

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

Transformative Breast Cancer Consortium Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-BCRP-TBCCA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 24, 2020
- **Invitation to Submit an Application:** July 29, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, October 6, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, October 8, 2020
- **Peer Review:** December 2020
- **Programmatic Review, Stage 1:** January 2021
- **Invitation for Oral Presentation:** February 2021
- **Programmatic Review, Stage 2:** March 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. 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

Applications to the Fiscal Year 2020 (FY20) Breast Cancer Research Program (BCRP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement is the Congressionally Directed Medical Research Programs (CDMRP). The BCRP was initiated in FY92 to support innovative, high-impact research, with a mission of ending breast cancer for Service members, Veterans, and the general public. Appropriations for the BCRP from FY92 through FY19 totaled \$3.56 billion. The FY20 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.army.mil/bcrp/pdfs/Breast%20Cancer%20Landscape.pdf>.

II.A.2. FY20 Overarching Challenges

Considering the current [breast cancer landscape](#) and the BCRP's mission, all FY20 BCRP Transformative Breast Cancer Consortium Award applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.*

- 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 that will fundamentally transform and disrupt the present breast cancer landscape. Justification must be provided in the application.

II.B. Award Information

The Transformative Breast Cancer Consortium Award is designed to support collaborations and ideas that will transform the lives of individuals with, and/or at risk for, breast cancer and will significantly accelerate progress toward ending breast cancer. Applicants must bring together different perspectives to develop new paradigms that will solve fundamental yet overarching problems in breast cancer. This award requires a team-based approach by a consortium of exceptional researchers and advocates, whose collaborative efforts will make a transformative impact in breast cancer. The transformation intended by the consortium must be in people's lives, and not in the healthcare or research system.

The consortium should have at least four, but no more than five, teams investigating different projects under a central hypothesis. No more than two teams may be based at one institution. Each team's work must be integrated within the consortium so that every component is working toward the consortium's central hypothesis. *Note: This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts, such as the National Cancer Institute (NCI) Specialized Programs of Research Excellence (SPORes), and it should not represent a collection of related Program Project grants or subprojects.*

The proposed consortium's work is expected to be innovative; the Transformative Breast Cancer Consortium Award will include funds for "seed projects" to pursue brand new, high-risk/high-reward concepts during the award period.

If the work proposed meets the criteria or scope of one of the FY20 BCRP Breakthrough Awards (see W81XWH-20-BCRP-BTA12-2 for Levels 1 and 2, W81XWH-20-BCRP-BTA3-2 for Level 3, and W81XWH-20-BCRP-BTA4-2 for Level 4), it is not appropriate for the Transformative Breast Cancer Consortium Award mechanism.

[*The Breast Cancer Landscape*](#) describes the reality of breast cancer and identifies overarching challenges to progress the field. ***Research funded under this award mechanism should result in answers that will fundamentally and significantly transform and disrupt the present landscape.***

Preference will be given to applications that include one or more of the following:

- Different disciplines that come together with one overarching plan to address ending breast cancer with an ecologic approach. An ecologic approach is one that brings together the different perspectives that affect the complexity of breast cancer and their interdependence, or looks at all aspects of the disease and brings together these different perspectives.
- Research that includes truly innovative and brand new paradigms in breast cancer that will address vital issues in a unique way. The issues may be one of the FY20 BCRP Overarching Challenges, the intersection of multiple Overarching Challenges, or with justification, may be a different issue that meets the intent of the award mechanism and addresses the mission of ending breast cancer.
- A plan for a deep, definitive dive into one of the FY20 BCRP Overarching Challenges or a fundamental issue that has not yet been asked or answered in a manner that has not yet been attempted.

Although not all inclusive, applications that propose the following as the primary effort(s) or central hypothesis of the consortium will not meet the intent of this award mechanism:

- NCI Program Project or SPORE grants or applications
- Conducting drug screens or testing a “cocktail” of therapeutics
- Targeting a single gene or protein
- Developing a new derivative or formulation of an old drug
- Conducting genomic landscape mapping analyses
- Seeking to improve existing technologies (e.g., mammography or magnetic resonance imaging [MRI] screening)

Synergistic, highly integrated, multidisciplinary, and multi-institutional research teams of leading scientists, clinicians, and consumer advocates must be assembled into a consortium to address a major problem in a way that could not be accomplished by a single investigator or group. While the teams are made up of different groups, each with its own Principal Investigator (PI), the teams must be working on the major problem identified in the Transformative Breast Cancer Consortium Award application and under the leadership of the Consortium Director. The research proposed in Transformative Breast Cancer Consortium Award applications may include Phase I clinical trials and collaborations with pharmaceutical or biotechnology industry scientists and/or companies, as appropriate. However, a clinical trial is not required, and the primary thrust of the application should not be a clinical trial. All applications submitted to the Transformative Breast Cancer Consortium Award must address the following key features:

1. IMPACT

Demonstrate potential to transform or improve the lives of individuals with, and/or at risk for, breast cancer. The time to the final impact may vary, but the outcomes of the effort must be transformative and significantly advance the BCRP’s mission of ending breast cancer. A clear and compelling presentation of how the effort will be transformative for individuals with, and/or at risk for, breast cancer must be provided. Applications proposing research that represents an incremental advance in breast cancer do not meet the intent of this award mechanism.

2. INNOVATION

Pursue innovative, high-risk/high-reward research that has the potential to change existing paradigms, or develop new paradigms. Innovative research may introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities. To support the pursuit of innovative concepts, a portion of the total direct budget costs (no more than 5%) must be reserved in the budget for “seed projects,” i.e., the development of new concepts that emerge during the course of the award. These “seed projects” should enable the research team to explore new avenues of high-risk/high-reward ideas that were not part of the original application, but that develop during the project and are within the scope of the overall vision of the research. Funds for “seed projects” may not be used for equipment or travel.

