Program Announcement for the Defense Health Agency

Breast Cancer Research Program Breakthrough Award Level 4

Funding Opportunity Number: HT942526BCRPBTA4

Pre-Application Due: June 12, 2026

Application Due: September 30, 2026

This program announcement must be read in conjunction with the General Application Instructions, version CD26_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read this funding opportunity announcement in the order it is written before beginning to prepare application materials.** It is the responsibility of the applicant to determine whether the proposed research meets the intent of this funding opportunity and that all parties meet eligibility requirements.
- **To support application preparation, additional resources are available** including an application process FAQ, a Guide for Intragovernmental & Intramural Applicants and a CDMRP Video Series detailing the application process.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Support Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing the Alt + left arrow keys (Windows) or command + left arrow keys (Macintosh) on your keyboard.

Click ⓘ to be taken to additional guidance and instructions within the General Application Instructions (GAI).

1. Basic Information About the Funding Opportunity

Summary: The fiscal year 2026 (FY26) Breast Cancer Research Program (BCRP) Breakthrough Award mechanism supports promising research with high potential to lead to or make breakthroughs in breast cancer. All applications must address at least one of the FY26 BCRP overarching challenges or provide adequate justification for exception. Applications must address the challenge in a way that can lead to a breakthrough and have major impact. The FY26 Breakthrough Award mechanism contains four different funding levels designed to support major (but not all) stages of research that will lead to clinical application. Each level specifies a distinct research scope. **This program announcement discusses the Breakthrough Award Level 4.**

Distinctive Features:

- **Clinical trials are required.**
- The research team must include two or more breast cancer consumer advocates.
- **This funding mechanism allows for a single Principal Investigator (PI), or two partnering PIs referred to as the Initiating PI and the Partnering PI.** For the Partnering PI Option (PPIO), only the Initiating PI will submit a pre-application, but both PIs will need to submit at the full application stage. Be advised, failure to submit all associated (Initiating and Partnering PI) applications by the deadline may result in administrative withdrawal.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly $21 million (M) to fund approximately one Breakthrough Award Level 4 application with a total cost cap of $21M. The maximum period of performance is four years. It is anticipated that the award made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. The award supported with FY26 funds will be made no later than September 30, 2027.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 12, 2026
- **Invitation to Submit an Application:** July 16, 2026
- **Application Submission Deadline:** 11:59 p.m. ET, September 30, 2026
- **End of Application Verification Period:** 5:00 p.m. ET, October 5, 2026
- **Peer Review:** December 2026
- **Programmatic Review:** January 2027
- **Invitation for Oral Presentation:** February 2027
- **Programmatic Review, Stage 2:** March 2027

Announcement Type: Initial

Funding Opportunity Number: HT942526BCRPBTA4

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural U.S. Department of War (DOW) organizations are eligible to apply, ***including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

2.1.2. Principal Investigator

Independent investigators affiliated with an eligible organization are eligible to be named as PI, Initiating PI, or Partnering PI on the application, regardless of ethnicity, nationality or citizenship status.

There are no limits on the number of pre-applications an investigator may submit as a PI, Initiating PI, or Partnering PI for this Breakthrough Award Level 4 program announcement.

This program announcement discourages investigators from being named on multiple pre-applications unless they are clearly addressing distinct research questions. Invited applications must include a brief description of all the applications in which the investigator is named as a PI, Initiating PI, Partnering PI, or collaborator under this Breakthrough Award Level 4 program announcement.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional recipient qualification requirements.

3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the BCRP. The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the BCRP 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 FY25 totaled $4.52 billion. The FY26 appropriation is $145M.

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.

The BCRP brief overview, called *The Breast Cancer Landscape*, describes what is currently known about the most pertinent topics that are consistent with the BCRP's mission of ending breast cancer. Considering the current breast cancer landscape and the program's mission, the BCRP seeks to invest in research that addresses the following **FY26 BCRP overarching challenges:**

- 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 do all of the following: improve survival, are more effective, and are less toxic
- Eliminate the mortality associated with metastatic breast cancer

3.1. Intent of the Breakthrough Award Level 4

The intent of the FY26 BCRP Breakthrough Award is to support promising research with high potential to lead to or make breakthroughs in breast cancer.

The FY26 BCRP Breakthrough Award contains four different funding levels, each intended to support a defined research scope. It is the responsibility of the PI to select the level that aligns with the scope of the proposed research. The PI should select the funding level based on the research scope defined in the program announcement, and not on the amount of the budget. ***The BCRP will not recommend for funding an application that does not meet the intent of the funding level selected, even if it might meet the intent of a different funding level.***

This program announcement discusses the FY26 BCRP Breakthrough Award Level 4 (BTA4).

Funding Level 4: This funding level supports large-scale projects, including comparative effectiveness trials, that will transform and revolutionize the clinical management of and/or the prevention of breast cancer. This funding level requires clinical trials. PIs should have experience in successfully leading large-scale projects and demonstrated ability (through personal experience or via a commitment from a collaborating clinical investigator) to implement a clinical trial successfully. Where relevant, the application must demonstrate proof of the availability of, and access to, necessary data, samples, cohort(s) and/or critical reagents for the proposed research. If the project requires U.S. Food and Drug Administration (FDA) or an equivalent international regulatory agency involvement, the application must include the following readiness requirements: proof of the availability of, and access to, clinical reagents that meet regulatory compliance guidelines; proof of the availability of, and access to, appropriate subject population(s); validated projections for patient recruitment; and proof of submission of an Investigational New Drug (IND), Investigational Device Exemption (IDE), or equivalent to the relevant regulatory agency.

