Program Announcement for the Department of Defense
Defense Health Program

Breast Cancer Research Program Breakthrough Award Level 3

Funding Opportunity Number: HT942525BCRPBTA3

Pre-Application Due: June 13, 2025

Application Due: September 10, 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 Level 3.**

Distinctive Features:

- **For this funding mechanism, small-scale clinical trials are allowed but not required.** Applications proposing projects with a clinical trial should be submitted under the Clinical Trial option.
- 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, 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 $25.2 million (M) to fund approximately four Breakthrough Award Level 3 applications with total cost caps of $5.6M for applications with a single PI or $7M if applying under the PPIO. The maximum period of performance is four years. 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 (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 13, 2025
- **Invitation to Submit an Application:** July 18, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, September 10, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, September 15, 2025
- **Peer Review:** November 2025
- **Programmatic Review:** January 2026

Announcement Type: Modified

Funding Opportunity Number: HT942525BCRPBTA3

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

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

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 3 program announcement.

Investigators are discouraged 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 3 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 Level 3

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 Level 3 (BTA3).

Funding Level 3: Advanced translational studies. Where relevant, the proposed research must be supported by proof of the availability of, and access to, necessary data, human samples, cohort(s), and/or critical reagents. If the proposed research will ultimately require U.S. Food and Drug Administration (FDA) or an equivalent international regulatory agency involvement, the project must be supported by demonstrated availability of, and access to, clinical reagents (e.g., therapeutics) and subject population(s). A realistic timeline for near-term clinical research, as defined elsewhere in this program announcement, must be stated. Small-scale clinical trials (e.g., first-in-human, phase 1/1b) may be appropriate.

3.1.1. Key Elements for the BTA3

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.

Consumer Advocates: Applications must include consumer advocate involvement. The research team must include two or more breast cancer consumer advocates, who will be integral 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. Interactions with other team members should be well integrated and ongoing, not limited to 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. Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Their role should be focused on providing objective input throughout the research effort and its potential impact for individuals with, or at risk for, breast cancer. The consumer advocates should have a high level of knowledge of current breast cancer issues and the appropriate background and/or training in breast cancer research to contribute to the project.

Partnering PI Option: The FY25 BCRP BTA3 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

[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.

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 efforts. ***To meet the intent of the PPIO, the BCRP discourages applicants from being named as a Partnering PI on multiple BTA3 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.

3.1.2. Other Important Considerations for the BTA3

Clinical trials are allowed. A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. 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

Funding Level 3 (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 **$5.6M**. 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 **$7M**. 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.

Clinical Trials

For applications that propose a clinical trial, funds may be requested for the full proposed period of performance (up to **four** years) to cover:

- Advanced preclinical work (e.g., Good Manufacturing Practice [GMP] production, pharmacokinetics, and toxicity testing) and/or clinical trial preparation (e.g., Investigational New Drug [IND], Institutional Review Board (IRB), and DOD Office of Human Research Oversight [OHRO] approval), which will be considered the base award; and
- Clinical trial work, which will be considered the optional research effort(s).

The approval of optional research effort(s) will be contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award. Approval may be dependent on the availability of future year appropriations. The budget and SOW for the base award and the optional research effort(s) must be severable. Additionally, the optional research effort period(s), if funded, must occur within the maximum period of performance (up to **four** years).

For All Funding Level 3 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 **four** years.

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

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

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for three investigators to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the FY25 BCRP Breakthrough Award Level 3.
- If applicable, 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 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.

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

- **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 3 as described in this program announcement. (500-character limit)
  - Will the proposed research include a clinical trial? If yes, briefly state the clinical intervention, subject population(s), and phase of the clinical trial. (500-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 FY25 BCRP Breakthrough Award Level 3 pre-applications in which the PI 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. Step 2: Full Application Components

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

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

  Outline for the Project Narrative: Describe the proposed project in detail using ***one*** of the two outlines below, depending on whether a clinical trial is proposed.

  - ***Outline for projects without a clinical trial:***
    - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. 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. Where relevant, describe the availability of, and access to, the data, human samples, cohort(s), and/or critical reagents (e.g., therapeutic molecules) necessary for the project, and provide appropriate letters of support in Attachment 2: Supporting Documentation. If applicable, describe resources available for the development of sufficient quantities of critical reagents under GMP guidelines. 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 FDA or an equivalent international regulatory agency, if applicable. For clinical research, see Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
- **Statistical Plan:** Describe the statistical plan in detail, 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.

– ***Outline for projects with a clinical trial:***

Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.

