

-ตรวจสอบ+ARC-

MUSIS

รหัสแฟ้ม.....  
เก็บเอกสารถึงปี พ.ศ.....

คณะเภสัชศาสตร์  
เลขที่รับ 4368  
วันที่ 9 ส.ค. 2565  
เวลา 9:12 น.

งานบริหารงานวิจัยและนวัตกรรม  
เลขที่รับ 614  
วันที่ 11/08/65  
เวลา.....



งานบริหารและส่งเสริมการวิจัย  
กองบริหารงานวิจัย มหาวิทยาลัยมหิดล  
โทร. 02-849-6252 โทรสาร. 02-849-6247

ที่ อว 78.016/ 4029  
วันที่ 9 สิงหาคม 2565

เรื่อง ประชาสัมพันธ์ทุนวิจัย Breast Cancer Research Program จากแหล่งทุน Department of Defense (DOD)

เรียน คณบดี / ผู้อำนวยการ

ด้วยแหล่งทุน Department of Defense (DOD) เปิดรับ pre-application และ full application ในหัวข้อ Breast Cancer Research Program เพื่อสนับสนุนงานวิจัยที่มีศักยภาพสูงที่จะทำให้เกิดความก้าวหน้าในการรักษาเมเร็งเต้านม โดยอาจารย์/นักวิจัย สามารถส่ง application ผ่านระบบออนไลน์ของแหล่งทุน electronic Biomedical Research Application Portal (eBRAP): <https://eBRAP.org> ซึ่งเปิดรับ pre-application ถึงวันที่ 22 กันยายน 2565 และ full application ในวันที่ 6 ตุลาคม 2565 ทั้งนี้ โครงการที่เสนอขอทุน ให้ปฏิบัติตามประกาศมหาวิทยาลัยมหิดลเรื่อง หลักเกณฑ์และอัตราเงินค่าธรรมเนียมพัฒนาการวิจัยของมหาวิทยาลัยและส่วนงาน ที่จัดเก็บจากโครงการวิจัยที่ได้รับเงินอุดหนุนจากแหล่งทุนภายนอกมหาวิทยาลัย พ.ศ. 2560 โดยระบุหมวดค่าธรรมเนียมอุดหนุนสถาบันในอัตราร้อยละ 10 และขอให้ดำเนินการตามที่ระบุในหนังสือชักชวนแนวปฏิบัติ เรื่องมาตรฐานการวิจัยของโครงการวิจัย รายละเอียดดังเอกสารที่แนบมาด้วยนี้ ทั้งนี้ อาจารย์/นักวิจัยที่สนใจสามารถศึกษารายละเอียดเพิ่มเติมได้ตามเอกสารที่แนบมาด้วยนี้ หรือเว็บไซต์ของแหล่งทุนที่ <https://cdmrp.army.mil/funding/bcrp>

ในการนี้ กองบริหารงานวิจัย มหาวิทยาลัยมหิดล จึงขอแจ้งข่าวประกาศทุนมายังท่าน เพื่อโปรดประชาสัมพันธ์ วิจัยดังกล่าวให้บุคลากรในหน่วยงานของท่านทราบโดยทั่วกัน และขอให้อาจารย์/นักวิจัย โปรดส่งเอกสารข้อเสนอโครงการผ่าน ส่วนงานต้นสังกัดมายังกองบริหารงานวิจัยภายในวันที่ 30 กันยายน 2565 เพื่อจัดทำเอกสาร Letter of Organizational Support ประกอบการส่ง full application ทั้งนี้หากส่วนงานจัดส่งข้อเสนอโครงการมายังมหาวิทยาลัยหลังจากวันที่มหาวิทยาลัย กำหนด มหาวิทยาลัยขอสงวนสิทธิ์ในการส่ง application เพื่อสมัครรับทุนดังกล่าว

จึงเรียนมาเพื่อโปรดทราบและโปรดประชาสัมพันธ์ข่าวต่อไปด้วย จักขอบคุณยิ่ง  
งานบริหารงานวิจัยและนวัตกรรม  
หมักม  
9 ส.ค. 65

เว้น กอวต (ฝ่ายบริหารงานวิจัย)

