Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Postdoctoral Fellowship Award

Funding Opportunity Number: W81XWH-09-BCRP-POSTDOC

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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 Postdoctoral Award mechanism was first offered in FY93. Since that time, 1,586 Postdoctoral (including Fellowship and Traineeship) Award proposals have been received and 525 have been recommended for funding. The Postdoctoral Fellowship Award supports exceptionally talented recent medical or other doctoral graduates in their pursuit of innovative, high-impact breast cancer research during their postdoctoral training and allows them to obtain the necessary experience for an independent career at the forefront of breast cancer research. ***Candidates for this award should exhibit a strong desire to pursue a career in breast cancer research.***

Under this award mechanism, the postdoctoral trainee is considered the Principal Investigator (PI) and, as such, should write the project narrative with appropriate direction from the mentor. While the PI is not required to have previous experience in breast cancer research, this proposal must focus on breast cancer research. Proposals must provide evidence of the PI's potential for success in becoming an independent breast cancer researcher based on his/her qualifications, characteristics, achievements, and letters of recommendations. The mentor (or co-mentor, if applicable) must possess the appropriate expertise and experience in breast cancer, to include peer reviewed breast cancer funding and publications, and clearly demonstrate a commitment to guiding the PI's research and training. The proposal should include information about the mentor's experience in conducting innovative research and how he/she intends to support the PI's innovative breast cancer research endeavors. If the mentor is not an experienced breast cancer researcher, then a formal co-mentorship by an established breast cancer researcher is required.

Proposals must provide details on the suitability of the PI's overall training plan and research project for attaining the goals of this mechanism. In addition, proposals must elaborate on the training environment in which the candidate will work and how it will facilitate the candidate's career development as an independent breast cancer researcher. Proposals with a multidisciplinary research approach to breast cancer are highly encouraged but not required.

C.   Eligibility

As of the application submission deadline, the PI must have been in the laboratory in which this research is to be performed for no more than 2 years, and he/she must have a total of less than 4 years of postdoctoral research experience (excluding clinical residency or fellowship training). The PI must successfully complete the requirements for a doctoral or medical degree by the time of award notification (September 2009). Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D.   Funding

- The maximum period of performance is **3** years.
- The maximum allowable funding for the entire period of performance is **$300,000** in direct costs.
- Up to $100,000 per year can be requested in direct costs.
- 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.
- Training awards usually have a different institutional indirect charge than research awards. Postdoctoral Fellowship Award applicants are encouraged to check with their institution concerning indirect costs.
- No salary support will be provided for the mentor(s), technicians, or other staff.

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

- Salary/stipend (PI only)
- Health insurance
- Research supplies
- Equipment
- Training
- Tuition
- Workshops
- 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 $8M of the $150M FY09 BCRP appropriation to fund approximately 25 Postdoctoral Fellowship 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

No change in PI is allowed for the Postdoctoral Fellowship Award once the application has been submitted. Changes in institution will be allowed only at the discretion of the Grants Officer. 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:	**February 25, 2009**
Confidential Letters of Recommendation:	**March 11, 2009**
Application Submission Deadline:	**March 11, 2009**
Scientific Peer Review:	**May 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.

- Proposal Information
- Proposal Contacts
- List of Individuals Providing Letters of Recommendation
- 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 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 (six-page limit)

     The PI must describe his or her career goals, the breast cancer research training program, and the proposed research project. Postdoctoral Fellowship Award proposals must be written by the trainee, while also showing evidence of appropriate direction from the mentor(s).

     Describe the proposed project using the following outline:

     o **PI's Career Goals:** Describe the PI's career goals and how the proposed training and research experience will promote the PI's career development in breast cancer research or patient care. Discuss the PI's career/research plans after the completion of this award.

     o **Breast Cancer Training Program:** Describe the training plan, including a timeline, coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Explain how the

training plan will advance the PI's development as a breast cancer researcher and promote innovative thinking about breast cancer. Describe the mentor's background and experience in breast cancer research, and how the mentor will assist the PI in developing his or her career. Describe how the training plan is supported by the environment, including a description of ongoing breast cancer research at the institution. Include information on training or collaborations with other investigators.

- o **Research Project:** Describe the proposed innovative research project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to the PI's career goals and the potential impact it might have on breast cancer. Preliminary data is not required.

- Attachment 2: Supporting Documentation

  - o References Cited

  - o Acronyms and Symbol Definitions

  - o Facilities & Other Resources

  - o Description of Existing Equipment

  - o Publications and/or Patent Abstracts (five-document limit)

  - o Transcripts

  - o Letters of Institutional Support

  - o Letters of Collaboration (if applicable)

  - o Letter of Formal Co-Mentorship Support (if applicable): If the mentor is not an experienced breast cancer researcher, then a formal co-mentorship by an established breast cancer researcher is required. Provide a signed letter from the Chair of the department that acknowledges the formal designation and role of the co-mentor for the PI's training program.

