Fiscal Year 2020 Breast Cancer Research Program Reference Table of Award Mechanisms and Submission Requirements

| Award Mechanism | Eligibility | Key Mechanism Elements | Funding | Submission Deadline |
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| Breakthrough Award Levels 1 and 2 Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-20-BCRP- BTA12-2 | Investigators at all academic levels (or equivalent). Applications from postdoctoral fellows 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 for the Breakthrough Award. 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 scope of the scope of 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 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: Preclinical research that is already supported by substantial | Funding Level 1: Maximum funding of \$450,000 for direct costs (plus indirect costs) The maximum period of performance is 3 years. Funding Level 1 with Partnering PI Option: Maximum funding of \$750,000 for direct costs (plus indirect costs) The maximum period of performance is 3 years. Funding Level 2: Maximum funding of \$1 million (M) for direct costs (plus indirect costs) The maximum period of performance is 3 years. Funding Level 2 with Partnering PI Option: Maximum funding of \$1.5M for direct costs (plus indirect costs) The maximum period of performance is 3 years. Funding Level 2 with Partnering PI Option: Maximum funding of \$1.5M for direct costs (plus indirect costs) The 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) The maximum period of performance is 3 years. | Pre-Application (Letter of Intent): September 8, 2020 5:00 p.m. Eastern Time (ET) Application: September 22, 2020 11:59 p.m. ET |

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| Award Mechanism | | Key Mechanism Elements preliminary or published data and strongly validates clinical translation in a well-defined context within the <i>breast cancer landscape</i>. Funding Level 2 – Population Science and Prevention Studies: Preclinical research that is already supported by substantial preliminary or published data and strongly validates clinical translation in a well-defined context within the <i>breast cancer</i> <i>landscape</i>. 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 Levels 1 and 2 Submission of a Letter of Intent is required prior to full application submission. Each investigator may be named as a PI or Initiating PI on only one applications for which an investigator may be named as a Partnering PI. However, investigators are discouraged from being named as a Partnering PI. However, investigators are discouraged from being named as a Partnering PI on multiple FY20 Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful collaborations addressing distinct research questions. Additional funds are available for applications submitted under the Partnering PI Option or the Population Science and Prevention Studies Option. | Funding 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) • The maximum period of performance is 4 years. | Submission Deadline |

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| | | • Clinical trials are not allowed. | | |
| Breakthrough Award Level 3 Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-20-BCRP- BTA3-2 | Independent investigators at all academic levels (or equivalent). Investigators who were invited to be named on an application submitted under Funding Opportunity W81XWH-20-BCRP- BTA3 are not eligible to submit a pre-application for the same research project under the current Funding Opportunity, W81XWH- 20-BCRP-BTA3-2. | 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 PIs, termed Initiating and Partnering PIs, to collaborate on a single application. Different funding levels, based on the scope of research are available for the Breakthrough Award. 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 is a general description, although not all-inclusive, of the scope of research are vould be appropriate to propose under this funding level: Funding Level 3: Advanced translational studies with a high degree of project readiness. Where relevant, proof of availability of and access to necessary data, human samples, cohort(s), and/or critical reagents must be provided. If the proposed research would ultimately require U.S. Food and Drug Administration (FDA) involvement, applications must demonstrate availability of and access to clinical reagents (e.g., therapeutic molecules) and patient population(s). Applications must state a realistic timeline for near-term clinical | Funding Level 3: Maximum funding of \$3M in direct costs (plus indirect costs) The maximum period of performance is 4 years. Funding Level 3 with Partnering PI Option: Maximum funding of \$4M for direct costs (plus indirect costs) The maximum period of performance is 4 years. | Pre-Application (Preproposal): June 24, 2020 5:00 p.m. ET Invited Application: October 6, 2020 11:59 p.m. ET |