- เพื่อโปรดทราบ มหาวิทยาลัยมหิดล Breast Cancer Res. Program สนับสนุน Department of Defense (DOD) application สนับสนุนออนไลน์ที่ <https://eBRAP.org> วันที่ 22 ก.ย. 65 (pre-application) หรือ วันที่ 6 ต.ค. 65 สำหรับ Full application (ควรมีงบทำ overhead 10% ของ. และขอคืน) เอกสารขอเสนอ  
ผู้ประสานงาน: นายวรินทร์พิภพ ขยทีตภูมิรัตน์  
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ผ่านงานบริหารงานวิจัย กองบริหารงานวิจัย มหาวิทยาลัยมหิดล 29 ก.ย. 65  
หรืออีเมลที่คณะวิจัย L.O.S.

- สวมหน้ากากอนามัยทุกแห่ง
- ดันช่องหน้ามรณพจนกิจ

หมักม 9 ส.ค. 65

โปรดประชาสัมพันธ์บุคลากร

ณ อิมมูโนวิทยา  
10/8/65

รับเรื่องคืนจากห้องคณบดี+รองคณบดี  
วันที่ 10 ส.ค. 2565

ทราบ  
10 ส.ค. 2565

# 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 Levels 1 and 2

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-BCRP-BTA12-2

Assistance Listing 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), September 22, 2022
- Application Submission Deadline: 11:59 p.m. ET, October 6, 2022
- End of Application Verification Period: 5:00 p.m. ET, October 11, 2022
- Peer Review: December 2022
- Programmatic Review: March 2023

*This program announcement must be read in conjunction with the General Application Instructions, version 702. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."*

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## II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

### II.A. Program Description

Applications to the Fiscal Year 2022 (FY22) Breast Cancer Research Program (BCRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). 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 FY21 totaled \$3.94 billion. The FY22 appropriation is \$150 million (M).

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

#### II.A.1. The Breast Cancer Landscape

The BCRP has prepared a brief overview, *The Breast Cancer Landscape*, that describes what is currently known about the most pertinent topics that are consistent with the BCRP's mission of ending breast cancer. Applicants are strongly urged to read and consider *The Breast Cancer Landscape* before preparing their applications. *The Breast Cancer Landscape* may be found at <https://cdmrp.army.mil/bcrp/pdfs/Breast%20Cancer%20Landscape2021.pdf>.

#### II.A.2. FY22 BCRP Overarching Challenges

Considering the current *breast cancer landscape* and the BCRP's mission, all FY22 BCRP Breakthrough Award Levels 1 and 2 applications must address at least one of the following overarching challenges unless adequate justification for exception is provided.\* Simply identifying an overarching challenge is not sufficient. Applications must address the challenge in a way that can lead to or make a breakthrough and have a major impact.

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

- Determine why/how breast cancer cells lie dormant for years and then re-emerge; determine how to prevent lethal recurrence
- Revolutionize treatment regimens by replacing them with ones that are more effective, less toxic, and impact survival
- Eliminate the mortality associated with metastatic breast cancer

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

## II.B. Award Information

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

**Impact:** Research supported by the Breakthrough Award will have the potential for a major impact and accelerate progress toward ending breast cancer. The impact may be near-term or long-term, but must move beyond a minor advancement and have the potential to lead to a 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.

The current program announcement discusses the Breakthrough Award Levels 1 and 2. Funding Levels 3 and 4 are available under other program announcements (W81XWH-22-BCRP-BTA3-2 and W81XWH-22-BCRP-BTA4-2, respectively). The PI is strongly encouraged to review the research scope defined under each funding level as described in the corresponding Breakthrough Award program announcement before submitting the pre-application. An application that does not meet the intent of the funding level selected will not be recommended for funding, even if it might meet the intent of a different funding level.

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

- **Funding Level 1:** Innovative, high-risk/high-reward research that is in the earliest stages of idea development or is an untested theory that addresses an important problem. To foster research that yields new avenues of investigation, preliminary data are *not* required. Proof of concept is the anticipated outcome.

- **Funding Level 2:** Research that is already supported by substantial preliminary or published data and strongly validates clinical translation in a well-defined context within the *breast cancer landscape*.
- **Funding Level 2: Population Science and Prevention Studies:** Research that is already supported by substantial preliminary or published data and strongly validates clinical translation in a well-defined context within the *breast cancer landscape*. With compelling justification, population science and prevention studies may request higher levels of funding and an additional year in the period of performance. Such studies may require additional resources due to the participation of human subjects and/or use of human biospecimens.