- 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)

  State how the training program will be designed to offer a structured, well-rounded focused experience in breast cancer research for the PI. Include how the training program will foster the PI's likelihood to pursue a career in breast cancer research. State explicitly the potential impact of the proposed work on breast cancer research or patient care.

- Attachment 8: Innovation Statement (one-page limit)

Summarize how the proposal is innovative. The following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- o Study concept – Investigation of a novel idea and/or research question.

- o Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.

- o Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

- o Investigating the next logical step as an incremental advancement on published data is not considered innovative.

- Attachment 9: Eligibility Statement
- Attachment 10: Federal Agency Financial Plan (if applicable)

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

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each, include mentor's biographical sketch)
- Key Personnel Current/Pending Support (include mentor's 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, Postdoctoral Fellowship Award proposals also require the submission of **three** confidential letters of recommendation by the individuals [including the primary mentor(s)] 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 in the eReceipt system 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 help desk at help@cdmrp.org or 301-682-5507.

- *Confidential letter(s) of recommendation from the mentor(s):* A letter must come from the PI's primary mentor, describing his/her commitment to the PI's training, career development, and mentorship. If the PI has a formal co-mentor, then that individual must also submit a letter of recommendation. Each mentor's letter of recommendation should describe:

- o The PI's potential to become a successful and independent breast cancer researcher;

- o The mentor's commitment to the training, career development, and mentorship of the PI, including details of the mentor's proposed interactions with the PI during the PI's training and how the mentor intends to support the PI's pursuit of innovative research endeavors;

- o The mentor's experience in conducting innovative research, evidence of current funding in breast cancer, and record of training other postdoctoral fellows;

- o The relevance of the proposed research project to training the PI in breast cancer and how the project reflects a measure of innovative thinking about breast cancer;

- o The PI's proposed research training program, including descriptions of the training environment, experience with laboratory techniques, conferences, and journal clubs, and how it will facilitate the PI's career development as a successful breast cancer researcher; and

- o The degree to which the PI participated in the idea development and proposal preparation.

- *Additional confidential letters of recommendation:* The remaining letter(s) should describe the PI's unique qualifications and accomplishments that highlight his/her potential for success in pursuing a career in breast cancer research. Specifically, each letter should offer the writer's perspective on:

  - o The PI's qualifications, characteristics, and achievements;

  - o The PI's potential for productivity and desire for establishing a successful career at the forefront of breast cancer research;

  - o The relevance of the proposed research project to training the PI in breast cancer; and

  - o The suitability of the mentor and training environment for providing the PI with a solid foundation in breast cancer research and the freedom to pursue innovative ideas.

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 criteria, which are listed in decreasing order of importance.

- **Principal Investigator**
  - How the PI's achievements (as reflected by exceptional academic performance, awards, honors, previous publications, and previous funding) indicate a potential for a successful career in breast cancer research.
  - How the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career at the forefront of breast cancer research.
  - How the letters of recommendation support the PI's high potential for success and dedication to a career in breast cancer research.
  - Whether the PI meets the appropriate eligibility requirements.

- **Mentor**
  - How the mentor is appropriately trained and well suited to guide this research project, including the mentor's experience in breast cancer research.
  - How the mentor's background, qualifications, research program, committed resources, and available time support his/her ability to supervise the PI's training and research project.
  - How the mentor's training achievements, as reflected by his/her previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in breast cancer research.
  - Whether the mentor's letter of recommendation indicates a high level of commitment to training the PI.
  - Whether the quality of the proposal suggests that the mentor provided appropriate guidance in its preparation.
  - Whether the mentor has prior evidence of conducting innovative research.

- **Training and Environment**
  - How comprehensive and detailed is the training plan for effectively advancing the PI's career in breast cancer research.
  - How the training will provide valuable experience to prepare the PI for an independent career at the forefront of breast cancer research.
  - How the scientific environment is appropriate for the proposed training and research.
  - How the training and research requirements are adequately supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the proposal provides evidence of a strong institutional commitment to research training in breast cancer.

- **Impact**
  - How the training program and research project will have an impact on the PI's expertise in breast cancer research or patient care.
  - How the project addresses a critical problem in breast cancer research.

- **Innovation**
  - How the proposed training program and environment promote the development of innovative breast cancer researchers.
  - Whether the proposed research is innovative in study concept or question, research methods or technologies, unique adaptations of existing methods or technologies, or other ways.

- **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 and/or logical reasoning.

- o How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- o How well the PI acknowledges potential problems and addresses alternative approaches.

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 impact and 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 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 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.

- 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 in Section V.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 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

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.