Program Announcement

I. GENERAL INFORMATION

This program announcement is being released prior to the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: Breast Cancer Research Program (BCRP) Predoctoral Traineeship Award.

B. Program Name: Department of Defense (DOD) Fiscal Year 2006 (FY06) BCRP.

C. Funding Opportunity Number: W81XWH-06-BCRP-PREDOC.

D. Agency Name: USAMRMC, Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

E. Agency Contact(s)

1. Questions related to the program announcement, proposal format, or required documentation: Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone:	301-619-7079
Fax:	301-619-7792
E-mail:	cdmrp.pa@amedd.army.mil
Mail:	Commander
	US Army Medical Research and Materiel Command
	ATTN: MCMR-ZB-C (BC06-PREDOC)
	1077 Patchel Street (Building 1077)
	Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by e-mail as follows:

Website:https://cdmrp.org (User's Guide located in upper right corner of the
proposal submission website)E-mail:help@cdmrp.org

F. Anticipated Instrument Type(s): The USAMRMC executes its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

Fax:	301-619-2937
E-mail:	<u>qa.baa@amedd.army.mil</u>
Mail:	Director
	US Army Medical Research Acquisition Activity
	ATTN: MCMR-AAA-R
	820 Chandler Street
	Fort Detrick, MD 21702-5014

G. Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.

H. Website to Access Application Package: Proposals must be submitted at <u>https://cdmrp.org</u>. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty downloading documents should contact the CDMRP as indicated in <u>Subsection I.E.2</u>.

I. Award/Regulatory Approval: The applicant may not use funds from this award to directly support research involving human subjects, human biological substances, or laboratory animals.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Predoctoral Traineeship Award is one of the mechanisms of the Breast Cancer Research Program (BCRP), which was established in FY92 to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 to FY05 totaled \$1.83 billion. During this time, 2,213 Predoctoral Traineeship Award proposals have been received and 858 have been recommended for funding. The FY06 appropriation is \$127.5 million (M).

B. Program Objectives: The overall goal of the FY06 BCRP is to promote research focused on eradicating breast cancer. Therefore, 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 potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances. Underinvestigated avenues of research and novel applications of existing technologies are strongly encouraged. The BCRP encourages risk-taking research; however, all projects must demonstrate solid scientific judgment and rationale.

The BCRP's objective within this context is to fund a balanced portfolio of scientifically meritorious research related to all aspects of breast cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic research, including all disciplines within

the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; ethics; and economics. Proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are strongly encouraged.

III. AWARD INFORMATION

The Predoctoral Traineeship Award prepares promising graduate students studying breast cancer under the guidance of a designated mentor for careers in breast cancer research. Individuals enrolled in a Ph.D. or M.D./Ph.D. program are encouraged to apply.

Proposals should emphasize:

- The trainee's talent, potential, and *commitment to breast cancer research*,
- The mentor's qualifications and experience in breast cancer research,
- The strong training program in breast cancer research at the trainee's institution,
- The innovative research environment, and
- The institution's commitment to training future leaders in breast cancer research.

Proposals must be written and signed by the trainee as the applicant and author, with appropriate direction from the mentor. The trainee must describe the proposed research project, breast cancer research training program, and his or her career goals in the body of the proposal (see <u>Subsection V.K</u>). The mentor is responsible for preparing certain components of the proposal (described in <u>Subsection V.L.7</u>). *Proposals will not be evaluated and awards will not be made for "to be named" trainees.*

The Predoctoral Traineeship Award is intended to support the trainee during dissertation research rather than during rotations or basic course work. Funding for Predoctoral Traineeship Awards can be requested for up to \$30,000 per year for direct costs. The performance period may be requested for up to 3 years. The maximum funding for a 3-year performance period is \$90,000 in direct costs. In addition, indirect costs should be added as appropriate. *A maximum indirect cost rate of 8% is allowed.* Any funding (direct costs) in excess of the allowable stipend must be used as direct support for the trainee.

These funds can cover the applicant's salary/stipend, tuition, health insurance, and travel to scientific/technical meetings. Although animal and human research may be proposed, such research will not be funded by these awards. These funds may be not be used for supplies or equipment.

The travel allotment is \$1,500 per year to attend scientific/technical meetings. Travel funding of \$1,500 also should be requested to attend a 3¹/₂-day DOD BCRP Era of Hope Meeting, which is held biennially to disseminate the results of DOD-sponsored research. If the grant has expired before the meeting is held, funding will be made available for funded investigators to participate in the meeting. It is anticipated that the next Era of Hope meeting will be held in October 2007.

The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants.

Approximately \$5M of this appropriation will be available to fund approximately 50 BCRP Predoctoral Traineeship Awards, depending on the quality and number of proposals received.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be graduate students under the guidance of a designated mentor who has experience in breast cancer research. Individuals enrolled in a Ph.D. or M.D./Ph.D. program are encouraged to apply.

