I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Breakthrough Award Level 3

Announcement Type: Initial

Funding Opportunity Number: HT942524BCRPBTA3

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 14, 2024
- **Invitation to Submit an Application:** June 14, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, August 6, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, August 9, 2024
- **Peer Review:** October 2024
- **Programmatic Review:** December 2024

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

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

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

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

II.A.1. The Breast Cancer Landscape

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

II.A.2. FY24 BCRP Overarching Challenges

Considering the current *breast cancer landscape* and the BCRP's mission, all FY24 BCRP Breakthrough Award Level 3 applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.* Simply identifying an overarching challenge is not sufficient. Applications must address the challenge in a way that can lead to or make a breakthrough and have a major impact.

- Prevent breast cancer (primary prevention)
- Identify determinants of breast cancer initiation, risk, or susceptibility
- Distinguish deadly from non-deadly breast cancers
- Conquer the problems of overdiagnosis and overtreatment
- Identify what drives breast cancer growth; determine how to stop it
- Identify why some breast cancers become metastatic

- Determine why/how breast cancer cells lie dormant for years and then re-emerge; determine how to prevent lethal recurrence

- Revolutionize treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival

- Eliminate the mortality associated with metastatic breast cancer

*Alternatively, with adequate justification, applications may identify and address another overarching challenge related to the breast cancer landscape. Justification must be provided in the application.

II.B. Award Information

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

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

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

The current program announcement discusses the Breakthrough Award Level 3. Funding Levels 1, 2, and 4 are available under other program announcements (HT942524BCRPBTA12 for Levels 1 and 2 and HT942524BCRPBTA4 for Level 4). The PI is strongly encouraged to review the research scope defined under each funding level as described in the corresponding Breakthrough Award program announcements before submitting the pre-application. An application that does not meet the intent of the funding level selected will not be recommended for funding, even if it might meet the intent of a different funding level.

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

Funding Level 3: Advanced translational studies with a high degree of project readiness. Where relevant, proof of availability of and access to necessary data, human samples, cohort(s), and/or critical reagents must be provided. If the proposed research would ultimately require U.S. Food and Drug Administration (FDA) involvement, applications must demonstrate availability

of, and access to, clinical reagents (e.g., therapeutic molecules) and patient population(s). Applications must state a realistic timeline for near-term clinical investigation. Small-scale clinical trials (e.g., first in human, phase 1/1b) may be appropriate.

Partnering PI Option: The Breakthrough Award encourages applications that include meaningful and productive partnerships between investigators. The Partnering PI Option is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. It is expected that funding will be balanced between both PIs unless appropriately justified. New partnerships are encouraged, but not required. The application is expected to describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. ***To meet the intent of the Partnering PI Option, applicants are discouraged from being named as a Partnering PI on multiple Breakthrough Award Level 3 applications unless they are clearly 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 Partnering PI Option.*** If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PIs, refer to Section II.D.2, Content and Form of the Application Submission.

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

Consumer Advocates: Applications are required to include consumer advocate involvement. The research team must include two or more breast cancer consumer advocates, who will be integral throughout the planning and implementation of the research project. Consumer advocates should be involved in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer, and they should be active in a breast cancer advocacy organization. Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. Their role should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, breast cancer. The consumer advocates

should have a high level of knowledge of current breast cancer issues and the appropriate background and/or training in breast cancer research to contribute to the project.

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

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

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

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

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

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

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

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

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

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

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

The anticipated direct costs budgeted for the entire period of performance for an FY24 BCRP Breakthrough Award Level 3 should not exceed **$4M** for applications with a single PI or **$5M** if applying under the Partnering PI Option. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $13.95M to fund approximately two BCRP Breakthrough Award Level 3 applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer and programmatic review, and the requirements of the government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

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

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

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

Awards are made to eligible ***organizations***, not to individuals.

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

II.C.1.b. Principal Investigator

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

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

Investigators are discouraged from being named on multiple pre-applications unless they are clearly addressing distinct research questions. Invited applications will be required to include a brief description of all the applications in which the PI is named as a PI, Initiating PI, Partnering PI, or collaborator under this Breakthrough Award Level 3 program announcement.