- **Background:** Describe in detail the rationale for the study, and include a literature review, preliminary studies, and/or preclinical data that led to the development of 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. Provide a summary of other relevant ongoing, planned, or completed clinical trials and describe how the proposed study differs. Include a discussion of any current clinical use of the intervention under investigation and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

  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 would be supported with funds from this award.
- **Objective/Specific Aims/Hypothesis:** Describe the purpose and objective of the study with detailed specific aims and hypotheses.

- **Research Strategy** (include only if laboratory research studies, ***separate from the clinical trial and associated analyses***, are proposed as a component of the application): Describe the planned laboratory research studies to be performed under this application and how they are ***clearly linked*** to the clinical trial. Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Where relevant, describe the availability of, and access to, the data, samples, and/or critical reagents (e.g., therapeutic molecules) necessary for the project and provide appropriate letters of support in Attachment 2: Supporting Documentation. If applicable, describe resources available for the development of sufficient quantities of critical reagents under GMP guidelines. 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 FDA or an equivalent international regulatory agency, if applicable.
- **Clinical Trial:** Provide detailed plans for initiating, conducting, and completing the clinical trial during the period of performance. As appropriate, briefly outline a plan for obtaining regulatory approvals necessary to initiate the clinical trial (e.g., active IND, Investigational Device Exemption (IDE), or equivalent status). Additional details should be provided in Attachment 11: Regulatory Strategy. Describe the type of clinical trial the team will perform (e.g., prospective, randomized, controlled), the study phase, and the study model (e.g., single group, parallel, crossover). Outline the proposed clinical trial methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - Identify the intervention to be tested and describe the projected outcomes.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the availability of, and access to, critical reagents (e.g., therapeutic molecules) necessary for the clinical trial and provide appropriate letters of support in Attachment 2: Supporting Documentation.
  - Identify the study population and specify the number of human subjects that will be enrolled. Describe the access to the study population, recruitment plans, and inclusion/exclusion criteria. Provide appropriate letters of support demonstrating access to the study population in Attachment 2: Supporting Documentation. Define each arm/study group of the proposed trial, if applicable, and describe how group assignment will occur. See Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.
- **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Ensure sufficient information is

provided to allow thorough evaluation of all statistical calculations during review of the application.

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

- **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.
  - **Consumer Advocate Letters of Commitment:** Provide a letter signed by each consumer advocate confirming their commitment to participate in the proposed project.
  - **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, including clinical trial participants if applicable. Provide a milestone plan for data/results dissemination, 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 tests performed as part of the study. Refer to the CDMRP's Policy on Data & Resources Sharing for more information about the CDMRP's expectations for making data and research resources publicly available.

- **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 requirement 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.

- **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?
  - How is the proposed research relevant to Service Members, Veterans, and their Families?

- **Attachment 5: Statement of Work (three-page limit for applications without a clinical trial or a six-page limit for applications with a clinical trial): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the FY25 BCRP Breakthrough Award Level 3, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW.

  The SOW should include 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 in multiple FY25 BCRP Breakthrough Award Level 3 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, or collaborator in multiple Breakthrough Award Level 3 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: Consumer Advocate Statement (one-page limit): Upload as "ConsumerAdvocate.pdf".** 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.
- **Attachment 10: Post-Award Transition Plan (one-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials (if applicable), and/or delivery to the commercial market (if applicable) after successful completion of the award (e.g., specific potential industry partners, specific funding opportunities to apply for). If the application does not include a clinical trial, provide a realistic timeline for near-term clinical research. In addition, provide a plan to distribute the findings or intervention to the breast cancer community.
- **Attachment 11: Regulatory Strategy (no page limit):** ***(Attachment 11 is only applicable and required for applications in which a clinical trial is proposed.)*** **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.
- State how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work.

For products/interventions that do not require regulation by the FDA or an equivalent international regulatory agency:

- Provide evidence that the clinical trial does not require regulation by the FDA or an equivalent international regulatory agency. Submissions providing "not applicable," "none," or similar responses do not satisfy this request. No further information for this attachment is required.

For products/interventions that require regulation by the FDA or an equivalent international 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. If an IND or IDE application is required and has not been submitted to the FDA, describe plans for IND or IDE application submission, including the timeline for submission. If an IND or IDE is required and has already been submitted to the FDA, provide the date of submission, the application number and a copy of the FDA letter acknowledging the submission. State the status of the IND or IDE application, and include copies of communications from the FDA relevant to the most recent status of the application. If available, provide a copy of the communication from the FDA indicating the IND or IDE application is active/safe to proceed.
  - If applicable, 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 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 12: Inclusion of Women and Minorities (five-page limit): Upload as "Inclusion.pdf".** ***(Attachment 12 is only applicable and required for applications that propose clinical research and/or clinical trials.)*** Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, 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.