3.1.1. Key Elements for the BTA4

Impact: Proposed research must have the potential for a major impact and accelerate progress toward ending breast cancer. The near-term and/or long-term impact must move beyond a minor advancement and have the potential to lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches. Applications must identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research.

Overarching Challenges: Considering the current breast cancer landscape and the BCRP's mission, all applications must address at least one of the above overarching challenges unless adequate justification for exception is provided.[1] 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. The BCRP strongly urges applicants to read and consider *The Breast Cancer Landscape* before preparing their applications.

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

Consumer Advocates: Applications must include two or more breast cancer consumer advocates as integral members of the research team throughout the planning and implementation of the research project. The investigator(s) should involve consumer advocates in the development of the research question, project design, oversight, and evaluation, as well as other significant aspects of the proposed project. Team members must maintain well-integrated and ongoing interactions with consumer advocates that extend beyond attending seminars and semi-annual meetings. As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer and are actively involved in a breast cancer advocacy organization. They must perform their role independently of their employment and cannot be employees of any organization participating in the application. The consumer advocates should have a high level of knowledge of current breast cancer issues and the

[1] With adequate justification, applications may identify and address another overarching challenge related to *The Breast Cancer Landscape*. Investigators must provide justification in the application.

appropriate background and/or training in breast cancer research to contribute to the project. The consumer role should focus on providing objective input throughout the research effort and its potential impact for individuals with, or at risk for, breast cancer.

Partnering PI Option: The BTA4 PPIO encourages applications that include meaningful and productive partnerships between 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 the Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. The PIs may have expertise in similar or disparate scientific disciplines, but each PI must 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 levels of effort to the conduct of the project. The application should balance funding between both PIs unless appropriately justified. The PPIO encourages, but does not require, new partnerships. The application should 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 proposed project, and why the work should be done together rather than through separate efforts. ***To meet the intent of the PPIO, the BCRP discourages applicants from being named as a Partnering PI on multiple BTA4 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions.*** 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 PPIO. 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 5.3, Submission Instructions.

In addition to items outlined above, when developing applications to the FY26 BCRP BTA4 mechanism, the BCRP strongly encourages applicants to provide sufficient evidence to demonstrate the following key considerations:

- Sufficient access to and availability of the study population.
- Adequate access to and availability of the intervention.
- Appropriate statistical considerations, data management and analysis plans appropriate for the proposed research.

3.1.2. Other Important Considerations for the BTA4

The FY26 BCRP BTA4 application review requires an ***invited*** oral presentation, as described in Section 4.4.

In accordance with the National Defense Authorization Act for Fiscal Year 2026, Section 732, CDMRP does not support the conduct of painful research (U.S. Department of Agriculture pain category D or E) involving domestic cats or dogs, except for studies relating to military or service animals.

Funding from this award mechanism must support a clinical trial.

Applicants seeking funding for research that does not meet the definition of a clinical trial should consider other FY26 BCRP funding opportunities that may be more appropriate for such research.

An informational resource for preparing an application, the Human Subject Research Resource, is available on the CDMRP website.

The proposed clinical trial is expected to begin no later than 12 months after the award date or 18 months after the award date for studies regulated by the Regulatory Agency. Unless otherwise noted, for the purposes of this funding opportunity, Regulatory Agency refers to the FDA or any equivalent international regulatory agency.

All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of clinical and preclinical research, such as those described in the STROBE, CONSORT, SPIRIT and ARRIVE 2.0 guidelines.

The proposed research must be relevant to Service Members, Veterans, their Families, and/or the American Public. PIs are encouraged to integrate and/or align their research projects with DOW and/or VA research laboratories and programs. Collaboration with the DOW and/or VA is also encouraged. A list of websites that may be useful in identifying additional information about ongoing DOW and VA areas of research interest or potential opportunities for collaboration can be found in Appendix 10 of the GAI.

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 task force recommendations and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and align with the FY26 BCRP priorities.

3.2. Funding Instrument

The funding instrument for 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 means that, after award, CDMRP staff will assist, guide, coordinate, and/or participate in project activities, including but not limited to, Milestone Meetings, wherein recommendations for continued funding will be made based on overall study progress.

3.3. Funding Details

Period of Performance: The maximum period of performance is **four** years.

Cost Cap: For applications with a single PI, the application’s total costs budgeted for the entire period of performance should not exceed **$21M**. For Partnering PI Option applications, the combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$21M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization’s negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate.

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

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

The appropriateness of the budget for the proposed research will be assessed during peer review.

For Partnering PI Option Applications: A separate award will be made to each PI's organization.

Direct Cost Restrictions: For this award mechanism, direct costs:

Must be requested for:

- Costs associated with meetings described in Section 8.3.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for three investigator(s) to travel to one scientific/technical meeting per year in addition to the required meeting described in Section 8.3. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY26 BCRP Breakthrough Award Level 4.
- Research subject compensation and reimbursement for trial-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOW organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Pre-Application Components

The initiating PI must submit the following pre-application components.