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

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment. Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or full application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

II.D. Application and Submission Information

II.D.1. Location of Application Package

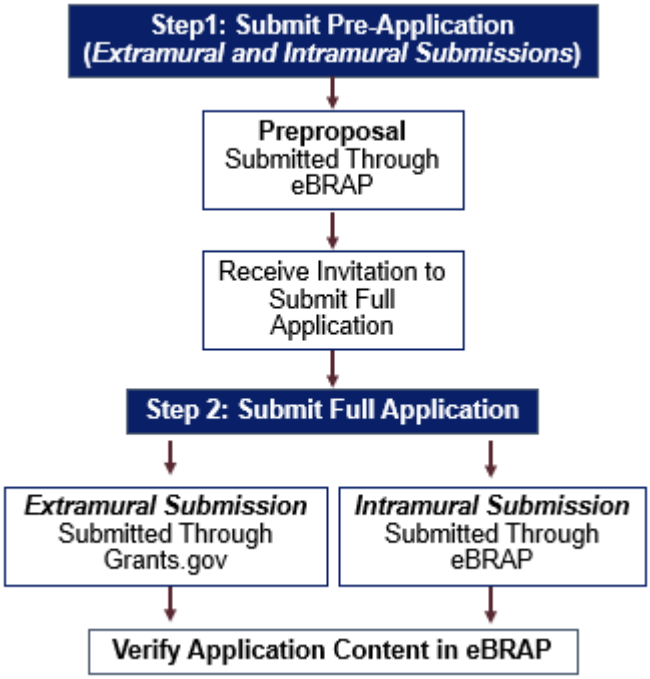
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the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

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

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Application Submission Workflow



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions. Download application package components for HT942524BCRPBTA3 from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524BCRPBTA3 from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

II.D.2. Content and Form of the Application Submission

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

Unnecessary duplication of funding, or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 BCRP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

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

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

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

Application Includes:	Select Option:
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

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

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).

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

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

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for additional information on pre-application submission):

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

- **Preproposal Narrative:** Provide responses in the appropriate data fields for the following:
  - What 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 proposed research lead to a fundamentally new approach that is significantly more effective than interventions already approved or in clinical development? (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 FY24 BCRP Breakthrough Award Level 3 pre-applications in which the PI is named as a PI, Initiating PI, Partnering PI, or collaborator. Include the CDMRP log number, role on the project, project title, specific aims, and a brief description of how each pre-application will address distinct research questions.

II.D.2.a.ii. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the Defense Health Program (DHP) 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 approach that is significantly more effective than interventions already approved or in clinical development.

- To what degree the scope of the proposed research is appropriate for Funding Level 3 as described in this program announcement.

II.D.2.a.iii. Notification of Pre-Application Screening Results

Following the pre-application screening, PIs and Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section I, Overview of 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.

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

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 Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. ***All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

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

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

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

(b) Attachments:

Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 2.

- **Attachment 1: Project Narrative (18-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information that expands the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

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

  - ***Outline for projects without a clinical trial:***

    - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. The application must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept, and, if applicable, efficacy in an in vivo system.

    - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

    - **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.

    - **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Where relevant, describe the accessibility to the data, cohort(s), and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the project. If applicable, describe resources available for the development of sufficient quantities of critical reagents under Good Manufacturing Practice (GMP) guidelines. Address potential pitfalls and problem areas and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable. For clinical research, see Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

- **Statistical Plan:** Describe the statistical plan in detail including power analysis, as appropriate, for the research proposed.

- **Research Team:** Describe how the combined backgrounds and breast cancer-related expertise of the research team will enable successful conduct of the project.

– ***Outline for projects <u>with</u> a clinical trial:***

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

- **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial. Importantly, describe the studies showing proof of concept and efficacy in in vivo system(s) that led to the current proposed work. Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant ongoing or recently completed clinical trials. 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.

  If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that would be supported with funds from this award.

- **Objectives/Specific Aims/Hypothesis:** Provide a description of the purpose and objectives of the study with detailed specific aims and hypotheses.

