

***Fiscal Year 2021 (FY21) Breast Cancer Research Program (BCRP)
Reference Table of Award Mechanisms and Submission Requirements***

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
<p>Breakthrough Award Levels 1 and 2</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number:</p> <p>W81XWH-21-BCRP-BTA12-2</p>	<ul style="list-style-type: none"> • Investigators at all academic levels (or equivalent) • Applications from postdoctoral fellows are encouraged under Funding Levels 1 and 2 • <i>Each investigator may be named as a Principal Investigator (PI) or Initiating PI on only one application per funding level for the Breakthrough Award Levels 1 and 2</i> • <i>There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. However, investigators are discouraged from being named as a Partnering PI on multiple FY21 Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful collaborations addressing distinct research questions.</i> 	<ul style="list-style-type: none"> • Supports promising research that has high potential to lead to or make breakthroughs in breast cancer. • Research should have the potential for a major impact and accelerate progress toward ending 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 partner on a single application. <ul style="list-style-type: none"> ○ 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. ○ <i>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.</i> 	<p>Funding Level 1:</p> <ul style="list-style-type: none"> • Maximum funding of \$450,000 for direct costs (plus indirect costs) • The maximum period of performance is 3 years. <p>Funding Level 1 with Partnering PI Option:</p> <ul style="list-style-type: none"> • Maximum funding of \$750,000 for direct costs (plus indirect costs) • The maximum period of performance is 3 years. <p>Funding Level 2:</p> <ul style="list-style-type: none"> • Maximum funding of \$1 million (M) for direct costs (plus indirect costs) • The maximum period of performance is 3 years. <p>Funding Level 2 – Population Science and Prevention Studies:</p> <ul style="list-style-type: none"> • Maximum funding of \$1.5M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. <p>Funding Level 2 with Partnering PI Option:</p> <ul style="list-style-type: none"> • Maximum funding of \$1.5M for direct costs (plus indirect costs) • The maximum period of performance is 3 years. 	<p>Pre-Application (Letter of Intent): August 31, 2021 5:00 p.m. Eastern time</p> <p>Application: September 14, 2021 11:59 p.m. Eastern time</p>

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		<p>Different funding levels, based on the scope of research, are available for the Breakthrough Award. Each level has a defined research scope. It is the responsibility of the PI to select the level that aligns with the scope of the proposed research. The funding level should be selected based on the research scope of the proposed research and not the amount of the budget.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 <i>breast cancer landscape</i>. • 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 <i>breast cancer 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. 	<p>Funding Level 2 – Population Science and Prevention Studies – Partnering PI Option:</p> <ul style="list-style-type: none"> • Maximum funding of \$2M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	

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		<p><u>Funding Levels 1 and 2</u></p> <ul style="list-style-type: none"> • Submission of a Letter of Intent is required prior to full application submission. • Additional funds are available for applications submitted under the Partnering PI Option or the Population Science and Prevention Studies Option. • Clinical trials are not allowed. 		
<p>Breakthrough Award Level 3 Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: W81XWH-21-BCRP-BTA3-2</p>	<ul style="list-style-type: none"> • Independent investigators at all academic levels (or equivalent). • <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 for the Breakthrough Award Level 3.</i> • <i>Investigators are discouraged from being named on multiple pre-applications unless they are clearly addressing distinct research questions.</i> 	<ul style="list-style-type: none"> • Supports promising research that has high potential to lead to or make breakthroughs in breast cancer. • Research should have the potential for a major impact and accelerate progress toward ending 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. • Applications are expected to identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research. • Partnering PI Option allows two PIs, termed Initiating and Partnering PIs, to partner on a single application. <ul style="list-style-type: none"> ○ Each PI is expected to bring distinct contributions to the application. 	<p>Funding Level 3:</p> <ul style="list-style-type: none"> • Maximum funding of \$4M in direct costs (plus indirect costs) • The maximum period of performance is 4 years. <p>Funding Level 3 with Partnering PI Option:</p> <ul style="list-style-type: none"> • Maximum funding of \$5M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Preproposal): June 24, 2021 5:00 p.m. Eastern time</p> <p>Invited Application: October 5, 2021 11:59 p.m. Eastern time</p>

