



**Program Announcement for the Defense Health Agency**

# **Breast Cancer Research Program Breakthrough Award Level 3**

Funding Opportunity Number: HT942526BCRPBTA3

Pre-Application Due: June 12, 2026

Application Due: September 30, 2026

*This program announcement must be read in conjunction with the General Application Instructions, version [CD26\\_01](#).*

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## Before You Begin

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

## Who to Contact for Support

### eBRAP Help Desk

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

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

### Grants.gov Support Center

800-518-4726  
International: 1-606-545-5035  
[support@grants.gov](mailto:support@grants.gov)

*Questions regarding  
Grants.gov registration  
and Workspace.*

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

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

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# 1. Basic Information About the Funding Opportunity

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

**Funding Details:** The Congressionally Directed Medical Research Programs (CDMRP) expects to allot roughly \$12.6 million (M) to fund approximately two Breakthrough Award Level 3 applications with total cost caps of \$5.6M for applications with a single PI or \$7.0M if applying under the PPIO. The maximum period of performance is four years. It is anticipated that awards made from this FY26 funding opportunity will be funded with FY26 funds, which will expire for use on September 30, 2032. Awards supported with FY26 funds will be made no later than September 30, 2027.

### Submission and Review Dates and Times

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

**Announcement Type:** Initial

**Funding Opportunity Number:** HT942526BCRPBTA3

**Assistance Listing Number:** 12.420

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## 2. Eligibility Information

### 2.1. Eligible Applicants

#### 2.1.1. Organization

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

#### 2.1.2. Principal Investigator

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

***There are no limits on the number of pre-applications an investigator may submit as a PI, Initiating PI, or Partnering PI for this Breakthrough Award Level 3 program announcement.***

This program announcement discourages investigators from being named on multiple pre-applications unless they are clearly addressing distinct research questions. Invited applications must include a brief description of all the applications in which the investigator is named as a PI, Initiating PI, Partnering PI, or collaborator under this Breakthrough Award Level 3 program announcement.

### 2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

### 2.3. Other

Awards are made to eligible ***organizations***, not to individuals. Refer to the GAI for additional [recipient qualification requirements](#).

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### 3. Program Description

The Defense Health Agency Contracting Activity (DHACA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP is the program office managing this FY26 funding opportunity as part of the BCRP. The CDMRP is located within the Defense Health Agency Research and Development (DHA R&D), which is a part of the Department of Defense, DOD, herein referred to using the secondary title Department of War, DOW. Congress initiated the BCRP in FY92 to support innovative, high-impact research, with a mission of ending breast cancer for Service Members and their Families, Veterans, and the general public. Appropriations for the BCRP from FY92 through FY25 totaled \$4.52 billion. The FY26 appropriation is \$145M.

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

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

- Prevent breast cancer (primary prevention)
- Identify determinants of breast cancer initiation, risk, or susceptibility
- Distinguish deadly from non-deadly breast cancers
- Conquer the problems of overdiagnosis and overtreatment
- Identify what drives breast cancer growth; determine how to stop it
- Identify why some breast cancers become metastatic
- Determine why/how breast cancer cells lie dormant for years and then re-emerge; determine how to prevent lethal recurrence
- Revolutionize treatment regimens by replacing them with ones that do all of the following: improve survival, are more effective, and are less toxic
- Eliminate the mortality associated with metastatic breast cancer

#### 3.1. Intent of the Breakthrough Award Level 3

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

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

**This program announcement discusses the FY26 BCRP Breakthrough Award Level 3 (BTA3).**

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**Funding Level 3:** This funding level supports advanced translational studies. Where relevant, the application must demonstrate proof of the availability of, and access to, necessary data, samples, cohort(s), and/or critical reagents for the proposed research. If the project will ultimately require U.S. Food and Drug Administration (FDA) or an equivalent international regulatory agency involvement, the application must demonstrate availability of, and access to, clinical reagents (e.g., therapeutics) and subject population(s). A realistic timeline for near-term clinical research is required. Small-scale clinical trials (e.g., first-in-human, phase 1/1b) are allowed but not required.

