

# **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**

**Breakthrough Award Levels 1 and 2**

**Announcement Type: Initial**

**Funding Opportunity Number: HT942524BCRPBTA12**

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

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 16, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, May 30, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, June 4, 2024
- **Peer Review:** July 2024
- **Programmatic Review:** September 2024

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

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Breast Cancer Research Program (BCRP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. The BCRP was initiated in FY92 to support innovative, high-impact research, with a mission of ending breast cancer for Service Members and their Families, Veterans, and the general public. Appropriations for the BCRP from FY92 through FY23 totaled \$4.24 billion. The FY24 appropriation is \$150 million (M).

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

#### II.A.1. The Breast Cancer Landscape

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

#### II.A.2. FY24 BCRP Overarching Challenges

Considering the current [breast cancer landscape](#) and the BCRP's mission, all FY24 BCRP Breakthrough Award Levels 1 and 2 applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.\* Simply identifying an overarching challenge is not sufficient. Applications must address the challenge in a way that can lead to or make a breakthrough and have a major impact.

- 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 intent of the Breakthrough Award is to support promising research that has high potential to lead to or make breakthroughs in breast cancer. The critical components of this award mechanism are:

**Impact:** Research supported by the Breakthrough Award will have the potential for a major impact and accelerate progress toward ending breast cancer. The impact may be near-term or long-term but must move beyond a minor advancement and have the potential to lead to a fundamentally new approach that is significantly more effective than interventions already approved or in clinical development. Applications are expected to identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research.

**Research Scope:** The Breakthrough Award is structured with four different funding levels. The levels are designed to support major (but not all) stages of research that will lead to clinical application. Each level has a defined research scope. It is the responsibility of the Principal Investigator (PI) to select the level that aligns with the scope of the proposed research. The funding level should be selected based on the research scope defined in the program announcement, and not on the amount of the budget.

The current program announcement discusses the Breakthrough Award Levels 1 and 2. Funding Levels 3 and 4 are available under other program announcements (HT942524BCRPBTA3 and HT942524BCRPBTA4, respectively). The PI is strongly encouraged to review the research scope defined under each funding level as described in the corresponding Breakthrough Award program announcement before submitting the pre-application. An application that does not meet the intent of the funding level selected will not be recommended for funding, even if it might meet the intent of a different funding level.

The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under the current program announcement:

- **Funding Level 1:** Innovative, high-risk/high-reward research that is in the earliest stages of idea development or is an untested theory that addresses an important problem. To foster research that yields new avenues of investigation, preliminary data are *not* required. Proof of concept is the anticipated outcome.

- **Funding Level 2:** Research that is already supported by substantial preliminary or published data and strongly validates clinical translation in a well-defined context within the [breast cancer landscape](#).
- **Funding Level 2: Population Science and Prevention Studies:** Population Science and Prevention Studies should involve investigations into why certain human patient populations differ in cancer risk or clinical prognosis. The studies should focus on the analysis of human data and biospecimens. Research should be already supported by substantial preliminary or published data and strongly validate clinical translation in a well-defined context within the [breast cancer landscape](#). With compelling justification, population science and prevention studies may request higher levels of funding and an additional year in the period of performance.

**Partnering PI Option:** The Breakthrough Award encourages applications that include meaningful and productive partnerships between investigators. The Partnering PI Option is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. It is expected that funding will be balanced between both PIs unless appropriately justified. New partnerships are encouraged, but not required. The application is expected to describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. *To meet the intent of the Partnering PI Option, applicants are discouraged from being named as a Partnering PI on multiple Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions. Applications in which a mentor and their current postdoctoral fellow or junior investigator are named as Initiating and Partnering PIs do not meet the intent of the Partnering PI Option. Applications where one PI is providing samples, animal models, or investigational agents while the other PI is conducting most, or all of the experiments and analyses, do not meet the intent of the Partnering PI Option.* If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PIs, refer to [Section II.D.2, Content and Form of the Application Submission](#).

