# **Program Announcement**

# **Department of Defense Congressionally Directed Medical Research Programs**

# **Breast Cancer Research Program**

# **Predoctoral Traineeship Award**

Funding Opportunity Number: W81XWH-10-BCRP-PREDOC

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#### I. FUNDING OPPORTUNITY DESCRIPTION

## A. Program Description

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 FY09 totaled over \$2.3 billion. The FY10 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 Predoctoral Traineeship Award was first offered in FY93. Since that time, 3,521 Predoctoral Traineeship Award applications have been received, and 1,195 have been recommended for funding. The Predoctoral Traineeship Award supports the training of promising graduate students studying breast cancer under the guidance of a designated mentor to prepare them for successful careers in breast cancer research. Under this award mechanism, the predoctoral trainee is considered the Principal Investigator (PI) and, as such, should write the application with appropriate direction from the mentor. The mentor, who may be a junior or senior faculty member, must clearly demonstrate a commitment to guiding the PI's research and training, and must have a track record in breast cancer research. If the mentor is not an experienced breast cancer researcher, then a formal co-mentorship by an established breast cancer researcher is required.

Applications should emphasize:

- The PI's talent, potential, and *commitment to breast cancer research*,
- The mentor's (and co-mentor's, if applicable) qualifications and experience in breast cancer research,
- The level of the mentor's (and co-mentor's, if applicable) support of the PI's research and training,
- The strength of the training program in breast cancer research, and
- The institution's commitment to training future leaders in breast cancer research.

## C. Eligibility

PIs must be graduate students enrolled in a Ph.D. or M.D./Ph.D. program. Applications submitted for "to be named" trainees are not allowed and will be administratively withdrawn. Refer to General Application Instructions, 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 \$120,000 in direct costs.
- Up to \$40,000 per year can be requested in direct costs; direct costs in excess of the stipend must be used as direct support for the PI and may not be used for research costs.
- In addition to the direct costs, indirect costs may be proposed in accordance with the organization's negotiated rate agreement, up to a maximum rate of 8%.
- The Predoctoral Traineeship Award should support the PI during dissertation research only.
- It is expected that the mentor will have adequate funding to support the PI's research.

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

- Salary/stipend (PI only)
- Tuition
- Health insurance
- Training
- Workshops
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings.
- Other direct costs as described in the General Application Instructions for the Detailed Budget and Justification.

In addition, funding must be requested for the PI to attend one 3½-day Department of Defense BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$11M of the \$150M FY10 BCRP appropriation to fund approximately 90 Predoctoral Traineeship 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 upon the availability of Federal funds for this program.

#### E. Award Administration

No change in PI is allowed for the Predoctoral Traineeship Award once the application has been submitted. Changes in institution or mentor will be allowed only at the discretion of the Grants Officer. Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2011. Refer to the General Application Instructions, Appendix 4, for general award administration information.

#### II. TIMELINE FOR SUBMISSION AND REVIEW

• Pre-application Submission Deadline: 5:00 p.m. Eastern time (ET), March 24, 2010

• Confidential Letters of Recommendation: 5:00 p.m. ET, April 7, 2010

• Application Submission Deadline: 11:59 p.m. ET, April 7, 2010

Scientific Peer Review: May 2010
 Programmatic Review: July 2010

Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.

#### III. SUBMISSION PROCESS

Submission is a two-step process requiring both (1) pre-application submission through the CDMRP eReceipt system (<a href="https://cdmrp.org/">https://cdmrp.org/</a>) and (2) application submission through Grants.gov (<a href="http://www.grants.gov/">http://www.grants.gov/</a>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

PIs and organizations identified in the application should be the same as those identified in the pre-application. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the eReceipt help desk at <a href="help@cdmrp.org">help@cdmrp.org</a> or 301-682-5507.

## A. Step 1 – Pre-Application Components

All pre-application components must be submitted through the CDMRP eReceipt system by 5:00 p.m. ET on the deadline.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs: (Refer to the General Application Instructions for additional information on pre-application submission.)

- Proposal Information Tab 1
- Proposal Contacts Tab 2
- Collaborators and Conflicts of Interest (COI) Tab 3
   Include mentor(s) names in the COI list.
- Required Files Tab 4

**Letter of Intent (LOI) Narrative (one-page limit):** Provide a brief description of the research to be conducted. LOI Narratives are used for program planning purposes only

(e.g., reviewer recruitment) and *will not be reviewed* during either the peer or programmatic review sessions.

List of Individuals Providing Confidential Letters of Recommendation: Enter into the appropriate data fields the names, position titles, email addresses, and phone numbers for three individuals, including the PI's mentor(s), who will provide letters of recommendation. Each individual will receive an email generated from the CDMRP eReceipt system containing specific instructions on how to upload his/her letter.

- Submit Pre-application Tab 5
- Other Documents Tab

Not applicable.