3. CONSORTIUM TEAM

Integrate a team of preeminent investigators and advocates from appropriate disciplines and institutions. 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. Emphasis must be placed on integrating the most highly qualified investigators and advocates to focus on the research problem, regardless of their location. These investigators must include highly accomplished scientists, clinicians, and promising young investigators in the targeted areas of research who collectively represent the best team to solve the problem(s) identified. The proposed research effort should be broad enough to require a multidisciplinary approach that is reflected in the composition of the research team. ***Inclusion of scientists from nontraditional disciplines is encouraged.***

The award mechanism is structured with a Consortium Director and at least three, but no more than four, Team PIs representing at least two institutions. The Consortium Director is responsible for the day-to-day management of the consortium, as well as for leading one of the teams. The Consortium Director, together with the Team PIs, are jointly responsible for leading and executing the proposed research projects that are integrated into a central hypothesis and will result in answers that will fundamentally and significantly transform and disrupt the present [breast cancer landscape](#). Please see the top of this section, Section II.B, Award Information, for more details.

Incorporate breast cancer consumer advocates into every aspect of the proposed consortium’s activities. Applications are required to include consumer advocate involvement. The consortium team must include at least one breast cancer consumer advocate per team. The consumer advocates are expected to represent the perspective of the patient population(s) that are most

relevant to the consortium's proposed research. Breast cancer consumer advocates must have an active role in every aspect of the proposed consortium's work ***including consortium conception and design***, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. Consumer advocates must be integrated into and play an active role in the leadership and decision-making committees for the consortium at each participating institution. Examples of appropriate integration include membership on the advisory board(s) and steering committee(s), participation in each project/aim team, and attendance at all consortium-related meetings. ***As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer, they should be part of a breast cancer advocacy organization, and their role in the project should be independent of their employment. They cannot be employees of any of the institutions participating in the application. They must have a high level of familiarity and training involving science and current issues in breast cancer research.***

4. IMPLEMENTATION

Provide a strategy for implementation. Projects must demonstrate solid scientific rationale, and applications ***must*** include published and/or preliminary data that support the feasibility of their hypotheses and/or approaches. The application must include a detailed plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the milestones, and explains how these solutions will ultimately be translated to individuals with, and/or at risk for, breast cancer. It is expected that the proposed plan will present an exceptional level of innovation and creativity.

Accelerate research progress through communication. Communication between and among consortium team members is essential to the success of the consortium. Applications must include a strategy for sharing data in real time and using information technologies to facilitate timely and effective communication and cooperation. The communication plan should specify the processes and tools to be used for regular and structured communication, data management, project meeting scheduling, and reviews of research findings, ensuring multidisciplinary authorship of all publications arising from the consortia's work, and other issues of common concern to the consortium and its investigators. The consortium should take full advantage of state-of-the-art communication and data sharing tools in addition to formal and informal meetings. The framework for the communication plan must be part of the application and the individuals who will maintain the data sharing and communications technologies must be identified.

Provide an effective, coordinated administrative management plan that integrates and optimizes the research and collaborations. The Consortium Director is required to commit an appropriate level of time and effort – ***at least 25%*** – to direct and manage an initiative of this magnitude. The Consortium Director must have the scientific ability to oversee large research programs and a proven record of leadership, including experience in the effective use of communication tools and the management of multifaceted and multidisciplinary projects. The administrative management plan must explain how the consortium will be organized and managed. The administrative management plan also must describe procedures and processes that will be used to maximize the resources (e.g., databases, animal models) and products (e.g.,

antibodies) generated by the consortium and how these resources and products will be made available to the scientific community.

Award Structure: The Transformative Breast Cancer Consortium Award is structured to accommodate up to five PIs (the Consortium Director and three or four Team PIs). The Consortium Director will be responsible for the majority of the administrative tasks associated with application submission. The Consortium Director and Team PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Consortium Director and Team PIs, refer to [Section II.D.2, Content and Form of the Application Submission](#).

The PIs and consumer advocates will be required to present an update on progress toward accomplishing research milestones and goals of the consortium and each project at an annual In-Progress Review (IPR) Meeting for the Transformative Breast Cancer Consortium Award. The intent of the IPR Meeting is to assess research progress, address problems, and define future directions. Annual IPR Meetings will be held in the National Capital Region at the conclusion of Year 1 and every subsequent year in the period of performance and will be attended by members of the BCRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer to facilitate oversight and provide feedback to the consortium. Continued funding may be contingent upon the successful completion of specific research milestones and goals. Research milestones from the approved SOW will be determined during the award negotiation process. ***Failure to complete each milestone may result in forfeiture of award funding.***

In addition to IPR Meetings, each consortium must hold bi-annual workshops, which may be held at the PIs' institutions or virtually, to facilitate ongoing communication and exchange of information within the consortium, as well as with advisory board(s) and/or steering committee(s).

A Congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the 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 FY20 BCRP priorities.

The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.

The types of awards made under the Program Announcement will be assistance agreements. An assistance agreement is appropriate when the Federal Government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of

a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY20 BCRP Transformative Breast Cancer Consortium Award will not exceed **\$20M**. Refer to [Section II.D.5, Funding Restrictions](#), for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately \$32M to fund one Transformative Breast Cancer Consortium Award application. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific 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 FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Clinical trials (e.g., up to and including Phase I or equivalent) are allowed. A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of

the interventions on biomedical or behavioral health-related outcomes. 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 Code of Federal Regulations, Title 32, Part 219 (32 CFR 219).

