

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Breast Cancer Research Program**

### **Transformative Vision Award**

**Funding Opportunity Number: W81XWH-12-BCRP-TVA**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 3, 2012
- **Invitation to Submit an Application:** June 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 15, 2012
- **Peer Review:** October 2012
- **Programmatic Review, Stage 1:** December 2012
- **Invitation for Oral Presentation:** December 2012
- **Programmatic Review, Stage 2:** January 2013

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications for the Breast Cancer Research Program (BCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The BCRP was established in fiscal year 1992 (FY92) to support innovative research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY11 totaled over \$2.6 billion. The FY12 appropriation is \$120 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of the vision to end breast cancer. Specifically, the BCRP seeks to accelerate high-impact research, encourage innovation and stimulate creativity, bring new investigators into the breast cancer field, and facilitate multidisciplinary collaborations.

### B. Award Information

The BCRP Transformative Vision Award supports research projects that will fulfill an extraordinary vision for dramatically affecting the prevention or treatment of breast cancer. This award requires a plan that will test and achieve the vision as quickly as possible through the translation of the research ideas to individuals with, and/or those at risk for, breast cancer. The scope of the effort may include a broad spectrum of research spanning from basic to clinical studies. The critical components of this award mechanism are:

**Vision and Impact:** A vision for a new approach that will have a revolutionary impact on the prevention or treatment of breast cancer must be articulated. The time to the final impact may vary, but the success of the vision must be transformative and significantly advance the goal of ending breast cancer. A clear and compelling presentation of how the vision is transformative for individuals with, and/or those at risk for, breast cancer must be provided.

**Implementation:** The vision must be supported by a detailed plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the milestones, and explains how these solutions will be translated to individuals with, and/or those at risk for, breast cancer. It is expected that the proposed plan will present an exceptional level of innovation and creativity and that the Principal Investigator (PI) will assemble the team necessary to realize the vision.

The PI is expected to have demonstrated experience in successfully leading large, focused projects. The PI should create an environment that fosters and supports innovation and creativity, with consistent, intensive interaction within the research team in a way that engages all members of the team in all aspects of the research plan.

**Consumer Advocates:** *The research team must include two or more breast cancer consumer advocates who will be integrally involved throughout the planning and implementation of the research project. Consumer advocates should be involved in the identification of the research project, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well-integrated and ongoing, not limited to attending seminars and semi-annual meetings. As lay*

***representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer, they should be part of a breast cancer advocacy organization, and their role in the project should be independent of their employment. They cannot be employees of any of the institutions participating in the application. They must have a high level of familiarity and training involving current issues in breast cancer research.***

The Transformative Vision Award will be supported in two Stages. Stage I (Years 1-2) will enable the team to lay the groundwork for the research and to test the basic concepts of the vision. Stage II (Years 3-5) will allow the expansion of the project to proceed to accomplishment of the vision. Before moving from Stage I to Stage II, the PI(s) will be required to present an update on progress toward accomplishing the goals of the project at a 1-day Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be attended by members of the BCRP Integration Panel (IP), Congressionally Directed Medical Research Programs (CDMRP) staff, and the Grants Officer. Annual Milestone Meetings will also be held during Stage II.

In addition, five percent of the total direct costs of the award must be reserved in the budget for “seed projects,” i.e., the development of new ideas that may emerge during the course of the award. These seed projects should enable the research team to explore new avenues of high-risk, high-impact ideas that were not part of the original application, but that develop during the project and are within the scope of the overall vision of the research. Applications for seed projects must be submitted for Government review and approval. Details regarding the process for submittal will be outlined in the award document. Funds for seed projects will be restricted for use until approved for release by the Grants Officer and may not be used for equipment or travel. (See Section I. D., Funding below.)

***Partnering PI Option:*** The Transformative Vision Award encourages applications that include meaningful and productive collaborations between investigators. Although not required, the research team may include up to three PIs, who will each receive a separate award. One partner is designated as the Initiating PI and the other PI(s) is (are) designated as the Partnering PI(s). The Initiating and Partnering PI(s) have different submission requirements; however, all PIs should contribute to the preparation of a single application. The collaborative partners may have expertise in similar or disparate scientific disciplines, but each partner is expected to bring different strengths to the application. It is the responsibility of the collaborating investigators to describe how their combined expertise in the collaboration will better address the research question and explain why the work should be done together rather than through separate efforts.

