

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Impact Award

Funding Opportunity Number: W81XWH-09-BCRP-IMPT

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Objectives

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 FY08 totaled \$2.2 billion. The FY09 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 Impact Award supports unique research projects or ideas (from small- to large-scale) that specifically focus on scientific and clinical breast cancer issues, which, if successfully addressed, could ultimately revolutionize the understanding and/or treatment of breast cancer and move closer to the goal of eradicating the disease. The critical components of this award mechanism are as follows:

**Impact:** The most important aspect of the Impact Award is the potential of the proposed research to have a radical, revolutionary impact on an area of paramount importance in breast cancer. The research project may be basic, translational, or clinical. The potential impact may be near-term or long-term, but it must be transformative. *It is the responsibility of the applicant to clearly and explicitly articulate the potential impact on breast cancer, including how it would be transformative.*

**Research Question:** Research proposed under the Impact Award must address an underexplored issue of critical significance in breast cancer. The BCRP particularly encourages applications that focus on less explored or poorly understood areas that are of high importance in breast cancer, such as those related to prevention, susceptibility, protection, recurrence, and metastasis. The proposed work must be based on a sound overall research strategy and may be from any discipline or combination of disciplines (from all areas of basic, translational, clinical, behavioral, and epidemiological research).

Applications submitted under the Impact Award mechanism should not meet the intent of the other award mechanisms offered by the BCRP in FY09.

*NEW for FY09: A preproposal is required as part of the pre-application; application submission is by invitation only.*

### **C. Eligibility**

Principal Investigators (PIs) can be at any academic level (or equivalent). Refer to Application Instructions and General Information, 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 **\$2M** in direct costs.
- 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 your institution's negotiated rate agreement.

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Support for multidisciplinary collaborations
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Congressionally Directed Medical Research Programs (CDMRP) requires attendance at the triennially scheduled 3½-day Department of Defense BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

***The CDMRP expects to allot \$17M of the \$150M FY09 BCRP appropriation to fund approximately five Impact 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 on the availability of Federal funds for this program.***

### **E. Award Administration**

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

## II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

<b>Pre-application Submission Deadline:</b>	<b>March 12, 2009</b>
<b>Invitation to Submit Proposal:</b>	<b>April 24, 2009</b>
<b>Application Submission Deadline:</b>	<b>June 17, 2009</b>
<b>Scientific Peer Review:</b>	<b>July 2009</b>
<b>Programmatic Review:</b>	<b>September 2009</b>

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

## III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/), and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization 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.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

### A. Step 1 – Pre-Application Components and Submission

***Pre-application submission is the required first step.*** The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time on the deadline date**. Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Preproposal Narrative (one-page limit)
  - Describe the proposed project and discuss the scope of the potential impact if the project is successful. State how this project meets the intent of the Impact Award mechanism.
- Pre-Application Supporting Documentation

- References Cited (one-page limit)
- Biographical Sketches (four-page limit per individual)

**Preproposal Screening:** Preproposals will be reviewed by the BCRP Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates. PIs whose preproposals meet the intent of the award mechanism will be invited to submit applications. Each PI will be notified as to whether they have been invited to submit an application.

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

*Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless a letter of invitation has been received.* Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov ([www.grants.gov](http://www.grants.gov)).

Each application submission must include the completed application package of forms and attachments identified in [www.grants.gov](http://www.grants.gov) for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

### **1. SF-424 (R&R) Application for Federal Assistance Form**

### **2. Attachments Form**

- Attachment 1: Project Narrative (15-page limit)

Throughout the Project Narrative, the PI must clearly convey how the proposed research, if successful, would have an extraordinarily high impact by revolutionizing the understanding and/or treatment of breast cancer and ultimately advancing upon the goal of eradicating breast cancer. The research strategy should be based on sound scientific rationale, outlined in detail, and fully supported by preliminary data, and/or published reports.

Describe the proposed research using the following outline:

- **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.
- **Research Strategy:** 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
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support
  - Letters of Collaboration (if applicable)
  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract (one-page limit)
- Attachment 4: Public Abstract (one-page limit)
- Attachment 5: Statement of Work (SOW; three-page limit)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (one-page limit)

Describe the ultimate vision for how the proposed work, if successful, will have a transformative, revolutionary impact on an area of paramount importance to breast cancer. Describe how the proposed work could advance toward the goal of eradicating breast cancer.

- Attachment 8: Federal Agency Financial Plan (if applicable)
- Attachments 9-15: Subaward Detailed Budget and Justification (if applicable)

### **3. Research & Related Senior/Key Person Profile (Expanded)**

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

### **4. Research & Related Project/Performance Site Location(s) Form**

## 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 submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions 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).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Impact Statement).

### B. Review Criteria

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

- **Research Strategy and Feasibility**
  - How the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature and/or 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.

- **Research Question**
  - Whether the project addresses a critical yet underexplored area of paramount importance to breast cancer.
- **Impact**
  - How the proposed research, if successful, would revolutionize the understanding and/or treatment of breast cancer.
  - The potential for the proposed research to ultimately have a radical, transformative impact on breast cancer.
  - How the proposed research would move closer to the goal of eradicating breast cancer.
- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed work.
  - Appropriateness of the levels of effort for successful conduct 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 institutional support are appropriate for the proposed research.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Budget**
  - How the budget is appropriate for the proposed research.
- **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 that maintain the program's broad portfolio:

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



Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by IP members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals, objectives, and areas of encouragement of the program.

## **V. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from 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).

### **B. Modifications**

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

### **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- Any FY09 IP member 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 FY09 IP members may be found at <http://cdmrp.army.mil/research>

- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- 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 USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

## **VI. CONTACT INFORMATION**

**A. Program Announcement/Funding Opportunity, application format, or required documentation:** To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. 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  
Fax: 301-619-7792  
Email: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)

**B. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507  
Website: <https://cdmrp.org>  
Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**C. Grants.gov:** Questions related to application submission through the [Grants.gov](http://www.grants.gov) ([http://www.grants.gov/](http://www.grants.gov)) portal should be directed to the Grants.gov help desk, which is available Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726

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

***Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.***