

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Transformative Vision Award

Funding Opportunity Number: W81XWH-10-BCRP-TVA

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

The Breast Cancer Research Program (BCRP) was established in fiscal year 1992 (FY92) to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY09 totaled over \$2.3 billion. The FY10 appropriation is \$150 million (M).

The BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

### **B. Award Description**

The BCRP Transformative Vision Award supports research projects to realize an extraordinary vision for dramatically affecting the prevention or treatment of breast cancer, and a plan to test and achieve the vision as quickly as possible. The critical components of this award mechanism are:

**Vision:** The most important aspect of the Transformative Vision Award is the articulation of the vision for a new approach to significantly impact the prevention or treatment of breast cancer. The final impact may be near-term or long-term, but the success of the vision must be transformative on breast cancer. A careful presentation of the state-of-the-art, and how the vision will transform this state, must be described.

**Implementation:** The vision must be supported by a detailed plan that identifies critical milestones and clearly outlines the innovations and technical solutions that will be implemented to accomplish the milestones. 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 should have demonstrated experience in successfully leading large, focused projects. The scope of the research effort may include a broad spectrum of research spanning from basic to clinical studies, with the end result leading to a revolutionary impact on an area of paramount importance in breast cancer prevention or treatment.

The Transformative Vision Award will be supported in two phases. Phase I will enable the team to lay the groundwork for the research project and to test the basic concepts of the vision. Phase II will allow the expansion of the project to proceed to accomplishment of the vision.

### **C. Eligibility**

PIs can be at any academic level (or equivalent). Refer to General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable funding for the entire period of performance is **\$12M** in direct costs.
- The applicant may request up to \$2M in direct costs for years 1 and 2 (Phase I). Phase I will be funded using allocations from the FY10 BCRP congressional appropriation.
- A combined total of \$10M in direct costs may be requested for option years 3, 4, and 5 (Phase II). Option years will be funded with future congressional appropriations, if available. A total of three option years will be allowed.
- Exercising the options for continued performance in Phase 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 awardee. At 1.5 years, the PI and his/her team will be required to present an update on the award's accomplishments at a Milestone Meeting, to be held in the Baltimore/Washington, DC area and attended by members of the Integration Panel, CDMRP staff, and the Grants Officer. Milestone Meetings also will be held prior to exercising option years 4 and 5. After each Milestone Meeting, the Integration Panel will make a recommendation on whether to exercise the option to provide funding for an additional 1 year period of performance.
- The applicant must submit a comprehensive budget that details the projected funding needed for the entire period of performance, to include Phases I and II.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 5-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement.

Within the guidelines provided in the General Application Instructions, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel to Milestone Meetings in the Baltimore/Washington, DC area
- Travel costs of up to \$3,600 per year to attend scientific/technical meetings
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification

In addition, funding must be requested for the PI and key personnel on the research team to attend one 3½-day Department of Defense BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

*The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$9M of the \$150M FY10 BCRP appropriation to fund Phase I of approximately three Transformative Vision Award applications, 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.*

#### **E. Award Administration**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

## **II. TIMELINE FOR SUBMISSION AND REVIEW**

- **Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 18, 2010**
- **Invitation to Submit an Application: April 2010**
- **Application Submission Deadline: 11:59 p.m. ET, June 23, 2010**
- **Scientific Peer Review: July 2010**
- **Programmatic Review: September 2010**

*Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.*

## **III. SUBMISSION PROCESS**

Submission is a two-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/>). *Applications will be invited based on pre-application screening.*

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

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

## A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by **5:00 p.m. ET on the deadline**. 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.

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 for additional information on pre-application submission.):

- **Proposal Information – Tab 1**
- **Proposal Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**
- **Required Files – Tab 4**

**Preproposal Narrative (three-page limit):** The Preproposal Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- State the overarching problem or question in breast cancer that will be the focus of the proposed project. Describe the vision for a new approach to develop a solution for the problem or question. Discuss the anticipated effects on the prevention or treatment of breast cancer if the project is successful, and how the effects would be transformative.

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

- References Cited: List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
  - Key Personnel Biographical Sketches (four-page limit per individual)
- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

Not applicable.

**Pre-Application Screening:** Pre-applications will be screened the BCRP Integration Panel (IP) based on the following criteria:

- Adherence to the intent of the award mechanism

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

## **B. Step 2 – Application Components**

***Applications will not be accepted unless the PI has received a letter of invitation.*** Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<http://www.grants.gov/>). Applications must be submitted **by 11:59 p.m. ET on the deadline.**

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission.):

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

### **2. Attachments Form**

- **Attachment 1: Project Narrative (15-page limit):** Upload as “ProjectNarrative.pdf.”