### 3.1.1. Key Elements for BTA3

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

**Overarching Challenges:** Considering the current breast cancer landscape and the BCRP's mission, all applications must address at least one of the above [overarching challenges](#) unless adequate justification for exception is provided.<sup>1</sup> Simply identifying an overarching challenge is not sufficient. Applications must address the challenge in a way that can lead to or make a breakthrough and have a major impact. The BCRP strongly urges applicants to read and consider [The Breast Cancer Landscape](#) before preparing their applications.

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

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

**Partnering PI Option:** The BTA3 PPIO encourages applications that include meaningful and productive partnerships between two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be the Partnering PI. Both PIs should contribute significantly to the development and execution of the proposed research project. The PIs may have expertise in

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<sup>1</sup> With adequate justification, applications may identify and address another overarching challenge related to [The Breast Cancer Landscape](#). Investigators must provide justification in the application.

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similar or disparate scientific disciplines, but each PI must bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar levels of effort to the conduct of the project. The application should balance funding between both PIs unless appropriately justified. The PPIO encourages, but does not require, new partnerships. The application should describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the proposed project, and why the work should be done together rather than through separate efforts. *To meet the intent of the PPIO, the BCRP discourages applicants from being named as a Partnering PI on multiple 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

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

[Clinical research](#) including projects involving human data, human anatomical substances, and/or interaction with human subjects, is permitted. [Clinical trials](#) are allowed, but not required, within this funding opportunity.

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

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

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the task force [recommendations](#) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and align with the FY26 BCRP priorities.

## 3.2. Funding Instrument

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

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### 3.3. 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 **\$7.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

#### **Clinical Trial Option Applications:**

For applications that propose a clinical trial, the applicant may request funds 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 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) are contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award. Approval will depend on the availability of future year appropriations. The base award and optional research effort(s) must have severable budgets and statements of work (SOWs). 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 FY26 BCRP Breakthrough Award Level 3.
- If applicable, research subject compensation and reimbursement for study-related out-of-pocket costs (e.g., travel, lodging, parking, costs associated with caregiving, and resources/equipment to enable participation).

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# 4. Application Contents and Format

## 4.1. Application Overview

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

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



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



## 4.2. Pre-Application Components

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

***Upload documents as individual PDF files unless otherwise noted. Files must comply with the [formatting guidelines](#) listed in the GAI.***

- **Preproposal Narrative:** Provide responses in the appropriate data fields for the following:
  - Which BCRP [overarching challenge\(s\)](#) will the proposed research address? If “other,” state the overarching challenge and provide justification within the context of [The Breast Cancer Landscape](#). Simply identifying an overarching challenge is not sufficient. (200-character limit)
  - How will the proposed research lead to a major impact for the overarching challenge(s)? Explain how the research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer. (2,000-character limit)
  - How will the proposed research move beyond a minor advancement? How will the research lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches? (2,000-character limit)
  - Briefly state how the scope of the proposed research is appropriate for [Funding Level 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 FY26 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

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aims, and a brief description of how each pre-application will address distinct research questions.

### 4.3. Full Application Components

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

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

#### 4.3.1. Full Application Components for the PI or Initiating PI

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

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

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

##### (b) Attachments:

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

- **Attachment 1: Project Narrative (18-page limit): Upload as “ProjectNarrative.pdf”.** 

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/Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the specific aims of the study.

**Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas, and present alternative methods and approaches. Applications proposing translational research should 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,

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provide sufficient details for evaluation. If using human subjects or human biological samples, describe the study population and provide a detailed plan for the recruitment of human subjects or the acquisition of samples. Where relevant, describe the accessibility to the data, 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. Describe data reporting procedures and plans to assure that the documentation will support a regulatory filing with the FDA or an equivalent international regulatory agency, if applicable. Consult appropriate [guidelines](#) to ensure that relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

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 program will request a clinical trial protocol.**

- **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 funding from this award would support.

- **Objectives, Specific Aims and Hypothesis:** Describe the purpose and objectives of the study with detailed specific aims and hypotheses.
- **Research Strategy** (include only if the application proposes laboratory research studies, **separate from the clinical trial and associated analyses**): Describe the planned laboratory research studies 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. Provide a well-developed, well-integrated, and detailed research

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plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. 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. Describe the reporting procedures and plans to assure 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. Consult appropriate [guidelines](#) to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.