Upload documents as individual PDF files unless otherwise noted. Files must comply with the formatting guidelines listed in the GAI.

- **Preproposal Narrative:** Provide responses in the appropriate data fields for the following:
  - Which BCRP overarching challenge(s) will the proposed research address? If "other," state the overarching challenge and provide justification within the context of the breast cancer landscape. Simply identifying an overarching challenge is not sufficient. (200-character limit)
  - How will the proposed research 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. (2,000-character limit)
  - How will the proposed research move beyond a minor advancement? How will the research lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches? (2,000-character limit)
  - Briefly state how the scope of the proposed research is appropriate for Funding Level 4 as described in this program announcement. (500-character limit)
  - Project Readiness: State the clinical intervention, subject population(s), and phase of the clinical trial proposed. Describe a plan for project readiness by the full application deadline with respect to the availability of, and access to, clinical reagents (e.g., therapeutics) that meet regulatory compliance guidelines; the availability of, and access to, appropriate subject population(s); and submission of an IND, IDE, or equivalent to the Regulatory Agency by the FY26 BCRP Breakthrough Award Level 4 application submission deadline, if applicable. (3,000-character limit)

- **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:
  - One page for additional information that the PI can use, at their discretion, to provide supporting data or rationale for the pre-application.
  - If applicable, one page to provide a list of all FY26 BCRP Breakthrough Award Level 4 pre-applications in which the investigator is named as a PI, Initiating PI, Partnering PI or collaborator. Include the CDMRP log number, role on the project, project title, specific aims, and a brief description of how each pre-application will address distinct research questions.

4.3. Full Application Components

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

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

4.3.1. Full Application Components for the PI or Initiating PI

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

IMPORTANT: *When completing the SF424 R&R, enter the* ***eBRAP log number*** *assigned during pre-application submission into* ***Block 4a – Federal Identifier****.*

(b) Attachments:

Each attachment of the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines in the GAI.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf".**

  Describe the proposed project in detail using the outline below. It should be evident that the proposed study meets the definition of a clinical trial.

  - **Background:** Describe in detail the scientific rationale for the study. Provide a review and analysis of the available literature and completed/ongoing studies relevant to the proposed clinical trial.
    - Describe the preliminary studies and/or preclinical data that support the proposed clinical trial. Importantly, describe the studies showing proof of concept and efficacy in in vivo system(s) that led to the current proposed clinical trial.
    - Summarize key preclinical pharmacological findings, dosage studies and other clinical studies (if applicable) that examine the safety and stability (as appropriate) of the intervention.

- Provide a summary of other relevant ongoing, planned or completed clinical trials, and describe how the proposed study differs.

For proposed clinical trials initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source(s) of prior funding. Identify the specific portions of the study that funding from this award would support.

- **Intervention:** Identify the intervention to be tested. Include the following components, as applicable: intervention type (drug, device, surgical, etc.), complete name and composition, source, general concept of design, and administration route. Indicate who holds the intellectual property rights to the intervention, if applicable, and how the PI has obtained access to those rights, along with access to the intervention itself, for conduct of the clinical trial. As applicable, appropriate letters of commitment should be provided in Attachment 2: Supporting Documentation, demonstrating the study team's access to the intervention(s) for the duration of the clinical trial. Describe how the intervention addresses current clinical needs and how it compares with currently available interventions and/or standards of care.
- **Objectives, Specific Aims and Hypotheses:** Describe the purpose of the proposed study with detailed objectives. State the hypothesis/research question to be tested in the proposed clinical trial and detail the specific aims that will address the hypothesis/research question.
- **Study Design:** Describe the proposed clinical trial in sufficient detail to evaluate its appropriateness and feasibility, relating to both the scientific success of the study and setting reasonable expectations of what study participants will experience. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - Describe the type of study to be performed. Outline the proposed clinical trial methodology and study variables in sufficient detail to demonstrate a clear course of action and justification. Describe the interaction with the human subject, including the study intervention that they will experience, and include the dose and administration route. Provide sufficient detail in chronological order for a person not involved in the study to understand what the study participant will experience.
  - Provide a schedule (e.g., flowchart or diagram) of study intervention(s), evaluation(s), and follow-up procedures, including, if applicable, the biospecimen that will be collected, the collection schedule and amount. Describe measures to ensure consistency of dosing. Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. Include a description of controls, as appropriate. Specify the approximate number of study participants to be enrolled. Indicate whether subjects, clinicians, data analysts and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias.
  - Define all endpoints/outcome measures relevant to the objectives of the study; explain why they were chosen, and describe how, when and where they will be measured. Include all evaluations that will be made for study purposes. If questionnaires or other research data collection instruments will be used, include a copy of them in Attachment 2: Supporting Documentation. Describe the reliability and validity of the selected endpoints/outcome measures and

evaluations, along with the applicable quality standards. Explain how the results of evaluations and/or data collection instruments will be used to meet the objectives of the study (or to monitor safety of human subjects).

- Briefly describe the study population and the inclusion and exclusion criteria that will be used to meet the needs of the proposed clinical trial. Additional details should be provided in Attachment 6: Study Population Recruitment and Safety Plan.

