Project Team PIs) and one consumer advocate may attend.***

  The presentation will consist of the following, with the total presentation time not to exceed 45 minutes:

  - A 3- to 5-minute introductory talk by the Consortium Director consisting of no more than five slides.
  - For each project, a 5- to 7-minute talk by the Project Team PI or Consortium Director who is leading the project consisting of no more than five slides.
  - A 5-minute talk by the consumer advocate consisting of no more than five slides.
  - A 5-minute summary presentation by the Consortium Director consisting of no more than five slides.

Following the presentation, there will be a 30-minute question-and-answer session with the Programmatic Panel members. The questions below will be topics for discussion during the presentation and the question-and-answer session. Teams who are invited must prepare a presentation that specifically addresses the following four questions within the total presentation time of no more than 45 minutes, without addressing specific aspects of the application:

- What conceptual or intellectual or scientific barriers do you consider are most urgent to overcome in order to end breast cancer and how will your consortium address them?
- How will the consortium's team-based approach challenge existing paradigms or develop new paradigms that will fundamentally and significantly transform and disrupt the present *breast cancer landscape*?
- How will your consortium take a team-based, integrated approach and make a transformative impact in people's lives?
- How will your consortium create an environment that fosters innovation?

### 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 combined direct costs budgeted for the entire period of performance should not exceed **$25M**. 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.

To support the pursuit of innovative ideas, a portion of the total direct costs (no more than 5%) must be reserved in the budget for "seed projects." These "seed projects" should be developed during the project and must be within the scope of the overall vision of the research. Direct costs for these "seed projects" should be allocated into the "other direct cost" category of the year 1 budget. Funds for "seed projects" may not be used for equipment or travel.

Research milestones to be accomplished by the end of each year in the period of performance must be clearly defined in the consortium SOW and will be finalized during award negotiations. The Consortium Director, Project Team PIs, and consumer advocates will be required to present an update on progress toward accomplishing research milestones and goals of the consortium and each project at an annual IPR Meeting. IPR Meetings will either be held in person in the National Capital Region or virtually, at the discretion of the government. The intent of the IPR Meeting is to assess research progress, address problems, and define future directions. Annual IPR Meetings will be held at the conclusion of year 1 and every subsequent year in the period of performance and will be attended by members of the BCRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer.

In addition to IPR Meetings, each consortium must hold biannual workshops, which may be held at the PIs' institutions or virtually, to facilitate ongoing communication and exchange of information within the consortium, as well as with advisory board(s) and/or steering committee(s).

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.

A separate award will be made to each PI's organization.

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

- Travel costs for the PIs and consumer advocates to present project information or disseminate project results at biannual consortium workshops during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that these meetings will be held at one of the PIs' institutions or virtually (if necessary). These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel costs for Consortium Director, Project Team PIs, and consumer advocates to attend annual IPR Meetings during the period of performance in years 1, 2, 3, and 4. For planning purposes, it should be assumed that in-person 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):

- Consortium-related meetings, teleconferences, and travel between/among participating investigators.

- Costs related to identifying and acquiring research resources.

- Computers and software required to participate in the consortium.

- Other costs associated with planning and developing the consortium collaborations, communications, and resources.

- Costs for two investigators per project to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/ technical meetings is to present project information or disseminate project results from the BCRP Transformative Breast Cancer Consortium 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**, which are of equal importance:

- **Impact**

    - 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.

- **Overarching Challenge**

  - Whether the application explicitly states an overarching challenge(s) in breast cancer the proposed research will address.

  - To what degree a deep, definitive dive into the overarching challenge(s) or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will fundamentally and significantly transform and disrupt the current *breast cancer landscape*.

- **Research Strategy**

  - To what degree the proposed overall research strategy to address the consortium's central hypothesis is appropriate and feasible.

  - 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.

  - How well the scientific rationale supports the proposed research and its feasibility for each proposed project as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.

  - For clinical research projects other than clinical trials, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

  - How well the central hypothesis, project objectives, specific aims, experimental design, methods, and analyses are developed.

  - Whether there is documented availability of, access to, and quality control for all data, cohort(s), and/or critical reagents, where relevant.

  - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.

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

  - How well the application acknowledges potential pitfalls and problem areas and addresses alternative methods and approaches.

- **Statistical Plan**
    - To what degree an appropriate statistical plan is provided, including power analysis.
    - If applicable, whether the clinical trial is designed with enough statistical power to meet the objectives of the study.
- **Consortium Team**
    - To what degree the Consortium Director's research experience and leadership skills make them well-qualified for the role.
    - To what degree the Project Team PIs bring different strengths and/or expertise to the application.
    - To what degree the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach.
    - How the consortium team's background and expertise are appropriate to accomplish the proposed projects.
    - How the consortium team's combined expertise will better address the research question than through separate efforts.
    - How appropriate the level of effort is for the Consortium Director, who must commit a minimum level of time and effort of 25% to direct and manage the consortium, as well as to lead their own project team.
    - Whether each Project Team PI has committed an appropriate level of effort.
    - To what degree the consumer advocates contributed to the consortium conception and design.
    - To what degree the consumer advocates will play an integral role in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public.
    - To what degree the consumer advocates' knowledge of current breast cancer issues and their background and/or training in breast cancer research will contribute to the proposed consortium.
    - How well the consumer advocates represent the perspectives of the patient population(s) most relevant to the consortium's proposed work.
- **Consortium Plan**
    - To what degree the integration plan demonstrates the necessary integration across the consortium in all aspects, including administration, logistics, and substance.

- To what degree the application describes substantive integration across and among teams and provides a detailed explanation of the research processes that will be integrated.

