I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Breakthrough Award Level 3

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-BCRP-BTA3

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), March 13, 2020

- **Invitation to Submit an Application:** April 17, 2020

- **Application Submission Deadline:** 11:59 p.m. ET, June 24, 2020

- **End of Application Verification Period:** 5:00 p.m. ET, June 26, 2020

- **Peer Review:** August 2020

- **Programmatic Review:** October 2020

This Program Announcement must be read in conjunction with the General Application Instructions, version 20190530. 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."

TABLE OF CONTENTS

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 $150M.

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 Breakthrough Award Level 3 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 related to the breast cancer landscape. Justification must be provided in the application.

II.B. Award Information

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

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

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

The current Program Announcement discusses the Breakthrough Award Level 3. Funding Levels 1, 2, and 4 are available under other Program Announcements (W81XWH-20-BCRP-BTA12 for Levels 1 and 2 and W81XWH-20-BCRP-BTA4 for Level 4). The PI is strongly encouraged to review the research scope defined under each funding level as described in the corresponding Breakthrough Award Program Announcements before submitting the pre-application.

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

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

Food and Drug Administration (FDA) involvement, applications must demonstrate availability of, and access to, clinical reagents (e.g., therapeutic molecules) and patient population(s). Applications must state a realistic timeline for near-term clinical investigation. Small-scale clinical trials (e.g., first in human, Phase I/Ib) may be appropriate.

Partnering PI Option: The Breakthrough Award encourages applications that include meaningful and productive collaborations between investigators. The Partnering PI Option is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Initiating and Partnering PIs each have different submission requirements, as described in [Section II.D.2, Content and Form of the Application Submission](#); however, both PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work (SOW), and other required components. If recommended for funding, each PI will be named to an individual award within the recipient organization. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. New collaborations are encouraged, but not required. The application is expected to describe how the PIs' combined expertise will better address the research question and explain why the work should be done together rather than through separate efforts. ***To meet the intent of the Partnering PI Option, applicants are discouraged from being named as a Partnering PI on multiple Breakthrough Award Level 3 applications unless they are clearly addressing distinct research questions.***

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

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

A Congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, CDMRP encourages applicants to review the recommendations (https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research) and

submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY20 BCRP priorities.

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

The anticipated direct costs budgeted for the entire period of performance for the FY20 BCRP Breakthrough Award Funding Level 3 will not exceed **$3M** for applications with a single PI or **$4M** if applying under the Partnering PI Option. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The CDMRP expects to allot approximately $22.4M to fund approximately four Breakthrough Award Level 3 applications. 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.

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

The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). 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.

An assistance agreement (grant or cooperative 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. 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 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.

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. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application as a stand-alone study. Submission to HRPO of protocols involving more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Applications that involve recruitment of human subjects must indicate the quarterly enrollment targets across all sites in [Attachment 5: Statement of Work (SOW)](#). Successful applicants will work with USAMRAA to establish milestones for human subjects recruitment. Continued support for the project will be based upon satisfactory progress in meeting the established milestones. 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.

Clinical trials are allowed. A clinical trial is 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.

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. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled, "Research Involving Animals." ***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.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 2, Section K.

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, other 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.

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

The 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 PI, Initiating PI, or Partnering PI on an application.

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.

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

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

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 program and funding cycle is prohibited and will result in administrative withdrawal of the duplicative application(s).

Extramural Submission: An application submitted by an organization to Grants.gov.

Intramural DoD Submission: An application submitted by a DoD organization to eBRAP.

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.

Extramural Submissions:

- 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 Submissions:

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

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

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*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Application Submission: All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Application Submission: Full applications must be submitted through the online portals as described below.

Extramural Organization Submissions: Full applications from extramural organizations must be submitted through Grants.gov Workspace. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Intramural DoD Organization Submissions: Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to 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. 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. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement.

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.

Partnering PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email in order to associate their full application package with that of the Initiating PI. After following the link, the Partnering PI must verify their contact information, organization, and designation as an extramural or intramural submission within eBRAP.*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the

Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering 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 PI (single PI) or Initiating PI (Partnering PI Option) 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 organization and associated PI(s) 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 PI 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. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contacts**

  Enter contact information for the PI. 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 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.