**Partnering PI Option:** The Breakthrough Award encourages applications that include meaningful and productive partnerships between investigators. The Partnering PI Option is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. The application should clearly demonstrate that both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. It is expected that funding will be balanced between both PIs unless appropriately justified. New partnerships are encouraged, but not required. The application is expected to describe how the PIs' unique expertise combined as a partnership will better address the research question, how the unique expertise that each individual brings to the application is critical for the research strategy and completion of the SOW, and why the work should be done together rather than through separate efforts. *To meet the intent of the Partnering PI Option, applicants are discouraged from being named as a Partnering PI on multiple Breakthrough Award Levels 1 and 2 applications unless they are clearly addressing distinct research questions. Applications in which a mentor and their current postdoctoral fellow or junior investigator are named as Initiating and Partnering PIs do not meet the intent of the Partnering PI Option. Applications where one PI is providing samples, animal models, or investigational agents while the other PI is conducting most or all of the experiments and analyses do not meet the intent of the Partnering PI Option.* If recommended for funding, each PI will be named to an individual award within the recipient organization. For individual submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

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

*Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.* Applications seeking support for a clinical trial may be submitted to the FY22 BCRP Breakthrough Award Level 3 and Level 4 program announcements (W81XWH-22-BCRP-BTA3-2 and W81XWH-22-BCRP-BTA4-2, respectively).

A congressionally mandated Metastatic Cancer Task Force was formed with the purpose of identifying ways to help accelerate clinical and translational research aimed at extending the lives of advanced state and recurrent patients. As a member of the Metastatic Cancer Task Force, the CDMRP encourages applicants to review the recommendations (<https://health.mil/Reference-Center/Congressional-Testimonies/2018/05/03/Metastatic-Cancer-Research>) and submit research ideas to address these recommendations provided they are within the limitations of this funding opportunity and fit within the FY22 BCRP priorities.

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

The types of awards made under the program announcement will be assistance agreements. An assistance agreement is appropriate when the federal government transfers a “thing of value” to a “state, local government,” or “other recipient” to carry out a public purpose of support or stimulation authorized by a law of the United States instead of acquiring property or service for the direct benefit and use of the U.S. government. An assistance agreement can take the form of a grant or cooperative agreement. The level of involvement on the part of the Department of Defense (DOD) during project performance is the key factor in determining whether to award a grant or cooperative agreement. If “no substantial involvement” on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

The anticipated direct costs budgeted for the entire period of performance for an FY22 BCRP Breakthrough Award Funding Level 1 will not exceed **\$450,000** for applications with a single PI or **\$750,000** if applying under the Partnering PI Option.

The anticipated direct costs budgeted for the entire period of performance for an FY22 BCRP Breakthrough Award Level 2 will not exceed **\$1.0M** for applications with a single PI or **\$1.5M** if applying under the Partnering PI Option.

The anticipated direct costs budgeted for the entire period of performance for an FY22 BCRP Breakthrough Award Funding Level 2, Population Science and Prevention Studies will not exceed **\$1.5M** for applications with a single PI or **\$2.0M** if applying under the Partnering PI Option. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to Section II.F.1, Federal Award Notices.

*The CDMRP expects to allot approximately \$22.6M to fund approximately 15 Breakthrough Level 1 and 2 Award 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.*

**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 USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. Allow up to 3 months to complete the HRPO regulatory review and approval process following submission of *all required and complete* documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

If the proposed research involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

**Clinical research is defined** as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. **Note:** Studies that meet the requirements for IRB Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

**Clinical trials are not allowed:** A clinical trial is defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**Research Involving Animals:** All research funded by the FY22 BCRP Breakthrough Award Levels 1 and 2 involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition



to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is *not* required. *Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.* Refer to the General Application Instructions, Appendix 1, for additional information.

## **II.C. Eligibility Information**

### **II.C.1. Eligible Applicants**

**II.C.1.a. Organization:** All organizations, including foreign organizations, foreign public entities, and international organizations, are eligible to apply.

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

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

**Extramural Organization:** An eligible non-DOD organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD, and research institutes.

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

The USAMRAA makes awards to eligible organizations, not to individuals.