– **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Ensure sufficient information is provided to allow for a thorough evaluation of statistical calculations during review of the application.

- Include a complete power analysis to demonstrate that the proposed clinical trial's anticipated sample size is appropriate to meet the objectives of the study. Describe all clinical and statistical justifications and assumptions that support the sample size calculations. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered.
- Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- For phase 3 clinical trials, describe plans for the valid and sufficiently powered analysis of group differences on the basis on sex, race and/or ethnicity as appropriate for the scientific goals of the study. Refer to the CDMRP Directive on the Inclusion of Women and Minorities as Subjects in Clinical Research for additional information on the requirements for phase 3 studies.

– **Pitfalls and Mitigation Strategy:** Describe potential challenges and discuss alternative methods/approaches that may be employed to overcome them.

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".**

There are no page limits for these components unless otherwise noted. Include only 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 in the Project Narrative using a standard reference format (include URLs, if available).

– **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; include 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 the original or present government award under which the facilities or

equipment items are now accountable. There is not a standardized 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 Support:** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work for the duration of the proposed clinical trial. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Consumer Advocate Letters of Commitment:** Provide a letter signed by each consumer advocate confirming their commitment to participate in the proposed project.
- **Research Sharing Plan:** Describe the type of data or research resources to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical trial participants. If applicable, include the name of the repository(ies) where scientific data and resources arising from the proposed clinical trial will be archived. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

  Do not submit a copy of the National Institutes of Health (NIH) Data Management and Sharing Plan or duplicate the Data Management Plan, which will be requested only after a recommendation for funding is made.

  Refer to the CDMRP Directive on Sharing Data and Research Resources for more information about the CDMRP's expectations for making data and research resources publicly available.
- **Questionnaires and Other Research Data Collection Instruments:** Include a copy of the most recent version of questionnaires, data collection forms, rating scales, interview guides or other instruments. This should include any drafts that are currently in use or underdevelopment.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".**

  Write the technical abstract using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the ideas and rationale behind the proposed clinical trial.
  - **Overarching Challenge(s):** State the overarching challenge(s) that the proposed research will test, 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.
  - **Hypothesis/Objective(s):** State the objective(s) of the proposed clinical trial and the hypothesis/research question to be addressed.
  - **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
  - **Military Relevance:** Describe how the study is relevant to military health.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".**

  The lay abstract should address the points outlined below ***in a manner that is readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms and abbreviations. ***Do not duplicate the technical abstract.***

  - Clearly describe the scientific rationale, objective 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 timeline for achieving 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?
    - How is the proposed research relevant to Service Members, Veterans and their Families?

- **Attachment 5: Statement of Work (six-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the Suggested SOW Format.

  For guidance on preparing the SOW, refer to the Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work. Include milestones for data or research resource(s) sharing.

  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: Study Population Recruitment and Safety Plan (no page limit): Upload as "StudyPopPlan.pdf".** Include the components listed below.
  - **Enrollment Distribution:** Provide anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race and ethnicity using the Public Health Service (PHS) Inclusion Enrollment Report. The enrollment table(s) should be appropriate to the objectives of the study.
  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical trial. If limiting inclusion by age, race, ethnicity or sex, provide strong rationale based on justification from scientific literature, preliminary data or other relevant considerations. List and describe any evaluations (e.g., laboratory procedures, history or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Describe how the study population represents the population anticipated to benefit from the intervention.
  - **Study Population Availability:** Demonstrate that the research team has access to the proposed study population at each site. Describe the approximate number, pertinent demographic information and other relevant characteristics of the study population at each enrollment site. Indicate whether the actual size of available study population may be affected by ongoing clinical trials that compete for the same population. If the proposed research involves access to military and/or VA patient populations and/or DOW or VA resources or databases, describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Also include a plan for obtaining any required data sharing, memorandum of understanding or other agreements required to access and publish data. Refer to the GAI, Appendix 4, for additional considerations.
  - **Recruitment and Retention Process:** Explain methods for identification of potential study participants (e.g., medical record review, obtaining sampling lists, health care provider identification). Describe the recruitment process in detail; address who will identify potential study participants, who will recruit them, and what methods will be used to recruit them. Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study. If study participants will be compensated, include a detailed description of and justification for the compensation plan. Describe the methods that will be employed to retain participants within the study. Discuss past efforts in recruiting and retaining study participants for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Estimate the potential for participant loss to follow up and how such loss will be handled/mitigated. Indicate whether the study team has considered barriers to clinical trial participation and, if applicable, how the team aims to mitigate or overcome these barriers.
  - **Women and Minorities Recruitment/Retention Strategy:** Describe the strategy for recruitment, enrollment and retention specific to women and minorities in the clinical trial appropriate to the objectives of the study.
  - **Informed Consent Process:** Specifically describe the plan for obtaining informed consent from study participants; include information regarding the timing and location of the consent process. If minors or other populations that cannot provide informed

consent are included in the proposed clinical trial, describe the plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent. Appendix 6 of the GAI contains additional considerations unique to DOW-sponsored research.