- **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. Consult appropriate guidelines to ensure relevant aspects of rigorous and reproducible research are adequately planned for and, ultimately, reported.
  - ❖ Identify the intervention the clinical trial will test and describe the projected outcomes.
  - ❖ Define the study variables and describe how the study team will measure them. 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 the trial will enroll. 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. Ensure the application provides sufficient information to allow for a thorough evaluation of statistical calculations during review of the application. Include a power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. Explain any anticipated subgroup analyses and demonstrate that such analyses will be appropriately powered. Ensure the application provides sufficient information to

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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”.** 

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

- **References Cited:** List the references cited in the Project Narrative using a standard reference format (include URLs, if available).
- **List of Abbreviations, Acronyms and Symbols:** Provide a list of abbreviations, acronyms and symbols.
- **Facilities, Existing Equipment and Other Resources:** Describe the facilities and equipment available for performance of the proposed project; include any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference the original or present government award under which the facilities or equipment items are now accountable. There is not a standardized form for this information.
- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- **Letters of Support:** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI’s Department Chair, or appropriate organization official, should also confirm that the PI(s) meet [eligibility criteria](#). If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOW collaborator(s) and/or access to military populations, databases or DOW resources. If applicable, provide a letter of support signed by the VA Facility Director(s), or an individual designated by the VA Facility Director(s), confirming access to VA patients, resources and/or VA research space.
- **Consumer Advocate Letters of Commitment:** Provide a letter signed by each consumer advocate confirming their commitment to participate in the proposed project.
- **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Sex as a Biological Variable (SABV) 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

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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.

- **Research Sharing Plan:** Describe the type of data or research resources to be made publicly available as a result of the proposed work. Describe the mechanism (e.g., direct sharing, repository, mixed mode) by which data and resources generated during the period of performance will be shared with the research community and other affected communities, including clinical research participants. If applicable, include the name of the repository(ies) where scientific data and resources arising from the proposed study will be archived. Identify and provide the rationale for any data or resources that will not be shared (e.g., for intellectual property, feasibility, cost, or other considerations). The plan should also protect participant privacy, confidential and proprietary data, and performer/third-party intellectual property. Provide a milestone plan for disseminating data/results including when data and resources will be made available to other users. In cases where the study participant could potentially derive medical or other benefit from the information, explain whether the results of screening and/or study participation will be shared with the participant or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

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

Refer to the [CDMRP Directive on Sharing Data and Research Resources](#) for more information about the CDMRP's expectations for making data and research resources publicly available.

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

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

- **Background:** Present the scientific rationale behind the proposed research project.
- **Overarching Challenge(s):** State the [overarching challenge\(s\)](#) that the proposed research will test, and briefly state how the project will address the challenge in a way that can lead to or make a breakthrough and have a major impact. Simply identifying an overarching challenge is not sufficient.
- **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Provide evidence or rationale that supports the hypothesis/objective.
- **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.
- **Military Relevance:** Describe how the study is relevant to military health.


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

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

- Clearly describe the scientific rationale, objective and aims of the application.
- Describe the ultimate applicability of the research.
  - Which [overarching challenge\(s\)](#) does this research address?
  - What types of patients or at-risk individuals will it help and how will it help them?
  - What are the potential clinical applications, benefits and risks?
  - What is the projected timeline for achieving a patient-related outcome?
  - How will the proposed project lead to or make a breakthrough in breast cancer and accelerate progress toward the BCRP’s mission of ending breast cancer?
  - How is the proposed research relevant to Service Members, Veterans, and their Families?

- **Attachment 5: Statement of Work (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 guidance on preparing the SOW, 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 is most appropriate for the proposed effort. Include milestones for data or research resource(s) sharing.

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

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

The statement should address the points outlined below written *in a manner that is readily understood by readers without a background in science or medicine*. **DO NOT restate the research strategy as part of the Impact Statement.**

- Articulate concisely how the proposed project will have a major impact on at least one of the [overarching challenges](#).
- Explain how the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.
- Explain briefly how the proposed research will lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
- Identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research. Justify how these individuals would benefit from the project.
- Explain briefly how the proposed research is relevant to Service Members, Veterans, and their Families.