### **II.C.1.b. Principal Investigator**

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

Applications are encouraged for postdoctoral fellows. A Mentorship Statement (see Attachment 9) is required for applications submitted with a PI who is a postdoctoral fellow.

***Each investigator may be named as a PI or Initiating PI on only one application per funding level for this Breakthrough Award Levels 1 and 2 program announcement.***

There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. To meet the intent of the Partnering PI Option, investigators are discouraged from being named as a Partnering PI on multiple FY22 BCRP Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions. Applications will be required to include a brief description of all the

applications in which the PI is named as a PI, Initiating PI, Partnering PI, collaborator, or mentor under this Breakthrough Award Levels 1 and 2 program announcement.

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

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

### **II.C.2. Cost Sharing**

Cost sharing/matching is not an eligibility requirement.

### **II.C.3. Other**

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this program announcement.

## **II.D. Application and Submission Information**

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

### **II.D.1. eBRAP and Grants.gov**

**eBRAP** (<https://ebrap.org>) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (<https://grants.gov>), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

**Grants.gov** is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

Contact information for the eBRAP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

### ***Extramural Submission:***

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

### ***Intramural DOD Submission:***

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

***Note: Applications from an intramural DOD organization or from an extramural federal government organization may be submitted to Grants.gov through a research foundation.***

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

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

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process.*** Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at [help@eBRAP.org](mailto: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 eBRAP Help Desk at [help@eBRAP.org](mailto: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/>).

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 applicant must contact the eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

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

- **Tab 1 – Application Information**

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

- **Tab 2 – Application Contacts**

Enter contact information for the 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 applicants identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

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

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

FY22 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 eBRAP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

- **Tab 4 – Conflicts of Interest**

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

- **Tab 5 – Pre-Application Files**

**Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions. An invitation to submit is *not* required.

- **Tab 6 – Submit Pre-Application**

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

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

*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://grants.gov/>) for extramural organizations or through eBRAP (<https://ebrap.org/>) for intramural organizations. See Table 1 below for more specific guidelines.

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

Extramural organizations must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view,

complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the *same version* of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the “Apply For Grants” page of Grants.gov (<https://www.grants.gov/web/grants/applicants/apply-for-grants.html>) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

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

**Table 1. Full Application Submission Guidelines**

| Extramural Submissions  | Intramural DOD Submissions   |
|---|--|
| <b>Application Package Location</b>   |  |
| Download application package components for W81XWH-22-BCRP- BTA12-2 from Grants.gov ( <a href="https://grants.gov">https://grants.gov</a> ) 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-22-BCRP- BTA12-2 from eBRAP ( <a href="https://ebrap.org">https://ebrap.org</a> ).  |
| <b>Full Application Package Components</b>  |  |
| <b>SF424 Research &amp; Related Application for Federal Assistance Form:</b> Refer to the General Application Instructions, Section III.A.1, for detailed information.  | <b>Tab 1 – Summary:</b> Provide a summary of the application information.<br><b>Tab 2 – Application Contacts:</b> 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: <ul style="list-style-type: none"> <li>• <u>Attachments</u></li> <li>• <u>Research &amp; Related Personal Data</u></li> <li>• <u>Research &amp; Related Senior/Key Person Profile (Expanded)</u></li> <li>• <u>Research &amp; Related Budget</u></li> <li>• <u>Project/Performance Site Location(s) Form</u></li> <li>• <u>Research &amp; Related Subaward Budget Attachment(s) Form</u></li> </ul> | <b>Tab 3 – Full Application Files:</b> Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components: <ul style="list-style-type: none"> <li>• <u>Attachments</u></li> <li>• <u>Key Personnel</u></li> <li>• <u>Budget</u></li> <li>• <u>Performance Sites</u></li> </ul> <b>Tab 4 – Application and Budget Data:</b> Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form. |

| Extramural Submissions   | Intramural DOD Submissions   |
|--|--|
| <b>Application Package Submission</b>  |  |
| <p><b>Create a Grants.gov Workspace.</b><br/>Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.</p> <p><b>Submit a Grants.gov Workspace Package.</b><br/>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 <b>at least 24-48 hours prior to the close date</b> to allow time to correct any potential technical issues that may disrupt the application submission.</p> <p><b>Note:</b> If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID <i>prior to</i> the application submission deadline. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p> | <p><b>Submit package components to eBRAP (<a href="https://ebrap.org">https://ebrap.org</a>).</b></p> <p><b>Tab 5 – Submit/Request Approval Full Application:</b> 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. <b><i>Do not password protect any files of the application package, including the Project Narrative.</i></b></p>  |
| <b>Application Verification Period</b>   |  |
| <p>The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b></p>   | <p>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 <b><i>with the exception of the Project Narrative and Research &amp; Related Budget Form.</i></b> Your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline.</p> |

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

**Partnering PI Option:** The CDMRP requires separate full application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. 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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.