- **Risks/Benefits Assessment:**
  - **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Address special precautions to be taken by the human subjects before, during and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention). If applicable, identify any potential risk to the study personnel.
  - **Risk management and emergency response:** Appropriate to the study's level of risk, describe how safety monitoring and reporting to the Institutional Review Board (IRB) and Regulatory Agency (if applicable) will be managed and conducted. Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, including who will be responsible for the costs of such care.
  - **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 7: Regulatory Strategy (no page limit): If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".** Answer the following questions and provide supporting documentation as applicable.
  - State the product/intervention name.

  For products/interventions that do not require regulation by a Regulatory Agency:

  - Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information about this attachment is required.

  For products that require regulation by a Regulatory Agency:

  - Describe the overall regulatory strategy and product development plan that will be performed during the project's period of performance to support the planned product indication/label. Include, as appropriate, a description of the regulatory application submission strategy.
    - State whether the product is FDA-approved, -licensed, or -cleared, and marketed in the United States. If the product is marketed in the United States, state the product label indication. State whether the proposed research involves a change to the approved label indication.
    - If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use and whether an IND or IDE application was submitted. ***If an IND or IDE is required, the application must be submitted to the FDA prior to the FY26 BCRP Breakthrough Award Level 4 application***

submission deadline. The IND or IDE should be specific for the investigational product (i.e., not a derivative or alternate version of the product) and include an indication to be tested in the proposed clinical trial. Provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission.

- Provide a summary of any meetings the research team had with regulatory agencies or consultants regarding the proposed research; include key outcomes, action items and recommendations. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
- If the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- **Attachment 8: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as "Personnel.pdf".** The Study Personnel and Organization attachment should include the components listed below.
  - **Consumer Advocate Statement:** The PI or Initiating PI should write the Consumer Advocate Statement. Provide the names of at least two consumer advocates and their affiliation with a breast cancer advocacy organization(s). Describe the integral roles that the consumer advocates will play in the planning, design, implementation, and evaluation of the research. 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 project. Explain how the consumer advocates' experience and expertise will be integrated into the research project and management of the collaboration.
  - **Partnership Statement (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 proposed work. Explain how the partnership will better address the research question and why the work should be done together rather than through separate efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar levels of effort to the conduct of the project. Explain the plan to balance funding between both PIs or otherwise provide appropriate justification.
  - **Organizational Chart:** Provide an organizational chart that identifies key members of the study team and an outline of the governing structure for multi-institutional studies. Identify collaborating organizations, centers and/or departments, and name each person's position on the project; include any separate laboratory or testing centers. Identify the data and clinical coordinating center(s), and note any involvement from Contract Research Organizations, as appropriate, including the location of the organization. If applicable, identify the Regulatory Agency sponsor and any external consultants or other experts who will assist with Regulatory Agency sponsor applications. While there is no specified format for this information, a table(s) or diagram is recommended.
  - **Study Personnel Description:** Describe the composition of the study team in enough detail to determine whether the team includes relevant subject matter

expertise to accomplish the proposed work. Include the roles of individuals named in the organizational chart, along with any external consultants or advisors who will provide critical guidance and input to the study team (e.g., statistician, regulatory expert, commercialization consultant, clinical ethicist, patient advocate). Study coordinator(s) should be included. Describe how the levels of effort for each individual are appropriate to successfully support the proposed clinical trial.

- **Study Management Plan:** Describe the day-to-day management of the proposed clinical trial. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial involves more than one institution, clearly describe the multi-institutional structure governing the research protocol(s) across all participating institutions. If applicable, describe how communication and data transfer between/among the collaborating institutions will occur, as well as how data, specimens and/or imaging products obtained during the study will be handled and shared. Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 9: Post-Award Transition Plan (three-page limit): Upload as "Transition.pdf".** Discuss the anticipated methods and strategies necessary to move the anticipated research outcome (e.g., intervention, product, methodology, finding) to the next phase of development (e.g., clinical trials, commercialization and/or delivery to the civilian or military market), assuming a positive outcome from the proposed clinical trial. Investigators are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop the transition plan. Applicants are encouraged to explore developing relationships with industry and/or other funding agencies or investors to facilitate moving the product into the next phase of development when preparing the transition plan. ***The post-award transition plan should:***

  - Include a detailed plan for distribution of findings or intervention to the breast cancer community.
  - Name the project's anticipated research outcomes, including knowledge products and/or clinical products for development. A "knowledge product" is a non-materiel product that aims to transition into medical practice, training, tools, or to support materiel solutions. Additionally, it serves to educate or impact behavior throughout the continuum of care, including primary prevention of negative outcomes.
  - Include a timeline with defined milestones describing the logical next steps to advance the research outcome to the next stage of clinical development/implementation/dissemination. Include steps regarding Regulatory Agency approval as appropriate.
  - Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are in place or will be established to execute the steps described above. Include a discussion of the funding strategy necessary to transition the research outcome to the next level of investigation, development, and/or commercialization. The discussion should include potential opportunities for securing funding through commercial sponsorship, venture capital, federal or nonfederal funding opportunities, or other relevant resources.
  - As appropriate, discuss ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award. Include a plan for resolving intellectual and material

property issues among participating organizations. If the intellectual property rights are not owned by the applicant, PI or a member of the study team, describe the planned next steps necessary to make the product available to the target population.