  Partnering PI Option: The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

  The PI must enter the name of each consumer advocate on the research team and indicate the consumer advocate's role in the drop-down list.

- **Tab 4 – Conflicts of Interest (COIs)**

  List all individuals other than collaborators and key personnel who may have a COI 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:** Provide responses in the appropriate data fields for the following:

- What BCRP overarching challenge(s) will the proposed research address? If "other," state the overarching challenge and provide justification within the context of the *breast cancer landscape*. (200-character limit)

- How will the proposed research lead to a solution for the overarching challenge(s)? (2,000 character limit)

- How will the proposed research move beyond a minor advancement? How will the proposed research lead to a new approach that is fundamentally better than interventions already approved or in clinical development? (2,000-character limit)

- Briefly state how the scope of the proposed research is appropriate for Funding Level 3. (500-character limit)

- What period of performance is requested? (1-4 years)

- Will the proposed research include a clinical trial? If yes, briefly state the clinical intervention, subject population(s), and phase of the clinical trial. (500-character limit)

○ **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to the following:

- One page for additional information that the PI can use, at their discretion, to provide supporting data or rationale for the pre-application.

- If applicable, one page to provide a list of all FY20 BCRP Breakthrough Award Level 3 pre-applications in which the PI is named as a PI, Initiating PI, Partnering PI, or collaborator. Include the CDMRP log number, role on the project, project title, specific aims, and a brief description of how each pre-application will address distinct research questions.

- **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:

- ○ Whether the pre-application addresses at least one overarching challenge that meets the program's goals.

- ○ To what degree the pre-application proposes research that will lead to a solution for the overarching challenge.

- ○ To what degree the pre-application moves beyond a minor advancement.

- ○ To what degree the requested funding level is appropriate.

Note: The scope of research proposed in the pre-application must align with the research scope for Funding Level 3. Funding Levels 1, 2, and 4 are available under different Program Announcements (W81XWH-20-BCRP-BTA12 for Levels 1 and 2 and W81XWH-20-BCRP-BTA4 for Level 4). It is the responsibility of the PI to select the level that aligns with the scope of the proposed research. The funding level should be selected based on the research scope defined in the Program Announcement, and not on the amount of the budget. PIs whose pre-applications request a funding level that is not deemed appropriate for the scope of the research proposed will not be invited to submit an application.

- **Notification of Pre-Application Screening Results**

    Following the pre-application screening, PIs and Initiating PIs 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 full applications 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 PI or Initiating PI.

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.

Table 1. Full Application Submission Guidelines

Extramural Submissions	Intramural DoD Submissions
Application Package Location	
Download application package components for W81XWH-20-BCRP-BTA3 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-BTA3 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.	**Tab 1 – Summary:** Provide a summary of the application information. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • 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 (if applicable)	**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: • Attachments • Key Personnel • Budget • Performance Sites **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.

Extramural Submissions	Intramural DoD Submissions
Application Package Submission	
Create a Grants.gov Workspace. Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission. **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. **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 *prior to* the application submission deadline.	**Submit package components to eBRAP (https://ebrap.org).** **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.
Application Verification Period	
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 *with the exception of the Project Narrative and Research & Related Budget Form*.	After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business Official and PI(s) 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 *with the exception of the Project Narrative and Research & Related Budget Form*. 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.

Extramural Submissions	Intramural DoD Submissions
Further Information	
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. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.	Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements.

Both Extramural and Intramural Organizations: Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. 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.

Partnering PI Option: The CDMRP requires separate full application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering 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 (Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

Application Components for the PI or Initiating PI

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

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.

  - **Attachment 1: Project Narrative (18-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs 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.

    – **Outline for the Project Narrative:** Describe the proposed project in detail using _**one**_ of the two outlines below, depending on whether or not a clinical trial is proposed.

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

      - **Overarching Challenge:** State explicitly which overarching challenge(s) the proposed research will address.

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

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

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

      - **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for evaluation. Explain how this research strategy will meet the research goals and milestones. Where relevant,

describe the accessibility to the data, cohort(s), and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the project. 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 FDA, if applicable.