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- **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 efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar levels of effort to the conduct of the project. Explain the plan to balance funding between both PIs or otherwise provide appropriate justification.

- **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 FY26 BCRP Breakthrough Award Level 3 applications. Attachment 8 will be available for the 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 after the award begins that the study team would initiate the anticipated clinical trial, taking into account any required advanced preclinical work.

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### ***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 the study team will perform 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 the clinical trial requires an IND or IDE application and the study team has not submitted it to the FDA, describe plans for IND or IDE application submission, including the timeline for submission. If the product requires an IND or IDE application and the study team has submitted it 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 study team will conduct the clinical trial 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

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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 available on eBRAP. 
- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form (*if applicable*): Upload as “IGBudget.pdf”.** If an [intramural DOW organization](#) will be a collaborator in the performance of the project, complete a separate budget for that organization using the [Suggested Intragovernmental/Intramural Budget](#) form available on eBRAP. 

### (c) Additional Application Materials:

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



Grants.gov



eBRAP.org

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

- **Biographical Sketch**  
*Biographical sketches or equivalent must be submitted for the breast cancer consumer advocates.*
- **Current/Pending Support**  
*Intragovernmental applicants must include their internally supported research and development programs.*

---

#### ii. Research & Related Budget

**Partnering PI Option:** *Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for Partnering PI, or vice versa, even if they are located within the same organization. Refer to [Section 3.3, Funding Details](#), for detailed budget information.*

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#### iii. Project/Performance Site Location(s)

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

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### 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*):

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### (b) Attachments:

- [Attachment 5: Statement of Work \(three-page limit\): Upload as “SOW.pdf”](#). Each PI must submit an identical copy of a jointly created SOW.
- [Attachment 13: Representations \(Grants.gov submissions only\): Upload as “RequiredReps.pdf”](#).
- [Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as “IGBudget.pdf”](#).

### (c) [Additional Application Materials](#):

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



Grants.gov



eBRAP.org

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#### i. Research & Related Senior/Key Person Profile

- **Biographical Sketch**

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

- **Current/Pending Support**

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

---

#### ii. Research & Related Budget

*Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Partnering PI should not include budget information for the Initiating PI, or vice versa, even if they are located within the same organization. Refer to [Section 3.3, Funding Details](#), for detailed budget information.*

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#### iii. Project/Performance Site Location(s)

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

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## 4.4. Other Application Elements

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



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

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# 5. Submission Requirements

## 5.1. Location of Application Package

Download the application package components for HT942526BCRPBTA3 from [Grants.gov](#) or [eBRAP](#), depending on which submission portal will be used.

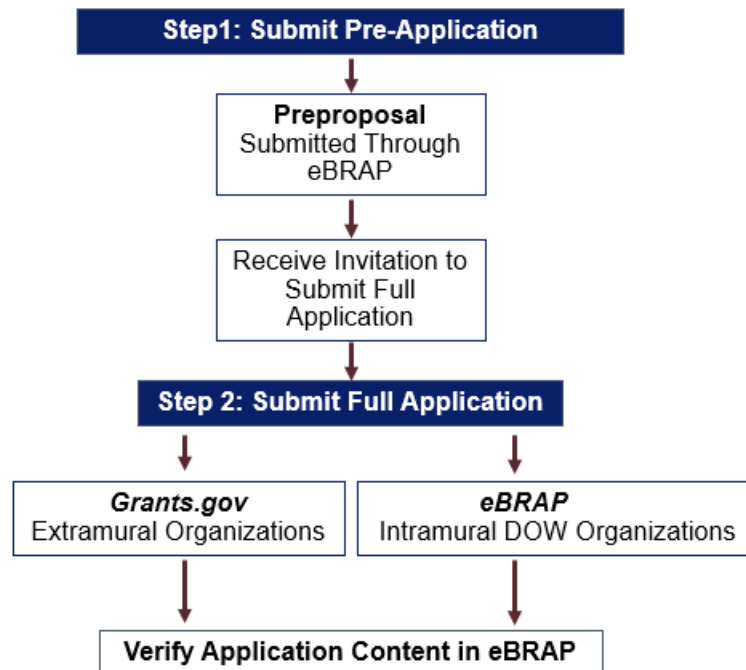
## 5.2. Unique Entity Identifier and System for Award Management

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

## 5.3. Submission Instructions

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


### *Application Submission Workflow*



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### 5.3.1. Pre-Application Submission

All pre-application components must be submitted by the PI or Initiating PI through [eBRAP](#), including the submission of contact information for the Partnering PI if selecting either Partnering PI option. 