- **Attachment 1: Project Narrative (page limit varies by funding level; see below for page limits): Upload as “ProjectNarrative.pdf”.** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
  - **Page Limit:** Page limits for the Project Narrative are correlated with the application’s funding level:
    - **Funding Level 1:** Seven-page limit
    - **Funding Level 2:** Fourteen-page limit
    - **Funding Level 2 – Population Science and Prevention Studies:** Fourteen-page limit
  - **Outline for Project Narrative:** Describe the proposed project in detail using the outline below.
    - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Preliminary data are not required, but are allowed, for Funding Level 1 applications. For Funding Level 2 applications, provide sufficient preliminary data to support the feasibility of the work proposed. Whether or not preliminary data are available, 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. Address potential pitfalls and problem areas and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the U.S. Food and Drug Administration (FDA), if applicable. For clinical research, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the

study, including a description of the composition of the proposed study population in terms of sex/gender, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Please see the definition of clinical research in Section II.B, Award Information.

- **Statistical Plan:** Describe the statistical plan 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.
- **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 demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.
- **Letter of Recommendation (only applicable and required for applications submitted with a PI who is a postdoctoral fellow; one-page limit is recommended):** A letter of recommendation provided on organizational letterhead from the mentor(s) should describe:
  - The degree to which the PI participated in the development of the research idea
  - How well the PI can manage the technical and administrative aspects of the award
  - How well the PI can successfully accomplish the proposed research
- **Public Health Service (PHS) Inclusion Enrollment Report (if applicable):** Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The PHS Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **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.
- **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.
  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **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.
- o **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 following outline.

- **Background:** Present the ideas and reasoning behind the proposed work.
- **Overarching Challenge(s):** State the overarching challenge(s) that will be addressed and briefly state how the project will address the challenge in a way that can lead to or make a breakthrough and have a major impact. Simply identifying an overarching challenge is not sufficient.
- **Objective/Hypothesis:** State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State the specific aims of the study.
- **Study Design:** Briefly describe the study design, including appropriate controls.
- **Impact:** Briefly describe how the proposed project will lead to a major impact for the overarching challenge(s). Explain how the research meets the requirement for high potential to lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- **Innovation (required for Funding Level 1 applications only):** Explain how the proposed research is innovative and will investigate a novel idea or research question that introduces a new paradigm or challenges existing paradigms.
- o **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 the rationale, objectives, and aims of the application in a manner readily understood by readers without a background in science or medicine.
    - 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 or at-risk individuals will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
  - How will the proposed project lead to or make a breakthrough in breast cancer and accelerate progress toward the BCRP’s mission of ending breast cancer?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
- **Attachment 5: Statement of Work (three-page limit): Upload as “SOW.pdf”.** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). Recommended strategies for assembling the SOW can be found at <https://ebrap.org/eBRAP/public/Program.htm>.

For the Breakthrough Award Levels 1 and 2 mechanism, refer to the “*Suggested SOW Strategy Generic Research*” document for guidance on preparing the SOW and use the blank SOW format titled “Suggested SOW Format”. The SOW must be in PDF format prior to attaching.

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

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

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

***DO NOT restate the research strategy as part of the Impact Statement.***

- Articulate concisely how the proposed project will have a major impact on at least one of the overarching challenge(s).
- Explain how the project meets the requirement for high potential to accelerate progress toward ending breast cancer substantially beyond an incremental advance.