- **Research Strategy (include only if laboratory research studies are proposed as a component of the application):** Describe the laboratory research studies that will be performed under this award and how they are ***clearly linked*** to the clinical trial. Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Where relevant, describe the availability of, and access to, necessary data and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the proposed research. If applicable, describe resources available for the development of sufficient quantities of critical reagents under GMP. Provide a well-developed, well-integrated research strategy that supports the feasibility of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Clinical Trial:** Provide detailed plans for initiating, conducting, and completing the clinical trial during the period of performance. As appropriate, outline a plan for obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other FDA approvals). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

  - Identify the intervention to be tested and describe the projected outcomes.

  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.

  - Describe the availability of, and access to, critical reagents (e.g., therapeutic molecules) necessary for the clinical trial.

  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of, and access to, sufficient subjects to meet accrual goals for the clinical trial.

  - ***Inclusion of Women and Minorities in Study.*** Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. See Attachment 12 for the required strategy for the inclusion of women and minorities appropriate to the objectives of the study.

  - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).

- **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.

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

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. The Supporting

Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

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

- **References Cited:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present government award under which the facilities or equipment items are now accountable. There is no form for this information.

- **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If articles are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the program announcement, such as those from members of Congress, do not impact application review or funding decisions.

- **Letters of Collaboration *(if applicable)*:** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work.

    - Availability of, and access to, quality control for all data, critical reagents (e.g., therapeutic molecules, human samples), and/or cohorts.

    - Availability of, and access to, the appropriate patient population(s).

    - Consumer Advocate Letters of Commitment: Provide a letter signed by each consumer advocate confirming their commitment to participate on the research team.

- Multi-Site Clinical Trial Participating Institution Letters of Commitment (if applicable): If proposing to conduct a multi-site clinical trial, provide a letter of commitment signed by each participating organization confirming its commitment to participate in the clinical trial.

If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

– **Commercial Entity Letters of Commitment *(if applicable)*:** If the proposed study involves the use of a commercially produced investigational drug, device, or biologic, provide a letter of commitment from the commercial entity indicating the availability of the product for the duration of the study, support for the proposed phase of research, and support for the indication to be tested.

– **Intellectual Property:** Information can be found in the 2 CFR 200.315, "Intangible Property."

- **Intellectual and Material Property Plan *(if applicable)*:** Provide a plan for resolving intellectual and material property issues among participating organizations.

– **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content.

– **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly available.

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

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

– **Background:** The ideas and reasoning behind the proposed work.

- **Overarching Challenge(s):** State the overarching challenge(s) that will be addressed and briefly state how the project will address the challenge in a way that can lead to or make a breakthrough and have a major impact. Simply identifying an overarching challenge is not sufficient.

- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- **Specific Aims:** State the specific aims of the study.

- **Study Design:** Briefly describe the study design, including appropriate controls.

- **Impact:** Briefly describe how the proposed project will lead to a major impact for the overarching challenge(s). Explain how the research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.

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

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

  - Clearly describe the rationale, objective, and aims of the application.

  - Describe the ultimate applicability of the research.

    - Which overarching challenge(s) does this research address?

    - What types of patients or at-risk individuals will it help and how will it help them?

    - What are the potential clinical applications, benefits, and risks?

    - What is the projected time it may take to achieve a patient-related outcome?

    - How will the proposed project lead to or make a breakthrough in breast cancer and accelerate progress toward the BCRP's mission of ending breast cancer?

- **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 the eBRAP "Funding Opportunities & Forms" web page

(https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

For the Breakthrough Award Level 3 mechanism, refer to either the "Example: Assembling a Clinical Research and/or Clinical Trial Statement of Work" or "Example: Assembling a Generic Statement of Work", whichever example is most appropriate for the proposed effort, for guidance on preparing the SOW. Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

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

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

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

  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 approach that is significantly more effective than interventions already approved or in clinical development.
  - Identify the breast cancer patients or at-risk individuals and justify how they would benefit from the proposed research.

- **Attachment 7: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.)*** Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain how funding will be balanced between both PIs or otherwise provide appropriate justification.