**Personnel:** Applications are expected to include an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.

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

Applications seeking support for a clinical trial may be submitted to the FY24 BCRP Breakthrough Award Level 3 and Level 4 program announcements (HT942524BCRPBTA3 and HT942524BCRPBTA4, respectively).

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

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

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

***Clinical trials are not allowed. A clinical trial is defined*** in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

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

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

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

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

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 BCRP Breakthrough Award Funding Level 1 should not exceed **\$450,000** for applications with a single PI or **\$750,000** if applying under the Partnering PI Option.

The anticipated direct costs budgeted for the entire period of performance for an FY24 BCRP Breakthrough Award Level 2 should not exceed **\$1.0M** for applications with a single PI or **\$1.5M** if applying under the Partnering PI Option.

The anticipated direct costs budgeted for the entire period of performance for an FY24 BCRP Breakthrough Award Funding Level 2, Population Science and Prevention Studies, should not exceed **\$1.5M** for applications with a single PI or **\$2.0M** if applying under the Partnering PI Option. 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 \$20.9M to fund approximately 14 Breakthrough Award Levels 1 and 2 applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.*

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

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

**Extramural Organization:** An eligible non-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**

Investigators at all academic levels (or equivalent) are eligible to be named as a PI, Initiating PI, or Partnering PI on an application.

Applications are encouraged for postdoctoral fellows. A Mentorship Statement (see [Attachment 9](#)) is required for applications submitted with a PI who is a postdoctoral fellow.

***Each investigator may be named as a PI or Initiating PI on only one application per funding level for this Breakthrough Award Levels 1 and 2 program announcement.***

There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. To meet the intent of the Partnering PI Option, investigators are discouraged from being named as a Partnering PI on multiple FY24 BCRP Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions. Applications will be required to include a brief description of all the applications in which the investigator is named as a PI, Initiating PI, Partnering PI, collaborator, or mentor under this Breakthrough Award Levels 1 and 2 program announcement.

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

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

Refer to [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

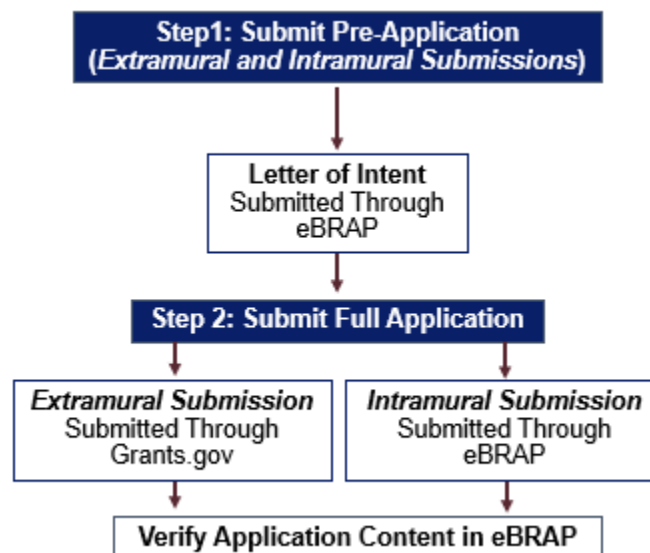
Submission is a two-step process requiring both a **pre-application** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a **full application** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission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

HT942524BCRPBTA12 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 HT942524BCRPBTA12 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](mailto:help@eBRAP.org) or 301-682-5507.

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

Regardless of submission type (i.e., extramural or intramural), all pre-application components must be submitted by the PI or Initiating PI through eBRAP (<https://eBRAP.org/>), including the submission of contact information for the Partnering PI if exercising the Partnering PI Option.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP.