***The CDMRP intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.***

### **C. Eligibility Information**

- PIs must be at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

Applications with a **single PI** or **Partnering PI Option** have the same funding levels.

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$12M** (for Stage I, Stage II and seed projects) plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant(s) may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The applicant(s) may request up to **\$2.6M** in direct costs for Years 1-2 (Stage I). Stage I will be funded using allocations from the FY12 BCRP Congressional appropriation
- The applicant(s) may request up to **\$10M** in direct costs for option Years 3-5 (Stage II). The combined total direct costs for Stage I and II may not exceed **\$12M**. Option years will be funded with future Congressional appropriations, if available. A total of three 1-year options will be allowed.
- Exercising the options for Stage II will be contingent on receipt of sufficient Congressional appropriations to the BCRP, submission and approval of written progress reports, and acceptable performance of the recipient. Milestones for the approved Statement of Work (SOW) will be finalized during award negotiation. Before moving from Stage I to Stage II, the PI(s) will be required to present an update on progress toward accomplishing the goals of the project at a Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be attended by members of the BCRP IP, CDMRP staff, and the Grants Officer. Annual Milestone Meetings will also be held during Stage II. ***Failure to complete each milestone may result in forfeiture of the subsequent installment of Transformative Vision Award funding.***
- Five percent of the total direct costs must be allocated and reserved for funding "seed projects," i.e., the development of new ideas that emerge during the course of the award. Direct costs for these seed projects should be allocated into the "other direct cost" category of the Year 1 budget. These funds will be restricted for use until approved for release by the Grants Officer. Funds for seed projects may not be used for equipment or travel.
- The applicant must submit a comprehensive budget, broken down by year, that details the projected funding needed for the entire period of performance, to include Stages I and II and the seed projects.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI and key personnel on the research team, including consumer advocates, to attend three 1-day Milestone Meetings in the National Capital Region. Costs associated with travel to these meetings should be included in Years 2, 3, and 4 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- Travel for the PI and key personnel on the research team, including consumer advocates, to attend two Department of Defense (DoD) BCRP Era of Hope meetings, which are held to disseminate the results of BCRP-sponsored research. Costs associated with travel to these meetings, up to \$1,800 per person, should be included in Years 2 and 5 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$3,600 per year to attend scientific/technical meetings

*The CDMRP expects to allot approximately \$3.9M of the \$120M FY12 BCRP appropriation to fund Stage I of approximately one Transformative Vision Award application, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

## II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

**Partnering PI Option:** The Transformative Vision Award mechanism is structured to accommodate up to three PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, SOW, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI(s). The Partnering PI(s) will then be notified separately by email. Please note that the Partnering PI(s) must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive a

letter of invitation via email from the CDMRP. The letter will provide the information necessary to begin application submission through Grants.gov.

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

#### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-12-BCRP-TVA.

#### **B. Pre-Application Submission Content and Form**

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

**Partnering PI Option:** *The Initiating PI is responsible for submission of all pre-application components.*

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY12 BCRP IP members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507.

**Partnering PI Option:** The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI section.

- **Required Files – Tab 4**

**Pre-Application Narrative (five-page limit):** The Pre-Application Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Pre-Application Narrative should include the following:

- State the problem or question in breast cancer that will be solved by the success of the proposed project.

- Describe the transformative vision for a new approach to develop a necessary solution for the problem or question.
- Discuss how the project, if successful, will have a revolutionary impact on breast cancer prevention or treatment and how it will significantly advance the goal of ending breast cancer.
- Describe the challenges associated with implementing the vision and how they will be overcome.
- Outline the overall organization of key personnel, including consumer advocates, and adequately describe each team member's role in the project.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- References Cited
- Key Personnel Biographical Sketches (four-page limit per individual)
  - Include consumer advocates' biographical sketches
  - Include the Partnering PI(s) if applying under the Partnering PI Option
- **Submit Pre-Application – Tab 5**

*This tab must be completed for the pre-application to be accepted and processed by the CDMRP.*

- **Other Documents Tab**

No additional documents are required.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DoD and CDMRP, pre-applications will be screened based on adherence to the intent of the award mechanism

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **C. Application Submission Content and Form**

*Applications will not be accepted unless the PI or Initiating PI has received a letter of invitation.*

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the

Grants.gov portal (<http://www.grants.gov/>). For the Transformative Vision Award, additional application components are also required and should be submitted as directed below.