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined in <u>Subsection IV.B</u>, "Institutions" below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at <u>http://epls.arnet.gov</u>. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110).

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.¹ Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at <u>http://cdmrp.army.mil/spp</u> under "Minority Institutions."

Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

¹Executive Orders 12876, 12900, and 13021

C. Duplicate Submissions: Submission of the same research project to the FY06 BCRP to different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Proposals will be evaluated according to peer and programmatic review criteria in <u>Section VI</u>.

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at <u>https://cdmrp.org</u>:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	Copy the LOI into the data field. Click the "Save and Forward Letter of Intent" button to automatically create the LOI.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative at the applicant's institution.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/ SOW	Typed or Cut and Paste	Enter the Technical Abstract, Public Abstract, Impact Statement, and SOW in separate data fields.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
List of Individuals Providing Letters of Recommendation	Required Files	Typed or Cut and Paste	Enter the names, position titles, e-mail addresses, and phone numbers of individuals providing letters of recommendation.
Budget Information	Required Files	PDF	Upload as a PDF file.

Item	Tab	Format	Action
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative Responsibility: The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant's institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative's Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA ^a - Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, May 23, 2006.

^aUS Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt Online Proposal Submission System at <u>https://cdmrp.org</u>. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- Font Size: 12 point or larger.
- Font Type: Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).

- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Margins: Must be at least 0.5 inch (1.27 cm) in all directions.
- Print Area: 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).
- Color, High-Resolution, and Multimedia Objects: Proposals may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- Language: English.

Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

C. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. *Failure to adhere to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection.*

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Applicant does not meet eligibility criteria described in <u>Subsection IV.A</u>.
- Required Supporting Documentation is missing including:
 - Official transcripts
 - Letters of recommendation
 - List of dissertation committee members
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

For any sections of a proposal with a defined page limit, pages exceeding the specified limit will be removed from the proposal 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.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

D. Letter of Intent (LOI): An LOI (a brief description of the proposal) is entered in a data field under "My Proposals: Create New Proposal." The LOI is saved when the "Save and Forward Letter of Intent" button is selected. The LOI may be modified under "Proposal Information" at anytime before the applicant submits this information by clicking "Finalize for CR Approval." The LOI should be submitted by *April 26, 2006* at <u>https://cdmrp.org</u>.

E. Proposal Information: Applicants are required to submit the Proposal Information as described in <u>https://cdmrp.org</u> before uploading the proposal, supporting documentation, and budget information.

• A *Title/Referral Page* for the proposal will be generated from the information uploaded in eReceipt and appended to the proposal electronically by the CDMRP eReceipt system.

F. Proposal Contacts: The Proposal Contacts *must* include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant's institution. The Proposal Contacts must be approved by the Contract Representative at the applicant's institution.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators, consultants, and subawardees. In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.

H. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Each abstract must include the applicant's name and the title of the proposal. A structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important in both the peer review and programmatic review processes. Programmatic review is based on the Integration Panel's review of these two abstracts as part of the peer review summary statements; therefore, it is of paramount importance that the applicant submit abstracts that describe the proposed work fully. Each abstract must be entered into the appropriate data field under the "Abstract/Impact/SOW" tab of the CDMRP eReceipt system.

Applicants can type the abstracts or "cut and paste" them from a word processing application into the respective data fields. *Spell out all Greek letters, other non-English letters, and symbols.*

Abstracts of all funded proposals will be posted on the CDMRP website at <u>http://cdmrp.army.mil</u>. Proprietary or confidential information should *not* be included in either the technical or the public abstract.

1. Technical Abstract: Sample technical abstracts can be found at

<u>https://cdmrp.org/samples.cfm</u>. The structured technical abstract must provide a clear and concise overview of the proposed work. Use the outline below when preparing the structured technical abstract.

• Training Plan

- Describe the how the training plan supports the applicant's career goals in breast cancer research.
- Describe the innovative nature of the applicant's training plan.

• 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.
- Impact: Provide a brief statement explaining the impact of the proposed work to the program goals. Describe how the proposed project will have an impact on breast cancer research or patient care.

2. Public Abstract: Sample public abstracts can be found at

https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose and rationale of the study to a non-scientifically trained audience. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. **Do not duplicate the technical abstract.**

- Describe the applicant's career goals in breast cancer research or patient care.
 - How does the training plan support the applicant in attaining these goals?
 - How does the research plan support the applicant 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 consumer-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
 - What types of contributions will this study make to advance research?

• How will the research enhance this or other studies being conducted?

I. Impact Statement – 5,700-character limit, including spaces (approximately one page): The Impact Statement is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type the Impact Statement into the data field or "cut and paste" it from a word processing application.