# **B.** Step 2 – Application Components

Applications are submitted by the Authorized Organizational Representative (AOR) through Grants.gov (<a href="http://www.grants.gov/">http://www.grants.gov/</a>). Applications must be submitted by 11:59 p.m. ET on the deadline.

Each application submission must include the completed application package of forms and attachments identified in Grants.gov for this Program Announcement/Funding Opportunity.

The Grants.gov application package consists of the following components (Refer to the General Application Instructions, Section II.B., for additional information on application submission.):

**1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

#### 2. Attachments Form

• Attachment 1: Project Narrative (6-page limit): Upload as "ProjectNarrative.pdf."

The PI must describe the proposed research project, breast cancer research training program, and his/her career goals in the body of the application. Predoctoral Traineeship Award applications must be written by the trainee, while also showing evidence of appropriate direction from the mentor.

Describe the proposed project using the following outline:

- PI's Career Goals: Describe the PI's career goals and how the proposed training will promote the PI's career in breast cancer research or patient care. Discuss the PI's career 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. Describe the mentor's background and experience in breast cancer research, and how the mentor will assist the PI in developing his/her career. Explain how the training

- plan will advance the PI's development as a breast cancer researcher. 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.
- Research Project: Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to breast cancer.
- Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted*.
  - References Cited: List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.
  - List of Acronyms and Symbols: Provide a list of acronyms and symbols (e.g., PCR = polymerase chain reaction).
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project, and any additional facilities or equipment proposed for acquisition at no cost to the US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.
  - List of Dissertation Committee Members: Provide a list of the trainee's dissertation committee members, including name, institution, degrees, position, and area(s) of expertise.
  - Transcripts: Include a copy of the PI's transcripts from both undergraduate and graduate institutions. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations.
  - 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 Director of the graduate program that acknowledges the formal designation and role of the co-mentor for the PI's training program.
- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."
  - Training Plan

- Describe how the training plan supports the PI's career goals in breast cancer research.
- Describe how the proposed research project will train the PI to make valuable contributions to the study or treatment of breast cancer.

#### Research Plan

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design, including appropriate controls.

## • Attachment 4: Public Abstract (one-page limit): Upload as "PublicAbs.pdf."

- Describe the scientific objective and rationale for the proposal in a manner readily understandable by non-scientists.
  - Do not duplicate the technical abstract
- o Describe the PI's career goals in breast cancer research or patient care.
  - How does the training plan support the PI in attaining these goals?
  - How does the research plan support the PI in attaining these goals?
- Describe the ultimate applicability of the research.
  - What types of patients will it help, and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
- What are the likely contributions of this study to advancing the field of research?
- How will the research enhance this or other studies being conducted?
- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.

Include both the training plan and research plan in the SOW.

• Attachment 6: Detailed Budget and Justification (no page limit): Upload as "Budget.pdf." Use the Detailed Budget and Justification form (available for download on the Full Announcement page in Grants.gov). Refer to the General Application Instructions, Section II.B., for detailed information.

- Attachment 7: Subaward Detailed Budget and Justification (if applicable) (no page limit): Use a separate Detailed Budget and Justification form for each subaward budget. Combine into a single file and upload as "SubBudgets.pdf." Refer to the General Application Instructions, Section II.B., for detailed information.
- **3.** Research & Related Senior/Key Person Profile (Expanded) Form: Refer to the General Application Instructions, Section II.B., for detailed information.
  - PI Biographical Sketch (four-page limit): Upload as "Biosketch\_LastName.pdf."
  - PI Current/Pending Support (no page limit): Upload as "Support\_LastName.pdf."
  - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch\_LastName.pdf."
    - o Include mentor's and co-mentor's (if applicable) biographical sketch.
  - Key Personnel Current/Pending Support (no page limit): Upload as "Support\_LastName.pdf."
    - o Include mentor's and co-mentor's (if applicable) current/pending support.
- **4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.B., for detailed information.

**Additional Application Components:** In addition to the completed Grants.gov application package of forms and attachments, BCRP Predoctoral Traineeship Award applications also require the following components:

- 1. Confidential Letters of Recommendation (three letters total, two pages each): Three confidential letters of recommendation must be submitted by the individuals (including the mentor[s]) designated during the pre-application process. All letters must be submitted electronically through the CDMRP eReceipt system by 5:00 p.m. ET on the application deadline. The PI should monitor whether the letters have been received; however, the PI is not 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:
    - The PI's potential to become a breast cancer researcher;

- 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 verification that the PI will perform their
  dissertation work in the mentors lab;
- The mentor's experience in conducting breast cancer research, evidence of current funding in breast cancer, and record of training other predoctoral students;
- The relevance of the proposed research to training the PI in breast cancer;
- 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 breast cancer researcher;
- The degree to which the PI participated in the idea development and application preparation, and the degree to which the PI will participate in the execution of the proposal if funded.
- Additional confidential letters of recommendation: The remaining letter(s) should highlight the PI's potential for success in pursuing a career in breast cancer research. Specifically, each letter should include the writer's perspective on:
  - The PI's qualifications, characteristics, and achievements,
  - The PI's potential for productivity and desire for establishing a career in breast cancer research,
  - The suitability of the mentor(s), research project, and training environment for providing the PI with a solid foundation in breast cancer research.

