Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Era of Hope Postdoctoral Award

Funding Opportunity Number: W81XWH-08-BCRP-EHPA

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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 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

2.   eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt helpdesk, 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/) portal should be directed to 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 through 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 well before the proposal submission deadline.

- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.

- Failing to request "send me change notification e-mails" from Grants.gov.

- Not contacting HELP DESKS until just before or after deadlines.

- Not completing the pre-application submission before the mandatory pre-application deadline (pre-application remains in draft status).

- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. 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 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 Era of Hope Postdoctoral Award mechanism was first offered in FY06. Since that time, 44 Era of Hope Postdoctoral Award proposals have been received and 16 have been recommended for funding. The Era of Hope Postdoctoral Award supports exceptionally talented recent doctoral graduates who possess both the ambition and the ability to pursue highly innovative breast cancer research during their postdoctoral training. ***Research proposed for funding by the Era of Hope Postdoctoral Award mechanism should challenge current scientific dogma*** and demonstrate that the applicant has an ability to look beyond tradition and convention. Award recipients will be expected to challenge the status quo through creative, high-risk, potentially high-gain research that ultimately may lead to the eradication of breast cancer.

Candidates for this award should exhibit a strong desire to pursue a career in breast cancer research. Candidates should provide evidence that they are the "best and brightest" among their peers. Proposals must provide evidence of the candidate's potential for success in pursuing innovative research based on his or her qualifications, characteristics, achievements, and letters of recommendation. 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 research proposal must focus on breast cancer research. The mentor must possess the appropriate expertise in breast cancer, have current peer reviewed breast cancer funding, and clearly demonstrate a commitment to guiding the PI's research and training.

The proposed research must be clearly outlined and the innovative nature of the planned research project and/or training must be explicitly stated. Proposals with a multidisciplinary research approach to breast cancer are highly encouraged but not required. The proposal should include information about the mentor's experience in conducting innovative research and how he or she intends to support the PI's innovative breast cancer research endeavors. Proposals involving clinical trials do not meet the intent of this award mechanism.

Proposals must provide details on the suitability of the PI's overall training plan 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 innovator at the forefront of breast cancer research.

Individuals must be nominated to be considered for this award mechanism; self-nominations will not be accepted (NEW FOR FY08). Do not submit an Era of Hope Postdoctoral Award proposal unless you receive a letter of invitation.

C. Eligibility

As of the proposal submission deadline (June 19, 2008), the PI should not have been in the laboratory or research setting in which the proposed postdoctoral research is to be performed for more than 2 years and should have a total of less than 4 years of postdoctoral research experience (excluding clinical residency or clinical fellowship training). The PI must have successfully

completed the requirements for a doctoral or medical degree at the time of award notification (approximately November-December 2008). Proposals submitted for "to be named" trainees will be administratively withdrawn.

Refer to Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for an Era of Hope Postdoctoral Award can be requested for up to $90,000 per year for direct costs for up to a 3-year performance period plus indirect costs as appropriate. No salary support will be provided for the mentor.

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

- salary/stipend
- health insurance
- research supplies
- equipment
- training
- tuition
- workshops
- support for multidisciplinary collaborations
- travel between collaborating institutions
- travel to scientific/technical meetings

Era of Hope Postdoctoral Award recipients will be required to attend an annual 1½-day LINKS (Leading Innovative Networking and Knowledge Sharing) meeting along with BCRP Innovator, Era of Hope Scholar, and Multidisciplinary Postdoctoral Award recipients, the BCRP Integration Panel, and CDMRP staff for the purpose of open communication and mutual benefit. In addition, the CDMRP requires attendance at the biennially scheduled 3½-day DOD BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

Training awards usually have a different institutional indirect charge than research awards. Era of Hope Postdoctoral Award applicants are encouraged to check with their institution concerning indirect costs.

The CDMRP expects to allot $5M of the $138M FY08 BCRP appropriation to fund approximately 12-14 Era of Hope Postdoctoral Award proposals, depending on the quality and number of proposals received. Funding of proposals received in response to this program announcement is contingent on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions, Appendix 5, for general information on changes in award personnel or institution.