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| | | investigation. Small-scale clinical trials (e.g., first in human; Phase I/Ib) may be appropriate. | | | |
| | | Additional Elements | | | |
| | | • Submission of a pre-application is required; <i>application submission is by invitation only</i> . | | | |
| | | • There are no limits on the number of pre-applications for which an investigator may be named as a PI, Initiating PI, or Partnering PI. Investigators are discouraged from being named on multiple pre-applications unless they are clearly addressing distinct research questions. | | | |
| | | • Additional funds are available for Funding Level 3 applications submitted under the Partnering PI Option. | | | |
| | | • Applications must include two or more breast cancer advocates on the research team. | | | |
| | | • Clinical trials are allowed. | | | |
| Breakthrough Award Level 4 Go to: | • Independent investigators at all academic levels (or equivalent). | • Supports promising research that has high potential to lead to or make breakthroughs in breast cancer. | Funding Level 4 and Funding Level 4 with Partnering PI Option: | Pre-Application (Preproposal): June 24, 2020 | |
| Program Announcement | • Investigators who were invited to be named on an | • Potential impact of the research may be | • Maximum funding of \$10M | 5:00 p.m. ET | |
| General Application Instructions | application submitted under Funding Opportunity W81XWH-20-BCRP- BTA4 are not eligible to submit a pre-application for the same research project | application submitted under | near-term or long-term, but it must move beyond a minor advancement | for direct costs (plus indirect costs) | Invited Application: October 6, 2020 |
| Grants.gov Funding Opportunity Number: W81XWH-20-BCRP- | | and have the potential to lead to a new approach that is fundamentally better than interventions already approved or in clinical development. | • The maximum period of performance is 4 years. | 11:59 p.m. ET | |
| BTA4-2 | | • Partnering PI Option allows two PIs, termed Initiating and Partnering PIs, to collaborate on a single application. | | | |
| | | Different funding levels, based on the scope of research, are available for the Breakthrough Award. It is the responsibility of the PI to select the funding level that is most appropriate for | | | |

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| | | 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 is a general description, although not all-inclusive, of the scope of research projects that would be appropriate to propose under this funding level: | | |
| | | 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 Device Exemption application to the FDA, if applicable. Additional Elements | | |
| | | required; <i>application submission is by invitation only</i> . | | |

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| | | There are no limits on the number of pre-applications for which an investigator may be named as a PI, Initiating PI, or Partnering PI. Investigators are discouraged from being named on multiple pre-applications unless they are clearly addressing distinct research questions. Applications must include two or more breast cancer advocates on the research team. <i>Clinical trials are required.</i> | | |
| Era of Hope Scholar Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-20-BCRP- EOHS-2 | Independent investigator within 6 years of their last training position (e.g., postdoctoral fellowship, medical residency, clinical fellowship) as of the application submission deadline. Postdoctoral fellows, clinical fellows (including residents and interns), and other researchers currently in training positions are not eligible. | 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. Applications 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. Experience in breast cancer research is not required; however, the application must focus on breast cancer, and the PI must maintain a 50% dedication of their full-time professional effort during the award period to breast cancer research. Applications must include two or more breast cancer advocates on the 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) The maximum period of performance is 4 years. | Pre-Application (Letter of Intent): September 8, 2020 5:00 p.m. ET Application: September 22, 2020 11:59 p.m. ET Confidential Letters of Recommendation Submission Deadline: September 25, 2020 5:00 p.m. ET |