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. ***Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Application Instructions, Appendix 1, for additional information.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. ***Intramural Submission: Application submitted by a DoD organization for an intramural investigator working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.***

USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels (or equivalent) are eligible to be named as a Consortium Director or Team PI on an application.

The Consortium Director is required to commit and maintain at least 25% level of time and effort during the award period to direct and manage the consortium.

An investigator may be named as Consortium Director on only one pre-application.

There are no limits on the number of pre-applications for which an investigator may be named as a Team PI for this Transformative Breast Cancer Consortium Award.

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

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at <https://orcid.org/>.

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 in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to [Section II.H.2, Administrative Actions](#), for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

II.D. Application and Submission Information

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same FY20 BCRP funding cycle is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submission:

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org.

Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.

II.D.1. Address to Request Application Package

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in [Section II.G, Federal Awarding Agency Contacts](#).

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

Submission is a two-step process requiring both *pre-application* (eBRAP.org) and *full application* (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to [Table 1. Full Application Guidelines](#)).

The application title, eBRAP log number, 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 CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Team PIs: The Consortium Director must complete the pre-application submission process and submit the contact information for each Team PI. Each Team PI will then be notified of the pre-application submission separately by email. *Each Team PI must follow the link in the notification email in order to associate their full application package with that of the Consortium Director. After following the link, each Team PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.* If not previously registered, the Team PIs must register in eBRAP. A new pre-application should not be initiated by the Team PIs. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Team PIs will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Team PI's required full application package components to eBRAP.

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

During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required during the full application submission process.

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-application components must be submitted by the Consortium Director through eBRAP (<https://eBRAP.org>). Because the invitation to submit an 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.

The applicant organizations and associated PIs identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

PIs with an ORCID identifier should enter that information in the appropriate field in the “My Profile” tab in the “Account Information” section of eBRAP.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

Submission of application information includes assignment of primary and secondary research classification codes, which may be found at <https://eBRAP.org/eBRAP/public/Program.htm>. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

Enter contact information for the Consortium Director. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 Research & Related Form). The Business Official must be either selected from the eBRAP list or invited in order for the pre-application to be submitted.

Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 Research & Related Form), and click on “Add Organizations to this Pre-application.” The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.

It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

Enter the name, organization, and role of all collaborators and key personnel associated with the application.

[FY20 BCRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to [Section II.H.2.c, Withdrawal](#), or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

The Consortium Director must enter the contact information for each Team PI.

The Consortium Director must enter the name of at least one consumer advocate for each team and indicate the consumer advocate's role in the drop-down list.

- **Tab 4 – Conflicts of Interest**

List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

- **Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit 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 that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should address the following:

- How will the proposed research fundamentally and significantly transform and disrupt the present [breast cancer landscape](#)?
- How does the consortium bring different disciplines together with one overarching plan to address breast cancer with an ecologic approach?
- How will the proposed research be innovative and introduce brand new paradigms in breast cancer?
- How will a deep, *definitive* dive into one of the FY20 BCRP Overarching Challenge(s) or other fundamental issue(s) be asked, answered, or addressed by the consortium in a manner that has not yet been attempted? Explain how and/or why this fundamental issue has not yet been asked or answered.

- How will the proposed research make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer? How will the outcomes of the proposed research significantly accelerate progress toward ending breast cancer?
- What is the overall organization of key personnel, including consumer advocates, and what will be each team member’s role in the consortium? How will the consortium team be integrated to address an overarching problem in breast cancer in a way that could not be accomplished by a single investigator or group?
- **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:
 - References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
 - One page for additional information that the PI can use, at their discretion, to provide supporting data or rationale for the pre-application.
 - Key Personnel Biographical Sketches (five-page limit per individual). *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

This tab must be completed for the pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Application Screening Criteria**

Pre-applications will be reviewed by the [BCRP Programmatic Panel](#), a group composed of scientists, clinicians, and consumers. PIs whose pre-applications meet the intent of the award mechanism will be invited to submit applications. To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the BCRP, pre-applications will be screened based on the following criteria:

- To what degree the proposed research will fundamentally and significantly transform and disrupt the present [breast cancer landscape](#).
- To what degree the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach.

- To what degree the proposed research is innovative and introduces brand new paradigms in breast cancer.
 - Whether the pre-application proposes a deep, *definitive* dive into one of the FY20 BCRP Overarching Challenge(s) or other fundamental issue(s) to be asked, answered, or addressed by the consortium in a manner that has not yet been asked or answered.
 - To what degree the proposed research will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer.
 - Whether the proposed research will significantly accelerate progress toward ending breast cancer.
 - To what degree the consortium team is integrated to address an overarching problem in breast cancer in a way that could not be accomplished by a single investigator or group.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, the Consortium Director will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated in [Section I, Overview of the Funding Opportunity](#). Invitations to submit a full application are based on the Pre-Application Screening Criteria listed above.

