

***Fiscal Year 2019 Breast Cancer Research Program
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: W81XWH-19-BCRP-BTA12-2</p>	<ul style="list-style-type: none"> • Investigators at all academic levels (or equivalent). • Applications are encouraged for postdoctoral fellows. A mentorship statement is required for applications submitted with a PI who is a postdoctoral fellow. 	<ul style="list-style-type: none"> • 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. <p>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.</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. 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 	<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 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>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>Pre-Application (Letter of Intent): August 22, 2019 5:00 p.m. Eastern Time (ET)</p> <p>Application: September 5, 2019 11:59 p.m. ET</p>

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		<p>well-defined context within the breast cancer landscape.</p> <ul style="list-style-type: none"> • 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. <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. • Each investigator may be named as a PI or Initiating PI on only one application 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, investigators are discouraged from being named 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 or the Population Science and Prevention Studies Option. • Clinical trials are not allowed. 	<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>Breakthrough Award Level 3</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-19-BCRP-BTA3-2</p>	<ul style="list-style-type: none"> • Independent investigators at all academic levels (or equivalent). 	<ul style="list-style-type: none"> • 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. <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 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 patient population(s). Applications must state a realistic timeline for near-term clinical investigation. Small-scale clinical trials (e.g., first in human; Phase I/Ib) may be appropriate. <p><u>Additional Elements</u></p> <ul style="list-style-type: none"> • Submission of a preproposal is required; application submission is by invitation only. • Each investigator may be named on only one pre-application as a PI or Initiating PI for this funding level. There are no 	<p>Funding Level 3:</p> <ul style="list-style-type: none"> • Maximum funding of \$3M 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 \$4M for direct costs (plus indirect costs) • The maximum period of performance is 4 years. 	<p>Pre-Application (Preproposal): June 26, 2019 5:00 p.m. ET</p> <p>Invited Application: September 25, 2019 11:59 p.m. ET</p>

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		<p>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 applications unless they are clearly unique, meaningful collaborations addressing distinct research questions.</p> <ul style="list-style-type: none"> • Additional Funds are available for Funding Level 3 applications submitted under the Partnering PI Option. • Applications must include two or more breast cancer consumer advocates on the research team. • Clinical trials are allowed. 		

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<p>Breakthrough Award Level 4</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-19-BCRP-BTA4-2</p>	<ul style="list-style-type: none"> • Independent investigators at all academic levels (or equivalent). 	<ul style="list-style-type: none"> • 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. <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: 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 	<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 26, 2019 5:00 p.m. ET</p> <p>Invited Application: September 25, 2019 11:59 p.m. ET</p>

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		<p>Investigational Device Exemption (IDE) application to the FDA, if applicable.</p> <p><u>Additional Elements</u></p> <ul style="list-style-type: none"> • Submission of a preproposal is required; application submission is by invitation only. • Each investigator may be named on only one pre-application as a PI or Initiating PI for this funding level. 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 applications unless they are clearly unique, meaningful collaborations addressing distinct research questions. • Additional Funds are available for Funding Level 4 applications submitted under the Partnering PI Option. • Applications must include two or more breast cancer consumer advocates on the research team. • Clinical trials are required. 		