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| Innovator Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-20-BCRP-INNOV-2 | Associate Professor or above (or equivalent). Previous BCRP Innovator Award recipients are ineligible. Investigators who were invited to be named on an application submitted under Funding Opportunity W81XWH-20-BCRP- INNOV are not eligible to submit a pre-application for the same research project under the current Funding Opportunity, W81XWH- 20-BCRP-INNOV-2. | Supports visionary individuals who have demonstrated exceptional creativity, innovative work, and paradigm-shifting leadership in any field including, but not limited to, breast cancer. Provides opportunity to pursue novel, visionary, high-risk ideas that could accelerate progress toward ending breast cancer. Experience in breast cancer research is not required; however, the application must focus on breast cancer, and the PI must maintain a 50% dedication of their full-time professional effort during the award period to breast cancer research. Applications must include two or more breast cancer advocates on the research team. Submission of a pre-application is required; application submission is by invitation only. | Maximum funding of \$7M for direct costs (plus indirect costs) The maximum period of performance is 4 years. | Pre-Application: (Preproposal) June 24, 2020 5:00 p.m. ET Invited Application: October 6, 2020 11:59 p.m. ET Confidential Letters of Recommendation Submission Deadline: October 8, 2020 5:00 p.m. ET |
| Transformative Breast Cancer Consortium Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: W81XWH-20-BCRP- TBCCA | • Independent investigators at all academic levels (or equivalent) | Supports collaborations and ideas that will transform the lives of individuals with, and/or at risk for, breast cancer and will significantly accelerate progress toward ending breast cancer. The proposed consortium's work must pursue innovative, high-risk/high-reward research that has the potential to change existing paradigms, or develop new paradigms. Requires a synergistic, highly integrated, multidisciplinary, and multi-institutional research team of leading scientists, clinicians, and consumer advocates who will be assembled into a consortium to address a major problem in a way that could not be accomplished by a single investigator or group. | Maximum funding of \$20M for direct costs (plus indirect costs) The maximum period of performance is 4 years. | Pre-Application (Preproposal): June 24, 2020 5:00 p.m. ET Invited Application: October 6, 2020 11:59 p.m. ET |

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| | | This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts, such as the National Cancer Institute (NCI) Specialized Programs of Research Excellence (SPOREs), and it should not represent a collection of related Program Project grants or subprojects. | | |
| | | • Research funded under this award mechanism should result in answers that will fundamentally and significantly transform and disrupt the present breast cancer landscape. | | |
| | | Preference will be given to applications that include one or more of the following: | | |
| | | • Different disciplines that come together with one overarching plan to address ending breast cancer with an ecologic approach. An ecologic approach is one that brings together the different perspectives that affect the complexity of breast cancer and their interdependence, or looks at all aspects of the disease and brings together these different perspectives. | | |
| | | • Research that includes truly innovative and brand new paradigms in breast cancer that will address vital issues in a unique way. The issues may be one of the FY20 BCRP Overarching Challenges, the intersection of multiple Overarching Challenges, or with justification, may be a different issue that meets the intent of the award mechanism and addresses the mission of ending breast cancer. | | |
| | | • A plan for a deep, definitive dive into one of the FY20 BCRP Overarching Challenges or a fundamental issue that has not yet been asked or answered in a manner that has not yet been attempted. | | |

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| | | Although not all inclusive, applications that proposes the following as the primary effort(s) or central hypothesis of the consortium will not meet the intent of this award mechanism: | | |
| | | • NCI Program Project or SPORE grants or applications | | |
| | | • Conducting drug screens or testing a "cocktail" of therapeutics | | |
| | | • Targeting a single gene or protein | | |
| | | • Developing a new derivative or formulation of an old drug | | |
| | | Conducting genomic landscape mapping analyses | | |
| | | • Seeking to improve existing technologies (e.g., mammography or magnetic resonance imaging [MRI] screening) | | |
| | | Additional Elements | | |
| | | • Submission of a pre-application is required; <i>application submission is by invitation only</i> . | | |
| | | • The award mechanism is structured with a Consortium Director and at least three, but not more than four, Team PIs. | | |
| | | • An investigator may be named as Consortium Director on only one pre- application. | | |
| | | • There are no limits on the number of pre-applications for which an investigator may be named as a Team PI. | | |
| | | • Applications must include at least one breast cancer consumer advocate per team. | | |
| | | • Clinical trials (up to and including | | |

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| | | Phase I or equivalent) are allowed. | | |
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