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

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

Outline for projects <u>with</u> a clinical trial. (Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.):

- **Overarching Challenge:** State explicitly which overarching challenge(s) the proposed research will address.

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

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

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

- **Research Strategy (include only if laboratory research studies are proposed as a component of the application):** Describe the laboratory research studies that will be performed under this award and how they are ***clearly linked*** to the

clinical trial. Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Where relevant, describe the availability of, and access to, necessary data and/or critical reagents (e.g., therapeutic molecules, human samples) necessary for the proposed research. Provide a well-developed, well-integrated research strategy that supports the feasibility of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

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

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

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

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

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

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

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

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

○ **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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 project 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 project. Letters of support not requested in the Program Announcement, such as those from members of Congress, do not impact application review or funding decisions.

– Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

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

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

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

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

- ▪ Good Manufacturing Practice (GMP) Compliance (if applicable): Provide information regarding the resources available to aid in the development of sufficient quantities of the reagent under GMP. If the reagent is to be provided from industrial sources, evidence of a cost-sharing plan must also be provided.

  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.

  - – 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 Code of Federal Regulations, Title 2, Part 200.315 (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.

  - – Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- ○ **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf".** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***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 work.

  - – Overarching Challenge(s): State the overarching challenge(s) that will be addressed.

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

  – Specific Aims: State the specific aims of the study.

  – Study Design: Briefly describe how the proposed project, if successful, will have an impact and accelerate progress toward ending breast cancer.

  – Impact: Briefly describe how the proposed project, if successful, will have an impact and accelerate progress toward ending breast cancer.

- ○ **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers. 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 of the research.

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

    ▪ What types of patients will it help and how will it help them?

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

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

    ▪ What is the likely impact of this study on ending breast cancer?

- ○ **Attachment 5: Statement of Work (three-page or six-page limit, specific to format required): 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 Breakthrough Award Level 3 mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format if a clinical trial is not proposed, or the SOW for "Clinical Research (Including Trials, Special Population)" if a clinical trial is proposed. 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) and commercial or organizational source(s) to be used.

- If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., IND and IDE applications) by the FDA or other Government agency.

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

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

○ **Attachment 6: Impact Statement (250 words or less recommended): Upload as "Impact.pdf".** *Do not restate the research strategy as part of the Impact Statement.*

- Articulate how the breakthrough project, if successful, will accelerate progress toward ending breast cancer.

- Explain how the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.

- Identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research.

○ **Attachment 7: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** *(Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.)* Describe the expertise of the Initiating and Partnering PIs. Describe the contribution and the time commitment of each PI toward the proposed research project. Describe how the combined effort will better address the research question and explain why the work should be done together rather than through separate efforts.

○ **Attachment 8: Submissions Statement (one-page limit): Upload as "Submissions.pdf".** *(Attachment 8 is only applicable and required for applications in*

which the PI, Initiating PI, or Partnering PI is named in multiple FY20 BCRP Breakthrough Award Level 3 applications. Attachment 8 will be available for programmatic review only.)

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

– CDMRP Log Number, funding level, role on the project, project title, and specific aims.

– Brief description of how the application addresses a research question that is distinct from the other application(s).

○ **Attachment 9: Consumer Advocate Statement (one-page limit): Upload as "ConsumerAdvocate.pdf".** The Consumer Advocate Statement should be written by the PI or Initiating PI. Provide the names of the consumer advocates and their affiliation with a breast cancer advocacy organization(s). Describe the integral roles that the consumer advocates will play in the planning, design, implementation, and evaluation of the research. Describe how the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project. Explain how the consumer advocates' experience and expertise will be integrated into the research project and management of the collaboration.

○ **Attachment 10: Transition Plan (one-page limit): Upload as "Transition.pdf".** Provide information on potential methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award (e.g., specific potential industry partners, specific funding opportunities to apply for). If the application does not include a clinical trial, provide a realistic timeline for near-term clinical investigation. In addition, provide a plan to distribute the findings or intervention to the breast cancer community.

○ **Attachment 11: Regulatory Strategy (no page limit):** *(Attachment 11 is only applicable and required for applications in which a clinical trial is proposed.)* **If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "Regulatory.pdf".**

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

– State the product/intervention name.