- **Attachment 8: Submissions Statement (one-page limit): Upload as "Submissions.pdf".** ***(Attachment 8 is only applicable and required for applications in which the PI, Initiating PI, or Partnering PI is named in multiple FY24 BCRP Breakthrough Award Level 3 applications. Attachment 8 will be available for programmatic review only.)***

  Provide the following information for each individual named as a PI, Initiating PI, Partnering PI, or collaborator in multiple Breakthrough Award Level 3 applications:

  - CDMRP log number, funding level, role on the project, project title, and specific aims.

  - 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 Consumer Advocate Statement should be written by the PI or Initiating PI. 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: 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, and/or delivery to the commercial market 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 investigation. 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".**

  Describe the regulatory strategy using the following outline and provide supporting documentation as applicable.

  - State the product/intervention name.

  - State how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work (e.g., GMP production, pharmacokinetics, and toxicity testing) and/or clinical trial preparation (Institutional Review Board [IRB] and DOD Office of Human and Animal Research Oversight (OHARO) approval).

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

- Provide evidence that the clinical trial does not require regulation by a Regulatory Agency. No further information for this attachment is required.

For products/interventions that require regulation by the FDA or an international regulatory agency:

- 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 for the route of administration, dosage level, and/or subject population. Indicate whether the proposed research involves a change that increases the risks associated with using the product. State whether the product is being promoted for an off-label use (where promotion involves the sale of a marketed product).

- If the product is not currently FDA-approved, -licensed, or -cleared, state the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification. Identify the regulatory sponsor.

- If an IND or IDE is required and the application has not been submitted to the FDA, describe plans for IND or IDE application submission including when it will be submitted. If an IND or IDE is required and the application has already been submitted to the FDA, provide the date of submission, the application number, and a copy of the FDA letter acknowledging the submission. Provide an explanation of 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 the clinical trial will be conducted at international sites, provide equivalent information and supporting documentation relevant to the product indication/label and regulatory approval and/or filings in the host country(ies).

- Provide the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), nonclinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support phase 1 testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- Describe the overall regulatory strategy and product development plan that will support the planned product indication/label. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types

of FDA meetings that will be held/planned. Include considerations for compliance with current GMP, GLP, and Good Clinical Practice guidelines.

- **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/gender, race, and ethnicity, 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, which is a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **Attachment 13: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 8, Section B, Representations.

- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

  - Include biographical sketches for team members, including consumer advocates.

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

Partnering PI Option: 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 the Partnering PI even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete the separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

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

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

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

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit for applications without a clinical trial or a six-page limit for applications with a clinical trial): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 13: Representations *(Extramural Submissions Only)*: Upload as "RequiredReps.pdf".**

- **Attachment 14: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

- **Key Personnel Biographical Sketches (five-page limit each):** Upload as "Biosketch_LastName.pdf".

  - Include biographical sketches for team members, including consumer advocates.

- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

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

  - ***The initiating and Partnering PI must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are***

located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.
- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 14.

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

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

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

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

II.D.4. Submission Dates and Times

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

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity.

II.D.5. Funding Restrictions

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

Funding Level 3 (single PI):

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

The application's direct costs budgeted for the entire period of performance should not exceed **$4M**. 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.

Clinical Trials

For applications that propose a clinical trial, funds may be requested for the full proposed period of performance (up to **4** years) to cover:

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

The approval of optional research effort(s) will be contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award. Approval may be dependent on the availability of future year appropriations. The budget and SOW for the base award and the optional research effort(s) must be severable. Additionally, the option research effort period(s), if funded, are to be conducted within the maximum period of performance (up to 4 years).

Funding Level 3 with Partnering PI Option:

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

The application's combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate.

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

The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

Clinical Trials

For applications that propose a clinical trial, funds may be requested for the full proposed period of performance (up to **4** years) to cover:

- Advanced preclinical work (e.g., GMP production, pharmacokinetics and toxicity testing) and/or clinical trial preparation (e.g., IND approval, IRB and DOD 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 the optional research effort(s) will be contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award. Approval may be dependent on the availability of future year appropriations. The budget and SOW for the base award and optional research effort(s) must be severable. Additionally, the option research effort period(s), if funded, are to be conducted within the maximum period of performance (up to 4 years).