- Explain briefly how the proposed research will lead to a fundamentally new approach that is significantly more effective than interventions already approved or in clinical development.
  - Identify the breast cancer patients or at-risk individuals and justify how they would benefit from the proposed research.
- **Attachment 7: Partnership Statement (one-page limit): Upload as “Partnership.pdf”.** *(Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.)* Describe the partnership and combined expertise of the Initiating and Partnering PIs that are critical for the research strategy and completion of the SOW. Explain how the partnership will better address the research question and why the work should be done together rather than through separate individual efforts. Explain how both PIs have equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project. Explain how funding will be balanced between both PIs or otherwise provide appropriate justification.
  - **Attachment 8: Submissions Statement (one-page limit): Upload as “Submissions.pdf”.** *(Attachment 8 is only applicable and required for individuals who are named on multiple Breakthrough Award Levels 1 and 2 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, collaborator, or mentor in multiple FY22 BCRP Breakthrough Award Levels 1 and 2 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: Mentorship Statement (one-page limit): Upload as “Mentorship.pdf”.** *(Attachment 9 is only applicable and required for applications in which the PI is a postdoctoral fellow.)* Identify the PI’s mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor’s experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor’s commitment to the PI’s project, including details of their proposed interactions with the PI and how they will support the PI’s research endeavors.
  - **Attachment 10: Innovation Statement (one-page limit): Upload as “Innovation.pdf”.** *(Attachment 10 is only applicable and required for applications submitted under Funding Level 1.)* Describe how the proposed research is innovative and will investigate a novel idea or research question that introduces a new paradigm or challenges existing paradigms. Investigating the next logical step or continuation of a previous research project is not considered innovative.

- **Attachment 11: 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 12: Suggested Collaborating DOD Military Facility Budget Format, if applicable: Upload as “MFBudget.pdf”.** If a military facility (Military Health System facility, research laboratory, medical treatment facility, dental treatment facility, or a DOD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete a separate budget, using “Suggested Collaborating DOD Military Facility Budget Format”, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC 1681[a] 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”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

- For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
- o Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
  - Include biographical sketches for research team members.
  - Include mentor’s (and co-mentor’s, if applicable) biographical sketch, if the PI is a postdoctoral fellow.
- o Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
  - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support, if the PI is a postdoctoral fellow.

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

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

- **Extramural Applications Only**

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



- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.
- **Intramural DOD Collaborator(s):** Complete the “Suggested Collaborating DOD Military Facility Budget Format” and upload to Grants.gov attachment form as Attachment 12. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DOD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

**Suggested DOD Military Budget Format:** A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. *Note:* Applicants should complete a separate military budget using “Suggested Collaborating DOD Military Facility Budget Format” (available for download on the eBRAP “Funding Opportunities & Forms” web page [<https://ebrap.org/eBRAP/public/Program.htm>]) (Attachment 12) 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.

For the Partnering 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 limit): Upload as “SOW.pdf”.** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

- **Attachment 9: Mentorship Statement (one-page limit): Upload as “Mentorship.pdf”.** (*Attachment 9 is only applicable and required for applications in which the PI is a postdoctoral fellow.*) Identify the PI’s mentor(s) and provide a description of their qualifications to mentor the PI in the successful execution and completion of the proposed work. Describe the mentor’s experience in breast cancer research and their success in research projects relevant to the current application. Describe the mentor’s commitment to the PI’s project, including details of their proposed interactions with the PI and how they will support the PI’s research endeavors.
- **Attachment 11: 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 12: Suggested Collaborating DOD Military Facility Budget Format: Upload as “MFBudget.pdf”.** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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

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

- **PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf”.** The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.
- **PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.**
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf”.
  - Include biographical sketches for research team members.
  - Include mentor’s (and co-mentor’s, if applicable) biographical sketch, if the PI is a postdoctoral fellow.
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf”.
  - For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.
  - For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.
  - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support, if the PI is a postdoctoral fellow.

**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 a separate DOD military budget, using Suggested Collaborating DOD Military Facility Budget Format (available for download on the eBRAP “Funding Opportunities & Forms” web page

[<https://ebrap.org/eBRAP/public/Program.htm>]), and upload to Grants.gov attachment form as **Attachment 12**. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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

The applicant organization must be registered as an entity in SAM (<https://www.sam.gov/SAM/>) and receive confirmation of an “Active” status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (<https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management>), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. **All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.** USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update>). Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. **Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see below).** 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**

**For Both Extramural and Intramural Applicants:** eBRAP allows an organization’s representatives and PIs to view and modify the full application submissions associated with them. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in an email to the PI and in the “Full Application Files” tab in eBRAP. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline. The***

***Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

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

***Intramural DOD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and 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 descriptions.***

##### **Funding Level 1 (single PI):**

The maximum period of performance is 3 years.