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

Applications will not be accepted unless notification of invitation has been received by the Consortium Director.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (<https://www.grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Application Guidelines

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should

be used by each person. Check the version number of the Adobe software on each user’s computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

Do not password protect any files of the application package, including the Project Narrative.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-20-BCRP-TBCCA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission.	Download application package components for W81XWH-20-BCRP-TBCCA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.	<p>Tab 1 – Summary: Provide a summary of the application information.</p> <p>Tab 2 – Application Contacts: This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.</p>
<p>Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(s) Form • Additional Application Component(s) 	<p>Tab 3 – Full Application Files: Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:</p> <ul style="list-style-type: none"> • Attachments • Key Personnel • Budget • Performance Sites • Other <p>Tab 4 – Application and Budget Data: Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form.</p>

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
<p>Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p>Submit a Grants.gov Workspace Package. An application may be submitted through Workspace by clicking the “Sign and Submit” button on the “Manage Workspace” page, under the “Forms” tab. Grants.gov recommends submission of the application package at least 24-48 hours prior to the close date to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p>Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>	<p>Submit package components to eBRAP (https://ebrap.org).</p> <p>Tab 5 – Submit/Request Approval Full Application: After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. <i>Do not password protect any files of the application package, including the Project Narrative.</i></p>
<u>Application Verification Period</u>	
<p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i></p>	<p>After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PIs will receive email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package may be modified <i>with the exception of the Project Narrative and Research & Related Budget Form.</i> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p>

Extramural Submissions	Intramural DoD Submissions
Further Information	
<p>Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the “Confirmation” page that is generated after submission.</p> <p>Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.</p>	<p>Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.</p>

The CDMRP requires separate full application package submissions for the Consortium Director and each Team PI, even if more than one of the PIs is located within the same organization. The Consortium Director and Team PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Consortium Director and each Team PI’s) must be submitted by the full application submission deadline.*

The full application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

Application Components for the Consortium Director

II.D.2.b.ii. Full Application Submission Components

- **Extramural Applications Only**

SF424 Research & Related Application for Federal Assistance Form: Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications**

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 4.

For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or have incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB, and the file size for the entire full application

package may not exceed 200 MB. *It is important to include the attachment name as a header on each page of the attachment files.*

- **Attachment 1: Project Narrative (40-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 that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed consortium in detail using the outline below.

- **Overarching Challenge:** State explicitly which overarching challenge(s) in breast cancer the proposed research will address. Describe how a deep, *definitive* dive into the overarching challenge or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will fundamentally and significantly transform and disrupt the current *breast cancer landscape*.
- **Central Hypothesis:** State the consortium’s central hypothesis to be tested.
- **Projects and Objectives:** Briefly explain the consortium’s proposed projects that will each be led by the Consortium Director and Team PIs and explain the objective(s) to be reached by each project. Explain how the projects will support the consortium’s central hypothesis.

For each proposed project, provide the following details using this outline. Start each project on a separate page:

- **Title:** Provide a title for each project.
- **Project Leader:** Identify the project leader (either the Consortium Director or one of the Team PIs) and any key personnel, as appropriate.
- **Background:** Describe in detail the rationale for the study and reasoning on which the proposed research is based. Provide sufficient preliminary data to support the feasibility of the work proposed. The application must demonstrate logical reasoning and provide a sound scientific rationale 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/Objective:** State the hypothesis to be tested and/or the objective(s) 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). 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 supported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable.

- **Clinical Strategy (if applicable):** *Only small-scale (e.g., up to and including Phase I or equivalent) clinical trials are allowed.* Provide detailed plans for initiating and conducting the clinical trial during the course of the award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other FDA approvals). If an IND or IDE is required, the IND/IDE application must be submitted to the FDA within 12 months of the award start date. Describe the type of clinical trial to be performed (e.g., treatment, prevention, diagnostic), the phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover). Provide preclinical and/or clinical evidence to support the safety of the intervention.
 - Provide a description of the clinical trial design, including all study variables, controls, and end points that will be used and/or assessed.
 - Identify the intervention to be tested and describe the projected outcomes. Describe how the proposed intervention compares with currently available interventions and/or standards of care. 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 appropriate).
 - Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from who the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team has access to the proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress.

- List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide justification for exclusions.

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. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- Describe the process for obtaining informed consent and any screening procedures required to determine eligibility for study participation.
 - Define each arm/study group of the proposed trial, if applicable. Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures). Explain the specific action to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). If multiple site studies are involved, state the approximate number of subjects to be enrolled at each site.
 - Outline the timing and procedures planned during the follow-up period. Estimate the potential for subject loss to follow-up, and how such loss will be handled/mitigated.
 - Provide evidence to document the availability of, and access to, all critical reagents, including the intervention itself, if applicable, for the duration of the proposed trial.
 - Provide a description of the clinical trial design, including all study variables, controls, and end points that will be used and/or assessed.
 - Describe how quality control will be addressed. Describe how compliance with current Good Laboratory Practice (GLP), GMP, and Good Clinical Practice (GCP) guidelines will be established, monitored, and maintained, as applicable.
 - Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, and statistician) possesses the appropriate expertise in conducting clinical trials.
- **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 applicable. 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.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named “Support.pdf”.** Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. 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 that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **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 projects and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not 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 projects. 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:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.

- Consumer Advocate Letters of Commitment: Provide letters signed by each project’s breast cancer consumer advocate, confirming their commitment to participate on the research team.
- 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 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 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.
- **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. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Use the outline below:

- Background: Present the ideas and reasoning behind the proposed research.
- Overarching Challenge: State the overarching challenge(s) in breast cancer the proposed research will address. Describe how a deep, *definitive* dive into the overarching challenge or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will fundamentally and significantly transform and disrupt the current [*breast cancer landscape*](#).
- Central Hypothesis: State the consortium’s central hypothesis to be tested.
- Projects and Objective: Briefly explain the consortium’s proposed projects that will each be led by the Consortium Director and Team PIs and explain the objective(s) to be reached by each project. Explain how the projects will support the consortium’s central hypothesis.
- Innovation: Briefly describe how the consortium, if successful, will change existing paradigms, or develop new paradigms.
- Impact: Explain how the consortium will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf”.** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted

publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- Clearly describe, in a manner readily understood by lay persons, the rationale, objective, and aims of the application.
 - Do not duplicate the technical abstract.
- Describe the ultimate applicability and impact of the research.
 - What overarching challenge(s) in breast cancer will this research address?
 - How will the consortium change existing paradigms or develop new paradigms?
 - What types of patients will the outcomes of the consortium 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?
 - What is the potential transformative impact of this study on individuals with, and/or at risk for, breast cancer?
- **Attachment 5: Statement of Work (six-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Transformative Breast Cancer Consortium Award mechanism, use the SOW format example titled, “SOW for Collaborative PI projects.” The SOW must be in PDF format prior to attaching.