– State how many months into the award the anticipated clinical trial would be initiated after the award begins, taking into account any required advanced preclinical work (e.g., GMP production, pharmacokinetics, and toxicity testing) and/or clinical trial preparation (IRP and DoD HRPO approval).

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

– Explain why the product/intervention is exempt from oversight. Provide confirmation that the trial does not require regulation by the FDA/regulatory agency in writing from the IRB of record or the FDA/regulatory agency. No further information for this Attachment is required.

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

– State whether the product is FDA-approved, -licensed, or -cleared and marketed in the U.S.

– If the product/intervention **has** already received FDA approval:

  ▪ Provide a copy of the acceptance letter from the FDA.

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

– If the product/intervention **has not** already received FDA approval:

  ▪ State the planned indication/use. Indicate whether the product would be classified as a drug, device, biologic, or combination product. Indicate whether the FDA has confirmed the proposed classification.

  ▪ Identify the regulatory sponsor. Include a signed sponsor commitment letter acknowledging the regulatory sponsor's understanding of all sponsor responsibilities and commitment to oversee execution of the study.

  ▪ Describe the overall regulatory strategy and product development plan that will support the planned product indication. Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, and the types of FDA meetings that will be held/planned. Include considerations for compliance with current GMP, Good Laboratory Practice (GLP), and Good Clinical Practice (GCP) guidelines.

  ▪ If the clinical trial involves the use of a drug that has not been approved by the FDA for the proposed investigational use, then an IND application to the FDA that meets all requirements under 21 CFR 312 may be required and must be submitted to the FDA by the application submission deadline. If the investigational product is a device, evidence that an IDE application that meets all requirements under 21 CFR 812 has been submitted to the FDA by the application

submission deadline, or that the device is exempt or qualifies for an abbreviated IDE is required. The Government reserves the right to withhold or withdraw funding if an IND or IDE is necessary but has not been submitted to the FDA by the application submission deadline, or if documented status of the IND or IDE has not been obtained within 18 months of the award date.

- If a drug is to be used in the proposed clinical trial, describe the current status for manufacturing development (e.g., manufacturer's name, GMP-compliant lots available, status of stability testing), non-clinical development (e.g., test facility name, status of pivotal GLP toxicology studies to support Phase I testing), and clinical development (e.g., clinical site name, safety profile, status of any completed or ongoing clinical trials).

- If a device is to be used in the proposed clinical trial, indicate who holds the intellectual property rights to the intervention, in applicable, and how the PI has obtained access to those rights for the conduct of the clinical trial.

○ **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: DoD Military Budget Form(s), 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 the DoD Military Budget Form, 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 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.

Partnering PI Option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 DoD Military Budget Form 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.

DoD Military Budget Form: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. **Note:** Applicants should complete the **DoD Military Budget Form (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 the Partnering PI, if applying under the Partnering PI Option

---

The Partnering 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 Initiating PI.

The Initiating PI must identify if the Partnering 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). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - ○ **Attachment 5: Statement of Work (three-page or six-page limit, specific to format required): 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 Initiating PI and the Partnering 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: DoD Military Budget Form: 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 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".

Initiating and Partnering 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 the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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.

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

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 retrieved files against the specific Program Announcement requirements, and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement. ***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 Budget Form cannot be changed after the application submission deadline.

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 PI(s) 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 requested funding level should be aligned with the scope of the research proposed and the funding level [description](#).

Funding Level 3 (single PI):

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

The anticipated direct costs budgeted for the entire period of performance will not exceed **$3M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Clinical Trials

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

- Advanced preclinical work (e.g., GMP production, pharmacokinetics and toxicity testing) and/or clinical trial preparation (e.g., IND approval, IRB and DoD HRPO approval), which will be considered the base award; and

- Clinical trial work, which will be considered the optional research effort(s).

The approval of optional research effort(s) will be contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award.

Approval may be dependent on the availability of future year appropriations. The application must include two separate, but related, budgets and SOWs for the base and the option(s), not to exceed a combined **$3M** in direct costs. The budget for the option(s) should be submitted using the Research & Related Subaward Budget Attachment(s) Form. Also, these option periods, if funded, are to be conducted within the maximum period of performance (up to 4 years).

