Fiscal Year 2023 (FY23) Department of Defense Breast Cancer Research Program (BCRP) Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Breakthrough Award Levels 1 and 2 Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-BTA12	 Investigators at all academic levels (or equivalent) Applications from postdoctoral fellows are encouraged under Funding Levels 1 and 2. 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. 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 FY23 Breakthrough Award Levels 1 and 2 applications unless they are clearly unique, meaningful partnerships addressing distinct research questions. 	 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 fundamentally new approach that is significantly more effective than interventions already approved or in clinical development. Partnering PI Option allows two PIs, termed the Initiating and Partnering PIs, to collaborate on a single application. 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> 	 Funding Level 1: The maximum allowable funding for the entire period of performance is \$450,000 for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 3 years. Funding Level 1 with Partnering PI Option: The maximum allowable funding for the entire period of performance is \$750,000 for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum allowable funding for the entire period of performance is \$750,000 for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 3 years. Funding Level 2: The maximum allowable funding for the entire period of performance is \$1 million (M) for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum allowable funding for the entire period of performance is \$1 million (M) for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 3 years. 	Pre-Application (Letter of Intent): March 28, 2023 5:00 p.m. Eastern time Application: April 11, 2023 11:59 p.m. Eastern time

Award Mechanism Eligit	lity Key Mechanism Elements	Funding	Submission Deadline
	 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. 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: 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: Studies that investigate why certain human patient populations differ in cancer risk or clinical prognosis. The studies should focus on the analysis of human data and biospecimens and, with compelling justification, may request higher levels of funding and an additional year in the period of performance. Funding Levels 1 and 2 Submission of a Letter of Intent is required prior to full application submission. 	 Funding Level 2 – Population Science and Prevention Studies: The maximum allowable funding for the entire period of performance is \$1.5M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. Funding Level 2 with Partnering PI Option: The maximum allowable funding for the entire period of performance is \$1.5M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 3 years. Funding Level 2 – Population Science and Prevention Studies with Partnering PI Option: The maximum allowable funding for the entire period of performance is 3 years. 	
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Era of Hope Scholar Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-EOHS	 Independent, non- mentored investigators within 6 years of their last training position as of the application submission deadline (excluding time spent on family medical leave) Postdoctoral fellows, clinical fellows (including residents and interns), and other researchers currently in training positions are not eligible. 	 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 should have demonstrated experience in forming effective partnerships and collaborations and must 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 commit a minimum of 25% level of time and effort during the period of performance to conduct breast cancer research under this award. Additional Elements Submission of a Letter of Intent is required prior to full application submission. Applications must include two or more breast cancer advocates on the research team. 	 The maximum allowable funding for the entire period of performance is \$3M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. 	Pre-Application (Letter of Intent): March 28, 2023 5:00 p.m. Eastern time Application: April 11, 2023 11:59 p.m. Eastern time Confidential Letters of Recommendation Submission Deadline: April 14, 2023 5:00 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Clinical Research Extension Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-CREA2	 Investigators at all academic levels (or equivalent) There are no limitations on the number of applications for which an investigator may be named as a PI, Initiating PI, or Partnering PI for the Clinical Research Extension Award. Investigators are discouraged from being named on multiple applications unless they are clearly addressing distinct research questions. 	 Supports research that extends the data collection, follow-up, and analysis of breast cancer clinical research studies. The intent of this mechanism is to increase the clinically relevant impact of breast cancer patient participation in clinical research by addressing the knowledge lost due to limited or early termination of patient follow-up and sample collection and analysis. Although not all-inclusive, research proposed under this mechanism may entail a deeper molecular analysis of clinical samples, initiation of new correlative studies, biomarker validation, or continuing clinical follow-up of patients currently/previously enrolled in an open/ongoing or completed clinical trial. Partnering PI Option allows two PIs, termed the Initiating and Partnering PIs, to collaborate on a single application. Each PI is expected to bring a distinct contribution 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. Additional Elements Submission of a Letter of Intent is required prior to full application submission. Clinical trials are not allowed. 	 Clinical Research Extension Award: The maximum allowable funding for the entire period of performance is \$5M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. Clinical Research Extension Award with Partnering PI Option: The maximum allowable funding for the entire period of performance is \$6M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. 	Pre-Application (Letter of Intent): March 28, 2023 5:00 p.m. Eastern time Application: April 11, 2023 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
NEW for FY23: Transformative Breast Cancer Consortium Development Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-TBCCDA	 Independent investigators at all academic levels (or equivalent) Investigators named as Consortium Director on a pre-application or full application submitted under funding opportunity HT945-23- BCRP-TBCCA are not eligible. 	 Provides the time and resources needed to bring investigators and breast cancer advocates together to establish a consortium framework and conduct preliminary research that will support application to a future, full Transformative Breast Cancer Consortium Award (pending availability of funds). Supports the following: (1) development of the infrastructure of a multi-institutional research team inclusive of scientists, clinicians, and breast cancer advocates (e.g., building appropriate collaborations, outlining integration, research management, administrative management, and communication plans, and devising an intellectual property plan), (2) generation of preliminary data to serve as proof of concept or for project integration, (3) acquisition of research resources, and (4) development of a framework of necessary statistical analyses. Additional Elements Submission of a Letter of Intent is required prior to full application submission. PIs are required to include breast cancer advocate(s) on the research team. 	 The maximum allowable funding for the entire period of performance is \$100,000 for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 1 year. 	Pre-Application (Letter of Intent): March 28, 2023 5:00 p.m. Eastern time Application: April 11, 2023 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Transformative Breast Cancer Consortium Award Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-TBCCA	 Independent investigators at all academic levels (or equivalent) The Consortium Director is required to commit and maintain a minimum level of time and effort of 25% during the period of performance to direct and manage the consortium and to lead their own project team. An investigator may be named as Consortium Director on only one preapplication. There are no limits on the number of preapplications for which an investigator may be named as a Project Team PI. Investigators named as PI (Consortium Director) on a pre-application or full application submitted under funding opportunity HT945-23-BCRP-TBCCDA are not eligible to be named as Consortium Director under the current funding opportunity. 	 Supports collaborations and ideas that will transform or improve 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, project teams, each 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 Transformative Breast Cancer Consortium 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. 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. 	 The maximum allowable funding for the entire period of performance is \$25M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. 	Pre-Application (Preproposal): March 29, 2023 5:00 p.m. Eastern time Invited Application: June 28, 2023 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
		• Research funded under this award mechanism should result in answers that will fundamentally and significantly transform and disrupt the present breast cancer landscape.		
		Applications must include the following:		
		• 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 FY23 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 FY23 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 FY23 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.		