- To what degree the consortium's research management plan will accomplish the research goals by identifying critical milestones, innovations, and technical solutions, and explains how these solutions will be translated to individuals with, and/or at risk for, breast cancer.

- To what degree the consortium management plan will facilitate group interactions, adherence to regulatory requirements, administrative interactions, and oversight.

- How well the application describes an effective and coordinated administrative management plan for how the consortium will be organized/managed and will utilize procedures to maximize the use of resources and eliminate unnecessary duplication of efforts.

- How well the application specifies processes and tools to be used for project meeting scheduling, reviews of research findings, authorship of publications, and other issues of common concern to the consortium and its investigators.

- How well the application describes a detailed communication plan between and among consortium team members and their institutions.

- How well the application's strategy for sharing data in real time and using information technologies will facilitate timely and effective communication and cooperation among consortium members.

- Whether the application identifies the individual(s) who will maintain the data sharing and communication technologies.

- **Transition Plan and Regulatory Strategy**

  - How well the application describes expected outcomes from the proposed research efforts that are specific, measurable, and include the intended user.

  - Whether the application describes a funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care.

  - How well the application describes collaborations and other resources that will be used to provide continuity of development.

  - For knowledge outcomes, how well the knowledge gained will be further developed, disseminated, and incorporated into clinical/patient care and/or distributed to the breast cancer community.

  - If applicable, how well the development plan and FDA regulatory strategy will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines (if applicable).

- If applicable, whether the application describes numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.

- To what degree the application describes a feasible schedule and milestones for bringing outcomes to the next phase of development or near-term clinical investigation.

- If applicable, how well the application addresses ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future.

- **Clinical Strategy** ***(only applicable if a clinical trial is proposed)***

  - Whether the type of clinical trial (e.g., treatment, prevention, diagnostic), phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover) proposed is appropriate to meet the project's objectives.

  - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.

  - Whether the application demonstrates access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

  - How well the application identifies potential barriers to accrual (e.g., slow or low enrollment, poor retention) and unexpected delays and presents adequate mitigation plans to resolve them.

  - How well the inclusion and exclusion criteria are justified and meet the needs of the proposed trial.

  - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approval), if appropriate.

  - To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.

  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.

- **Innovation**

  - To what degree the proposed consortium's research will introduce a new paradigm, look at existing problems from new perspectives, or exhibits other highly creative qualities.

  - How well the application describes the innovations and technical solutions that will be implemented to accomplish the consortium's overall research goals.

- How well the application describes a plan for potential "seed projects" that may emerge over the course of the award to allow pursuit of high-risk/high-reward ideas.

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**
  - To what extent the scientific environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - Whether the quality and extent of institutional support are appropriate for the proposed research.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

### II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 BCRP, as evidenced by the following:

  **Stage 1:** During the first stage of programmatic review, applications will be selected for Stage 2 using the following equally considered criteria:

  - Adherence to the intent of the award mechanism
  - Program portfolio composition

- Relative impact
- Relative innovation

**Stage 2 (Oral Presentation):** During the second stage of programmatic review, the following criteria will be used:

- Understanding of conceptual or intellectual or scientific barriers in breast cancer and articulation of how the consortium will address them
- Articulation of how the consortium's team-based approach will challenge existing paradigms or develop new paradigms that will fundamentally and significantly transform and disrupt the present breast cancer landscape
- Articulation of how the consortium will take a team-based, integrated approach and make a transformative impact in people's lives
- Consortium's capability to create an environment that fosters innovation

### 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 the Consortium Director or Project Team PIs are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

An organizational transfer of an award supporting the Consortium Director or Project Team PIs is discouraged. The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed.

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.

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

### II.F.4. Reporting

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

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

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.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $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 pre-application or full applications, the following administrative actions may occur.

### II.H.2.a. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- More than one pre-application is received in which the same investigator is named as the Consortium Director. Only the first pre-application received will be accepted; additional applications will be administratively rejected.

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

- Submission of an application for which a letter of invitation was not issued.

- 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.
- The PI does not meet the eligibility criteria.
- 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 invited application proposes a different consortium effort than that described in the pre-application.
- Application fails to name at least one breast cancer consumer advocate per project team as required by this program announcement.
- All associated (Consortium Director and each Project Team PI) applications are not submitted by the deadline.

**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 | |
|---|---|---|
| | Consortium Director | Project Team PI(s) |
| **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" | ☐ | |
| Innovation Statement – Attachment 7, upload as "Innovation.pdf" if applicable | ☐ | |
| Consortium Plan – Attachment 8, upload as "ConsortiumPlan.pdf" | ☐ | |
| Consumer Advocate Statement – Attachment 9, upload as "ConsumerAdvocate.pdf" | ☐ | |
| Data and Research Resources Sharing Plan – Attachment 10, upload as "Sharing.pdf" | ☐ | |
| Transition Plan and Regulatory Strategy (three-page limit) – Attachment 11, upload as "Transition.pdf" | ☐ | |
| Inclusion of Women and Minorities – Attachment 12, upload as "Inclusion.pdf" | ☐ | |
| Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf" | ☐ | ☐ |
| Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 14, 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 | 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 |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FDA | U.S. Food and Drug Administration |
| FY | Fiscal Year |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| GMP | Good Manufacturing Practice |
| IDE | Investigational Device Exemption |
| IND | Investigational New Drug |
| IPR | In-Progress Review |
| IRB | Institutional Review Board |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NCI | National Cancer Institute |
| 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 |
| SPORE | Specialized Program of Research Excellence |
| 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 |