- **Attachment 10: Impact Statement (two-page limit): Upload as "Impact.pdf".**

  The statement should address the points outlined below written ***in a manner that is readily understood by readers without a background in science or medicine. 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 challenges.
  - 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 strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
  - Identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research. Justify how these individuals would benefit from the project.
  - Explain briefly how the proposed research is relevant to Service Members, Veterans, and their Families.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations document available on eBRAP.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOW organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the Suggested Intragovernmental/Intramural Budget form available on eBRAP.

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal, as found within the GAI.

Grants.gov	eBRAP.org

i. Research & Related Senior/Key Person Profile (Expanded)

- **Biographical Sketch**

  Biographical sketches or equivalent must be submitted for the breast cancer consumer advocates.

- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Partnering PI Option: *Initiating and Partnering PIs must 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 Partnering PI, or vice versa, even if they are located within the same organization. Refer to Section 3.3, Funding Details, for detailed budget information*

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.3.2. Full Application Components for the Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

(a) SF424 Research & Related Application for Federal Assistance Form *(Grants.gov submissions only)*:

(b) Attachments:

- **Attachment 5: Statement of Work (six-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Additional Application Materials:

The following are additional forms for application submission. Follow the instructions specific to the submission portal found within the GAI.

Grants.gov	eBRAP.org

i. Research & Related Senior/Key Person Profile

- **Biographical Sketch**

  Biographical sketches or equivalent must be submitted for the breast cancer consumer advocates.

- **Current/Pending Support**

  Intragovernmental applicants must include their internally supported research and development programs.

ii. Research & Related Budget

Initiating and Partnering PIs must 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 Partnering PI should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to Section 3.3, Funding Details, for detailed budget information.

iii. Project/Performance Site Location(s)

iv. Research & Related Subaward Budget Attachment(s) *(if applicable, Grants.gov submissions only)*

4.4. Other Application Elements

Oral Presentation: PI(s) named in applications selected for Programmatic Review, Stage 2 must give an oral presentation (see Section 6.2.3, Programmatic Review). This presentation will take place in the National Capital Area or virtually, at the discretion of the government, and is tentatively scheduled for March 2027. ***If applying under the Partnering PI Option, both the Initiating and Partnering PIs will attend and give the oral presentation.***

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

- Without addressing your specific project, what conceptual or intellectual barriers do you consider the most urgent to overcome in the overarching challenges(s) you selected/ identified?
- Without addressing the specific technical/scientific aspects of your project, how do you envision transitioning the breakthrough results from your proposed research into a near-term clinical impact for individuals with, or at risk of, breast cancer?
- Without addressing the specific technical/scientific aspects of your project, what leadership skills will you use in your research team's effort and beyond to transform and revolutionize the clinical management and/or prevention of breast cancer?

If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.

The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942526BCRPBTA4 from Grants.gov or eBRAP, depending on which submission portal will be used.

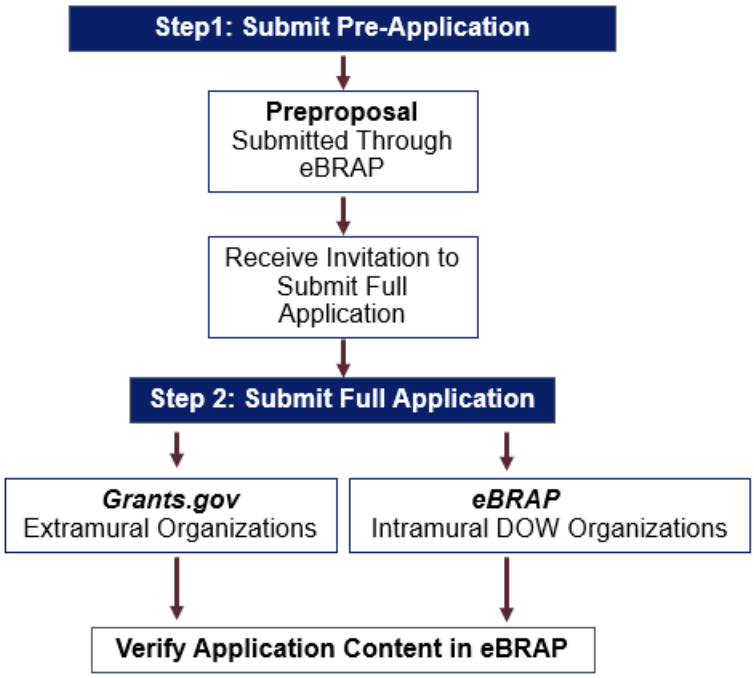
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier (UEI) generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration.

5.3. Submission Instructions

The CDMRP uses two portal systems to accept pre- and full application submissions. The workflow below shows which portal system to use for pre- and full application submissions, respectively.

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP, including the submission of contact information for the Partnering PI if selecting 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. Contact the eBRAP Help Desk if any changes need to be made.

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 instructions provided in the email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

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 associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

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

When starting the pre-application, PIs should select a Mechanism Option appropriate to their pre-application:

Application Includes:	Select Mechanism Option:
Single PI	No Option
Initiating PI and Partnering PI	Partnering PI Option

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace.

eBRAP Submissions: Only intramural DOW organizations may submit full applications through eBRAP.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission. ***The Project Narrative and Research & Related Budget Form cannot be changed after the***

application submission deadline. Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the application verification period ends. The full application cannot be modified once the application verification period ends.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The DHACA cannot make allowances/exceptions for submission problems encountered by the applicant.***

Submission dates and times are specified in Section 1, Basic Information.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

Submitting applications that propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).