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, March 27, 2008**
- **Invitation to Submit Proposal**   **April 25, 2008**
- **Confidential Letters of Recommendation 5:00 p.m. Eastern time, June 19, 2008**
- **Proposal Submission Deadline:**   **11:59 p.m. Eastern time, June 19, 2008**
- **Peer Review:**   **August 2008**
- **Programmatic Review:**   **September 2008**

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/) and (2) a proposal submission (***requires a letter of invitation***) through Grants.gov (http://www.grants.gov/).

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 pre-application deadline***. The PI and Organization 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. In addition to the specific instructions below, refer to the Application Instructions for detailed information.

1. Nomination Submission

2. Nominee Identification

3. Nominee Biosketch (two-page limit)

4. Nomination Letter (two-page limit)

   The nominator should provide a letter describing the unique qualifications and accomplishments that exemplify how this nominee is among the best and brightest in his or her field. Self nominations will *not* be accepted *(NEW FOR FY08)*.

   The nomination letter should include:

   - The nominee's qualifications, characteristics, and achievements;

   - The nominee's potential for innovation and productivity;

   - The probability that the nominee will establish a successful career at the forefront of breast cancer research;

   - The innovation(s) of the proposed research project;

   - The potential impact the proposed research will have on breast cancer research or patient care; and

   - The suitability of the mentor and training environment for promoting innovation and providing the nominee with a solid foundation in breast cancer research.

5. Primary mentor's contact information

6. List of Three Individuals Providing Letters of Recommendation

Nomination Screening: Nominations will be reviewed by the BCRP Integration Panel, which is composed of scientists, clinicians, and consumer advocates. Nominees whose qualifications meet the intent of the award mechanism will be invited to submit proposals. Each nominee will be notified as to whether they have been invited to submit a proposal. The nomination letter will be provided to nominees who are invited to submit a proposal.

B. Step 2 – Proposal Components and Submission

Proposal submission will not be accepted unless the PI has been invited. Do not submit a proposal unless a letter of invitation has been received. Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) 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 www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. The PI and Organization 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 helpdesk at help@cdmrp.org or 301-682-5507. In addition to the

specific instructions below, 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

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

  Describe the proposed training and research project using the following outline:

  o Career/Research Plans: The PI should briefly discuss current and future career plans, including research and training goals (without listing specific projects), and how these would be affected if funding was awarded. The PI should describe his or her inspiration for pursuing innovative plans/goals that might differ from traditional career paths. Describe qualifications, characteristics and achievements that demonstrate why the PI should be considered one of the "best and brightest" among his/her peers. Provide examples that demonstrate the PI's unique potential to successfully pursue innovative breast cancer research and training.

  o Research Project: The PI must clearly articulate the innovative nature of the research project and include the potential impact it might have on breast cancer.

    Describe the proposed innovative research project using the following outline:

    - Background: Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this proposal.

    - Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

    - Specific Aims: Concisely explain the project's specific aims. If this proposal is part of a larger study, present only tasks that the DOD award would fund.

    - Research Strategy: Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. ***Please note that this award may not be used to support clinical trials.***

  o Training Program: Provide a detailed training plan that describes the qualifications of the mentor(s) and his or her area(s) of expertise and the appropriateness of the training environment. Describe coursework, conferences, and/or journal clubs in which the PI will participate and any training he/she will receive in new laboratory techniques. Explain how this environment will facilitate innovation and support the development of his/her career in breast cancer research.

- 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)
  - Transcripts
  - Mentor's Letter of Support (two-page limit)

    A letter from the PI's primary mentor describing his or her commitment to the PI's training, career development, and mentorship. The mentor's letter of support should describe:
    - The mentor's commitment to the training, career development, and mentorship of the PI;
    - The mentor's training and /or experience in conducting innovative breast cancer research and current funding in breast cancer;
    - The mentor's record of training other postdoctoral fellows;
    - The proposed training program and how it will facilitate the PI's career development as an innovator at the forefront of breast cancer research.
  - Letters of Institutional Support
  - Letters of Collaboration (if applicable)

- Attachment 3: Technical and Public Abstracts

  Both the training project and the research project should be emphasized.

