Program Announcement for the Department of Defense
Defense Health Program

Breast Cancer Research Program Breakthrough Award Levels 1 and 2

Funding Opportunity Number: HT942525BCRPBTA12

Pre-Application Due: June 13, 2025

Application Due: June 27, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_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 the 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 the funding opportunity and that all parties meet eligibility requirements.

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 Contact 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 Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: Supports promising research that has high potential to lead to or make breakthroughs in breast cancer. All applications must address at least one of the fiscal year 2025 (FY25) Breast Cancer Research Program (BCRP) overarching challenges, unless adequate justification for exception is provided. Applications must address the challenge in a way that can lead to or make a breakthrough and have major impact. The FY25 Breakthrough Award mechanism contains three different funding levels designed to support major (but not all) stages of research that will lead to clinical application. Each level has a defined research scope. **The current program announcement discusses the Breakthrough Award Levels 1 and 2.**

Distinctive Features:

- **This funding mechanism allows for applications submitted under Funding Level 1 or Funding Level 2. Funding Level 2 also includes a Population Science and Prevention Studies option.** With compelling justification, population science and prevention studies may request higher levels of funding and an additional year in the period of performance.
- **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, applications may be withdrawn if both the initiating and partnering applications are not submitted by the full application deadline or if the initiating or partnering application is administratively withdrawn.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $33.7 million (M) to fund approximately 20 Breakthrough Award Levels 1 and 2 applications with total cost caps of $0.75M (single PI) or $1.25M (PPIO) for Funding Level 1, $1.65M (single PI) or $2.5M (PPIO) for Funding Level 2, or $2.5M (single PI) or $3.35M (PPIO) for Funding Level 2 - Population Science and Prevention Studies. The maximum period of performance is **three** years for Breakthrough Award Funding Levels 1 and 2 and **four** years for Breakthrough Award Level 2 – Population Science and Prevention Studies. It is anticipated that awards made from this FY25 funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 13, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, June 27, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, July 2, 2025
- **Peer Review:** September 2025
- **Programmatic Review:** November 2025

Announcement Type: Modified

Funding Opportunity Number: HT942525BCRPBTA12

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply***, including foreign and domestic organizations, for-profit and nonprofit organizations, and public or private entities***.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

2.1.2. Principal Investigator

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

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

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

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

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

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 General Application Instructions, Appendix 1, for additional recipient qualification requirements.

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the BCRP. 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 FY24 totaled $4.39 billion. The FY25 appropriation is $130M.

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 has prepared a brief overview, *The Breast Cancer Landscape*, that describes what is currently known about the most pertinent topics that are consistent with the BCRP's mission of ending breast cancer. Considering the current breast cancer landscape and the program's mission, the BCRP seeks to invest in research that addresses the following 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 are more effective, less toxic, and impact survival
- Eliminate the mortality associated with metastatic breast cancer

3.1. Intent of the Breakthrough Award Funding Levels 1 and 2

The intent of the FY25 BCRP Breakthrough Award is to support promising research that has high potential to lead to or make breakthroughs in breast cancer.

The FY25 BCRP Breakthrough Award contains three 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 funding level selected should be based on the research scope defined in the program announcement and not on the amount of the budget. ***An application that does not meet the intent of the funding level selected will not be recommended for funding, even if it might meet the intent of a different funding level.***

The current program announcement discusses the FY25 BCRP Breakthrough Award Levels 1 and 2 (BTA12).

- **Funding Level 1:** Innovative, high-risk/high-reward research that is in the earliest stages of idea development or is an untested theory that addresses an important problem. To foster research that yields new avenues of investigation, preliminary data are ***not*** required. Proof of concept is the anticipated outcome.
- **Funding Level 2:** Research that is already supported by substantial preliminary or published data ***in breast cancer*** and strongly validates clinical translation in a well-defined context within the *breast cancer landscape*.
- **Funding Level 2: Population Science and Prevention Studies:** The studies should focus on the analysis of human data and biospecimens. Research should be already supported by substantial preliminary or published data ***in breast cancer*** and strongly validate clinical translation in a well-defined context within the *breast cancer landscape*. With compelling justification, population science and prevention studies may request higher levels of funding and an additional year in the period of performance.

3.1.1. Key Elements for the BTA12

Impact: Proposed research must have the potential for a major impact and accelerate progress toward ending breast cancer. The impact may be near-term or long-term but must move beyond a minor advancement and have the potential to lead to a fundamentally new 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. Applicants are strongly urged 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.

