Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Idea Award

Funding Opportunity Number: W81XWH-08-BCRP-IDEA

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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 help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

> Phone: 301-682-5507
>
> Website: https://cdmrp.org
>
> Email: help@cdmrp.org

3.   Grants.gov contacts: Questions related to submitting applications through the Grants.gov (http://www.grants.gov/) 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 emails" 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 $138.0 million (M).

The BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

B. Award Description

The BCRP Idea Award mechanism was first offered in FY93. Since that time, 12,797 Idea Award proposals have been received and 1,809 have been recommended for funding. The Idea Award supports highly innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will accelerate the eradication of breast cancer.

The BCRP seeks proposals from all areas of basic, translational, clinical, behavioral, and epidemiological research. ***The Idea Award is designed to promote new ideas; therefore, proposals need not include preliminary data.***

Innovation and Impact are the most important aspects of the Idea Award.

> **Innovation:** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.
>
> Examples of research that are not innovative, and will not be considered for funding under this mechanism include:
>
> - Exploring a previously tested hypothesis in a different cell line or in a new population.
> - Using a published series of in vitro assays to further characterize a model system.
> - Incorporating known biomarkers into in vitro or clinical models of breast cancer.
> - Investigating the next logical step or incremental advancement of published data.
>
> **Impact:** Research that has high potential impact may significantly accelerate the eradication of breast cancer.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's innovation and the potential impact on breast cancer.

C. Eligibility

Investigators at all academic levels (or equivalent) are eligible to submit proposals.

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

D. Funding

Funding for an Idea Award can be requested for up to $375,000 for direct costs for up to a 3-year performance period plus indirect costs as appropriate. PIs with proposals for population-based studies may request a maximum of $650,000 for direct costs for up to a 5-year performance period plus indirect costs as appropriate. However, such a request must be accompanied by a compelling justification.

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

- salary

- research supplies

- equipment

- clinical costs

- support for multidisciplinary collaborations

- travel between collaborating institutions

- travel to scientific/technical meetings

The CDMRP requires attendance at the biennially scheduled 3 1/2-day DOD BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

The CDMRP expects to allot $35M of the $138M FY08 BCRP appropriation to fund approximately 60 Idea 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

An award that includes a clinical trial cannot be transferred to another institution.

Refer to the Application Instructions, Appendix 5, for general award administration information.

III.   TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline:**   **5:00 p.m. Eastern time, April 16, 2008**
- **Proposal Submission Deadline:**   **11:59 p.m. Eastern time, May 14, 2008**
- **Peer Review:**   **July 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 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 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. Proposal Information

2. Proposal Contacts

3. Collaborators and Conflicts of Interest (COI)

4. LOI narrative

B. Step 2. Proposal Components and Submission

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

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. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The package includes:

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

2. Attachments Form

   - Attachment 1: Project Narrative (6-page limit)

     Throughout the Project Narrative describe how the proposed research is innovative and the potential impact it will have on breast cancer. Presentation of preliminary data is not required. However, PIs must demonstrate logical reasoning and a sound

scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive.

Describe the proposed project using the following outline:

- o Background: Present the ideas and reasoning behind the proposed work. Cite relevant literature.

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

- o Specific Aims: Concisely explain the project's specific aims to be funded by this proposal.

- o Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Describe the statistical plan if appropriate for the research proposed. 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 and statistical plan.

- 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 (5-document limit)

  - o Letters of Institutional Support

  - o Letters of Collaboration (if applicable)

  - o Intellectual and Material Property Plan (if applicable)

- Attachment 3: Technical and Public Abstracts

- Attachment 4: Statement of Work (SOW)

- Attachment 5: Impact Statement

  Describe the ultimate vision for how the proposed work, if successful, will accelerate the eradication of 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:

  - 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 Clinical interventions - Use of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- 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 or incremental advancement on published data is not considered innovative.
- Attachment 7: Clinical Protocol (if applicable)
- 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)
- Key Personnel Current/Pending Support

4. Research & Related Budget Form
- Budget Justification

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

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

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

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 programmatic review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a 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 programmatic 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 or Impact 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.

   - **Innovation**
     - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.
     - How the proposed research represents more than an incremental advance upon published data.

   - **Impact**
     - How the project would make a significant contribution to the eradication of breast cancer.
     - How the potential gain warrants the perceived risk.

   - **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 PI acknowledges potential problems and addresses alternative approaches.

   - **Personnel**
     - How the research team's background and expertise are appropriate to accomplish the proposed work.
     - How the levels of effort are appropriate for successful conduct of the proposed work.

   - **Environment**
     - How the scientific environment is appropriate for the proposed research.

- o How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - o How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
  - o 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.

3. **Clinical Protocol Review (if applicable)**

All clinical trials will be scientifically reviewed according to the following criteria as applicable. The reviewers will evaluate:

- **Trial Design**
  - o How the scientific rationale and preliminary data, including critical review and analysis of the literature and laboratory and preclinical evidence, support the proposed trial and its feasibility.
  - o How well the aims, hypothesis or objectives, experimental design, methods, data collection procedures, and analyses are developed.
  - o How the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, and standardization of procedures) are adequate.
  - o How the recruitment, informed consent, and screening processes for volunteers will be conducted.
  - o Whether the inclusion, exclusion, and randomization criteria are adequate.
- **Clinical Impact**
  - o How this study will affect the treatment and/or management of the disease.
  - o How this study will affect the magnitude and scope of potential clinical applications.

- **Intervention, Drug, or Device**

  o The appropriateness of the intervention, drug, or device to be tested in the clinical trial.

  o The availability and purity of the substance to be used in the clinical trial (if applicable).

  o Documentation that an IND/IDE has been submitted (if applicable).

- **Feasibility**

  o The feasibility of the proposed clinical study.

  o The plans for addressing unanticipated delays (e.g., slow accrual) and completing the proposed study within the performance period.

  o The availability of volunteers for the clinical trial, the prospect of their participation, and the likelihood of volunteer attrition.

  o The progress toward obtaining local IRB approval of the clinical protocol and informed consent form.

- **Statistical Plan (as appropriate for phase of study)**

  o How the statistical plan, including sample size projections and power analysis, is adequate for the trial and all proposed correlative studies.

  o The consistency of the data analysis plan with the study objectives.

- **Personnel**

  o How the clinical trial team's background and expertise are appropriate to accomplish the proposed work (i.e., statistical expertise, expertise in the disease, and clinical trials).

  o The appropriateness of the levels of effort for successful conduct of the proposed work.

- **Environment**

  o The evidence of an appropriate scientific environment, clinical setting, and the accessibility of institutional resources to support the clinical trial at each participating center.

  o Whether the clinical trial requirements are supported adequately by the accessibility to facilities and resources (including collaborative arrangements).

  o The institutional commitment from each participating institution.

  o The intellectual and material property plan that is agreed upon by each participating institution.

- **Ethics and/or Regulatory Issues**

  o How the ethical considerations, information privacy, and assessment of risks and benefits of participation in the clinical trial will be addressed.

- o The plan for dealing with adverse events, which should include named agencies or offices to be notified in this event and point of contact information.

- o The plans for data disposition during and after the clinical trial.

- o The procedures for protocol modifications during the course of the study.

- o The plans for data and safety monitoring.

- **Budget**

  - o How the budget is appropriate for the proposed clinical trial.

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 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 pre-application process, 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 the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.