While it is allowable to propose similar research projects to different programs within the CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's Directive on Research Duplication.

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.

Members of the FY26 BCRP Programmatic Panel must not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY26 BCRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

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

- Whether the pre-application addresses at least one overarching challenge that meets the program's goals.
- To what degree the proposed research will lead to a major impact for the overarching challenge.
- To what degree the proposed research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- To what degree the proposed research moves beyond a minor advancement and will lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
- To what degree the scope of the proposed research is appropriate for Funding Level 4 as described in this program announcement.
- Whether the pre-application describes a plan for project readiness by the application submission deadline.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be evaluated individually according to the following **scored criteria**, which are of equal importance:

- **Impact**
  - 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 strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
  - To what degree the application justifies how the identified breast cancer patients or at-risk individuals would benefit from the proposed research. Research benefiting a single subtype is considered impactful as long as the impact for that subtype is high.
- **Research Strategy and Feasibility**
  - How well the scientific rationale for the proposed clinical trial is supported by the review and analysis of the available literature and completed/ongoing studies.
  - To what degree the application includes preclinical and/or clinical evidence to support the safety and stability (as appropriate) of the intervention.
  - How well the specific aims/hypotheses/research question, study design, experimental methods, data collection procedures and evaluations are designed to address the clinical objective and purpose of the study.
  - How well studies are designed to achieve reproducible and rigorous results, including the endpoints/outcomes to be measured.
  - To what degree the planned route and schedule of study intervention(s), evaluations(s) and follow-up procedures are reasonable for study participants to experience.
  - How well potential challenges and alternative strategies are discussed.
  - Whether there is evidence indicating availability of the intervention from its source, for the duration of the proposed clinical trial (if applicable).
  - If applicable, whether measures are described to ensure the consistency of dosing.
- **Recruitment, Accrual, Retention**
  - To what degree the plan for recruiting, enrolling and retaining study participants is reasonable to meet the needs of the proposed clinical trial.
  - How well the application identifies possible delays (e.g., slow/low enrollment, poor retention) and presents adequate mitigation plans to resolve them.
  - To what degree the number of study participants to be enrolled is reasonable based upon the proposed timeline, study procedures, available study population, inclusion/exclusion criteria and planned efforts to achieve accrual goals.
  - To what extent the strategy for the recruitment of women and minorities and the distribution of the proposed enrollment on the basis of age, sex, rate and/or ethnicity are appropriate for the proposed research.

- If applicable, whether the justification for limiting inclusion of any demographic group is sufficiently strong.

- **Regulatory Strategy and Transition Plan**
  - Whether the application includes documentation that the study is exempt from regulatory agency oversight, or that the IND or IDE application (and/or international equivalent) has been submitted to the Regulatory Agency, as appropriate.
  - How well the documentation provided supports the feasibility of acquiring an active IND or IDE (and/or international equivalent) covering the proposed trial, if applicable.
  - To what extent the regulatory strategy and product development plan are well described and appropriate to support the product indication or product label change, if applicable.
  - To what degree the next logical steps to be taken upon successful completion of the proposed clinical trial are realistic and appropriate to bring the research outcome(s) to the next stage of clinical development/implementation/dissemination.
  - Whether the application has a plan to distribute the findings or intervention to the breast cancer community.
  - To what degree the collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) intended to help advance the research outcome(s) are established and/or achievable.
  - To what degree ownership rights/access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award are considered and planned for.
- **Statistical Plan and Data Analysis**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power anaylsis for the study, and as applicable, any subgroup analysis.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study, or whether the justification for a single-sex study is sufficiently strong.
  - If a phase 3 trial is proposed, whether the plans for the valid analysis of group differences on the basis of sex, race and/or ethnicity are appropriate for the proposed research.
- **Ethical Considerations**
  - Whether the population selected to participate in the trial stands to benefit from the knowledge gained.
  - How the level of risk to human subjects is minimized and how the safety monitoring and reporting plan is appropriate for the level of risk.
  - To what degree the process of seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
  - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study.

- If applicable, to what degree barriers to clinical trial participation have been considered and/or addressed.

- **Personnel and Communication**
  - Whether the application includes an appropriate and robust research/clinical team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
  - Whether the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
  - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures, multi-institutional structure governing the research protocol(s)) are appropriate and meet the needs of the proposed clinical trial.
  - Whether the application names two or more consumer advocates that meet the criteria according to the program announcement.
  - How well the application integrates consumer advocates into the planning, design, implementation, and evaluation of the research.
  - To what degree the consumer advocates' knowledge of current breast cancer issues and how their background and/or training in breast cancer research will contribute to the project.
- **Partnership *(only applicable 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 proposed work.
  - To what degree the partnership will better address the research question together rather than through separate individual efforts.
  - How well the application reflects both PIs' equal intellectual contribution to the project's design and their similar levels of effort devoted to the conduct of the project.
  - Whether the application proposes balanced funding between both PIs or otherwise includes appropriate justification.

