Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Multi-Team Award

Funding Opportunity Number: W81XWH-09-BCRP-MTA

TABLE OF CONTENTS

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 BCRP Multi-Team Award mechanism is a new award for FY09. The Multi-Team Award supports the creation of a collaborative research project among three teams, each led by a Principal Investigator (PI) with a history of creativity and innovation, to focus on a critical area of breast cancer. The Multi-Team Award should create an environment that fosters and supports innovation and creativity, with consistent, intensive interaction across teams in a way that engages all members of the teams in all aspects of the research project. The multi-team approach is expected to transform the research process through the integration of basic and clinical disciplines, substantive cross-disciplinary training among the team members, and integral participation of consumer advocates. The requirements for this award are as follows:

Research Question: Research proposed under the Multi-Team Award must focus on a question of significant importance to breast cancer that has been inadequately addressed, or for which there may be an absence of an established paradigm or technical framework. The research question should address overarching issues that have broad implications for the disease and risk management (e.g., risk factors, dormancy) and not focus merely on the study of specific pathways or genes. Clinical research or a clinical trial (Phase 0, I, I/II, or II) must be included as part of the proposed work.

PIs and Teams: The Multi-Team Award PIs must include at least one basic scientist, one clinician, and one additional individual from an appropriate area of expertise (e.g., epidemiology). At least two different institutions must be involved. Each of the three PIs is expected to have a track record of innovation and creativity and be well qualified to lead his/her respective team in this intensive collaboration. The collaborating PIs should work together to develop the research plan, determine the management structure, and prepare the application. It should be clear that all PIs have an equal level of intellectual input into the proposed project. Collectively, the members of the teams should represent the appropriate diversity of expertise necessary for addressing the research question. Effort is expected to be balanced among the three PIs and their teams, unless otherwise justified.

Consumer Advocates: Each PI's team must include one or more breast cancer consumer advocates who will be integrally involved throughout the planning and implementation of the research project and management of the collaboration. Consumer advocates should be involved in the identification of the research question, project design, oversight, recruitment, and evaluation, in addition to other areas. The consumer advocates must be individuals who have been diagnosed with breast cancer, and they should have a high level of training and familiarity with current issues in breast cancer research.

Team Interaction and Training: Regular in-person meetings and cross-training among members of all three teams are requirements of this award. The in-person multi-team meetings are intended to assess research progress, address problems, and define future directions. These meetings must take place at least twice a year and must be attended by all three PIs, key research team members, and consumer advocates. It is also expected that frequent (e.g., weekly) meetings of all team members will occur using phone conference/webcast communications technology to share data and monitor progress toward specific aims. A server should be established that makes team member presentations and source data available to all team members. To provide immersive training and interaction across disciplines, at least two key members of each research team must dedicate time to working on the funded research in another collaborating team's laboratory or clinic. This cross-training may be accomplished through one extensive visit of several weeks or through several separate visits.

The PIs must present a clear plan for how they would manage and facilitate meaningful collaboration among the separate research teams to enable successful completion of the proposed research. Participating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation. The proposal should include an organizational chart identifying the roles of all team members and the workflow within and between labs. The required Statement of Work (SOW) should indicate specific milestones and how specific aims toward these milestones will be staged or integrated. Key decision points in the organizational/work flow chart and SOW should be clearly defined and their impact on the overall project should be clear.

A preproposal is required as part of the pre-application; application submission is by invitation only.

C. Eligibility

This award supports three independent, faculty-level (or equivalent) PIs representing basic, clinical, and one additional area of expertise. Refer to Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **4** years.
- The maximum allowable, combined funding for the entire performance period is **$4.5M** in direct costs.
- The applicants may request the entire maximum direct cost amount for a project that may be less than the maximum 4-year period of performance.

- Regardless of the period of performance proposed, the applicants 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.
- A separate award will be made to each PI's institution.
- The PIs are expected to be equal partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Support for collaboration and training
- Support for bi-annual multi-team meetings
- 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 $23M of the $150M FY09 BCRP appropriation to fund approximately three Multi-Team 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.

Pre-application Submission Deadline:	**March 12, 2009**
Invitation to Submit Proposal:	**April 24, 2009**
Application Submission Deadline:	**June 17, 2009**

Scientific Peer Review:	**July 2009**
Programmatic Review:	**September 2009**

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/), and (2) an application submission through 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.

The Multi-Team Award is structured to accommodate three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other two PIs will be identified as the Partnering PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute to the preparation of the proposal. ***The Initiating PI must complete the pre-application process and submit contact information for each Partnering PI.***

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 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)

  The investigator is responsible for clearly addressing all of the following items:

  - Discuss the research question to be addressed by the teams. State how the proposed work meets the intent of the Integrated Multi-Team Research Award mechanism.
- Pre-Application Supporting Documentation
  - References Cited (one-page limit)
  - Key Personnel Biographical Sketches (four-page limit per individual)

Initiating and Partnering PI Responsibilities:

- The Initiating PI must complete the pre-application components listed above.
- The Initiating PI must enter the contact information for each Partnering PI in the "Partnering PI" section.
- Partnering PIs should collaborate with the Initiating PI in the preparation of the pre-application components.