If any changes need to be made, the applicant should contact the eBRAP Help Desk at [help@eBRAP.org](mailto: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:
Funding Level 1 and Single PI	Funding Level 1
Funding Level 1 and Initiating PI and Partnering PI	Funding Level 1 – Partnering PI Option
Funding Level 2 and Single PI	Funding Level 2
Funding Level 2 and Initiating PI and Partnering PI	Funding Level 2 – Partnering PI Option
Funding Level 2 Population Science and Prevention Studies and Single PI	Funding Level 2 – Population Science and Prevention Studies
Funding Level 2 Population Science and Prevention Studies and Initiating PI and Partnering PI	Funding Level 2 – Population Science and Prevention Studies – Partnering PI Option

**Partnering PI Option:** After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk ([help@ebrap.org](mailto: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).

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

- The Partnering PI will not be able to view and modify their full application during the verification period in eBRAP.
- Any intramural Partnering 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 detailed instructions regarding pre-application submission):

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

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

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

**Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and Partnering 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 Initiating and Partnering PIs during pre-application submission. ***All associated applications (the Initiating PI's and the Partnering 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 CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

### **II.D.2.b.ii. Full Application Submission Components for the PI or Initiating PI**

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

- 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 (page limit varies by funding level; see below for page limits): 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.
  - **Page Limit:** Page limits for the Project Narrative are correlated with the application’s funding level:
    - **Funding Level 1:** Seven-page limit
    - **Funding Level 2:** Fourteen-page limit
    - **Funding Level 2 – Population Science and Prevention Studies:** Fourteen-page limit
  - **Outline for Project Narrative:** Describe the proposed project in detail using the outline below.
    - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Preliminary data are not required, but are allowed, for Funding Level 1 applications. For Funding Level 2 applications, provide sufficient preliminary data to support the feasibility of the work proposed. Whether or not preliminary data are available, the application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project 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 or Objective:** State the hypothesis to be tested or the objective 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. 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 reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable. For clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **Statistical Plan:** Describe the statistical plan including power analysis, as appropriate, for the research proposed.
- **Research Team:** Describe how the combined backgrounds and breast cancer-related expertise of the research team will enable successful conduct of the project.
- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five

published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.
- **Letters of Collaboration (*if applicable*):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.
- **Letter of Recommendation (*only applicable and required for applications submitted with a PI who is a postdoctoral fellow; one-page limit is recommended*):** A letter of recommendation provided on organizational letterhead from the mentor(s) should describe:
  - The degree to which the PI participated in the development of the research idea
  - How well the PI can manage the technical and administrative aspects of the award
  - How well the PI can successfully accomplish the proposed research
- **Inclusion Enrollment Plan (*only required if clinical research is proposed*):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, 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 IRB review) are exempt from this requirement.
- **Good Manufacturing Practice (GMP) Compliance (*if applicable*):** Provide information regarding the resources available to aid in the development of sufficient quantities of the reagent under GMP.
- **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."
  - **Intellectual and Material Property Plan (*if applicable*):** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, [DoD Instructions 3200.12](#). *Do not duplicate the Data and Research Resources Sharing Plan.* Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to CDMRP’s Policy on Data & Resource Sharing located on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm> for more information about CDMRP’s expectations for making data and research resources publicly available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf”.** The technical abstract is used by all reviewers. *Abstracts of all funded research projects will be posted publicly.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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 work.
- **Overarching Challenge(s):** State the overarching challenge(s) that will be addressed and briefly state how the project will address the challenge in a way that can lead to or make a breakthrough and have a major impact. Simply identifying an overarching challenge is not sufficient.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Briefly describe how the proposed project will lead to a major impact for the overarching challenge(s). Explain how the research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.