The anticipated direct costs budgeted for the entire period of performance will not exceed **\$450,000**. 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 **\$450,000** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

##### **Funding Level 1 with Partnering PI Option:**

- The maximum period of performance is 3 years.
- The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **\$750,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect

costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **\$750,000** or use an indirect cost rate exceeding each organization's negotiated rate.

**Funding Level 2 (single PI):**

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1.0M**. 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 **\$1.0M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

**Funding Level 2 – Population Science and Prevention Studies (single PI):**

- The maximum period of performance is **4** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$1.5M**. 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 **\$1.5M** direct costs or using an indirect cost rate exceeding the organization's negotiated rate.

**Funding Level 2 with Partnering PI Option:**

- The maximum period of performance is **3** years.
- The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **\$1.5M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **\$1.5M** or use an indirect cost rate exceeding each organization's negotiated rate.

**Funding Level 2 – Population Science and Prevention Studies 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 PI's and the Partnering PI's applications will not exceed **\$2.0M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **\$2.0M** or use an indirect cost rate exceeding each organization's negotiated rate.

### **For All Funding Levels:**

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 3 or 4 years.

**Partnering PI:** The anticipated combined direct costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI will not exceed the maximum allowable direct costs for the selected funding level. A separate award will be made to each PI's organization.

**Applications Submitted with a PI Who Is a Postdoctoral Fellow:** The PI of the award is expected to manage the budget during the award period, not their mentor.

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

- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY22 BCRP Breakthrough Award Levels 1 and 2 award.

Must not be requested for:

- Clinical trial costs

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

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

### **II.D.6. Other Submission Requirements**

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

## II.E. Application Review Information

### II.E.1. Criteria

#### II.E.1.a. Peer Review

To determine technical merit, all applications will be evaluated according to the following **scored criteria** (the Impact and Research Strategy criteria are of equal importance, followed by Personnel and Partnership [if applicable]):

- **Impact**

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

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

- **Research Strategy**

- 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, if applicable (preliminary data are not required under Funding Level 1, but are required under Funding Level 2).
- How well the hypothesis, objectives, and specific aims are developed.
- How well the experimental design, methods, and analyses are developed and support completion of the specific aims.
- How well the application acknowledges potential pitfalls and problem areas and addresses alternative methods and approaches.
- How well the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined milestones to be accomplished by the end of each year in the period of performance.



- If applicable, whether data will be appropriately reported and documented to support a regulatory filing with the FDA.
- If applicable, whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment are appropriate for the proposed research.
- Whether an appropriate statistical plan including power analysis, as appropriate, is provided.
- **Personnel**
  - Based on the biographical sketches, 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.
  - How appropriate the levels of effort are for successful conduct of the proposed work.
  - **Applications Submitted by Postdoctoral Fellows:**
    - To what degree the application demonstrates that the PI has the potential to manage the technical and administrative aspects of the award and successfully accomplish the proposed research.
    - To what degree the application demonstrates that the PI will have appropriate mentorship to successfully conduct and complete the project.
- **Partnership (*only applicable to Partnering PI Option applications*)**
  - How well the partnership and combined expertise of the Initiating and Partnering PIs contribute to the research strategy and completion of the SOW.
  - To what degree the partnership will better address the research question together rather than through separate individual efforts.
  - How well the application reflects that both PIs contribute equal intellectual input into the design of the project and will devote similar and appropriate levels of effort to the conduct of the project.
  - Whether funding will be balanced between both PIs or is otherwise appropriately justified.