Preproposal Screening: Preproposals will be reviewed by the BCRP Integration Panel, 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).

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 and General Information for detailed requirements of each component.

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting their application to Grants.gov, each Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system. ***Each PI also must submit an identical copy of a jointly created SOW.***

Application Components for the Initiating PI:

The Initiating PI must submit all Grants.gov application package components as listed in items 1-4 below.

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

2. **Attachments Form**

   - Attachment 1: Project Narrative (25-page limit)

     Within the Project Narrative, the PIs must clearly explain how the proposed research, if successful, would answer a question of significant importance to breast cancer. The research strategy should be outlined in detail and fully supported by preliminary data, published reports, and/or sound scientific rationale. ***The***

collaborating PIs should work together to develop the research plan and write the Project Narrative.

Describe the proposed work and team interaction using the following outline:

- **Background:** Present the ideas and reasoning behind the proposed work. Describe the major question in breast cancer research that is the focus of the proposal. Describe previous experience most pertinent to this proposal. Cite relevant literature.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **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. For use of human subjects or human biological samples, include a detailed plan for the recruitment of subjects or the acquisition of samples, including the source(s) and availability.
- **Research Teams and Environment:** Describe how the background in innovative research, research experience, and leadership skills make each PI well qualified to coordinate this collaborative effort. Discuss the qualifications of the team members and how they possess the appropriate expertise necessary to address the research question. Describe the research environments and how the facilities and resources will support the research requirements and the collaborative project.
- **Consumer Advocate Participation:** Describe the integral roles that consumer advocate(s) will play in the planning, design, implementation, and evaluation of the research. Describe the consumer advocate's previous training and familiarity with current issues in breast cancer. Explain how the consumer advocate's experience and expertise will be integrated into the research project and management of the collaboration.
- **Team Interaction and Training:** Describe how the PIs will collectively manage the collaboration among the three teams, and include an organizational chart identifying the roles of all team members and the workflow within and between labs. Present an overall management plan to facilitate group interactions, data sharing, adherence to regulatory requirements, administrative support, and oversight. Describe how the management plan will integrate and optimize research efforts and result in a unified collaborative effort. Provide a clear strategy to ensure cross-team participation and real-time communication of results, issues, problems, and progress. Include plans for conducting two in-person multi-team meetings per year. Present a detailed plan for implementing the required cross-training of at least two key members from each research team. Describe how the cross-training experience will augment the research team's efforts and will contribute to the impact of the proposed work.

- 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
- Attachment 3: Technical Abstract (one-page limit)
- Attachment 4: Public Abstract (one-page limit)
- Attachment 5: Statement of Work (three-page limit). The Initiating and Partnering PIs must submit an identical, jointly created SOW.
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (one-page limit)

  Describe how the combination of the research teams, the active integration of the consumer advocates, and the cross-training of the team members will collectively transform the research process, and address a question of significant importance to breast cancer. Describe the ultimate vision for how the proposed work, if successful, will have a significant impact on 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). Include all investigators and consumer advocates.
   - Key Personnel Current/Pending Support

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

Application Components for each Partnering PI:

The application submission process for each Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov. Each Partnering PI will be contacted via email by the CDMRP eReceipt system and provided with the information necessary to begin application submission through Grants.gov. Please note that each Partnering PI 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.

Each Partnering PI package includes only the following items from the list above:

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

2. **Attachments Form**

   - Attachment 5: Statement of Work (SOW; three-page limit).

     The Initiating and Partnering PIs must submit an identical, jointly created SOW.
   - Attachment 6: Detailed Budget and Justification
   - Attachment 8: Federal Agency Financial Plan (if applicable)
   - Attachments 9-15: Subaward Detailed Budget and Justification (if applicable)

3. **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 Question**
  - How the research addresses a key question of major importance to breast cancer.
  - How the proposed research, if successful, will have a significant impact on breast cancer.
  - How the proposed research is translational in nature and whether it includes a clinical component.
- **Research Teams**
  - How the background of innovative research, research experience, and leadership skills of each PI make him/her well qualified to coordinate this collaborative effort.
  - Whether the PIs represent both basic and clinical areas of expertise.
  - How the background and expertise of the research team members are appropriate to accomplish the proposed work.
  - How the levels of effort are appropriate for successful conduct of the proposed work.
- **Consumer Advocate Participation**
  - How the consumer advocates are integrally involved in the research and management processes of each participating team.
  - How the qualifications and background of the consumer advocates are appropriate to their involvement in the proposed collaboration.
- **Team Interaction and Training**
  - How the overall management plan will integrate and optimize research and collaborations and result in a unified research effort.
  - How well the plan for cross-training of team members is developed.
  - Whether there is a detailed plan for implementing the required in-person multi-team meetings.
  - How the teams plan to maximize use of resources and avoid unnecessary duplication of effort.
  - How well the PIs outline a clear strategy and plan to ensure cross-team participation and real-time communication of results, issues, problems, and progress.

- **Research Strategy and Feasibility**
    - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and/or logical reasoning.
    - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
    - How well the PIs acknowledge potential problems and address alternative approaches.
- **Environment**
    - 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 innovation and 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 Integration Panel (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:

- 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/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 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

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

C. Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to the Grants.gov help desk. 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, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time
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.