

Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Concept Award

Funding Opportunity Number: W81XWH-08-BCRP-CA

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I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using 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

2. 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

3. Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to the Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list 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.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources also should be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's [DUNS number](https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) (https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the [Central Contractor Registry \(CCR\)](http://www.ccr.gov/) (<http://www.ccr.gov/>) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>).
- Not contacting the appropriate [help desks](#) before the respective deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline, thereby causing the pre-application to remain in draft status (**NOTE: "Submit" button must be pressed for pre-application to be complete**).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. (**NOTE: Each Program Announcement/Funding Opportunity requires a specific application package**).
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by [submission deadline](#).

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and 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 FY07 totaled \$2.1 billion. The FY08 appropriation is \$138.0 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 and alliances. 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, 8,561 Concept Award proposals have been received and 986 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 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/rodorphrpo.asp>).

C. Eligibility

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution. Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. Refer to the Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for a Concept Award can be requested for up to \$75,000 for direct costs and for up to a 12-month performance period, plus indirect costs as appropriate.

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

- Salary
- Research supplies
- Travel to scientific/technical meetings
- Travel between collaborating institutions

- Other direct costs as described in Application Instructions for the Research & Related Budget Form Section F – Other Direct Costs

The CDMRP expects to allot approximately \$10M of the \$138M FY08 BCRP appropriation to fund approximately 85-95 Concept Award proposals, depending on the quality and number of proposals received. Funding of proposals 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 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 USAMRMC Contracting Office. Refer to the Application Instructions, Appendix 5, for general award administration information.

III. TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time, November 6, 2008
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, November 20, 2008
- **Scientific Peer Review:** January 2009
- **Programmatic Review:** March 2009

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

IV. 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) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and Organizations identified in the proposal 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](#) by **5:00 p.m. Eastern time on the deadline date**. Refer to the Application Instructions for detailed information.

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

B. Step 2: Proposal Components and Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. Proposals must be submitted electronically by the Authorized Organizational Representative through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in Grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

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

Members of each review panel 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 is prohibited and will result in administrative withdrawal 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 withdrawal 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 regarding the importance of this work to breast cancer.
- **References:** Cite relevant literature references using Attachment 2.

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.

- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
- Attachment 3: Statement of Work (SOW) (Two-page limit)
- Attachment 4: Federal Entity Financial Plan (if applicable)

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

- PI Biographical Sketch

Although requested, the Biographical Sketch will not be forwarded for review due to the blinded nature of each level of review for this award. The biographical sketch will be used for administrative purposes only.

4. Research & Related Budget Form

- Budget Justification

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

6. R&R Subaward Budget Attachment(s) Form (If applicable)

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

Proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals 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 and overall goals of the program. 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 and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel. Violations of the nondisclosure 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 proposal review process to gain protected evaluation information or to influence the evaluation process. Likewise, persons involved in the proposal review process are prohibited from communicating the program priorities, other than what is listed in this program announcement, to PIs and/or also are prohibited from being involved in the proposal development (including the pre-application process, concept design, budget, and supporting documentation). Violations of these prohibitions will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the scientific peer 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 is prohibited and will result in administrative withdrawal 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 withdrawal of the proposal.

B. Review Criteria

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

- Innovation
 - How the proposed concept is innovative
 - Whether the concept is untested (no preliminary data allowed)
- Relevance
 - How the study is relevant to breast cancer
- Research Strategy
 - Whether the research strategy is appropriate to answer the question

2. Programmatic Review: Criteria used by the IP to make funding recommendations that maintain the program's broad portfolio include:

- 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 IP and recommended for funding to the Commanding General, USAMRMC

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Scientific peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in pre-application or proposal rejection. ***Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.***

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- PI's name or institution is included in the Project Narrative.
- Use of "I," "our," "this institution," or similar phrases that make it possible to identify the PI and/or institution through the references listed.
- Budget is missing.
- FY08 BCRP IP member(s) is named as a collaborator or participant in the proposal.
- FY08 BCRP IP member(s) is found to be involved in any capacity in the pre-application and proposal processes including, but not limited to, concept design, proposal development, budget preparation, and the development of any supporting document.

A list of the FY08 BCRP members may be found at <http://cdmrp.army.mil>.

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for scientific peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for scientific peer review.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.