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		<ul style="list-style-type: none"> ○ 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. ○ <i>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.</i> <p>Different funding levels, based on the scope of research are available for the Breakthrough Award. Each level has a defined research scope. It is the responsibility of the PI to select the level that aligns with the scope of the proposed research. The funding level should be selected based on the research scope and not on the amount of the budget.</p> <p>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:</p> <p>Funding Level 3: Advanced translational studies with a high degree of project readiness. Where relevant, proof of availability of and access to necessary data, human samples, cohort(s), and/or critical reagents must be provided. If the proposed research would ultimately require U.S. Food and Drug Administration (FDA) involvement, applications must demonstrate availability of and access to clinical reagents (e.g., therapeutic molecules) and patient population(s). Applications must state a realistic timeline for near-term clinical investigation. Small-scale clinical trials (e.g., first in human; phase 1/1b) may be appropriate.</p>		

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		<p><u>Additional Elements</u></p> <ul style="list-style-type: none"> • Submission of a pre-application is required; <i>application submission is by invitation only.</i> • 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. 		
<p>Breakthrough Award Level 4 Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: W81XWH-21-BCRP-BTA4-2</p>	<ul style="list-style-type: none"> • Independent investigators at all academic levels (or equivalent). • <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 on an application.</i> • <i>Investigators are discouraged from being named on multiple pre-applications unless they are clearly addressing distinct research questions.</i> 	<ul style="list-style-type: none"> • Supports promising research that has high potential to lead to or make breakthroughs in breast cancer. • Research should have the potential for a major impact and accelerate progress toward ending 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. • Applications are expected to identify the breast cancer patients or at-risk individuals who would ultimately benefit from the proposed research. • Partnering PI Option allows two PIs, termed Initiating and Partnering PIs, to partner on a single application. <ul style="list-style-type: none"> ○ Each PI is expected to bring distinct contributions to the application. 	<p>Funding Level 4 and Funding Level 4 with Partnering PI Option:</p> <ul style="list-style-type: none"> • Maximum funding of \$10M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Preproposal): June 24, 2021 5:00 p.m. Eastern time</p> <p>Invited Application: October 5, 2021 11:59 p.m. Eastern time</p>

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		<ul style="list-style-type: none"> ○ 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. ○ <i>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.</i> <p>Different funding levels, based on the scope of research are available for the Breakthrough Award. Each level has a defined research scope. It is the responsibility of the PI to select the level that aligns with the scope of the proposed research. The funding level should be selected based on the research scope and not on the amount of the budget.</p> <p>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:</p> <ul style="list-style-type: none"> ● 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: 		

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		<p>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 or Investigational Device Exemption application to the FDA, if applicable.</p> <p><u>Additional Elements</u></p> <ul style="list-style-type: none"> • Submission of a pre-application is required; <i>application submission is by invitation only.</i> • Applications must include two or more breast cancer advocates on the research team. • Clinical trials are required. 		
<p>Era of Hope Scholar Award</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: W81XWH-21-BCRP-EOHS-2</p>	<ul style="list-style-type: none"> • 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. • <i>An investigator may be named on only one FY21 Era of Hope Scholar Award application as a PI.</i> 	<ul style="list-style-type: none"> • Supports individuals early in their careers who have demonstrated significant potential to effect meaningful change in breast cancer. • Individuals should be exceptionally talented scientists who have shown that they are the “best and brightest” in their field(s) through extraordinary creativity, vision, innovation, and productivity. • PIs must demonstrate experience in forming effective partnerships and collaborations and exhibit strong potential for future leadership in breast cancer research. • Applications should articulate a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention. • <i>Experience in breast cancer research is not required;</i> however, the application must focus on breast cancer, and the PI must maintain a 50% dedication of their 	<ul style="list-style-type: none"> • Maximum funding of \$3M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Letter of Intent): August 31, 2021 5:00 p.m. Eastern time</p> <p>Application: September 14, 2021 11:59 p.m. Eastern time</p> <p>Confidential Letters of Recommendation Submission Deadline: September 17, 2021 5:00 p.m. Eastern time</p>

