

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Concept Award

Funding Opportunity Number: W81XWH-09-BCRP-CA

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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 into 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 Concept Award mechanism was first offered in FY99. Since that time, 10,081 Concept Award proposals have been received, and 1073 have been recommended for funding. The Concept Award supports the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to breast cancer. The Concept Award is not intended to support a logical progression of an already established research project but, instead, supports high-risk studies that have the potential to reveal entirely new avenues for investigation.

Presentation of preliminary data is not allowed. However, a rationale for the proposed work must be provided.

Use of human subjects and human biological substances: Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]). ***Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.*** For studies using only commercially available unidentified specimens, a Claim of Exemption Form will be requested. Additional information regarding exempt status may be found on the USAMRMC Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphpo.asp>).

C. Eligibility

All investigators, including postdoctoral fellows (or equivalent), are eligible to submit applications. Refer to the Application Instructions & General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 1 year.
- The maximum allowable funding for the entire period of performance is **\$75,000** in direct costs.
- 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 & General Information, funds can cover:

- Salary
- Research supplies
- Travel to scientific/technical meetings
- Travel between collaborating institutions
- Other direct costs as described in Application Instructions & General Information, Detailed Budget and Justification

The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$10M of the \$150M FY09 BCRP appropriation to fund approximately 85-90 Concept Award applications, depending upon the quality and number of proposals 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

No change in Principal Investigator (PI) will be allowed once the proposal has been submitted. Changes in institution are discouraged and will be allowed only at the discretion of the Grants Officer. Refer to the Application Instructions & General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Submission is a two-step process consisting of (1) pre-application submission and (2) application submission. *Pre-application submission is a required first step.*

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| Pre-application Submission Deadline: | October 29, 2009, 5:00 p.m. Eastern time (ET) |
| Application Submission Deadline: | November 12, 2009, 11:59 p.m. ET |
| Scientific Peer Review: | January 2010 |
| Programmatic Review: | March 2010 |

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

III. SUBMISSION PROCESS

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 or 301-682-5507.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

A. Step 1: Pre-Application Components and Submission

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. ET on the deadline date**. Refer to the Application Instructions & General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative

B. Step 2: Application Components and Submission

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in 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 & General Information for detailed requirements of each component.

The package includes:

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

Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, identifying or making references to the PI or

the institution in the Project Narrative or Acronyms list is prohibited and will result in administrative rejection of the proposal. In addition, the use of “I,” “our,” “this institution,” or similar phrases that make it possible to identify the PI and/or institution through the references listed will result in administrative rejection of the proposal.

- **Attachment 1: Project Narrative (One-page limit)**

The investigator must clearly explain how the proposed research is innovative and relevant to breast cancer research. *Preliminary data is not allowed.* However, PIs must demonstrate logical reasoning and a sound scientific rationale for the proposal to be competitive.

Describe the proposed project using the following outline:

- **Innovation:** Innovation should be the primary feature of the proposed study.
- **Hypothesis/Rationale/Purpose:** State the rationale for the proposed research. Do not include preliminary data.
- **Objectives:** State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study.
- **Methods:** Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.
- **Significance/Relevance:** Provide a brief statement, in nontechnical terms, describing the importance of this research to breast cancer.

The one-page limit of the Project Narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. *The Project Narrative will be available for both peer and programmatic review.*

- **Attachment 2: Supporting Documentation**

- References Cited (Limited to 5 references)
- Acronyms and Symbol Definitions

- **Attachment 3: Statement of Work (SOW) (Two-page limit)**

- **Attachment 4: Detailed Budget and Justification**

- **Attachment 5: Federal Agency Financial Plan (if applicable)**

- **Attachments 6-15: Subaward Detailed Budget and Justification (if applicable)**

3. Research & Related Project/Performance Site Location(s) Form

Although requested, the Statement of Work (SOW), Detailed Budget and Justification, Federal Agency Financial Plan (if applicable), Subaward Detailed Budget and Justification (if applicable), and PI Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. These documents will be used for administrative purposes only.

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.htm>.

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 proposals based on one or more of the required attachments or supporting documentation.

Reviewers will be blinded to the identity of the PI and the PI's institution. Due to the blinded nature of the review process, identifying or making references to the PI or the institution within the Project Narrative or Acronyms list is prohibited and will result in administrative rejection of the proposal. In addition, the use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed, will result in administrative rejection of the proposal.

B. Review Criteria

1. Peer Review: All proposals will be evaluated according to the following criteria, which are all of equal importance:

- **Innovation**
 - How the proposed concept is innovative.
 - Whether the concept is untested (no preliminary data allowed).
- **Relevance**
 - How the proposed research is relevant to breast cancer.

- **Research Strategy**

- Whether the research strategy is appropriate to answer the question.

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

- **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 innovation,
- 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 the Integration Panel (IP) and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command (USAMRMC). 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 emphasis of the program.

V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- PI's name or institution is included in the Project Narrative or Acronyms list.
- Use of "I," "our," "this institution," or similar phrases in the Project Narrative that make it possible to identify the PI and/or institution through the references listed.
- 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 email from CDMRP with a request to provide certain missing supporting documents (excluding those listed directly above in Section 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 peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 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 FY09 IP members may be found at <http://cdmrp.army.mil/bcrp/panel09.htm>.
- 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.
- Inclusion of studies that do not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]).

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

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. ET.

Phone: 301-682-5507
Website: <https://cdmrp.org>
Email: help@cdmrp.org

C. Grants.gov contacts: 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. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726
Email: 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.