Funding Level 3 with Partnering PI Option:

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

The anticipated combined direct costs budgeted for the entire period of performance for the Initiating and Partnering PIs' applications will not exceed **$4M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. No combined budget will be approved by the Government exceeding **$4M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

Clinical Trials

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

- Advanced preclinical work (e.g., GMP production; pharmacokinetics and toxicity testing) and/or clinical trial preparation (e.g., IND approval, IRB and DoD HRPO approval), which will be considered the base award; and

- Clinical trial work, which will be considered the optional research effort(s).

The approval of the optional research effort(s) will be contingent upon the completion of advanced preclinical work (if applicable) and all necessary regulatory approvals under the base award. Approval may be dependent on the availability of future year appropriations. The Initiating and Partnering PIs' applications must include two separate, but related, budgets and SOWs for the base and the option(s), not to exceed a combined **$4M** in direct costs. The budget for the option(s) should be submitted using the Research & Related Subaward Budget Attachment(s) Form. Also, these option periods, if funded, are to be conducted within the maximum period of performance (up to 4 years).

For All Funding Level 3 Options:

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary

- Research supplies

- Equipment

- Clinical research costs

- Support for multidisciplinary collaborations, including travel

- Travel costs for up to three investigators to travel to one scientific/technical meeting per year to present project information or disseminate project results from the FY20 BCRP Breakthrough Award Level 3

Awards made to extramural organizations will consist solely of assistance agreements (grants and cooperative agreements). 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.

Partnering PI Option: Application packages from associated extramural partners will be funded through assistance agreements.

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***.

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. The time is considered when establishing the award's period of performance. 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.

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

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

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

- **Impact**

  Assuming the objectives/goals of the proposed research project are realized, the following criteria apply:

  ○ To what degree the proposed research could lead to a solution for an overarching challenge in breast cancer.

  ○ To what degree the project could lead to or make a breakthrough and accelerate progress toward ending breast cancer.

  ○ Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.

  ○ Whether the proposed research would ultimately benefit breast cancer patients or individuals at risk for breast cancer.

- **Research Strategy and Feasibility**

  ○ How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.

  ○ How well the hypothesis, objectives, 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 problems and addresses alternative approaches.

- How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.

- **Statistical Plan**

  - Whether an appropriate statistical plan is provided, including power analysis.

- **Transition Plan**

  - Whether the application states a realistic timeline for clinical investigation.

  - To what degree the application demonstrates feasible methods and strategies to move the research finding to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.

  - Whether the application has a plan to distribute the findings or intervention to the breast cancer community.

- **Personnel**

  - Whether the application includes an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.

  - Whether the levels of effort are appropriate for successful conduct of the proposed work.

  - Whether two or more consumer advocates are named in the application and meet the criteria according to the Program Announcement.

  - How well consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.

  - To what degree the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project.

  - **Partnering PI Option:** To what degree the partners' combined expertise will better address the research question.

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

- **Environment**

  - Whether the scientific environment is appropriate for the proposed research.

  - How well the research requirements are supported by the availability of, and access to, facilities and resources (including collaborative arrangements).

- Whether the quality and extent of institutional support are appropriate for the proposed research.

    - If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**

    - Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.

    - Whether the budget is appropriate for the proposed research.

- **Application Presentation**

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

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

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

- **Impact**

    Assuming the objectives/goals of the proposed research project are realized, the following criteria apply:

    - To what degree the proposed research could lead to a solution for an overarching challenge in breast cancer.

    - To what degree the project could lead to or make a breakthrough and accelerate progress toward ending breast cancer.

    - Whether the proposed research will move beyond a minor advancement and will lead to a new approach that is fundamentally better than interventions already approved or in clinical development.

    - Whether the proposed research would ultimately benefit breast cancer patients or individuals at risk for breast cancer.

- **Clinical Strategy**

    - Whether the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.

    - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.

- ○ How well the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.

- ○ Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approval), if appropriate.

- ○ Whether potential challenges and alternative strategies are appropriately identified.