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		<p>full-time effort during the award period to breast cancer research.</p> <ul style="list-style-type: none"> • 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. • Clinical trials are allowed. 		
<p>Innovator Award Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number: W81XWH-21-BCRP-INNOV-2</p>	<ul style="list-style-type: none"> • Associate Professor (or equivalent) or above. • Previous BCRP Innovator Award recipients are ineligible. • <i>An investigator may be named as PI on only one Innovator Award pre-application.</i> 	<ul style="list-style-type: none"> • Supports <i>visionary individuals</i> who have demonstrated exceptional creativity, innovative work, and paradigm-shifting leadership in any field including, but not limited to, breast cancer. • Provides these individuals with the opportunity and freedom to pursue novel, visionary, high-risk ideas that could accelerate progress toward ending breast cancer. • <i>Experience in breast cancer research is not required</i>; however, the application must focus on breast cancer, and the PI must maintain a 50% dedication of their full-time 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; <i>application submission is by invitation only.</i> • Clinical trials are allowed. 	<ul style="list-style-type: none"> • Maximum funding of \$7M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Preproposal): June 24, 2021 5:00 p.m. Eastern time</p> <p>Application: October 5, 2021 11:59 p.m. Eastern time</p> <p>Confidential Letters of Recommendation Submission Deadline: October 7, 2021 5:00 p.m. Eastern time</p>

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<p>Transformative Breast Cancer Consortium Award</p> <p>Go to:</p> <ul style="list-style-type: none"> • Program Announcement • General Application Instructions <p>Grants.gov Funding Opportunity Number:</p> <p>W81XWH-21-BCRP-TBCCA-2</p>	<ul style="list-style-type: none"> • Independent investigators at all academic levels (or equivalent) • The Consortium Director is required to commit and maintain at least 25% level of time and effort during the award period. • <i>An investigator may be named as Consortium Director on only one pre-application.</i> • <i>There are no limits on the number of pre-applications for which an investigator may be named as a Team PI.</i> 	<ul style="list-style-type: none"> • 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. • 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. • The consortium should have at least four, but no more than five, teams investigating different projects under a central hypothesis. Each team’s work must be integrated within the consortium so that every component is working toward the consortium’s central hypothesis. • The proposed consortium’s overall work is expected to be innovative. In addition, the award will include funds for “seed projects” to pursue brand new, high-risk/high-reward concepts that arise from the work, during the award period. <p><i>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.</i></p> <ul style="list-style-type: none"> • Research funded under this award mechanism should result in answers that will fundamentally and significantly transform and disrupt the present breast cancer landscape. 	<ul style="list-style-type: none"> • Maximum funding of \$25M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Preproposal): June 24, 2021 5:00 p.m. Eastern time</p> <p>Invited Application: October 5, 2021 11:59 p.m. Eastern time</p>

		<p>Applications must include the following:</p> <ul style="list-style-type: none">• Research that includes truly innovative and brand-new paradigm shifting work in breast cancer that will address vital issues in a unique way. The issues may be one (or more) of the FY21 BCRP 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. If the application identifies a different fundamental issue, it must be coupled with at least one of the FY21 BCRP Overarching Challenges.• Research that includes different disciplines that come together to address ending breast cancer with an ecologic approach. The consortium's proposed research must look at all aspects of the disease and bring together these different perspectives into one overarching plan for a deep, definitive dive into the FY21 BCRP Overarching Challenge(s) or other fundamental issue identified in the application. The plan also should include issues related to the hypothesis that have not been previously addressed or answered.• A plan that describes in detail the integration across the consortium in all aspects, including administration, logistics, and substance. Applications must describe the substantive integration across and among teams that are necessary for the work. The required communication plan and administrative management plan will not suffice to show integration, nor will identifying individual team members who will cross teams. A detailed explanation of the substantive research processes that will be integrated is required. <p>Although not all inclusive, applications that proposes the following as the primary effort(s) or central hypothesis of the</p>		
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		<p>consortium will not meet the intent of this award mechanism:</p> <ul style="list-style-type: none"> • 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 screening) <p><u>Additional Elements</u></p> <ul style="list-style-type: none"> • 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. • Applications must include at least one breast cancer consumer advocate per team. • Clinical trials (up to and including phase 1 or equivalent) are allowed but not required, and the primary thrust of the application should not be a clinical trial. 		