**Partnering PI Option:** *The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI. Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.*

### **Application Components for single PIs or for the Initiating PIs under the Partnering PI Option.**

**Grants.gov application package components:** For the Transformative Vision Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

**1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

#### **2. Attachments Form**

- **Attachment 1: Project Narrative (25-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed research in detail using the outline below. Throughout the Project Narrative, clearly convey how the proposed research, if successful, will have a revolutionary impact by transforming the prevention or treatment of breast cancer, and ultimately advancing the goal of ending breast cancer.

Describe the proposed research for Stages I and II using the following outline:

- State the overarching problem or question in breast cancer that will be the focus of the proposed research.
- Background: Present the ideas and reasoning behind the proposed research. Describe previous experience most pertinent to this application. The research strategy should be based on sound scientific rationale and be supported by preliminary data and a critical review and analysis of the relevant literature and the state of the art.
- Hypothesis: State the hypothesis to be tested.
- Specific Aims: Concisely describe the research’s specific aims to be funded by this award.
- Implementation: Present a detailed plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the milestones, and explains how these innovative solutions will be translated to individuals with, and/or those at risk for, breast cancer. Describe the experimental design, methods, and analyses including appropriate controls and statistical plan in sufficient detail for analysis. Address potential challenges and present solutions or alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

- Research Team and Environment: Describe how the PI's research experience and leadership skills make him/her well-qualified to coordinate this effort. Discuss the qualifications of the research team and how it will provide the appropriate expertise necessary to address the research question. Include an organizational chart identifying the roles of all team members, including consumer advocates. Present an overall management plan to facilitate group interactions, data sharing, adherence to regulatory requirements, administrative support, and oversight. Describe the research environment(s) and how the facilities and resources will support the research requirements and the project.

In addition, if applying under the Partnering PI Option, describe how the partners bring different strengths to the application. Describe how their combined expertise in the collaboration will better address the research question and explain why the work should be done together rather than through separate efforts. Outline how the PIs will collectively manage the collaboration and workflow to optimize research efforts.

- Consumer Advocate Participation: Describe the integral roles that consumer advocates will play in the planning, design, implementation, and evaluation of the research. Describe the consumer advocates' previous training and familiarity with current issues in breast cancer. Explain how the consumer advocates' experience and expertise will be integrated into the research project and management of the collaboration.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.***
  - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. ***Include a letter of collaboration from each of the consumer advocates.***
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design including appropriate controls.
  - Impact: Summarize briefly how the proposed project, if successful, will have a revolutionary impact on breast cancer prevention or treatment.

The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project’s key aspects.
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”
  - Describe the scientific objective and rationale for the application in a manner readily understandable by non-scientists.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability and impact of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.

**Partnering PI Option:** *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.*

Include a SOW that covers the work proposed for the entire period of performance, to include Stages I and II. SOWs for seed projects should not be submitted with the application; they should be submitted to the Government for review, approval, and release of funds as they emerge.

- **Attachment 6: Vision and Impact Statement (two-page limit):** Upload as “VisionImpact.pdf.”

Describe your vision for a new approach that will have a revolutionary impact on the prevention or treatment of breast cancer. Explain how fulfilling this vision will be transformative for individuals with, and/or those at risk for, breast cancer. Describe how the proposed research will significantly advance the goal of ending breast cancer. Outline how you believe your vision will be realized.

- **Attachment 7: Collaboration Statement (one-page limit):** Upload as “Collaboration.pdf.”

For applications submitted under the Partnering PI Option only, describe the expertise of the Initiating and Partnering PI(s). Describe the contribution and the time commitment of each collaborator toward the proposed research project. Describe how the collaborative effort will better address the research question and explain why the work should be done together rather than through separate efforts.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
  - Include consumer advocates.
  - Include the Partnering PI(s), if applying under the Partnering PI Option.
- Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

Include a detailed budget and justification that covers the projected funding needed for the entire period of performance, to include Stages I and II. A separate budget and justification is required for each year of the project. Funds reserved for seed projects should be allocated in a lump sum in the “other direct costs” category of the Year 1 budget and do not require details or justification at this time. The budget should include all key personnel, including consumer advocates.