- **Attachment 13: 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 14: 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. ***Biographical sketches or equivalent must be submitted for the breast cancer consumer advocates***.

- **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 for applications without a clinical trial or a six-page limit for applications with a clinical trial): Upload as “SOW.pdf”.** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 13: Representations *(Grants.gov submissions only)*: Upload as “RequiredReps.pdf”.**
- **Attachment 14: 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. ***Biographical sketches or equivalent must be submitted for the breast cancer consumer advocates.***

(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 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, 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 HT942525BCRPBTA3 from Grants.gov or eBRAP, depending on which submission portal will be used.

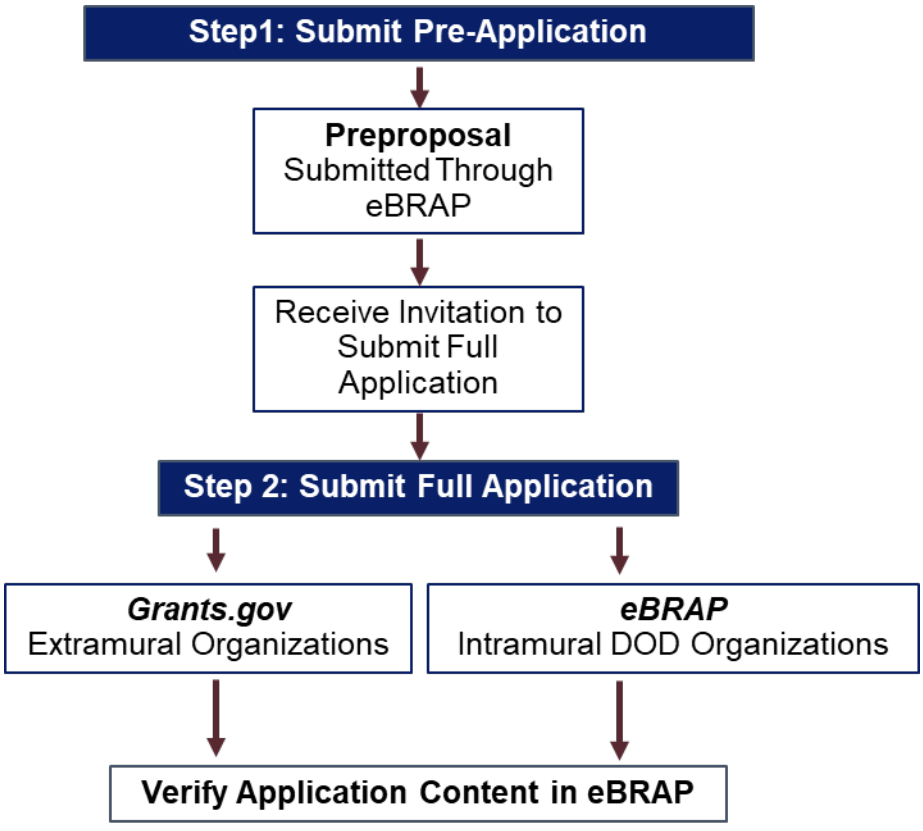
5.2. Unique Entity Identifier and System for Award Management

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:
Single PI and No Clinical Trial	No Option
Single PI and Clinical Trial	Clinical Trial
Initiating PI and Partnering PI with No Clinical Trial	Partnering PI Option
Initiating PI and Partnering PI with Clinical Trial	Clinical Trial – 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

To determine the technical 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 3 as described in this program announcement.

6.2.2. Peer Review Criteria

For applications without a clinical trial:

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

- **Impact**

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

  - To what degree the proposed 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.
  - 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.
  - Whether there is documented availability of, and access to, all necessary data, human samples, cohort(s), and/or critical reagents, where relevant.
  - If applicable, whether there are resources available for the development of sufficient quantities of critical reagents under GMP.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA or an equivalent international regulatory agency.
  - How well the application acknowledges potential pitfalls and problem areas, and addresses alternative methods and approaches.
  - 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.
  - 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.

- **Statistical Plan**
  - To what degree the application provides an appropriate statistical plan, including power analysis.
- **Transition Plan**
  - To what degree the application demonstrates feasible methods and strategies to move the project's finding to the next phase of development, clinical trials (if applicable), and/or delivery to the commercial market (if applicable) after successful completion of the award.
  - To what degree the application's timeline for near-term clinical research is realistic and appropriate.
  - Whether the application has an appropriate plan to distribute the findings or intervention to the breast cancer community.
- **Personnel**
  - 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.
  - Whether the levels of effort are appropriate for successful conduct of the proposed work.
  - Whether two or more consumer advocates are named in the application and meet the criteria according to the program announcement.
  - How well the consumer advocates are integrated 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 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.