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

- **Environment**

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

- How well the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
- Whether the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.
- **Innovation (Funding Level 1 only)**
  - To what degree the proposed research is innovative.
  - To what degree the proposed research will investigate a novel idea or research question, and not the next logical step or continuation of a previous research project.
  - Whether the proposed research introduces a new paradigm or challenges existing paradigms.
- **Budget**
  - Whether the **direct** costs exceed the allowable direct costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

#### **II.E.1.b. Programmatic Review**

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

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the Defense Health Program and FY22 BCRP, as evidenced by the following:
  - Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Relative impact
  - Relative innovation (Funding Level 1 only)

## II.E.2. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is **peer review**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section II.E.1.b, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at <https://cdmrp.army.mil/about/2tierRevProcess>. An information paper describing the funding recommendations and review process for the award mechanisms for the BCRP will be provided to the PI(s) 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 200.1, over the period of performance, the federal awarding agency is required to review and consider any information about the applicant that is available in the 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 FY22 funds are anticipated to be made no later than September 30, 2023. 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 the USAMRAA will contact the Business Official authorized to negotiate on behalf of the PI's organization.

**Pre-Award Costs:** An institution of higher education, hospital, or non-profit organization may, at its own risk and without the government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.A.5.

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

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

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

An organizational transfer of an award supporting the PI, Initiating PI, or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer.

Unless otherwise restricted, changes in PI, Initiating PI, or Partnering PI will be allowed at the discretion of the USAMRAA Grants Officer, provided the intent of the award mechanism is met.

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.

**New Requirement:** Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI, Partnering PI (if applicable), and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

## **II.F.3. Reporting**

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

Annual progress reports as well as a final progress report will be required.

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

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

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 may entail additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than \$10M are required to provide information to 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. These recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Representations (see General Application Instructions, Appendix 5, Section B).

## **II.G. Federal Awarding Agency Contacts**

### **II.G.1. eBRAP 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 eBRAP 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](mailto: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 eBRAP 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](mailto: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 702b. The program announcement numeric version code will match the General Application Instructions version code 702.

### **II.H.2. Administrative Actions**

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

#### **II.H.2.a. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- More than one application per funding level is received with the same investigator named as a PI or an Initiating PI. Only the first application received per funding level will be accepted; additional applications will be administratively rejected.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- **Partnering PI Option:** Failure to submit both associated (Initiating PI and Partnering PI) applications by the application submission deadline.

### II.H.2.b. Modification

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

### II.H.2.c. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY22 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 FY22 BCRP Programmatic Panel members can be found at <https://cdmrp.army.mil/bcrp/panels/panels22>.*
- 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 FY22, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<https://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and funding cycle.
- A clinical trial is proposed.



#### **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   | Single or 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                                     |                                   |                         |
|   | Mentorship Statement: Upload as Attachment 9 with file name "Mentorship.pdf" if applicable                                       |                                   |                         |
|   | Innovation Statement: Upload as Attachment 10 with file name "Innovation.pdf" if applicable                                      |                                   |                         |
|   | Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf"                         |                                   |                         |
|   | Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable |                                   |                         |

| <b>Application Components</b>                                    | <b>Action</b>  | <b>Single or Initiating PI Completed</b> | <b>Partnering PI Completed</b> |
|--|--|--|--------------------------------|
| 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 ( <b>extramural submissions only</b> ) | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field     |  |                                |
| Budget ( <b>intramural submissions only</b> )                    | Complete the Suggested DOD Military Budget Format, including justification                                 |  |                                |
| Project/Performance Site Location(s) Form                        | Complete form as instructed  |  |                                |
| Research & Related Subaward Budget Attachment(s) Form            | Complete form as instructed  |  |                                |

## 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                                  |
| 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  |
| GMP     | Good Manufacturing Practice                                  |
| HRPO    | Human Research Protection Office                             |
| IACUC   | Institutional Animal Care and Use Committee                  |
| IRB     | Institutional Review Board                                   |
| LOI     | Letter of Intent   |
| M       | Million  |
| MB      | Megabyte   |
| MIPR    | Military Interdepartmental Purchase Request                  |
| NIH     | National Institutes of Health                                |
| ORCID   | Open Researcher and Contributor ID, Inc.                     |
| ORP     | Office of Research Protections                               |
| PDF     | Portable Document Format                                     |
| PHS     | Public Health Service  |
| PI      | Principal Investigator                                       |
| SAM     | System for Award Management                                  |
| SOW     | Statement of Work  |
| STEM    | Science, Technology, Engineering, and/or Mathematics         |
| UEI     | Unique Entity Identifier                                     |
| URL     | Uniform Resource Locator                                     |
| USAMRAA | U.S. Army Medical Research Acquisition Activity              |
| USAMRDC | U.S. Army Medical Research and Development Command           |
| USC     | United States Code   |