The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

- Include the name(s) of the key personnel and contact information for each study site/subaward site.
- Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.
- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- Identify cell line(s), animal strain(s), and commercial or organizational source(s) to be used.
- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g. IRB/HRPO; IND and IDE applications) and animal research (IACUC/ACURO).
- The SOW should include a feasibility plan and timeline to conduct the research. The SOW must include specific research milestones, including “seed project” initiation, to be accomplished by the end of each year in the period of performance.

Each PI must submit an identical copy of a jointly created SOW. The contributions of the Consortium Director and each Team PI should be noted for each task.

- **Attachment 6: Impact Statement (250 words or less recommended; one-page limit): Upload as “Impact.pdf”. Do not restate the research strategy as part of the Impact Statement.**
 - Articulate how the proposed consortium’s research, if successful, will be make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer and will significantly advance the BCRP’s mission of ending breast cancer. Applications proposing research that represents an incremental advance in breast cancer do not meet the intent of this award mechanism.
- **Attachment 7: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.**
 - Describe how the proposed consortium’s research will introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities.
 - Outline the innovations and technical solutions that will be implemented to accomplish the research, and explain how these solutions will be translated to individuals with, and/or at risk for, breast cancer.
 - To support the pursuit of innovative ideas, describe the plan for potential “seed projects” that may emerge over the course of the award that will allow the consortium teams to pursue high-risk/high-reward ideas.
- **Attachment 8: Consortium Plan (five-page limit): Upload as “ConsortiumPlan.pdf”.**
 - **Consortium Team and Environment:** Describe how the consortium is composed of an integrated team of preeminent investigators and advocates from appropriate disciplines and institutions. Explain how the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach. Describe how the Consortium Director’s research experience and leadership skills make him/her well-qualified to be the Consortium Director. In addition, describe how each Team PI will bring a different strength and/or expertise

- to the application. Describe how the combined expertise of the Consortium Director, each Team PI, and consumer advocates in the consortium will better address the research question and explain why the work should be done together rather than through separate efforts. Explain how the consumer advocates will represent the perspective of the patient population(s) most relevant to the consortium's proposed work. Include an organizational chart identifying the roles of all team members, including consumer advocates. Describe the research environments and how each of the facilities and resources at all of the institutions will support the research requirements and the projects.
- **Research Management Plan:** Present a detailed research management plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the research goals, and explains how these solutions will be translated to individuals with, and/or at risk for, breast cancer.
 - **Consortium Management Plan:** Present an overall management plan to facilitate group interactions, adherence to regulatory requirements, administrative interactions, and oversight by advisory board(s) and/or steering committee(s). Provide an effective and coordinated administrative management plan that describes how the consortium will be organized and managed, specify the processes and tools to be used for data management, project meeting scheduling, reviews of research findings, authorship of publications arising from the consortium's work, and other issues of common concern to the consortium and its investigators. The administrative management plan must also describe procedures that maximize the use of resources and eliminate unnecessary duplication of efforts.
 - **Communication Plan:** Provide a detailed communication plan that describes how communication between and among consortium team members and their institutions will be accomplished. Provide a strategy for how data will be shared in real time and use information technologies that facilitate timely and effective communication and cooperation among consortium members. Identify the individual(s) who will maintain the data sharing and communications technologies.
 - o **Attachment 9: Consumer Advocate Statement (two-page limit): Upload as "ConsumerAdvocate.pdf".** The Consumer Advocate Statement should be written by the Consortium Director. Provide the name(s) of at least one consumer advocate for each team and their affiliation with a breast cancer advocacy organization(s). Explain how the consumer advocates contributed to the consortium conception and design. Describe the integral roles they will play in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public. Describe how the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the consortium. Explain how the consumer advocates' experience and expertise will be integrated into the research projects and management of the consortium.

- **Attachment 10: Data and Research Resource Sharing Plan (two-page limit): Upload as “Sharing.pdf”.** Describe how data and resources generated during the performance of the proposed research projects will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed projects. Specifically describe a plan to make animal models, tissue samples, and other resources developed as a part of the proposed research projects available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data and/or research resource sharing plan. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 11: Transition Plan and Regulatory Strategy (three-page limit): Upload as “Transition.pdf”.** Provide information on potential methods and strategies to move the consortium’s findings to the next phases of development and/or clinical use following the successful completion of the award. Articulate this information for the overall effort as well as the individual projects. Applicants are encouraged to work with their organization’s Technology Transfer Office (or equivalent) to develop the transition plan. Provide the components listed below, as appropriate:
 - A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be specific and measurable, and should include the intended user.
 - Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care (e.g., specific potential industry partners, specific funding opportunities to be applied for).
 - For Knowledge Products, a description of collaborations and other resources that will be used to provide continuity of development, including proposed development or modification of clinical practice guidelines and recommendations, provider training materials, patient brochures, and other clinical support tools, scientific journal publications, models, simulations, and applications. (A “Knowledge Product” is a non-materiel product that addresses an identified need, topic area, or capability gap; is based on current evidence and research; aims to transition into medical practice, training, tools, or to support materiel solutions [systems to develop, acquire, provide, and sustain medical solutions and capabilities]; and educates or impacts behavior throughout the continuum of care, including primary prevention of negative outcomes.)
 - For knowledge outcomes, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical/patient care or distributed to the breast cancer community.