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

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


***Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI.*** Partnering PIs are urged to associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

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

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

Application Includes:	Select Mechanism Option:
Single PI 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

### 5.3.2. Full Application Submission


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

**eBRAP Submissions:** Only [intramural DOW organizations](#) may submit full applications through eBRAP. 

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### 5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of the submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log in to eBRAP to review, modify and verify the full application submission.  ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the [application verification period](#) ends. The full application cannot be modified once the application verification period ends.

### 5.4. Submission Dates and Times

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

Submission dates and times are specified in [Section 1, Basic Information](#).

### 5.5. Intergovernmental Review

Not applicable for this funding opportunity.

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# 6. Application Review Information

## 6.1. Application Compliance Review

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

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

Including classified research data within the application and/or proposing research that may produce classified outcomes or outcomes deemed sensitive to national security concerns, may result in application withdrawal.



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

Additional restrictions and associated administrative responses are outlined in [Section 9.2, Administrative Actions](#).

## 6.2. Review Criteria

### 6.2.1. Pre-Application Screening Criteria

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

- Whether the pre-application addresses at least one [overarching challenge](#) that meets the program's goals.
- To what degree the proposed research will lead to a major impact for the overarching challenge.
- To what degree the proposed research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- To what degree the proposed research moves beyond a minor advancement and will lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
- To what degree the scope of the proposed research is appropriate for [Funding Level 3](#) as described in this program announcement.

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### 6.2.2. Peer Review Criteria

#### ***For applications without a clinical trial:***

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

- **Impact**
  - To what degree the proposed project will have a major impact on the [overarching challenge\(s\)](#).
  - To what degree the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.
  - Whether the proposed research will lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
  - To what degree the application justifies how the identified breast cancer patients or at-risk individuals would benefit from the proposed research. Research benefiting a single subtype is considered impactful as long as the impact for that subtype is high.
- **Research Strategy and Feasibility**
  - How well the scientific rationale 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 application develops the hypothesis, objective and specific aims.
  - How well the application develops the experimental design, methods and analyses, and to what degree the design, methods and analyses support completion of the specific aims.
  - How well the application acknowledges potential pitfalls and problem areas, and addresses alternative methods and approaches.
  - How well the application describes an appropriate plan for recruitment of human subjects or acquisition of human biological samples, if applicable; and whether there is documented availability of, and access to, all necessary data, 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 there is an appropriate plan for data reporting and documentation to support a regulatory filing with the FDA or an equivalent international regulatory agency.
  - How well the study is designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
  - If applicable, whether the strategy for the inclusion of women and minorities and the 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.

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- **Statistical Plan**
  - To what degree the application provides an appropriate statistical plan, including power analysis.
- **Post-Award 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 the application names two or more consumer advocates that meet the criteria according to the program announcement.
  - How well the application integrates consumer advocates into the planning, design, implementation and evaluation of the research.
  - To what degree the consumer advocates' knowledge of current breast cancer issues and how their background and/or training in breast cancer research will contribute to the project.
- **Partnership (*only applicable to Partnering PI Option applications*)**
  - How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the proposed work.
  - To what degree the partnership will better address the research question together rather than through separate individual efforts.
  - How well the application reflects both PIs' equal intellectual contribution to the project's design and their similar levels of effort devoted to the conduct of the project.
  - Whether the application proposes balanced funding between both PIs or otherwise includes appropriate justification.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable, including naming a specific repository(ies) where data and research resources will be stored, and providing a feasible plan for access to stakeholders.

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- **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 accessibility 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**
  - To what degree the proposed project will have a major impact on the [overarching challenge\(s\)](#).
  - To what degree the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.
  - Whether the proposed research will lead to a fundamentally new strategy or approach to preventing or ending breast cancer that is significantly more effective than current strategies or approaches.
  - To what degree the application justifies how the identified breast cancer patients or at-risk individuals would benefit from the proposed research. Research benefiting a single subtype is considered impactful as long as the impact for that subtype is high.
- **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 demonstrates 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 the application appropriately identifies potential challenges and alternative strategies in the implementation of the clinical trial.
  - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research.