**Partnering PI Option:** *Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI(s), even if they are at the same organization.*

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

**Application Components for the Partnering PI(s), if applying under the Partnering PI Option:**

*The Partnering PI(s) must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.*

The application submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov that includes:

1. **SF 424 (R&R) Application for Federal Assistance Form**
2. **Attachments Form**
  - **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating and Partnering PIs should be noted for each task.*
3. **Research & Related Budget Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”  
*Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget form for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization.*
4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

**Additional Application Components:** In addition to the completed Grants.gov application package of forms, Transformative Vision Award applications also require the following component:

**Oral Presentation:** PIs whose applications are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation that will be held in the National Capital Region area in January 2013. *If applying under the Partnering PI Option, the Initiating and Partnering PIs will attend and give the oral presentation.*

Each presentation will include a 10-minute talk by the PI(s), followed by a 20- to 30-minute question and answer session with IP members. The following questions will be the topics for discussion during the PI's talk and the question and answer session. PIs who are invited must prepare a presentation consisting of no more than four slides that specifically address these questions:

- Without addressing your specific project, what conceptual or intellectual barriers do you consider the most urgent to overcome in breast cancer prevention or treatment?
- How will your vision for a new approach have a revolutionary impact on breast cancer prevention or treatment?
- Without addressing the technical/scientific aspects of your project, how will you use your leadership skills to create an environment that fosters innovation and creativity?

#### **D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

#### **E. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the DoD and BCRP and the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence

the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## **B. Application Review Criteria**

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Vision and Impact**

- How the proposed research, if successful, will have a revolutionary impact on the prevention or treatment of breast cancer.
- How fulfilling the vision will be transformative for individuals with, and/or those at risk for, breast cancer.
- How the proposed research will advance the goal of ending breast cancer.

- **Implementation**

- How the vision is supported by a detailed plan that identifies critical milestones, outlines the innovations and technical solutions that will be implemented to accomplish the milestones, and explains how these solutions will be translated to individuals with, and/or those at risk for, breast cancer.
- How the scientific rationale supports the research and its feasibility, as demonstrated by the presentation of preliminary data and a critical review and analysis of the literature and the state of the art.
- How well the hypotheses, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the application acknowledges potential problems and addresses alternative approaches.
- Whether the application includes an appropriate statistical plan with power analysis, if applicable.
- For applications submitted under the Partnering PI Option, how the collaborative effort will support implementation of the research plan.

- **Personnel**

- Whether the PI(s) has experience in successfully leading large, focused projects.
- How the research team's background and expertise are appropriate to accomplish the proposed work.
- Appropriateness of the levels of effort for successful execution of the proposed work.
- How consumer advocates are integrated into the planning and implementation of the proposed research in a meaningful way.

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the quality and extent of organizational support are appropriate for the proposed research.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and BCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:

**Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:

- Ratings and evaluations of the peer reviewers
- Programmatic relevance
- Relative impact
- Program portfolio composition
- Adherence to the intent of the award mechanism

**Stage 2:** During the second stage of programmatic review, the following criteria will be used:

- Understanding of barriers in breast cancer prevention or treatment
- Articulation of a vision with a high potential for impact
- Leadership capability to create an environment that fosters innovation and creativity

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the pre-application:

- Pre-Application Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- **Partnering PI Option:** All associated (Initiating and Partnering PI) applications are not submitted by the deadline.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- A FY12 BCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY12 BCRP IP members can be found at <http://cdmrp.army.mil/bcrp/panels/panels12>.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Any of the PIs do not meet the eligibility criteria.

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative and National Policy Requirements**

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

#### **C. Reporting**

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

Attendance and presentation of progress reports at established Milestones Meetings will be required.

#### **D. Award Transfers**

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.		
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.		
	Upload Supporting Documentation (Support.pdf) as Attachment 2.		
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.		
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.		
	Upload Statement of Work (SOW.pdf) as Attachment 5.		
	Upload Vision and Impact Statement (VisionImpact.pdf) as Attachment 6.		
	Upload Collaboration Statement (if applicable) (Collaboration.pdf) as Attachment 7.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form	Complete form as instructed.		
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.		

<b>Additional Application Components</b>	<b>Action</b>	<b>Completed</b>	<b>Partnering PI Completed</b>
Oral Presentation	Confirm ability to give an oral presentation in the National Capital Region in January 2013 (if selected for Stage 2).		