For Both Funding Level 3 Options:

All direct and indirect costs of any subaward or contract must be included in the total 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 **4** years.

For this award mechanism, direct costs may be requested for:

- Travel in support of multidisciplinary collaborations.

- Costs for three investigators to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 BCRP Breakthrough Award Level 3.

II.D.6. Other Submission Requirements

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

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

For applications <u>without</u> a clinical trial:

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

- **Impact**

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

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

- **Research Strategy and Feasibility**

  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.
  - How well the hypothesis, objectives, and specific aims are developed.
  - How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
  - Whether there is documented availability of, access to, and quality control for all data, cohort(s), and/or critical reagents, where relevant.
  - If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
  - If applicable, whether there are resources available for the development of sufficient quantities of critical reagents under GMP.
  - If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
  - How well the application acknowledges potential pitfalls and problem areas and addresses alternative methods and approaches.
  - How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.

- **Statistical Plan**
    - To what degree an appropriate statistical plan is provided, including power analysis.
- **Transition Plan**
    - To what degree the application's timeline for near-term clinical investigation is realistic and appropriate.
    - To what degree the application demonstrates feasible methods and strategies to move the project's finding to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.
    - Whether the application has an appropriate plan to distribute the findings or intervention to the breast cancer community.
- **Personnel**
    - Whether the application includes an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
    - Whether the levels of effort are appropriate for successful conduct of the proposed work.
    - Whether two or more consumer advocates are named in the application and meet the criteria according to the program announcement.
    - How well consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
    - To what degree the consumer advocates' knowledge of current breast cancer issues and how their background and/or training in breast cancer research will contribute to the project.
- **Partnership** ***(only applicable to Partnering PI Option applications)***
    - How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the SOW.
    - To what degree the partnership will better address the research question together rather than through separate individual efforts.
    - How well the application reflects equal intellectual input by both PIs into the design of the project and similar and appropriate levels of effort devoted to the conduct of the project.
    - Whether funding will be balanced between both PIs or is otherwise appropriately justified.

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

- **Environment**
    - Whether the scientific environment is appropriate for the proposed research.
    - How well the research requirements are supported by the availability of, and access to, facilities and resources (including collaborative arrangements).
    - Whether the quality and extent of institutional support are appropriate for the proposed research.
    - If applicable, to what degree the intellectual and material property plan is appropriate.
- **Budget**
    - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
    - Whether the budget is appropriate for the proposed research and funding level.
- **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.

For applications <u>with</u> a clinical trial:

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

- **Impact**

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

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

- **Clinical Trial**
    - Whether the type of clinical trial (e.g., prospective, randomized, controlled) to be performed is appropriate to meet the project's objectives.
    - 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, the appropriate patient population(s), as well as the ability to recruit a sufficient number of subjects.
    - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
    - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approval), if appropriate.
    - Whether potential challenges and alternative strategies are appropriately identified.
    - To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.
- **Regulatory Strategy**
    - Whether the application states the product/intervention to be used.
    - Whether the application includes documentation that the study is exempt from FDA or other international agency regulation, or whether plans for IND or IDE application (and/or other international equivalent) to the FDA or other international regulatory agency are reasonable and appropriate.
    - For investigator-sponsored regulatory exemptions (e.g., IND, IDE, or other international equivalent), whether there is evidence of appropriate institutional support.
    - How well the application describes the current status for manufacturing development, non-clinical development, and clinical development.
    - To what degree the regulatory strategy and development plan to support the product indication/label are appropriate and well described.
- **Research Strategy and Feasibility** ***(applicable only to applications that include laboratory research studies)***
    - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, relevant, ongoing or recently completed clinical trials, logical reasoning, and preliminary data.
    - How well the hypothesis, objectives, and specific aims are developed.

- How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
- How well the application acknowledges potential pitfalls and addresses alternative approaches.
- Whether there is documented availability of, access to, and quality control for all data and/or critical reagents, where relevant.
- Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.
- Whether the proposed laboratory research studies are clearly linked to the proposed clinical trial.
- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.