Partnering PI Option: The FY25 BCRP BTA12 encourages applications that include meaningful and productive partnerships between investigators. The PPIO accommodates two PIs. One PI will be 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 of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI should bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. 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

[1] Alternatively, with adequate justification, applications may identify and address another overarching challenge related to The Breast Cancer Landscape. Justification must be provided in the application.

efforts. ***To meet the intent of the PPIO, the BCRP discourages applicants from being named as a Partnering PI on multiple BTA12 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions. Applications do not meet the intent of the PPIO if a mentor and their current postdoctoral fellow or junior investigator are named as Initiating and Partnering PIs.*** 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.

3.1.2. Other Important Considerations for the BTA12

Research involving human subjects, human anatomical substances, and human data is permitted; however, clinical trials are not allowed under this funding opportunity. Applications seeking support for a clinical trial may be submitted to the FY25 BCRP Breakthrough Award Level 3 program announcement (HT942525BCRPBTA3).

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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

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

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

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

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

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

The proposed research must be relevant to Service Members, Veterans, military beneficiaries, and/or the American public. Applications from investigators within the DOD and applications involving multidisciplinary collaborations among academia, industry, the DOD, the

U.S. Department of Veterans Affairs (VA), and other federal government agencies are highly encouraged. These relationships can leverage knowledge, infrastructure, and access to unique clinical populations that the collaborators bring to the research effort, ultimately advancing research that is of significance to Service Members, Veterans, and/or their Families.

3.2. CDMRP-wide Encouragements

The following encouragements are broadly applicable across many CDMRP programs, including the BCRP. Investigators are encouraged to consider addressing these areas in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY25 BCRP priorities.

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

3.3. Funding Instrument

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

3.4. Funding Details

The requested funding level should be aligned with the scope of the research proposed and the funding level description.

Funding Level 1 (Single PI or Partnering PI Option):

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

Cost Cap: For applications with a single PI, the application's total costs budgeted for the entire period of performance should not exceed **$750,000**. 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 **$1.25M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

For Partnering PI Option applications, a separate award will be made to each PI's organization.

Funding Level 2 (Single PI or Partnering PI Option):

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

Cost Cap: For applications with a single PI, the application's total costs budgeted for the entire period of performance should not exceed **$1.65M**. 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 **$2.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

For Partnering PI Option applications, a separate award will be made to each PI's organization.

Funding Level 2 – Population Science and Prevention Studies (Single PI or Partnering PI Option):

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 **$2.5M**. 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 **$3.35M**. 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.

For Partnering PI Option applications, a separate award will be made to each PI's organization.

For All Funding Level 1 and 2 Applications:

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 **three** or **four** years.

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

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

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

May be requested for (not all-inclusive):

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY25 BCRP Breakthrough Award Levels 1 and 2.

Must not be requested for:

- Clinical trial costs.

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 DOD 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. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

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

4.3. Step 2: Full Application Components

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.

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and the 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

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

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 listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (page limit varies by funding level; see below for page limits): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

- **Page Limit:** Page limits for the Project Narrative are correlated with the application's funding level:
  - **Funding Level 1:** Seven-page limit
  - **Funding Level 2:** 14-page limit
  - **Funding Level 2 – Population Science and Prevention Studies:** 14-page limit
- **Outline for Project Narrative:** Describe the proposed project in detail using the outline below.
  - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. For Funding Level 1 applications, preliminary data are not required, but may be included. For Funding Level 2 applications, provide sufficient preliminary data in breast cancer to support the feasibility of the work proposed. Whether or not preliminary data are available, the application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.
  - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
  - **Specific Aims:** Concisely explain the project's specific aims to be funded by this application.
  - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas, and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA) or an equivalent international regulatory agency, if applicable. For clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement. Anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex, race, and ethnicity should be provided as part of the application's Supporting Documentation (Attachment 2).
  - **Statistical Plan:** Describe the statistical plan including power analysis, as appropriate, for the research proposed.
  - **Research Team:** Describe how the combined backgrounds and breast cancer-related expertise of the research team will enable successful conduct of the project.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