- **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.

For applications with a clinical trial:

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

- **Impact**

  Note: Reviewers will evaluate how the proposed research will have an impact on the overarching challenge(s), assuming the objective/goals are realized.
  - To what degree the proposed project will have a major impact on the overarching challenge(s).
  - To what degree the project meets the requirement for high potential to lead 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.
  - How well the proposal justifies how the identified breast cancer patients or at-risk individuals would benefit from the proposed research.
- **Clinical Trial**
  - Whether the type of clinical trial and study model are appropriate to meet the project's objective.
  - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.
  - How well the application describes the availability of, and access to, critical reagents (e.g., therapeutic molecules) necessary for the clinical trial.
  - How well the application demonstrates access to the study population and describes appropriate recruitment plans and inclusion/exclusion criteria.
  - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining active IND, IDE, or equivalent status, if appropriate.
  - Whether potential challenges and alternative strategies are appropriately identified.
  - 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.
  - To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to accomplish by the end of each year in the period of performance.

- **Regulatory Strategy**
  - Whether the application states the intervention to be used.
  - Whether the application includes documentation that the study is exempt from FDA or equivalent international regulatory agency review, or whether plans for IND or IDE application (and/or other international equivalent) to the respective regulatory agency are reasonable and appropriate.
  - To what degree the regulatory strategy and development plan to support the product indication/label (if applicable) are appropriate and well described.
- **Research Strategy and Feasibility *(applicable only to applications that include laboratory research studies)***
  - 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.
  - How well the hypothesis, objectives, and specific aims are developed.
  - How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
  - Whether the proposed laboratory research studies are clearly linked to the proposed clinical trial.
  - Whether there is documented availability of, and access to, necessary data, samples and/or critical reagents, where relevant.
  - If applicable, whether there are resources available for the development of sufficient quantities of critical reagents under GMP.
  - 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.
  - 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.
- **Statistical Plan**
  - To what degree the application provides an appropriate statistical model and data analysis plan, including a power analysis demonstrating that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies.
  - If a subpopulation of a recruited sample population will be used for analysis, whether the application includes an appropriate statistical analysis to ensure appropriate power can be achieved within the subpopulation study.
- **Transition Plan**
  - To what degree the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market (if applicable) after successful completion of the award.
  - Whether the application has an appropriate plan to distribute the findings or intervention to the breast cancer community.

- **Personnel**
  - 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 are appropriate for successful conduct of the proposed work.
  - Whether the application includes two or more consumer advocates who meet the criteria according to the program announcement.
  - To what degree the investigator(s) integrated the consumer advocates into the planning, design, implementation, and evaluation of the research.
  - How well 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 that 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, 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.
  - If applicable, whether the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.
- **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

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, PIs and 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 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.

Funded clinical 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 Applicable Clinical Trials to register on ClinicalTrials.gov. Additional data reporting requirements will also apply to Applicable Clinical Trials supported under this funding opportunity. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

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

For all applications, annual technical progress reports as well as a final technical progress report will be required. For applications proposing a clinical trial, Quarterly and Annual Technical Reports, as well as a final technical report, will be required. 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 and/or clinical trials)***: 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.

The organizational transfer of an award or partnering awards 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.

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 pre-application:

- Preproposal Narrative is missing.
- Preproposal Narrative exceeds page limit.

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

- Submission of an application for which a letter of invitation was not issued.
- Project Narrative 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 invited application proposes a different research project than that described in the pre-application.
- The application does not address at least one of the FY25 BCRP Overarching Challenges and did not provide adequate justification for exception.
- The PI does not meet the eligibility criteria.
- 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.

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"	☐	
Submissions Statement – Attachment 8, upload as "Submissions.pdf"	☐	
Consumer Advocate Statement – Attachment 9, upload as "ConsumerAdvocate.pdf"	☐	
Post-Award Transition Plan – Attachment 10, upload as "Transition.pdf"	☐	
Regulatory Strategy – Attachment 11, upload as "Regulatory.pdf"	☐	
Inclusion of Women and Minorities – Attachment 12, upload as "Inclusion.pdf"	☐	
Representations ***(Grants.gov submissions only)*** **– Attachment 13, upload as "RequiredReps.pdf"**	☐	☐
Suggested Intragovernmental/Intramural Budget Form ***(if applicable)*** **– Attachment 14, upload as "IGBudget.pdf"**	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach 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
BTA3	Breakthrough Award – Funding Level 3
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
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
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
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 PI 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 Veteran Affairs