- **Statistical Plan**
  - To what degree an appropriate statistical model and data analysis plan is provided, including a complete power analysis.
  - Whether the clinical trial is designed with enough statistical power to demonstrate that the sample size is appropriate to meet the objectives of the study.
- **Transition Plan**
  - To what degree the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.
  - Whether the application has an appropriate plan to distribute the findings or intervention to the breast cancer community.
- **Personnel**
  - Whether the application includes an appropriate and robust research/clinical team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
  - Whether the levels of effort are appropriate for successful conduct of the proposed work.
  - Whether two or more consumer advocates are named in the application and meet the criteria according to the program announcement.

- To what degree consumer advocates are integrated 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 SOW.

  - To what degree the partnership will better address the research question together rather than through separate individual efforts.

  - How well the application reflects that equal intellectual input by both PIs into the design of the project and similar and appropriate levels of effort devoted to the conduct of the project.

  - Whether funding will be balanced between both PIs or is otherwise appropriately justified.

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

- **Environment**

  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).

  - Whether there is evidence for appropriate institutional commitment from each participating institution.

  - If applicable, whether the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.

- **Budget**

  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.

  - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

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

- Ratings and evaluations of the peer reviewers
- Relevance to the priorities of the DHP and FY24 BCRP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact

II.E.2. Application Review and Selection Process

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

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring that application and evaluation information will not be disclosed outside the review panel. Violations of confidentiality can result in the dissolution of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to a third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.1, over the period of performance, the

federal awarding agency is required to review and consider any information about the applicant that is available in SAM.

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

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

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

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

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

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

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

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

the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

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

II.F.2. PI Changes and Award Transfers

Changes in PI, Initiating PI, or Partnering PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis.

An organizational transfer of an award supporting a PI, Initiating PI, or Partnering PI is discouraged and will be evaluated on a case-by-case basis.

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

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

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

II.F.3. Administrative and National Policy Requirements

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

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

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

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

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC OHARO, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in 32 CFR 219. Funded studies are required to register the study in the National Institutes of Health clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

II.F.4. Reporting

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

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

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

Awards resulting from this program announcement may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10M are required to provide information to SAM about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a federal award. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

Phone: 800-518-4726; International 1-606-545-5035

Email: support@grants.gov

II.H. Other Information

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

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

II.H.2. Administrative Actions

After receipt of pre-applications or applications, the following administrative actions may occur.

II.H.2.a. Rejection

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

- Preproposal Narrative is missing.

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

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

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

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

- An FY24 BCRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including letters of support/recommendation. ***A list of the FY24 BCRP Programmatic Panel members can be found at https://cdmrp.health.mil/bcrp/panels/panels24***.

- The application fails to conform to this program announcement description.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess).

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.

- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP.

- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.

- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.

- The invited application proposes a different research project than that described in the pre-application.

- Submission of the same research project to different funding opportunities within the same program and funding cycle.

- The application does not address at least one of the FY24 BCRP Overarching Challenges and adequate justification for exception was not provided.

- **Partnering PI Option:** Failure to submit all associated (Initiating PI and Partnering PI) applications by the deadline.

- Application fails to include two consumer advocates on the research team as required by this program announcement.

II.H.2.d. Withhold

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

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	☐
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Partnership Statement – Attachment 7, upload as "Partnership.pdf" if applicable	☐	
Submissions Statement – Attachment 8, upload as "Submissions.pdf" if applicable	☐	
Consumer Advocate Statement – Attachment 9, upload as "ConsumerAdvocate.pdf"	☐	
Transition Plan – Attachment 10, upload as "Transition.pdf" if applicable	☐	
Regulatory Strategy – Attachment 11, upload as "Regulatory.pdf"	☐	
Inclusion of Women and Minorities – Attachment 12, upload as "Inclusion.pdf"	☐	
Representations *(Extramural submissions only)* – Attachment 13, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 14, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐

Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐
Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

BCRP	Breast Cancer Research Program
BTA12	Breakthrough Award – Funding Levels 1 and 2
BTA3	Breakthrough Award – Funding Level 3
BTA4	Breakthrough Award – Funding Level 4
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHP	Defense Health Program
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code