- **Innovation (*required for Funding Level 1 applications only*):** Explain how the proposed research is innovative and will investigate a novel idea or research question that introduces a new paradigm or challenges existing paradigms.
- **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 of the research.
  - Which overarching challenge(s) does this research address?
  - What types of patients or at-risk individuals will it 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?
  - How will the proposed project lead to or make a breakthrough in breast cancer and accelerate progress toward the BCRP’s mission of ending breast cancer?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Refer to the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Breakthrough Award Levels 1 and 2 mechanism, refer to “Example: Assembling a Generic Statement of Work”, for guidance on preparing the SOW. Use the “Suggested SOW Format” to develop the SOW for the proposed research. Submit as a PDF.

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

***Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly 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 concisely how the proposed project will have a major impact on at least one of the overarching challenge(s).
  - Explain how the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.
  - Explain briefly how the proposed research will lead to a fundamentally new approach that is significantly more effective than interventions already approved or in clinical development.
  - Identify the breast cancer patients or at-risk individuals and justify how they would benefit from the proposed research.
- **Attachment 7: Partnership Statement (one-page limit): Upload as “Partnership.pdf”. (*Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.*)** Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain how funding will be balanced between both PIs or otherwise provide appropriate justification.
  - **Attachment 8: Submissions Statement (one-page limit): Upload as “Submissions.pdf”. (*Attachment 8 is only applicable and required for individuals who are named on multiple Breakthrough Award Levels 1 and 2 applications. Attachment 8 will be available for programmatic review only.*)** Provide the following information for each individual named as a PI, Initiating PI, Partnering PI, collaborator, or mentor in multiple FY24 BCRP Breakthrough Award Levels 1 and 2 applications:
    - CDMRP log number, funding level, role on the project, project title, and specific aims.
    - Brief description of how the application addresses a research question that is distinct from the other application(s).
  - **Attachment 9: Mentorship Statement (one-page limit): Upload as “Mentorship.pdf”. (*Attachment 9 is only applicable and required for applications in***

*which the PI is a postdoctoral fellow.)* Identify the PI's mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor's experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor's commitment to the PI's project, including details of their proposed interactions with the PI and how they will support the PI's research endeavors.

- **Attachment 10: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** (*Attachment 10 is only applicable and required for applications submitted under Funding Level 1.*) Describe how the proposed research is innovative and will investigate a novel idea or research question that introduces a new paradigm or challenges existing paradigms. Investigating the next logical step or continuation of a previous research project is not considered innovative.
  - **Attachment 11: Representations (Extramural Submissions Only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
  - **Attachment 12: Suggested Intragovernmental/Intramural Budget Form (if applicable): Upload as "IGBudget.pdf".** If an [intramural DOD organization](#) will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The **total** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.
- (c) Research & Related Personal Data:** For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.
- (d) Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.
- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch\_LastName.pdf".
  - **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 research team members.
  - Include mentor’s (and co-mentor’s, if applicable) biographical sketch, if the PI is a postdoctoral fellow.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
  - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support, if the PI is a postdoctoral fellow.

**(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.

***Partnering PI Option:*** *The Initiating and the Partnering PI 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 Initiating PI should not include budget information for the Partnering PI 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 12](#).

### II.D.2.b.iii. Full Application Submission Components for the Partnering PI

The application submission process for the Partnering 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 (three-page limit): Upload as “SOW.pdf”.** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 9: Mentorship Statement (one-page limit): Upload as “Mentorship.pdf”.** (*Attachment 9 is only applicable and required for applications in which the PI is a postdoctoral fellow.*) Identify the PI’s mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor’s experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor’s commitment to the PI’s project, including details of their proposed interactions with the PI and how they will support the PI’s research endeavors.
- **Attachment 11: Representations (*Extramural Submissions Only*): Upload as “RequiredReps.pdf”.**
- **Attachment 12: 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 research team members.

- Include mentor’s (and co-mentor’s, if applicable) biographical sketch, if the PI is a postdoctoral fellow.
  - **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support\_LastName.pdf”.
    - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support if the PI is a postdoctoral fellow.
- (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 Initiating and the Partnering PI 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 Partnering PI should not include budget information for the Initiating PI, 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 12](#).