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
		• 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.		
		Although not all inclusive, applications that propose the following as the primary effort(s) or central hypothesis of the consortium will <i>not</i> 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 screening)		
		Additional Elements		
		• Pre-application submission is required; application submission is by invitation only.		
		• The award mechanism is structured with a Consortium Director and at least three, but not more than four, Project Team PIs.		

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Breakthrough Award	Independent investigators	 Applications must include at least one breast cancer consumer advocate per project 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. Supports promising research that has 	Funding Level 3:	Pre-Application
Level 3 Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-BTA3	 Independent investigators at all academic levels (or equivalent) There are no limits on the number of preapplications for which an investigator may be named as a PI, Initiating PI, or Partnering PI for the FY23 Breakthrough Award Level 3. Investigators are discouraged from being named on multiple preapplications unless they are clearly addressing distinct research questions. 	 Supports promising rescarent 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 fundamentally new approach that is significantly more effective than interventions already approved or in clinical development. Partnering PI Option allows two PIs, termed the Initiating and Partnering PIs, to partner on a single application. 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> 	 The maximum allowable funding for the entire period of performance is \$4M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. Funding Level 3 with Partnering PI Option: The maximum allowable funding for the entire period of performance is \$5M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. 	(Preproposal): March 29, 2023 5:00 p.m. Eastern time Invited Application: June 28, 2023 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
		 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. 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 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. Additional Elements		
		 Pre-application submission is required; application submission is by invitation only. 		
		• Applications must include two or more breast cancer advocates on the research team.		
		Clinical trials are allowed.		

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Breakthrough Award Level 4 Go to: • Program Announcement • General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-BTA4	 Independent investigators at all academic levels (or equivalent) There are no limits on the number of preapplications for which an investigator may be named as a PI, Initiating PI, or Partnering PI for the FY23 Breakthrough Award Level 4. Investigators are discouraged from being named on multiple preapplications unless they are clearly addressing distinct research questions. 	 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 fundamentally new approach that is significantly more effective than interventions already approved or in clinical development. Partnering PI Option allows two PIs, termed the Initiating and Partnering PIs, to partner on a single application. 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 or investigational agents while the other PI is performing most or all of the research and analyses do not meet the intent of the Partnering PI Option.</i> 	 Funding Level 4 and Funding Level 4 with Partnering PI Option: The maximum allowable funding for the entire period of performance is \$15M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. 	Pre-Application (Preproposal): March 29, 2023 5:00 p.m. Eastern time Invited Application: June 28, 2023 11:59 p.m. Eastern time

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
		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.		
		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:		
		 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 New Drug or Investigational Device Exemption application to the FDA, if applicable.		

Award Mechanism	Eligibility	Key Mechanism Elements	Funding	Submission Deadline
Award Mechanism Award Mechanism Innovator Award Go to: Program Announcement General Application Instructions Grants.gov Funding Opportunity Number: HT9425-23-BCRP-INNOV	Eligibility Eligibility • Associate Professor (or equivalent) or above • Previous BCRP Innovator Award recipients are ineligible.	 Key Mechanism Elements <u>Additional Elements</u> <u>Pre-application submission is required;</u> <u>application submission is by invitation</u> <u>only.</u> Applications must include two or more breast cancer advocates on the research team. Clinical trials are required. 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 these individuals with the opportunity and freedom 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 	 Funding Funding The maximum allowable funding for the entire period of performance is \$7M for direct costs. Indirect costs may be proposed in accordance with the institution's negotiated rate agreement. The maximum period of performance is 4 years. 	Submission DeadlinePre-Application (Preproposal): March 29, 2023 5:00 p.m. Eastern timeInvited Application: June 28, 2023 11:59 p.m. Eastern timeConfidential Letters of Recommendation Submission Deadline: June 30, 2023 5:00 p.m. Eastern time
		 Indit focus on ofeast cancer, and the Free must commit a minimum of 15% level of time and effort during the period of performance to conduct breast cancer research under this award. <u>Additional Elements</u> <i>Pre-application submission is required; application submission is by invitation only.</i> Applications must include two or more breast cancer advocates on the research 		
		 Clinical trials are allowed. 		