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**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable, including naming a specific repository(ies) where data and research resources will be stored, and providing a feasible plan for access to stakeholders.
- **Environment**
  - To what degree the scientific environment, clinical setting and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.

- **Budget**
  - 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.

6.2.3. 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 peer reviewers
- Relevance to the priorities of the FY26 BCRP, as evidenced by the following:

  Stage 1: During the first stage of programmatic review, the FY26 BCRP Programmatic Panel will evaluate applications for invitation to Stage 2 using the following criteria:

  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact

  Stage 2 (Oral Presentation): During the second stage of programmatic review, the FY26 BCRP Programmatic Panel will use the following criteria:

  - Understanding of the barriers to overcome in the overarching challenge(s) selected/identified.
  - Articulation of a realistic vision for transitioning the results of the project into a near-term clinical impact for individuals with, or at risk for, breast cancer.
  - Capability to lead efforts to transform and revolutionize the clinical management and/or prevention of breast cancer.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs 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 1, Basic Information about 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.

6.3.2. Full Application

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 subject to review and approval by a designated official. ***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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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 the SAM.

An applicant organization may review the 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.

In accordance with National Security Presidential Memorandum-33 and all associated laws, all fundamental research funded by the DOW must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the DOD Component Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt 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. After all awards are made, the CDMRP includes individual award information in a searchable database.

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 DHACA 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).***

Intragovernmental 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 DOW 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 DOW 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.

8. Post-Award Requirements

8.1. 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.

The GAI contains information regarding administrative requirements and national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the DHACA Terms and Conditions for further information.

If there are delinquencies in technical reporting requirements for any existing DHA or U.S. Army Medical Research and Development Command awards at the applicant organization, DHACA will not issue any new awards to the applicant organization until all delinquent reports have been submitted.

Applications recommended for funding that involve animals, human data, human specimens, human subjects or human cadavers must be reviewed for compliance with federal animal and/or human subjects protection requirements and must be approved by the DHA R&D Office of Research and Regulatory Compliance (ORRC), prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee (IACUC), IRB or Ethics Committee (EC) review.

Funded trials are required to post a copy of the informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Additionally, the CDMRP requires all funded clinical trials to register and submit study results on ClinicalTrials.gov.

8.2. Reporting

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

Enrollment reporting on the basis of sex, race and ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available in eBRAP.

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, using the template available on eBRAP, must be submitted with the final progress report.

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 the SAM about certain civil, criminal and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their 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.

8.3. Additional Requirements

PIs must attend an annual Milestone Meeting to present an update on progress toward accomplishing research milestones and goals. These meetings are held at held at the conclusion of year one and every subsequent year in the period of performance. For planning purposes, PIs should assume that in-person meetings will be held in the National Capital Area or virtually, at the discretion of the government. Members of the BCRP Programmatic Panel, CDMRP staff and the DHACA Grants Officer will attend.

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

The organizational transfer of an award supporting a clinical trial is strongly discouraged and, in most cases, will not be allowed. Approval of a transfer request will be on a case-by-case basis.

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

9. Other Information

9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26_01Td.

9.2. Administrative Actions

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

9.2.1. Rejection

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

- Submission of an application for which a letter of invitation was not issued.
- The Project Narrative is missing.
- The Budget is missing.
- The Study Population Recruitment and Safety Plan (Attachment 6) is missing.
- The Regulatory Strategy (Attachment 7) is missing.
- The Study Personnel and Organization (Attachment 8) is missing.

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

- Preproposal Narrative is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to reviewing all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

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

- A member of the FY26 BCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.

- The federal government recipient organization (including an intramural DOW organization): (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.
- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The 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 same research project is submitted to different funding opportunities within the same program and funding cycle.
- The proposed research is not a clinical trial.
- The application does not address at least one of the FY26 BCRP Overarching Challenges and did not provide adequate justification for an exception.
- The PI does not meet the eligibility criteria.
- An IND or IDE application and/or international equivalent has not been submitted prior to the application submission deadline for a study regulated by a relevant regulatory agency.
- The application fails to include two consumer advocates on the research team as required by this program announcement.
- **Partnering PI Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- The invited application proposes a different research project than that described in the pre-application.

9.2.4. 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 DHACA Grants Officer for a determination of the final disposition of the application.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance ***(Grants.gov submissions only)***	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) ***(eBRAP 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"	☐	☐
Study Population Recruitment and Safety Plan – Attachment 6, upload as "StudyPopPlan.pdf"	☐	
Regulatory Strategy – Attachment 7, upload as "Regulatory.pdf"	☐	
Study Personnel and Organization – Attachment 8, upload as "Personnel.pdf"	☐	
Post-Award Transition Plan – Attachment 9, upload as "Transition.pdf"	☐	
Impact Statement *(if applicable)* – Attachment 10, upload as "Impact.pdf"	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Additional Application Materials		
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	☐	☐
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	☐	☐
Research & Related Budget	☐	☐
Project/Performance Site Location(s)	☐	☐
Research & Related Subaward Budget Attachment(s) *(if applicable)*	☐	☐

Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting of In Vivo Experiments
BCRP	Breast Cancer Research Program
BTA4	Breakthrough Award Level 4
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PPIO	Partnering PI Option
R&D	Research and Development
RPPR	Research Performance Progress Report
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)

SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs