

**Defense Health Program  
Department of Defense Breast Cancer Research Program  
Funding Opportunities for Fiscal Year 2019 (FY19)**

**The FY19 Defense Appropriation provides \$130 million (M) to the Department of Defense Breast Cancer Research Program (BCRP)** to support innovative, high-impact research with clinical relevance that will accelerate progress to end breast cancer for Service members, Veterans, and the general public. As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency, J9 Research and Development Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for the anticipated Program Announcements/Funding Opportunities is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Materiel Command (USAMRMC).

The BCRP is providing the information in this pre-announcement to allow investigators time to plan and develop applications. FY19 BCRP Program Announcements and General Application Instructions for the following award mechanisms are anticipated to be posted on the Grants.gov website in January 2019. Pre-application and application deadlines will be available when the Program Announcements are released. This pre-announcement should not be construed as an obligation by the government.

Applications submitted to the FY19 BCRP must address one or more of the following overarching challenges:

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

<https://cdmrp.army.mil/pubs/press/2019/19bcrrpreann>

**Breakthrough Award**

- Investigators at all academic levels (or equivalent)
- Senior postdoctoral fellows who do not meet the eligibility requirements of the Breakthrough Fellowship
- Award are encouraged to apply under Funding Levels 1 and 2
- Supports promising research that has high potential to lead to or make breakthroughs in breast cancer.
- Potential impact of the research may be near-term or long-term, but it 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.

- Partnering PI Option allows two Principal Investigators (PIs), termed Initiating and Partnering PIs, to collaborate on a single application.
- Different funding levels, based on the scope of research, are available. It is the responsibility of the PI to select the funding level that is most appropriate for the research proposed. The funding level should be selected based on the scope of the research project, rather than the amount of the budget.

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

- **Funding Level 1:** Innovative, high-risk/high-reward research that is in the earliest stages of idea development. In order to foster research with clearly defined potential to yield new avenues of investigation, preliminary data are not required. Proof-of-concept is the anticipated outcome.
- **Funding Level 2:** Preclinical 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:** 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.
- **Funding Level 3:** Advanced translational studies with a high degree of project readiness. Where relevant, proof of availability of and access to necessary data, human samples, cohort(s), and/or critical reagents must be provided. If the proposed research would ultimately require US Food and Drug Administration (FDA) involvement, applications must demonstrate availability of and access to clinical reagents (e.g. therapeutic molecules) and subject population(s). Applications must state a realistic timeline for near-term clinical investigation. Small-scale clinical trials (e.g. first in human; Phase I/Ib) may be appropriate.
- **Funding Level 4:** Large-scale projects that will transform and revolutionize the clinical management and/or prevention of breast cancer. Human clinical trials are required. PIs are expected to have experience in successfully leading large-scale projects and demonstrated ability (through personal experience or via a commitment from a collaborating clinical investigator) to implement a clinical project successfully. Where relevant, applications must demonstrate availability of and access to necessary data, human samples, cohort(s), and/or critical reagents. For proposed research that will require FDA involvement, project readiness requirements at the time of application submission include: proof of availability of and access to clinical reagents (e.g. therapeutics) that meet regulatory compliance guidelines; proof of availability of and access to appropriate subject population(s); validated projections for patient recruitment; and submission of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application to the FDA, if applicable.

#### **Funding Levels 1 and 2:**

- Submission of a Letter of Intent is required prior to full application submission.
- Each PI may submit only one application as a PI or Initiating PI for each funding level. There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. However, applicants are discouraged from submitting as a Partnering PI on multiple applications unless

they are clearly unique, meaningful collaborations addressing distinct research questions.

- Additional funds are available for applications submitted under the Partnering PI Option.
- Clinical trials are not allowed.

**Funding Levels 3 and 4:**

- ***Submission of a preproposal is required; application submission is by invitation only.***
- Each PI may submit only one application as a PI or Initiating PI for each funding level. There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. However, applicants are discouraged from submitting as a Partnering PI on multiple applications unless they are clearly unique, meaningful collaborations addressing distinct research questions.
- Additional funds are available for Funding Level 3 applications submitted under the Partnering PI Option.
- PIs must include two or more breast cancer advocates on their research team. Clinical trials are allowed (Funding Level 3) or required (Funding Level 4).