- Details of the development plan and FDA regulatory strategy that will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines (if applicable). Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.
- A description of collaborations and other resources that will be used to provide continuity of development.
- A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA). If the application does not include a clinical trial, provide a realistic timeline for near-term clinical investigation.
- If applicable, ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government’s ability to access such products or technologies in the future.
- **Attachment 12: Representations, if applicable (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 5, Section B, Representations.
- **Attachment 13: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DoD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page <https://ebrap.org/eBRAP/public/Program.htm>, including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via

eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- PI Biographical Sketch (five-page limit): Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health (NIH) Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.
- 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 all team members, including consumer advocates.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf”.

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”. The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

The Consortium Director and Team 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 Consortium Director should not include budget information for Team PIs even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form (if applicable): Refer to the General Application Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DoD Collaborator(s):** Complete the “Suggested Collaborating DoD Military Facility Budget Format” and upload to Grants.gov attachment form as [Attachment 13](#). (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

Suggested DoD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Team PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using “Suggested Collaborating DoD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]) ([Attachment 13](#)) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

Application Components for each Team PI
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Each Team PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Consortium Director.

For each Team PI, the Consortium Director must identify if each Team PI will be named on an extramural or intramural application (in accordance with the guidelines in [Section II.C.1.a, Organization](#)) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). Each Team PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for each Team PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

Attachments:

- **Attachment 5: Statement of Work (six-page limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on

completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Consortium Director and each Team PI should be noted for each task.

- **Attachment 12: 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 5, Section B, Representations.
- **Attachment 13: Suggested Collaborating DoD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

Research & Related Personal Data: For extramural submissions (via Grants.gov) refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf”. The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- **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 all team members, including consumer advocates.
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf”.

Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as “BudgetJustification.pdf”.

The Consortium Director and Team PIs 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 each Team PI should not include budget information for the Consortium Director, even if they are located within the same organization. Refer to [Section II.D.5, Funding Restrictions](#), for detailed information.

Project/Performance Site Location(s) Form: For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.6, and for intramural submissions (via eBRAP), refer to General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

Research & Related Subaward Budget Attachment(s) Form:

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.)
- **Intramural DoD Collaborator(s):** Complete a separate DoD military budget, using Suggested Collaborating DoD Military Facility Budget Format (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]), and upload to Grants.gov attachment form as [Attachment 13](#). (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

Additional Application Component

In addition to the complete application package, Transformative Breast Cancer Consortium Award applications also require the following component:

- **Oral Presentation:** PIs named in Transformative Breast Cancer Consortium Award applications that are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation (see [Section II.E.1.b, Programmatic Review](#)) that will be held in the National Capital Region area and is tentatively scheduled for March 2021.

Each presentation will include a 30-minute talk by the Consortium Director and Team PIs, followed by a 30-minute question-and-answer session with Programmatic Panel members. The following questions will be topics for discussion during the PIs’ talk and the question-and-answer session. PIs who are invited must prepare a presentation consisting of no more than 10 slides that specifically address these questions:

- Without addressing your specific projects, what conceptual or intellectual barriers do you consider the most urgent to overcome in order to end breast cancer?

- How will the consortium’s team-based approach challenge existing paradigms or develop new paradigms that will fundamentally and significantly transform and disrupt the present [breast cancer landscape](#)?
- How will the consortium’s team-based approach make a transformative impact in people’s lives?
- Without addressing the technical/scientific aspects of the projects, how will the consortium create an environment that fosters innovation?

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub-recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Verify the status of the applicant organization’s Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI): Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

II.D.4. Submission Dates and Times

All submission dates and times are indicated in [Section I, Overview of the Funding Opportunity](#). Pre-application and application submissions are required. 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.

Applicant Verification of Full Application Submission in eBRAP

For Both Extramural and Intramural Applicants: eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific Program Announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***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 application submission deadline. The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

Extramural Submission: The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

Intramural DoD Submission: After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PIs will receive email notification of the status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form***, may be modified. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

II.D.5. Funding Restrictions

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

The anticipated combined direct costs budgeted for the entire period of performance for the Consortium Director and each Team PI's applications will not exceed **\$20M** (to include direct costs for "seed projects"). 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. The combined budgeted direct costs approved by the Government will not exceed **\$20M** or use an indirect cost rate exceeding each organization's negotiated rate.

To support the pursuit of innovative ideas, a portion of the total direct costs (no more than 5%) must be reserved in the budget for "seed projects." These "seed projects" should be developed during the project and must be within the scope of the overall vision of the research. Direct costs for these "seed projects" should be allocated into the "other direct cost" category of the Year 1 budget. Funds for "seed projects" may not be used for equipment or travel.

Research milestones to be accomplished by the end of each year in the period of performance must be clearly defined in the consortium SOW and will be finalized during award negotiations. The PIs and consumer advocates will be required to present an update on progress toward

accomplishing research milestones and goals of the consortium and each project at an annual IPR Meeting to be held in the National Capital Region. The intent of the IPR Meeting is to assess research progress, address problems, and define future directions. Annual IPR Meetings will be held at the conclusion of Year 1 and every subsequent year in the period of performance and will be attended by members of the BCRP Programmatic Panel, CDMRP staff, and the USAMRAA Grants Officer.