- ○ To what degree the SOW indicates a feasible plan and timeline to conduct the clinical trial and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.

- **Regulatory Strategy**

  - ○ How the regulatory strategy and development plan to support the product indication or product label change, if applicable, are appropriate and well described.

  - ○ Whether the application includes documentation that the study is exempt from FDA regulation, or that the IND or IDE application has been submitted to the FDA, as appropriate.

  - ○ For investigator-sponsored regulatory exemptions (e.g., IND, IDE), whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.

  - ○ Whether plans to comply with GMP, GLP, and GCP guidelines are appropriate.

- **Research Strategy and Feasibility (applicable only to applications that include laboratory research studies)**

  - ○ How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.

  - ○ How well the hypothesis, objectives, specific aims, experimental design, methods, and analyses are developed.

  - ○ How well the application acknowledges potential problems and addresses alternative approaches.

  - ○ Whether there is documented availability of, access to, and quality control for all data and/or critical reagents, where relevant.

  - ○ Whether there are resources available for the development of sufficient quantities of critical reagents under GMP, if applicable.

  - ○ Whether the proposed laboratory research studies are clearly linked to the proposed clinical trial.

- ○ If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.

  - ○ How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones to be accomplished by the end of each year in the period of performance.

- **Statistical Plan**

  - ○ Whether an appropriate statistical plan is provided, including power analysis.

  - ○ Whether the clinical trial is designed with enough statistical power to lead to meaningful results.

- **Transition Plan**

  - ○ To what degree the application demonstrates feasible methods and strategies to move the clinical trial findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.

  - ○ Whether the application has a plan to distribute the findings or intervention to the breast cancer community.

- **Personnel**

  - ○ Whether the application includes an appropriate and robust research/clinical team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.

  - ○ Whether the levels of effort are appropriate for successful conduct of the proposed work.

  - ○ Whether two or more consumer advocates are named in the application and meet the criteria according to the Program Announcement.

  - ○ To what degree consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.

  - ○ How well the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project.

  - ○ **Partnering PI Option:** To what degree the partners' combined expertise will better address the research question.

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

- **Environment**

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

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

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

- **Budget**

  ○ Whether the **direct** maximum costs are equal to or less than the allowable direct maximum costs as published in the Program Announcement.

  ○ Whether the budget is appropriate for the proposed research and funding level.

- **Application Presentation**

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

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:

  ○ Adherence to the intent of the award mechanism

  ○ Program portfolio composition

  ○ Relative impact

II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, 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. A PI 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.

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.

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

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

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

An organizational transfer of an award supporting the Initiating PI or Partnering PI 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 a transfer request will be on a case-by-case basis 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 USAMRAA 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.

In certain circumstances, the award Terms & 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 20190530a. The Program Announcement numeric version code will match the General Application Instructions version code 20190530.

II.H.2. Administrative Actions

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

II.H.2.a. Rejection

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

- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.

- Project Narrative exceeds page limit.

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

- Project Narrative is missing.

- Budget is missing.

II.H.2.b. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the 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/panels20.*

- 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.

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

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

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

II.H.2.d. Withhold

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

II.H.3. Application Submission Checklist

Application Components	Action	Initiating PI Completed	Partnering PI 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"		
	Partnership Statement: Upload as Attachment 7 with file name "Partnership.pdf" if applicable		
	Submissions Statement: Upload as Attachment 8 with file name "Submissions.pdf" if applicable		
	Consumer Advocate Statement: Upload as Attachment 9 with a file name "ConsumerAdvocate.pdf"		
	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf"		
	Regulatory Strategy: Upload as Attachment 11 with file name "Regulatory.pdf" if applicable		
	Representations (extramural submissions only): Upload as Attachment 12 with file name "RequiredReps.pdf" if applicable		

Application Components	Action	Initiating PI Completed	Partnering PI Completed
	DoD Military Budget Form(s): 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 DoD Military Budget Form and Justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form	Complete form as instructed		

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
COI	Conflict of Interest
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
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
M	Million
MIPR	Military Interdepartmental Purchase Request
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
STEM	Science, Technology, Engineering, and/or Mathematics
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRDC	U.S. Army Medical Research and Development Command
USC	United States Code