  - **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms and symbols.
  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
  - **Letters of 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. 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 DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
  - **Letter of Recommendation *(only applicable and required for applications submitted with a PI who is a postdoctoral fellow; one-page limit is recommended)*:** A letter of recommendation provided on organizational letterhead from the mentor(s) should describe:
    - The degree to which the PI participated in the development of the research idea.
    - How well the PI can manage the technical and administrative aspects of the award.
    - How well the PI can successfully accomplish the proposed research.
  - **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Data and Research Resources Sharing Plan:** Describe the type of data or research resources to be made publicly available as a result of the proposed work. Describe how data and resources generated during the period of performance will be shared with the research community and other affected communities. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.
- **Inclusion Enrollment Plan *(only required if clinical research is proposed)*:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.
- **Sex as a Biological Variable Strategy (two-page limit is recommended):** 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. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Technical abstracts should be written using the outline below. Clarity and completeness within the space limits are highly important.

  - **Background:** Present the ideas and reasoning behind the proposed research project.
  - **Overarching Challenge(s):** State the overarching challenge(s) addressed by the proposed research, 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:** State the hypothesis to be tested and/or objective to be reached. Provide evidence or rationale that supports the objective/hypothesis.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** 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 requirements for high

potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.

- **Relevance to Military Health:** Briefly describe how the proposed research is relevant to Service Members, Veterans, and their Families.
- **Innovation *(required for Funding Level 1 applications only)*:** Explain how the proposed research is innovative and will investigate a novel idea or research question that introduces a new paradigm or challenges existing paradigms.

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers and addresses issues of particular interest to the affected community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard; spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below ***in a manner that will be readily understood by readers without a background in science or medicine.*** Avoid overuse of scientific jargon, acronyms, and abbreviations.

  - Clearly describe the rationale, 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 time it may take to achieve a patient-related outcome?
    - How will the proposed project lead to or make a breakthrough in breast cancer and accelerate progress toward the BCRP's mission of ending breast cancer?
    - If the research is too basic for clinical applicability, describe the interim outcomes.
    - How is the proposed research relevant to Service Members, Veterans, and their Families?

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

  For the Breakthrough Award Funding Levels 1 and 2 mechanism refer to the "Example: Assembling a Generic Statement of Work", for guidance on preparing the SOW.

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

  Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The specific contributions of the Initiating PI and the Partnering PI should be clearly noted for each task.

- **Attachment 6: Impact Statement (300 words or less recommended; one-page limit): Upload as "Impact.pdf".**

  This statement should be written with a broad audience in mind, including 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 7: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.)*** Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the proposed work. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain the plan to balance funding between both PIs or otherwise provide appropriate justification.
- **Attachment 8: Submissions Statement (one-page limit): Upload as "Submissions.pdf".** ***(Attachment 8 is only applicable and required for applications in which the PI, Initiating PI or Partnering PI is named on multiple FY25 BCRP Breakthrough Award Levels 1 and 2 applications. Attachment 8 will be available for programmatic review only.)***

  Provide the following information for each individual named as a PI, Initiating PI, Partnering PI, collaborator, or mentor in multiple Breakthrough Award Levels 1 and 2 applications:

  - CDMRP log number, funding level, role on the project, project title, and specific aims.
  - A brief description of how the application addresses a research question that is distinct from the other application(s).
- **Attachment 9: Mentorship Statement (one-page limit): Upload as "Mentorship.pdf".** ***(Attachment 9 is only applicable and required for applications in which the PI is a postdoctoral fellow.)*** Identify the PI's mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor's experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor's commitment to the PI's project, including details of their proposed interactions with the PI and how they will support the PI's research endeavors.
- **Attachment 10: Innovation Statement (one-page limit): Upload as "Innovation.pdf".** ***(Attachment 10 is only applicable and required for applications submitted under Funding Level 1.)*** Explain how your proposed research addresses breast cancer in a fundamentally new way. Innovation requires a novel idea or approach that either introduces an entirely new paradigm or challenges existing paradigms in unprecedented

ways. It will result in a creative, but scientifically sound, transformation from existing approaches, methods, or strategies. The next step in an established process or targeting strategy, or building on significant preliminary data, does not meet the criteria for innovation.

- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. For more information, see the General Application Instructions, Appendix 8, Section B, Representations.
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively. ***If the PI is a postdoctoral fellow, include the mentor's (and co-mentor's, if applicable) biographical sketch and current/pending support.***

- **Biographical Sketch:** Upload as "**Biosketch_LastName.pdf**".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "**Support_LastName.pdf**".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.