Throughout the Project Narrative, the PI must clearly convey how the proposed research, if successful, would have an extraordinarily high impact by transforming the prevention or treatment of breast cancer, and ultimately advancing upon the goal of eradicating breast cancer.

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

- State the overarching problem or question in breast cancer that will be the focus of the proposed project.
- Background: Present the ideas and reasoning behind the proposed research. Describe previous experience most pertinent to this proposal. Cite relevant literature. Discuss the qualifications of the research team that will enable them to successfully complete the proposed work.
- Hypothesis: State the hypothesis to be tested.
- Specific Aims: Concisely explain the projects’ specific aims to be funded by this proposal.
- Implementation: Present a detailed plan that identifies critical milestones and clearly outlines the innovations and technical solutions that will be implemented to accomplish the milestones. The research strategy should be based on sound scientific rationale, and supported by preliminary data and a critical review and analysis of the literature and state-of-the-art. Describe the experimental design, methods, and analyses including appropriate controls and statistical plan in sufficient detail for analysis. Address potential problem areas and present

alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

- **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. *Each component has no page limit unless otherwise noted.*
  - References Cited: List all relevant references 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). The inclusion of Internet URLs to references is encouraged.
  - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
  - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract 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 they must be included. Extra items will not be reviewed.
  - Letters of Organizational Support (two-page limit per letter): 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 (if applicable) (two-page limit per letter): 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.
  - 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. Provide evidence or rationale that supports the objective/hypothesis.
  - 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 an impact on breast cancer research or patient care.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
  - Describe the scientific objective and rationale for the proposal in a manner readily understandable by non-scientists.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability 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?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
  - What are the likely contributions of this study to advancing the field of research?
  - How will the research enhance this or other studies being conducted?
- **Attachment 5: Statement of Work (SOW) (five-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.

*Include a SOW that covers the work proposed for the entire period of performance, to include Phases I and II.*

- **Attachment 6: Detailed Budget and Justification (no page limit):** Upload as “Budget.pdf.” Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.

*Include a Detailed Budget and Justification that covers the projected funding needed for the entire period of performance, to include Phases I and II.*

- **Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit):** Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as “SubBudgets.pdf.” Refer to the General Application Instructions, Section II.B., for detailed information.
- **Attachment 8: Vision and Impact Statement (two-page limit):** Upload as “VisionImpact.pdf.”

Describe the ultimate vision for how the proposed research, if successful, will have a revolutionary impact on an area of paramount importance in breast cancer prevention or treatment. Explain how the proposed research would transform the state-of-the-art. Describe how the proposed research could advance toward the goal of eradicating breast cancer.

**3. Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.B., 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.”
- Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

**4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

#### **IV. INFORMATION FOR APPLICATION REVIEW**

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

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring 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 may be found at <http://cdmrp.army.mil/fundingprocess.htm>.

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, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

## **B. Review Criteria**

**1. Peer Review:** All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance:

- **Vision**
  - Whether the PI articulates a vision for a new approach to significantly impact the prevention or treatment of breast cancer.
  - How the proposed research, if successful, would transform the state-of-the-art.
- **Implementation**
  - How the PI presents a detailed plan that identifies critical milestones, and clearly outlines the innovations and technical solutions that will be implemented to accomplish the milestones.
  - How the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, state-of-the-art, and the presentation of preliminary data.
  - How well the hypotheses, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether the proposal includes an appropriate statistical plan with power analysis, if applicable.
- **Impact**
  - How the proposed research, if successful, would revolutionize an area of paramount importance in breast cancer prevention or treatment.
  - How the proposed research would move closer to the goal of eradicating breast cancer.
- **Personnel**
  - Whether the PI 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.
- **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.

The following will not be individually scored, but may impact 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**
  - How the writing and components of the application influenced the review.

**2. Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations.

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

## **V. 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:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Submission of an application for which a letter of invitation was not received.

### **B. Modifications**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.

- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section V-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 application:

- FY10 BCRP Integration Panel (IP) member(s) is found to be involved 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 FY10 BCRP IP members may be found at <http://cdmrp.army.mil/bcrp/panel10.htm>.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- 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 detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.

### **D. Withhold**

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

## VI. CONTACT INFORMATION

**A. CDMRP Program Announcement Help Desk:** Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079  
Email: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)

**B. CDMRP eReceipt System Help Desk:** Questions related to the submission of the pre-application through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507  
Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**C. Grants.gov Contact Center:** Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 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
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 Public Abstract (PublicAbs.pdf) as Attachment 4	
	Upload Statement of Work (SOW.pdf) as Attachment 5	
	Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6	
	Upload Subaward Detailed Budget and Justification (SubBudgets.pdf) as Attachment 7	
	Upload Vision and Impact Statement (VisionImpact.pdf) as Attachment 8	
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	
Project/Performance Site Location(s) Form	Complete form as instructed	