Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Innovator Award

Funding Opportunity Number: W81XWH-09-BCRP-INNOV

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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 BCRP Innovator Award was first offered in FY01. Since that time, 182 Innovator Award applications have been received and 17 have been recommended for funding. The Innovator Award supports visionary individuals who have demonstrated creativity, innovative work, and leadership in any field including, but not limited to, breast cancer. These individuals will have the most potential for future ground-breaking achievements in breast cancer. The Innovator Award will provide these individuals with the funding and freedom to pursue their most novel, visionary, high-risk ideas that could ultimately lead to the eradication of breast cancer.

The Individuals may be from diverse organizations including, but not limited to, academic institutions, advocacy groups, government agencies, the private sector, the media, and/or professional societies. Since the intent of the Innovator Award mechanism is to recognize creative and innovative individuals rather than projects, the central feature of the award is the innovative contribution that the recipient can make to the eradication of breast cancer. As such, an individual selected to submit a full application is required to submit an essay addressing his/her area(s) of focus and how he/she will use the award to pursue his/her most creative vision in breast cancer research. The primary criteria for making these awards will be an individual’s past record of creativity, their promise for continued innovation in future work, and an indication of how this award will create and further innovative strategies to solve the breast cancer problem.

Experience in breast cancer research is not required; however, the application must focus on breast cancer, and it is expected that the recipient will commit a minimum of 50% of his/her full-time professional effort to breast cancer research during the tenure of this award.

Individuals must be nominated to be considered for this award mechanism; self-nominations will not be accepted. Do not submit an Innovator Award application unless you receive a letter of invitation.
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 $5M 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, you 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
- Training
- Workshops
- 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. In addition, Innovator Award recipients will be required to attend the biennial 1½-day LINKS (Leading Innovative Networking and Knowledge Sharing) meeting along with BCRP Era of Hope Scholar Award recipients, the BCRP Integration Panel (IP), and CDMRP staff for the purpose of open communication and mutual benefit.

_The CDMRP expects to allot $17M of the $150M FY09 BCRP appropriation to fund approximately two Innovator 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
- **Confidential Letters of Recommendation:** June 17, 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 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.

- Nomination Submission
- Nominee Identification
- Nominee Biographical Sketch (two-page limit)
• Nomination Letter (two-page limit)
  
The nominator should provide a letter describing the nominee’s unique qualifications and accomplishments that demonstrate how this nominee is a true visionary in his or her field. Self nominations will not be accepted.
  
The nomination letter should address the nominee’s:
  o Unique qualification that stress creativity in past work,
  o Likelihood of continued innovation, and
  o Potential for creativity in future work, specifically related to breast cancer.
• List of Three Individuals Providing Letters of Recommendation

Nomination Screening: Nominations will be reviewed by the BCRP IP, which is composed of scientists, clinicians, and consumer advocates. Nominees whose qualifications meet the intent of the award mechanism will be invited to submit applications. Selection will be based on the Nominee’s unique qualifications that stress creativity in past work, likelihood of continued innovation, and potential for creativity in future work, specifically related to breast cancer. Each nominee will be notified as to whether they have been invited to submit an application. The nomination letter will be provided to nominees who are 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 package includes:

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

2. Attachments Form

  • Attachment 1: Project Narrative (five-page limit)

    The content of the Project Narrative should state clearly why you, the PI, should be selected for this unique award and should address the following questions specifically from your perspective:
    o Current Status of Breast Cancer Research: Describe your views of the major problems/barriers in breast cancer that must be solved to accelerate progress and hasten the eradication of breast cancer.
- Vision of the Future: What do you foresee as the critical approaches that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems/barriers in breast cancer that you have defined?

- Specific Ideas: Summarize some of the key examples of specific innovative ideas that you envision pursuing under the auspices of this award. Explain why/how your ideas may challenge current assumptions and have a significant impact on the eradication of breast cancer. This should not be a summary of research methodology.

- Qualification for This Award: Explain how you are qualified to receive this award. Give some examples of breakthrough creative thinking that demonstrate your abilities as an innovator. How do your achievements reflect your capabilities as an innovator?

- 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)

- Attachment 3: Detailed Budget and Justification

- Attachment 4: Federal Agency Financial Plan (if applicable)

- Attachments 5-15: Subaward Detailed Budget and Justification (if applicable)

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

- PI Curriculum Vitae (no 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

Confidential Letters of Recommendation (three letters total, two pages each): In addition to the completed Grants.gov application package of forms and attachments, Innovator Award applications also require the submission of three confidential letters of recommendation by the individuals designated during the pre-application process. All letters of recommendation must be submitted electronically through the CDMRP eReceipt system by 5:00 p.m. Eastern time on the deadline date. The PI should monitor whether the letters have been received; however, the PI is not permitted or able to view these letters. If confidential letters of recommendation cannot be
submitted by the individuals named in the pre-application, the PI should contact the CDMRP eReceipt helpdesk at help@cdmrp.org or 301-682-5507.

Each letter of recommendation should describe the PI’s unique qualifications and accomplishments. Specifically, each letter should offer the writer’s perspective on the PI’s:

- Creative and original accomplishments,
- Visionary and leadership qualities, and
- Likelihood of innovation and productivity in breast cancer research.

Refer to the Application Instructions and General Information, Section II.B., for additional information regarding submission of the letters of recommendation.

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., Innovation Statement or Impact Statement).
B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following equally important criteria.

   • Principal Investigator
     o How the application reflects the PI’s creativity and innovative thinking and supports the likelihood that the PI could have a significant impact on breast cancer.
     o How the PI’s record of accomplishment demonstrates outstanding ability as an independent and visionary scholar/investigator.
     o Whether the PI indicates that he/she will commit at least 50% effort to breast cancer during the tenure of this award.

   • Relevance and Impact
     o How the PI’s vision for the tenure of the award addresses an important problem(s) in breast cancer.
     o How the PI’s goals have the potential to significantly impact breast cancer.

   • Vision and Ideas
     o How clearly described is the PI’s vision of what he/she hopes to accomplish during the tenure of the award.
     o How the PI’s ideas reflect original and innovative thinking.
     o How compelling is the PI’s vision for how this award will be used to pursue creative (potentially groundbreaking) work in breast cancer.

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

   • Budget
     o How the budget is appropriate for the proposed research.

   • Application Presentation
     o 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 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:

- Nomination Letter is missing.
- Nominee Biographical Sketch is missing.

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](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](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.