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 even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named “IGBudget.pdf”.

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)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 9: Mentorship Statement (one-page limit): Upload as “Mentorship.pdf”. *(Attachment 9 is only applicable and required for applications in which the PI is a postdoctoral fellow.)*** Identify the PI’s mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor’s experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor’s commitment to the PI’s project, including details of their proposed interactions with the PI and how they will support the PI’s research endeavors.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as “RequiredReps.pdf”.**

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively. ***If the PI is a postdoctoral fellow, include the mentor's (and co-mentor's, if applicable) biosketch and current/pending support information.***

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

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

Initiating and Partnering PI 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, even if they are located within the same organization. Refer to Section 3.4, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

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

4.4. Other Application Elements

- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instruction 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 HT942525BCRPBTA12 from Grants.gov or eBRAP, depending on which submission portal will be used.

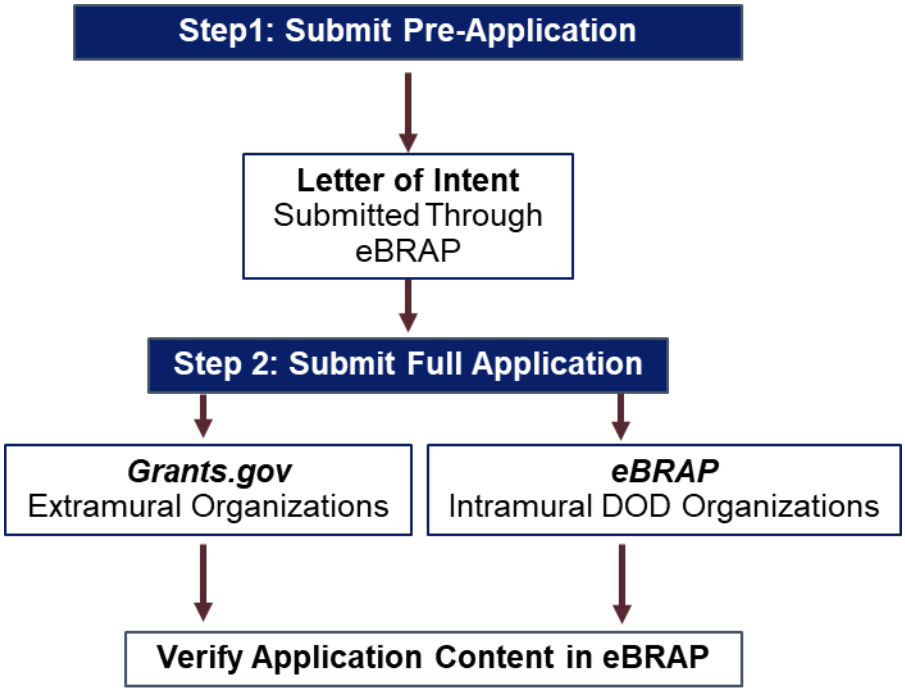
5.2. Unique Entity Identifier and System for Award Management

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 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. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI if exercising the Partnering PI Option.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Partnering PI Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information.*** 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:

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

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

Application Includes:	Select Option:
Funding Level 1 and Single PI	Funding Level 1
Funding Level 1 and Initiating PI and Partnering PI	Funding Level 1 – Partnering PI Option
Funding Level 2 and Single PI	Funding Level 2
Funding Level 2 and Initiating PI and Partnering PI	Funding Level 2 – Partnering PI Option
Funding Level 2 Population Science and Prevention Studies and Single PI	Funding Level 2 – Population Science and Prevention Studies
Funding Level 2 Population Science and Prevention Studies and Initiating PI and Partnering PI	Funding Level 2 – Population Science and Prevention Studies – Partnering PI Option

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of 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 into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure the proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted through the appropriate portal prior to the full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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 USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant.***

All submission dates and times are indicated in Section 1, Basic Information above.

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 funding cycle 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 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 full position 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. Refer to the General Application Instructions, Appendix 7, Section B.

Members of the FY25 BCRP Programmatic Panel should 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 FY25 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

Pre-applications submitted to this funding opportunity are used for program planning purposes only (e.g., reviewer recruitment) and will not be screened.

6.2.2. Peer Review Criteria

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

- **Impact**

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

  - To what degree the proposed project will have a major impact on the overarching challenge(s).
  - To what degree the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.