In addition to IPR Meetings, each consortium must hold bi-annual workshops, which may be held at the PIs' institutions or virtually, to facilitate ongoing communication and exchange of information within the consortium, as well as with advisory board(s) and/or steering committee(s).

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 must be requested for:

- Travel costs for the PIs and consumer advocates to present project information or disseminate project results at bi-annual consortium workshops during the period of performance in Years 1, 2, 3, and 4. For planning purposes, it should be assumed that the meeting will be held at one of the PIs' institutions or virtually. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- Travel costs for the PIs and consumer advocates to attend annual IPR Meetings during the period of performance in Years 1, 2, 3, and 4. For planning purposes, it should be assumed that the meetings will be held in the National Capital Region. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all inclusive):

- Consortium-related meetings, teleconferences, and travel among participating investigators.
- Costs related to identifying and acquiring research resources.
- Computers and general software required to participate in the consortium.
- Other costs associated with planning and developing the consortium collaborations, communications, and resources.

- Costs for two investigators per project to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the BCRP Transformative Breast Cancer Consortium Award.

For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct funds transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. *For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in the General Application Instructions, Section III.A.5.*

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

II.E. Application Review Information

II.E.1. Criteria

II.E.1.a. Peer Review

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

- **Impact**
 - To what degree the proposed consortium's research, if successful, will make a transformative impact on the lives of individuals with, and/or at risk for, breast cancer.
 - To what degree the proposed consortium's research will significantly advance the BCRP's mission of ending breast cancer.
- **Overarching Challenge**
 - Whether the application explicitly states an overarching challenge(s) in breast cancer the proposed research will address.
 - To what degree a deep, definitive dive into the overarching challenge or fundamental issue in breast cancer will ask, answer, or address the issue in a manner that has not yet been attempted and will fundamentally and significantly transform and disrupt the current [*breast cancer landscape*](#).

- **Research Strategy**
 - How well the scientific rationale supports the proposed research and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.
 - How well the central hypothesis, project objectives, specific aims, experimental design, methods, and analyses are developed.
 - Whether there is documented availability of, access to, and quality control for all data, cohort(s), and/or critical reagents, where relevant.
 - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.
 - 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.
- **Statistical Plan**
 - Whether an appropriate statistical plan is provided, including power analysis.
 - If applicable, whether the clinical trial is designed with enough statistical power to meet the objectives of the study.
- **Consortium Team**
 - To what degree the Consortium Director's research experience and leadership skills make him/her well-qualified for the role.
 - To what degree the Team PIs bring different strengths and/or expertise to the application.
 - To what degree the consortium brings different disciplines together with one overarching plan to address breast cancer with an ecologic approach.
 - How the consortium team's background and expertise are appropriate to accomplish the proposed projects.
 - How the consortium team's combined expertise will better address the research question than through separate efforts.
 - How appropriate the levels of effort are for the Consortium Director who must maintain at least 25% level of effort to direct and manage the consortium.
 - To what degree the consumer advocates contributed to the consortium conception and design.

- To what degree the consumer advocates will play an integral role in the planning, design, implementation, evaluation of the research, ongoing discussion, decisions and oversight, program evaluation, and dissemination of information to the public.
- To what degree the consumer advocates' knowledge of current breast cancer issues and their background or training in breast cancer research will contribute to the proposed consortium.
- How well the consumer advocates represent the perspectives of the patient population(s) most relevant to the consortium's proposed work.
- **Consortium Plan**
 - To what degree the consortium's research management plan will accomplish the research goals by identifying critical milestones, innovations and technical solutions, and explains how these solutions will be translated to individuals with, and/or at risk for, breast cancer.
 - To what degree consortium management plan will facilitate group interactions, adherence to regulatory requirements, administrative interactions, and oversight.
 - How well the application describes an effective and coordinated administrative management plan for how the consortium will be organized/managed and will utilize procedures to maximize the use of resources and eliminate unnecessary duplication of efforts.
 - How well the application specifies processes and tools to be used for data management, project meeting scheduling, reviews of research findings, authorship of publications, and other issues of common concern to the consortium and its investigators.
 - How well the application describes a detailed communication plan between and among consortium team members and their institutions.
 - How well the application's strategy for sharing data in real time and using information technologies will facilitate timely and effective communication and cooperation among consortium members.
 - Whether the application identifies the individual(s) who will maintain the data sharing and communication technologies.
- **Transition Plan and Regulatory Strategy**
 - How well the application describes expected outcomes from the proposed research efforts that are specific, measurable, and include the intended user.
 - Whether the application describes a funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market or incorporation into patient care.

- For Knowledge Products, whether a description of collaborations and other resources that will be used to provide continuity of development is provided.
 - For knowledge outcomes, how well the knowledge gained will be further developed, disseminated, and incorporated into clinical/patient care and/or distributed to the breast cancer community.
 - How well the development plan and FDA regulatory strategy will support the planned product indication, to include considerations for compliance with current GMP, GLP, and GCP guidelines (if applicable).
 - Whether the application describes numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.
 - How well the application describes collaborations and other resources that will be used to provide continuity of development.
 - To what degree the application describes a feasible schedule and milestones for bringing outcomes to the next phase of development or near-term clinical investigation.
 - If applicable, how well the application addresses ownership rights and/or access to the intellectual property necessary for the development and/or commercialization of products or technologies supported with this award and the Government's ability to access such products or technologies in the future.
- **Clinical Strategy (only applicable if a clinical trial is proposed)**
 - Whether the type of clinical trial (e.g., treatment, prevention, diagnostic), phase of trial and/or class of device (as appropriate), and the study model (e.g., single group, parallel, crossover) proposed is appropriate to meet the project's objectives.
 - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.
 - Whether the application demonstrates access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
 - How well the application identifies potential barriers to accrual (e.g., slow or low enrollment, poor retention) and unexpected delays and presents adequate mitigation plans to resolve them.
 - How well the inclusion and exclusion criteria are justified and meet the needs of the proposed trial.
 - 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.