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- 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.
- **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) is 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 strong preliminary data.
  - How well the application develops the hypothesis, objectives and specific aims.
  - How well the application develops the experimental design, methods, and analyses, and to what degree the design, methods, and analyses support completion of the specific aims.
  - Whether the application demonstrates that the proposed laboratory research studies are clearly linked to the proposed clinical trial.
  - How well the application acknowledges potential pitfalls and problem areas, and how well it addresses alternative methods and approaches.
  - 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.
  - If applicable, whether there is an appropriate plan for data reporting and documentation to support a regulatory filing with the FDA or an equivalent international regulatory agency.
  - How well studies are designed to achieve reproducible and rigorous results, including the choice of model and the endpoints/outcomes to be measured.
- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study objectives.
  - To what degree the sample size projections are adequate to ensure proper power analysis for the study, and as applicable, any subgroup analysis.
- **Post-Award 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.

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- 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 names two or more consumer advocates that meet the criteria according to the program announcement.
  - How well the application integrates consumer advocates into the planning, design, implementation and evaluation of the research.
  - 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 equal intellectual input by both PIs into the design of the project and similar levels of effort devoted to the conduct of the project.
  - Whether the application proposes balanced funding between both PIs or otherwise includes appropriate justification.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Research Sharing Plan**
  - To what extent the plan for sharing of project data and research resources is appropriate and reasonable, including naming a specific repository(ies) where data and research resources will be stored, and providing a feasible plan for access to stakeholders.
- **Environment**
  - To what 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 accessibility 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.

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### 6.2.3. Programmatic Review

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

- Ratings and evaluations of peer reviewers
- Relevance to the priorities of the FY26 BCRP, as evidenced by the following:
  - 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, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in [Section 1, Basic Information about the Funding Opportunity](#). No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

### 6.3.2. Full Application

All applications are evaluated by scientists, clinicians and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are subject to review and approval by a designated official. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section 6.2.3, Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found on the [CDMRP website](#).

Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a [limited time period](#) based on the fiscal year of the funds.

## 6.4. Risk, Integrity and Performance Information

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

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

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

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# 7. Federal Award Notices

For each compliant full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the application receipt and review process for the BCRP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website. After all awards are made, the CDMRP includes individual award information in a searchable [database](#).

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

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

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

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

An organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award.

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# 8. Post-Award Requirements


## 8.1. Administrative and National Policy Requirements


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

The GAI contains information regarding [administrative requirements](#) and [national policy requirements](#).

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

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

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

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

## 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 progress reports, as well as a final technical report will be required. Annual and final technical progress 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.

**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.

**Award Expiration Transition Plan:** An [Award Expiration Transition Plan](#) using the template available on eBRAP, must be submitted with the final progress report.

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to the SAM about certain civil, criminal and

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administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with their performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil and administrative proceedings as specified in the applicable [Representations](#).

### 8.3. Additional Requirements

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.

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# 9. Other Information

## 9.1. Program Announcement Version

Questions related to this program announcement should refer to the program name, the program announcement name and the program announcement version code CD26\_01d.

## 9.2. Administrative Actions

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

### 9.2.1. Rejection

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

- Submission of an application for which a letter of invitation was not issued.
- The Project Narrative is missing.
- The Budget is missing.

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

- Preproposal Narrative is missing.

### 9.2.2. Modification

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

### 9.2.3. Withdrawal

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

- A member of the FY26 BCRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- The application includes the name(s) of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY26, the identities of the peer review contractor and the programmatic review contractor may be found on the [CDMRP website](#).
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- The application from an extramural organization, including non-DOW federal agencies, is received through eBRAP.
- The federal government recipient organization (including an intramural DOW organization):
  - (a) cannot accept and execute the entirety of the requested budget in FY26 funds; and/or
  - (b) cannot coordinate the use of contractual, assistance or other appropriate agreements to provide funds to collaborators.