**Funding Level 1:**

Maximum funding of **\$450,000** for direct costs (plus indirect costs)

Maximum period of performance is **3** years

**Funding Level 1 – Partnering PI Option:**

Maximum funding of **\$750,000** for direct costs (plus indirect costs)

Maximum period of performance is **3** years

**Funding Level 2:**

Maximum funding of **\$1 million (M)** for direct costs (plus indirect costs)

Maximum period of performance is **3** years

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

Maximum funding of **\$1.5M** for direct costs (plus indirect costs)

Maximum period of performance is **3** years

**Funding Level 2 – Population Science and Prevention Studies**

Maximum funding of **\$1.5M** for direct costs (plus indirect costs)

Maximum period of performance is **4** years

**Funding Level 2 – Population Science and Prevention Studies – Partnering PI Option**

Maximum funding of **\$2M** for direct costs (plus indirect costs)

Maximum period of performance is **4** years

**Funding Level 3:**

Maximum funding of **\$3M** in direct costs (plus indirect costs)

Maximum period of performance is **4** years

**Funding Level 3 – Partnering PI Option:**

Maximum funding of **\$4M** for direct costs (plus indirect costs)

Maximum period of performance is **4** years

**Funding Level 4 and Funding Level 4 – Partnering PI Option:**

Maximum funding of **\$10M** for direct costs (plus indirect costs)

Maximum period of performance is **4** years

**Breakthrough Fellowship Award**

As of the application submission deadline, all eligible PIs must have:

- Successfully completed the requirements for a doctoral or medical degree, and
- Been in the laboratory or clinical research setting in which the proposed research is to be performed for no more than 2 years, and

- A total of less than 4 years' experience in a postdoctoral fellowship or mentored clinical research training program (excludes any clinical residency or fellowship training)

#### Mentor

- Must have breast cancer research experience, including current funding and recent publications
- Supports exceptionally talented, "best and brightest" recent doctoral or medical graduates in pursuit of innovative, high-impact breast cancer research.
- Proposed research must have high potential to lead to or make breakthroughs in breast cancer and show evidence of rigorous experimental design, sufficient experimental details, appropriate controls, pitfalls and alternatives, and a statistical plan.
- Individualized researcher development plan and mentorship should prepare the PI for an independent career at the forefront of breast cancer research or patient care.
- The PI is not required to have previous experience in breast cancer research.
- Submission of a Letter of Intent is required prior to full application submission.
- Maximum funding of **\$300,000** for direct costs (plus indirect costs)
- Maximum period of performance is **3** years

#### **Era of Hope Scholar Award**

- Independent, non-mentored investigators within 6 years of their last training position (e.g., postdoctoral fellowship, medical residency, clinical fellowship) as of the application submission deadline
- Supports exceptionally talented, early-career scientists who have demonstrated that they are the "best and brightest" in their fields through extraordinary creativity, vision, innovation, and productivity.
- PIs should articulate a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention.
- PIs must demonstrate experience in forming effective partnerships and collaborations and exhibit strong potential for future leadership in breast cancer.
- PIs are required to include two or more breast cancer advocates on their research team.
- Submission of a Letter of Intent is required prior to full application submission.
- Maximum funding of **\$3M** for direct costs (plus indirect costs)
- Maximum period of performance is **4** years

#### **Innovator Award**

- Associate Professor or above (or equivalent).
- Supports visionary individuals who have demonstrated exceptional creativity, innovative work, and paradigm-shifting leadership in any field.
- Provides opportunity to pursue novel, visionary, high-risk ideas that will accelerate progress toward ending breast cancer.
- PIs must include two or more breast cancer advocates on their research team.

***Submission of a preproposal is required; application submission is by invitation only.***

- Maximum funding of **\$5M** for direct costs (plus indirect costs).
- Maximum period of performance is **4** years

### **Distinguished Investigator Award**

- Assistant Professor or above (or equivalent) and more than 6 years beyond the PI's last training position as of the application submission deadline
- Seeks new paradigms in breast cancer research by supporting investigators who are established and recognized leaders with a renowned reputation as a researcher who has made groundbreaking contributions to advancing their field and who ***propose a fundamental shift from their track record of research.***
- Does not support continuation of or incremental changes from the PI's published line of research. A shift from a different malignancy to breast cancer may not constitute a fundamental shift.
- If the PI is not an established breast cancer researcher, he/she must clearly articulate a motivation and commitment for proposing a conceptual shift in his/her research and must include at least one collaborator with breast cancer expertise.
- PIs must include two or more breast cancer advocates on their research team.
- High-risk/high-reward projects pursuing innovative new paradigms are encouraged, but not required.
- ***Submission of a preproposal is required; application submission is by invitation only.***
- Maximum funding of **\$3M** for direct costs (plus indirect costs)
- Maximum period of performance is **4** years

A pre-application is required and must be submitted through the electronic Biomedical Research Application Portal (eBRAP) at <https://eBRAP.org> prior to the pre-application deadline. All applications must conform to the final Program Announcements and General Application Instructions that will be available for electronic downloading from the Grants.gov website. The application package containing the required forms for each award mechanism will also be found on Grants.gov. A listing of all CDMRP and other USAMRMC extramural funding opportunities can be obtained on the Grants.gov website by performing a basic search using CFDA Number 12.420.

Submission deadlines are not available until the Program Announcements are released. For email notification when Program Announcements are released, subscribe to program-specific news and updates under "Email Subscriptions" on the eBRAP homepage at <https://eBRAP.org>. For more information about the BCRP or other CDMRP-administered programs, please visit the [CDMRP website \(https://cdmrp.army.mil\)](https://cdmrp.army.mil).

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