- Attachment 4: Statement of Work (SOW)

- Attachment 5: Impact Statement

  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 how the proposed work will have an impact on breast cancer research or patient care. Describe how the combination of innovation and the expected results of the proposal will contribute to the goal of eradicating breast cancer.

- Attachment 6: Innovation Statement

  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:
  - 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 7: Eligibility Statement

- Attachment 8: 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)
     - o A biosketch of the PI's mentor is required.
   - Key Personnel Current/Pending Support
     - o Current/Pending Support for the PI's mentor is required.

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)

Confidential Letters of Recommendation (two-page limit): In addition to the completed Grants.gov application package of forms and attachments, Era of Hope Postdoctoral Award proposals also require the submission of three confidential letters of recommendation by the individuals (not including the primary mentor) designated during the pre-application process. 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 help desk at help@cdmrp.org or 301-682-5507.

Each letter should describe the PI's unique qualifications and accomplishments that highlight his or her potential for success in pursuing highly innovative research avenues. Specifically, each letter should offer the writer's perspective on:

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

- The PI's potential for innovation and productivity,

- The innovation of the proposed research project and its relevance to breast cancer,

- The nominee's potential to establish a successful career at the forefront of breast cancer research, and

- The suitability of the mentor and training environment for promoting innovation and providing the PI with a solid foundation in breast cancer research.

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

V.   INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All 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 program 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 non-disclosure 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 correcting actions. Correspondingly, 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. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement, Impact Statement, or Eligibility Statement).

B. Review Criteria

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

   - **Principal Investigator**
     - How the PI's background, academic performance, awards, and honors make him or her stand out from his or her peers as one of the "best and brightest."

- o Whether the PI shows exceptional potential for an independent career at the forefront of breast cancer research.
- o How the PI has demonstrated a strong personal commitment to pursuing a career in breast cancer research.
- o How the letters of recommendation support the PI's abilities and potential for a productive research career in breast cancer.

- **Mentor**
  - o How the mentor has demonstrated experience in breast cancer research.
  - o How the mentor's background, qualifications, research resources, and available time support his or her ability to supervise the PI's training program and research.
  - o How extensive is the mentor's previous research training experience with predoctoral students, postdoctoral or clinical fellows, residents, etc.
  - o How clearly the mentor indicates a commitment toward innovative research and training for the PI.
  - o Whether the mentor has prior evidence of conducting innovative research.

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

- **Impact**
  - o How the project addresses a critical problem in breast cancer.
  - o How the project makes an original and important contribution to the goal of advancing research on the prevention, detection, or treatment of breast cancer.

- **Research Strategy and Feasibility**
  - o How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data, and/or logical reasoning.
  - o How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - o How well the PI acknowledges potential problems and addresses alternative approaches.
  - o If the research plan requires statistical analyses, whether the proposal includes a clear statistical plan with power analysis.

- How well the subject recruitment plan supports the project and its feasibility if applicable.

- **Training and Environment**

  - How comprehensive and detailed is the training plan for effectively advancing the PI's career in innovative breast cancer research.

  - How the training has the potential to provide valuable experience for the PI to prepare him or her for an independent career at the forefront of breast cancer research.

  - How the training environment is appropriate for accomplishing the PI's goals.

  - How the research requirements will be adequately supported by the scientific environment, resources, and collaborative arrangements proposed.

  - How the proposal provides evidence of a strong institutional commitment to research training in breast cancer.

- **Budget**

  - How the budget is appropriate for the proposed research.

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

- 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 members 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. 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 pre-application:

- Nomination letter exceeds page limit.
- Nomination letter is missing.
- Nominee biosketch exceeds page limit.
- Nominee biosketch is missing.
- FY08 Integration Panel (IP) members are included in any capacity in the pre-application process and/or any supporting document. A list of the FY08 IP members may be found at http://cdmrp.army.mil.

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

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print Area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- FY08 Integration Panel (IP) members are included in any capacity in the proposal, budgets, and any supporting document. A list of the FY08 IP 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 peer review.

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

Proposals that appear to include plagiarized information 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.