- **Innovation**

- To what degree the proposed consortium’s research will introduce a new paradigm, look at existing problems from new perspectives, or exhibits other highly creative qualities.
- How well the application outlines innovations and technical solutions that will be implemented to accomplish the research, and explains how these solutions will be translated to individuals with, and/or at risk for, breast cancer.
- How well the application describes a plan for potential “seed projects” that may emerge over the course of the award to allow pursuit of high-risk/high-reward ideas.

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

- **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.

- **Environment**

- Whether the research 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.

- **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 mission of the DHP and FY20 BCRP, as evidenced by the following:

Stage 1: During the first stage of programmatic review, applications will be selected for Stage 2 using the following equally considered criteria:

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Relative impact
- Relative innovation

Stage 2 (Oral Presentation): During the second stage of programmatic review, the following criteria will be used:

- Understanding of conceptual or intellectual barriers in breast cancer
- Articulation of how the team-based approach for challenging existing paradigms or developing new paradigms that will fundamentally and significantly transform and disrupt the present breast cancer landscape
- Articulation of how the consortium's team-based approach will make a transformative impact in people's lives
- Consortium capability to create an environment that fosters innovation

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, on behalf of the DHA and the OASD(HA). *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.army.mil/about/2tierRevProcess>. An information paper describing

the funding recommendations and review process for the award mechanisms for the BCRP will be provided to the PI and posted on the CDMRP website.

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 panel. Violations of confidentiality can result in the dissolving 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 another 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 200.88, over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

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.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in [Section I, Overview of the Funding Opportunity](#).

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

II.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Awards supported with FY20 funds are anticipated to be made no later than September 30, 2021. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

After email notification of application review results through eBRAP, and if selected for funding, a representative from USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

Pre-Award Costs: An institution of higher education, hospital, or other non-profit 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. Refer to the General Application Instructions, Section III.B.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. 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.**

Federal Government Organizations: Funding made to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

II.F.1.a. PI Changes and Award Transfers

Changes in the Consortium Director or Team PIs are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

An organizational transfer of an award supporting the Consortium Director or Team PIs is discouraged. The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of transfer request will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

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 2, Section B, for general information on organization or PI changes.

II.F.2. 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 2, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

Refer to full text of the latest [DoD R&D General Terms and Conditions](#); the [General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions](#); and the [USAMRAA General Research Terms and Conditions with For-Profit Organizations](#) for further information.

II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Annual progress reports as well as a final progress report will be required. The Consortium Director applicant will be expected to report percentage protected time in Other Special Reporting Requirements section of the annual progress report.

Quarterly progress reports will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template “Award Expiration Transition Plan,” available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) under the “Progress Report Formats” section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

Awards resulting from this Program Announcement will incorporate 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 \$10,000,000 are required to provide information to FAPIIS 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. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to extramural application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

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

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the “Synopsis” page for the Program Announcement or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by 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 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

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.

- More than one pre-application is received in which the same investigator is named as the Consortium Director. Only the first pre-application received will be accepted; additional applications will be administratively rejected.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- All associated (Consortium Director and each Team PI) applications are not submitted by the deadline.

II.H.2.b. Modification

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

II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An [FY20 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. *A list of the FY20 BCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/bcrp/panels/panels20h>.*
- 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.

- 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 may be withdrawn.
- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the current FY20 BCRP funding cycle.
- The invited application proposes a different consortium effort than that described in the pre-application.
- Application fails to name at least one breast cancer consumer advocate per 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. Application Submission Checklist

Application Components	Action	Consortium Director Completed	Team PIs Completed
SF424 Research & Related Application for Federal Assistance (extramural submissions only)	Complete form as instructed		
Summary (Tab 1) and Application Contacts (Tab 2) (intramural submissions only)	Complete tabs as instructed		
Attachments	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf"		
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf"		
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf"		
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf"		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf"		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf"		
	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf"		
	Consortium Plan: Upload as Attachment 8 with file name "ConsortiumPlan.pdf"		
	Consumer Advocate Statement: Upload as Attachment 9 with file name "ConsumerAdvocate.pdf"		
	Data and Research Resource Sharing Plan: Upload as Attachment 10 with file name "Sharing.pdf"		
	Transition Plan and Regulatory Strategy: Upload as Attachment 11 with file name "Transition.pdf"		
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable		

Application Components	Action	Consortium Director Completed	Team PIs Completed
	Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 13 with file name "MFBudget.pdf" if applicable		
Research & Related Personal Data	Complete form as instructed		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget (extramural submissions only)	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget (intramural submissions only)	Complete the Suggested DoD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		
Additional Application Components	Action	Consortium Director Completed	Team PIs Completed
Oral Presentation	Confirm availability to give an oral presentation in the National Capital Region that is tentatively scheduled for March 2021 (if selected for Stage 2)		

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
BCRP	Breast Cancer Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
ET	Eastern Time
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
MRI	Magnetic Resonance Imaging
NCI	National Cancer Institute
NIH	National Institutes of Health
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PI	Principal Investigator
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SOW	Statement of Work
SPORE	Specialized Program of Research Excellence
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