State explicitly how the training program will be designed to offer a structured, well-rounded, and focused experience in breast cancer research. Include how the training program is innovative and will foster the likelihood that the trainee will pursue a career in breast cancer research. The Impact Statement will be available at both peer and programmatic reviews.

J. Statement of Work – 11,400-character limit, including spaces (approximately two

pages): The SOW is captured as a data field under the "Abstract/Impact/SOW" tab in the CDMRP eReceipt system. Applicants can type the SOW into the data field or "cut and paste" it from a word processing application.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include DOD-funded tasks only. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

The SOW should:

- Describe the training plan to be accomplished as tasks (tasks may relate to specific aims);
- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the period of the proposed effort;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

K. Proposal Main Body: Start section on a new page; six-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the proposal.

The proposal main body is uploaded as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

Describe the proposed project using the following outline:

1. Applicant's Career Goals: Describe the applicant's career goals and how the proposed training will promote the applicant's career in breast cancer research or patient care. Discuss the applicant's career plans after the completion of this award.

2. 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 applicant in developing his or her career. Explain how the training program is innovative and supported by the environment; this should include a description of ongoing breast cancer research at the institution. Include information on training or collaborations with other investigators.

3. Research Project: Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to breast cancer.

L. Supporting Documentation: Submit only material specifically requested in this program announcement. *This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.* Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting Documentation must be uploaded as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. All documents or letters that require signatures must be signed and incorporated into the Supporting Documentation file before it is submitted.

The first item in the Supporting Documentation file is the <u>Checklist/Table of Contents</u> page. The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

1. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.

2. References: Start section on a new page; no page limit. 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).

3. Biographical Sketches: Four-page limit per individual. Include biographical sketches for all key personnel, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower proposal scores. The <u>Biographical Sketch form</u> may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

4. Existing/Pending Support: Start section on a new page; no page limit. List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel on a separate page. If no support exists, enter "None." Proposals submitted under this program announcement should not duplicate other funded research projects.

5. Facilities/Equipment Description: No page limit. Describe the facilities available for performing the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment available for use at no cost to the USAMRMC. Indicate whether Government-owned facilities or equipment are proposed for use.

6. Transcripts: Provide official transcripts from undergraduate institutions and graduatelevel courses completed to date. All foreign language transcripts must be accompanied by a certified English translation.

7. Letters of Recommendation: The applicant must request letters of recommendation from individuals through the "Required files" tab of the CDMRP eReceipt system by entering their names, position titles, e-mail addresses, and phone numbers. Individuals submitting letters of recommendation will receive specific instructions on how to upload the letter. The applicant will be able to monitor only whether the letters have been received; the applicant will not be able to view these letters. All letters must be submitted prior to the submission deadline.

Provide the following:

- *A letter of recommendation from the mentor* describing his or her commitment to the applicant's training, career development, and mentorship in breast cancer research. The mentor should address the following in his or her letter of recommendation:
 - The applicant's potential to become a breast cancer researcher;
 - The mentor's proposed interactions with the candidate during the candidate's training;
 - The training environment including ongoing breast cancer research at the institution and how this training environment promotes innovation in its activities to train breast cancer researchers;
 - The research training program in which the applicant will participate including descriptions of coursework, experience with laboratory techniques, conferences, and journal clubs;
 - Research being performed under the mentor's direction and how this research is relevant to breast cancer;
 - How the mentor will assist in training the applicant for a career in breast cancer research;
 - The mentor's history of training predoctoral students;
 - The resources available to adequately support the trainee's project (specific details on existing support should be covered in the Existing/Pending Support section; see <u>Subsection V.L.4</u>); and
 - The degree to which the applicant participated in idea development and proposal preparation, and the degree to which the applicant will participate in the execution of the proposal if funded.

• Two additional letters of recommendation.

8. 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.

9. Letters of Support: Provide letters of support from any collaborating individuals or institutions.

10. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five publications are included in the submission, the extra items will not be peer reviewed.

M. Budget Information: Applicants must complete the <u>Detailed Cost Estimate form and the</u> <u>Budget Justification form</u>, and upload them as a single PDF file under the "Required Files" tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal's budget justification should include only DOD-funded tasks.

1. Funding Restrictions: The Predoctoral Traineeship Award is intended to support the trainee during dissertation research rather than rotations or basic course work. Funding for a Predoctoral Traineeship Award can be requested for up to \$30,000 per year for direct costs. The performance period may be requested for up to 3 years. The maximum funding for a 3-year performance period is \$90,000 in direct costs. In addition, indirect costs should be added as appropriate. *A maximum indirect cost rate of 8% is allowed.* Any funding (direct costs) in excess of the allowable stipend must be used as direct support for the trainee.