- Whether the proposed research will lead to a fundamentally new 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 Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data, if applicable (Funding Level 1 does not require preliminary data but Funding Level 2 does).
  - How well the hypothesis, objective, and specific aims are developed.
  - How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
  - How well the application acknowledges potential pitfalls and problem areas, and addresses alternative methods and approaches.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or an equivalent international regulatory agency.
  - Whether an appropriate statistical plan including power analysis, as appropriate, is provided.
  - How well the SOW indicates a feasible plan and timeline to conduct the research, and provides clearly defined milestones to accomplish by the end of each year in the period of performance.
  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
  - 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.
- **Personnel**
  - Based on the biographical sketches, whether the application includes an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
  - How appropriate the levels of effort are for successful conduct of the proposed work.
  - ***Applications Submitted by Postdoctoral Fellows:***
    - To what degree the application demonstrates that the PI has the potential to manage the technical and administrative aspects of the award and successfully accomplish the proposed research.
    - To what degree the application demonstrates that the PI will have appropriate mentorship to successfully conduct and complete the project.
- **Partnership *(applicable only to Partnering PI Option applications)***
  - How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the 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 equal intellectual input by both PIs into the design of the project and similar and appropriate levels of effort devoted to the conduct of the project.
- Whether the proposed funding is balanced between both PIs or is otherwise appropriately justified.

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**:

- **Environment**
  - To what extent the scientific environment and level of institutional support is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and access to facilities and resources.
  - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Innovation (Funding Level 1 only)**
  - To what degree the proposed research is innovative and addresses breast cancer in a fundamentally new way.
  - To what degree the proposed research will investigate a novel idea or approach and is not the next step in an established process or targeting strategy nor building on significant preliminary data.
  - Whether the proposed research either introduces an entirely new paradigm or challenges existing paradigms in unprecedented ways.
- **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 the peer reviewers
- Relevance to the priorities of the FY25 BCRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity
  - Program portfolio composition
  - Relative impact
  - Relative innovation (Funding Level 1 only)

6.3. Application Review and Selection Process

6.3.1. Pre-Application

There is no review and selection process for pre-applications submitted to this funding opportunity. ***CDMRP will NOT provide an invitation to submit a full application after pre-application submission.*** Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.

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 made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section 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 SAM.

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

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DOD 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 full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within six 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.

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. For additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

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.

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), 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. Refer to the General Application Instructions, Appendix 6, for additional information.

8.2. Reporting

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

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

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent five-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

8.3. Additional Requirements

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

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

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

9. Other Information

9.1. Program Announcement and General Application Instructions Versions

Questions related to this program announcement should refer to the program name, the program announcement name, and the program announcement version code CD25_01d. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

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:

- Pre-application was not submitted.
- Project Narrative is missing.
- Budget is missing.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for 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 FY25 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, 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.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.
- Applications submitted by a federal government organization (including an intramural DOD organization) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization 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.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and funding cycle.
- The application does not address at least one of the FY25 BCRP Overarching Challenges and did not provide adequate justification for an exception.
- More than one application per funding level is received with the same investigator named as a PI or an Initiating PI. Only the first application received per funding level will be accepted; additional applications will be administratively withdrawn.
- A clinical trial is proposed.
- **Partnering PI Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

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 USAMRAA 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"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Partnership Statement – Attachment 7, upload as "Partnership.pdf" if applicable	☐	
Submissions Statement – Attachment 8, upload as "Submissions.pdf" if applicable	☐	
Mentorship Statement – Attachment 9, upload as "Mentorship.pdf" if applicable	☐	☐
Innovation Statement – Attachment 10, upload as "Innovation.pdf" if applicable	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for PI and Senior/Key Persons (Biosketch_LastName.pdf)	☐	☐
Attach Current and Pending (Other) Support for PI and Senior/Key Persons (Support_LastName.pdf)	☐	☐
Budget **Include budget justification**	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable*)	☐	☐

Appendix 2. Acronym List

BCRP	Breast Cancer Research Program
BTA12	Breakthrough Award Levels 1 and 2
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
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
IACUC	Institutional Animal Care and Use Committee
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OUSD R&E	Office of the Under Secretary of Defense, Research and Engineering
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PPIO	Partnering Principal Investigator Option
RPPR	Research Performance Progress Report
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SOW	Statement of Work
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code
VA	U.S. Department of Veterans Affairs