#### 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 applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on scientific merit, the overall goals of the program, and specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP may be found at <a href="http://cdmrp.army.mil/fundingprocess">http://cdmrp.army.mil/fundingprocess</a>

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a nondisclosure 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. Organizational personnel and PIs are

prohibited from contacting persons involved in the 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 organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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).

#### B. Review Criteria

**1. Peer Review:** All applications will be evaluated according to the following criteria, which are listed in decreasing order of importance. The most significant evaluation criteria will be the PI's qualifications.

## • Principal Investigator

- How the PI's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for successful training in breast cancer research.
- How the PI's stated career goals demonstrate a commitment to pursuing a career as a breast cancer researcher or clinician.
- How the letters of recommendation support the PI's potential for productive breast cancer research.

## • Mentor (and Co-Mentor, if applicable)

- How the mentor is appropriately trained and well suited to guide this research project, including the mentor's experience in breast cancer research.
- Whether the mentor has current funding in breast cancer research.
- 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.
- The appropriateness of the mentor's research experience, research program, committed resources, and level of effort for the proposed training program.
- o If the quality of the application suggests that the mentor provided appropriate guidance in its preparation.
- Whether the mentor's letter of recommendation addresses each of the requested topics.

## • Training Program

- How the training focuses on breast cancer research.
- How well the PI has outlined an individualized training program that augments his/her expertise.
- How the training will prepare the PI for an independent career in breast cancer research.

- The appropriateness of the scientific environment for the proposed training.
- How the training requirements are adequately supported by the availability of facilities and resources (including collaborative arrangements).
- The impact the training program will have on the PI's expertise in breast cancer research or patient care.
- How the research project will train the PI to make valuable contributions to the study or treatment of breast cancer.
- The appropriateness of the expertise of the dissertation committee members.

## • Research Strategy and Feasibility

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
- The appropriateness of the research project for the training plan and the level of training for the PI.

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

## • Budget

• Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

## • Application Presentation

• How the writing and components of the application influenced the review.

#### Eligibility

- Whether the PI meets the eligibility requirements.
- **2. Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations.
  - Ratings and evaluations of the peer reviewers
  - Programmatic relevance
  - Program portfolio composition
  - Adherence to the intent of the award mechanism

#### 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).
- Pre-application is not submitted.

#### **B.** Modifications

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- 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 by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

#### C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY10 BCRP Integration Panel (IP) member(s) is found to be involved in the preapplication 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 FY10 BCRP IP members may be found at <a href="http://cdmrp.army.mil/bcrp/panel10">http://cdmrp.army.mil/bcrp/panel10</a>
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the detailed budget form exceed maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs with the exception of links to published references.
- The PI does not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.

#### 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 US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

#### VI. CONTACT INFORMATION

A. CDMRP Program Announcement Help Desk: Questions related to Program Announcement/Funding Opportunity content or submission requirements should be directed to the CDMRP Program Announcement help desk, which is available Monday through Friday from 7:30 a.m. to 4:00 p.m. ET. 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

Email: cdmrp.pa@amedd.army.mil

**B. CDMRP eReceipt System Help Desk:** Questions related to the submission of the preapplication through the eReceipt system should be directed to the CDMRP eReceipt system help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507 Email: help@cdmrp.org

**C. Grants.gov Contact Center:** Questions related to application submission through the Grants.gov portal should be directed to Grants.gov help desk, which is available 24 hours a day, 7 days a week. Please note that the CDMRP Program Announcement and eReceipt system help desks are unable to provide technical assistance regarding Grants.gov submissions.

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

# VII. APPLICATION SUBMISSION CHECKLIST

| Grants.gov Application Components                             | Action  | Completed |
|---|---|-----------|
| SF-424 (R&R) Application for Federal Assistance Form          | Complete form as instructed   |           |
| Attachments Form  | Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1  Upload Supporting Documentation (Support.pdf) as Attachment 2  Upload Technical Abstract (TechAbs.pdf) as Attachment 3  Upload Public Abstract (PublicAbs.pdf) as Attachment 4  Upload Statement of Work (SOW.pdf) as Attachment 5  Upload Detailed Budget and Justification (Budget.pdf) as Attachment 6  Upload Subaward Detailed Budget and Justification |           |
| Research & Related<br>Senior/Key Person Profile<br>(Expanded) | (SubBudgets.pdf) as Attachment 7  Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field  Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field  Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field  Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field  |           |
| Project/Performance Site<br>Location(s) Form                  | Complete form as instructed   |           |
| Additional<br>Application Components                          | Action  | Completed |
| Confidential Letters of Recommendation                        | Confirm upload to CDMRP eReceipt System   |           |