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- The application fails to conform to this program announcement description.
- The application includes URLs, with the exception of links in the References Cited and Publication and/or Patent sections.
- The application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- The same research project is submitted to different funding opportunities within the same program and funding cycle.
- The application does not address at least one of the [FY26 BCRP Overarching Challenges](#) and did not provide adequate justification for an exception.
- The PI does not meet the [eligibility criteria](#).
- The application fails to include two consumer advocates on the research team as required by this program announcement.
- **Partnering PI Option:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- The invited application proposes a different research project than that described in the pre-application.

### 9.2.4. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the DHACA Grants Officer for a determination of the final disposition of the application.

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## Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
<b>SF424 Research &amp; Related Application for Federal Assistance</b> <i>(Grants.gov submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Summary (Tab 1) and Application Contacts (Tab 2)</b> <i>(eBRAP submissions only)</i>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Attachments</b>		
<a href="#">Project Narrative</a> – Attachment 1, upload as “ProjectNarrative.pdf”	<input type="checkbox"/>	
<a href="#">Supporting Documentation</a> – Attachment 2, upload as “Support.pdf”	<input type="checkbox"/>	
<a href="#">Technical Abstract</a> – Attachment 3, upload as “TechAbs.pdf”	<input type="checkbox"/>	
<a href="#">Lay Abstract</a> – Attachment 4, upload as “LayAbs.pdf”	<input type="checkbox"/>	
<a href="#">Statement of Work</a> – Attachment 5, upload as “SOW.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<a href="#">Impact Statement</a> – Attachment 6, upload as “Impact.pdf”	<input type="checkbox"/>	
<a href="#">Partnership Statement</a> – Attachment 7, upload as “Partnership.pdf”	<input type="checkbox"/>	
<a href="#">Submissions Statement</a> – Attachment 8, upload as “Submissions.pdf”	<input type="checkbox"/>	
<a href="#">Consumer Advocate Statement</a> – Attachment 9, upload as “ConsumerAdvocate.pdf”	<input type="checkbox"/>	
<a href="#">Post-Award Transition Plan</a> – Attachment 10, upload as “Transition.pdf”	<input type="checkbox"/>	
<a href="#">Regulatory Strategy</a> <i>(if applicable)</i> – Attachment 11, upload as “Regulatory.pdf”	<input type="checkbox"/>	
<a href="#">Inclusion of Women and Minorities</a> <i>(if applicable)</i> – Attachment 12, upload as “Inclusion.pdf”	<input type="checkbox"/>	
<a href="#">Representations</a> <i>(Grants.gov submissions only)</i> – Attachment 13, upload as “RequiredReps.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<a href="#">Suggested Intragovernmental/Intramural Budget Form</a> <i>(if applicable)</i> – Attachment 14, upload as “IGBudget.pdf”	<input type="checkbox"/>	<input type="checkbox"/>
<b><a href="#">Additional Application Materials</a></b>		
<b>Research &amp; Related Senior/Key Person Profile (Expanded)</b>	<input type="checkbox"/>	<input type="checkbox"/>
Attach Biographical Sketch for Senior/Key Persons (Biosketch_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>
Attach Current/Pending Support for Senior/Key Persons (Support_LastName.pdf)	<input type="checkbox"/>	<input type="checkbox"/>

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<b>Research &amp; Related Budget</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Project/Performance Site Location(s)</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Research &amp; Related Subaward Budget Attachment(s) (<i>if applicable</i>)</b>	<input type="checkbox"/>	<input type="checkbox"/>

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## Appendix 2. Acronym List

ARRIVE	Animal Research: Reporting of In Vivo Experiments
BCRP	Breast Cancer Research Program
BTA3	Breakthrough Award Level 3
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
DHA	Defense Health Agency
DHA R&D	Defense Health Agency Research and Development
DHACA	Defense Health Agency Contracting Activity
DOD	U.S. Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DOW	U.S. Department of War
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GAI	General Application Instructions
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORRC	Office of Research and Regulatory Compliance
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PPIO	Partnering PI Option
R&D	Research and Development

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RPPR	Research Performance Progress Report
SABV	Sex as a Biological Variable
SAM	System for Award Management
SF424 R&R	Standard Form 424 (Application for Federal Assistance, Research & Related)
SOW	Statement of Work
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USC	United States Code
VA	U.S. Department of Veterans Affairs