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

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the “Full Application Files” tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. *The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP*

*validation or needs to be modified, an updated full application package must be submitted prior to the full application submission deadline.* Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the [application verification period](#). The full application cannot be modified once the application verification period ends.

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

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

### **II.D.4. Submission Dates and Times**

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

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

### **II.D.5. Funding Restrictions**

*The requested funding level should be aligned with the scope of the research proposed and the [funding level description](#).*

#### **Funding Level 1 (single PI):**

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

The application’s direct costs budgeted for the entire period of performance should not exceed **\$450,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

#### **Funding Level 1 with Partnering PI Option:**

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

The applications’ combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

**Funding Level 2 (single PI):**

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

The application's direct costs budgeted for the entire period of performance should not exceed **\$1.0M**. 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.

**Funding Level 2 – Population Science and Prevention Studies (single PI):**

The maximum period of performance is **4** years.

The application's direct costs budgeted for the entire period of performance should not exceed **\$1.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

**Funding Level 2 with Partnering PI Option:**

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

The applications' combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **\$1.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

**Funding Level 2 – Population Science and Prevention Studies with Partnering PI Option:**

The maximum period of performance is **4** years.

The applications' combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and each Partnering PI should not exceed **\$2.0M**. 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.

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

**For All Funding Levels:**

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

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3 or 4** years.



**Partnering PI:** The anticipated combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed the maximum allowable direct costs for the selected funding level. A separate award will be made to each PI's organization.

**Applications Submitted with a PI who is a Postdoctoral Fellow:** The PI of the award is expected to manage the budget during the award period, not their mentor.

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

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 BCRP Breakthrough Award Levels 1 and 2.

Must not be requested for:

- Clinical trial costs
- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.

#### **II.D.6. Other Submission Requirements**

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

### **II.E. Application Review Information**

#### **II.E.1. Criteria**

##### **II.E.1.a. Peer Review**

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, (the Impact and Research Strategy and Feasibility criteria are of equal importance, followed by Personnel and Partnership [if applicable]):

- **Impact**

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

- To what degree the proposed project will have a major impact on the overarching challenge(s).
- To what degree the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.
- Whether the proposed research will lead to a fundamentally new approach that is significantly more effective than interventions already approved or in clinical development.

- How well the application justifies how the identified breast cancer patients or at-risk individuals would benefit from the proposed research.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data, if applicable (preliminary data are not required under Funding Level 1, but are required under Funding Level 2).
  - How well the hypothesis, objectives, and specific aims are developed.
  - How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
  - How well the application acknowledges potential pitfalls and problem areas and addresses alternative methods and approaches.
  - How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research..
  - Whether an appropriate statistical plan including power analysis, as appropriate, is provided.
- **Personnel**
  - Based on the biographical sketches, whether the application includes an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
  - How appropriate the levels of effort are for successful conduct of the proposed work.
  - *Applications Submitted by Postdoctoral Fellows:*
    - To what degree the application demonstrates that the PI has the potential to manage the technical and administrative aspects of the award and successfully accomplish the proposed research.
    - To what degree the application demonstrates that the PI will have appropriate mentorship to successfully conduct and complete the project.

- **Partnership** (*applicable only to Partnering PI Option applications*)
  - How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the SOW.
  - To what degree the partnership will better address the research question together rather than through separate individual efforts.
  - How well the application reflects equal intellectual input by both PIs into the design of the project and similar and appropriate levels of effort devoted to the conduct of the project.
  - Whether funding will be balanced between both PIs, or is otherwise appropriately justified.

In addition, the following **unscored criteria** will also contribute to the overall evaluation of the application:

- **Environment**
  - Whether the scientific environment is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
  - Whether the quality and extent of institutional support are appropriate for the proposed research.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Innovation (Funding Level 1 only)**
  - To what degree the proposed research is innovative.
  - To what degree the proposed research will investigate a novel idea or research question, and not the next logical step or continuation of a previous research project.
  - Whether the proposed research introduces a new paradigm or challenges existing paradigms.
- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

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

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the Defense Health Program and FY24 BCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Relative innovation (Funding Level 1 only)

### **II.E.2. Application Review and Selection Process**

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure

of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

### **II.E.3. Integrity and Performance Information**

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

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

## **II.F. Federal Award Administration Information**

### **II.F.1. Federal Award Notices**

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

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

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

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

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

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

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

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

## **II.F.2. PI Changes and Award Transfers**

Changes in PI, Initiating PI, or Partnering PI 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 PI, Initiating PI, or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

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

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

## **II.F.3. Administrative and National Policy Requirements**

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review

requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

#### **II.F.4. Reporting**

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

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$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](mailto: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](mailto:support@grants.gov)

## **II.H. Other Information**

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

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

### **II.H.2. Administrative Actions**

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

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

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

- Pre-application was not submitted.
- More than one application per funding level is received with the same investigator named as a PI or an Initiating PI. Only the first application received per funding level will be accepted; additional applications will be administratively rejected.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

#### **II.H.2.b. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

#### **II.H.2.c. Withdrawal**

The following may result in administrative withdrawal of the full application:



- An FY24 BCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. *A list of the FY24 BCRP Programmatic Panel members can be found at <https://cdmrp.health.mil/bcrp/panels/panels24>.*
- The application fails to conform to this program announcement description.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.health.mil/about/2tierRevProcess>).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and funding cycle.
- The application does not address at least one of the [FY24 BCRP Overarching Challenges](#) and adequate justification for exception was not provided.
- **Partnering PI Option:** Failure to submit all associated (Initiating PI and Partnering PI) applications by the deadline.
- A clinical trial is proposed.

#### **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	
	PI/Initiating PI	Partnering PI
<b>SF424 Research &amp; Related Application for Federal Assistance</b> ( <i>Extramural submissions only</i> )	<input type="checkbox"/>	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> ( <i>Intramural submissions only</i> )	<input type="checkbox"/>	<input type="checkbox"/>
<b>Attachments</b>		
Project Narrative – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
Supporting Documentation – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
Technical Abstract – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
Lay Abstract – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
Statement of Work – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Impact Statement – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
Partnership Statement – Attachment 7, upload as “Partnership.pdf” if applicable	<input type="checkbox"/>	
Submissions Statement – Attachment 8, upload as “Submissions.pdf” if applicable	<input type="checkbox"/>	
Mentorship Statement – Attachment 9, upload as “Mentorship.pdf” if applicable	<input type="checkbox"/>	<input type="checkbox"/>
Innovation Statement – Attachment 10, upload as “Innovation.pdf” if applicable	<input type="checkbox"/>	
Representations ( <i>Extramural submissions only</i> ) – Attachment 11, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
Suggested Intragovernmental/Intramural Budget Form ( <i>if applicable</i> ) – Attachment 12, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Personal Data</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	<input type="checkbox"/>	<input type="checkbox"/>

<b>Research &amp; Related Budget</b> ( <i>Extramural submissions only</i> )	<input type="checkbox"/>	<input type="checkbox"/>
Include budget justification		
<b>Budget</b> ( <i>Intramural submissions only</i> )	<input type="checkbox"/>	<input type="checkbox"/>
Include budget justification		
<b>Project/Performance Site Location(s) Form</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) Form</b> ( <i>if applicable</i> )	<input type="checkbox"/>	<input type="checkbox"/>

## **APPENDIX 1: ACRONYM LIST**

BCRP	Breast Cancer Research Program
BTA12	Breakthrough Award – Funding Levels 1 and 2
BTA3	Breakthrough Award – Funding Level 3
BTA4	Breakthrough Award – Funding Level 4
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
GMP	Good Manufacturing Practice
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
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