These funds can cover the applicant's salary/stipend, tuition, health insurance, and travel to scientific/technical meetings. Although animal and human research may be proposed, such research will not be funded by these awards. These funds may be not be used for supplies or equipment.

The travel allotment is \$1,500 per year to attend scientific/technical meetings. Travel funding of \$1,500 also should be requested to attend a 3½-day DOD BCRP Era of Hope Meeting, which is held biennially to disseminate the results of DOD-sponsored research. If the grant has expired before the meeting is held, funding will be made available for funded investigators to participation participate in the meeting. It is anticipated that the next Era of Hope meeting will be held in October 2007.

The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants.

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. *Organizations must provide sufficient detail and budget justification so that*

the Government can determine the proposed costs to be allocable and reasonable for the proposed research. All costs must be entered in U.S. dollars.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (<u>http://farsite.hill.af.mil</u>), Contract Cost Principles and Procedures.
- Educational Institutions: Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- State, Local, and Tribal Governments: OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

Follow the instructions below when providing the information requested in the Detailed Cost Estimate form.

a. Personnel

i. Name: Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. *The applicant must be identified as the Principal Investigator of the proposal.*

ii. Role on Project: Identify the role of each participant listed. Describe his or her specific functions in the Budget Justification section of the Detailed Cost Estimate form.

iii. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the Budget Justification section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an

academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

iv. Annual Base Salary: Enter the annual institutional base salary for the trainee.

v. **Percentage of Effort on Project:** The applicant's qualifications and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid professional personnel, including the mentor.

vi. Salary Requested: Enter the salary in whole dollar figures for the trainee. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits may be requested for the trainee in accordance with institutional guidelines, provided the costs are treated consistently for all sponsors by the applicant's organization. Documentation to support the fringe benefits should be provided.

viii. Totals: Calculate the totals for the trainee and enter these as subtotals in the columns indicated.

b. Consultant Costs: Provide the names and organizational affiliations of all consultants. However, funds cannot be used for consultant costs.

c. Major Equipment: It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. *The purchase of major equipment from these funds is not allowed.*

d. Materials, Supplies, and Consumables: Funding for this award cannot be used for the purchase of materials, supplies, or consumables.

e. Travel Costs: Costs for travel to scientific/technical meetings may not exceed \$1,500 per year. Travel funding of \$1,500 also should be requested to attend a 3½-day DOD BRCP Era of Hope Meeting, which is held biennially to disseminate the results of DOD-sponsored research. If the grant has expired before the meeting is held, funding will be made available for funded investigators to participation participate in the meeting. It is anticipated that the next Era of Hope meeting will be held in October 2007.

Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly \$1,500 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).

f. Research-Related Subject Costs: Not applicable to the BCRP Predoctoral Traineeship Award.

g. Other Direct Costs: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.

h. Subaward Costs: Not applicable to the BCRP Predoctoral Traineeship Award.

i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed with a statement identifying whether the proposed rates are provisional or fixed. *A maximum indirect cost rate of 8% is allowed.*

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals in each budget category for all additional years of support requested and itemize these totals in the Budget Justification section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Direct costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the "Required Files" tab at https://cdmrp.org.

3. Budget Justification (third page of the Detailed Cost Estimate form): Each item in the budget must be clearly justified in the Budget Justification section of the Detailed Cost Estimate form.

4. Federal Agency Financial Requirement: Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

Start the plan on a new page at the end of the Budget Information section. The Federal Agency Financial Plan must be uploaded as part of the budget information prior to the submission deadline of *5:00 p.m. Eastern time, May 23, 2006*.

N. Regulatory Requirements: Completed and signed copies of the <u>Certificate of</u> <u>Environmental Compliance</u> and <u>Principal Investigator Safety Program Assurance</u> form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files. **O. USAMRAA-Required Documents:** The most current version of the institution's negotiated Rate Agreement, the <u>Certifications and Assurances for Assistance Agreements</u>, and the <u>Representations for Assistance Agreements</u> must be uploaded by the Contract Representative at the applicant's institution. These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system by the proposal submission deadline.

P. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline will not be considered for review. The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, May 23, 2006 deadline.

The timeline for the Predoctoral Traineeship Award is:

Online Letter of Intent:	Expected by April 26, 2006
Online Proposal Information:	Required prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time, May 23, 2006
Peer Review (First Tier):	August 2006
Programmatic Review (Second Tier):	November 2006
Request for Additional Documents:	As early as 2 weeks after the completion of
	programmatic review
Notification Letter:	Approximately 4 weeks after the completion
	of programmatic review
Award Start Date:	Anticipated between December 2006 and
	September 2007

Q. Electronic Submission Requirements: Electronic submission is required. Only proposals submitted as PDF files through the CDMRP eReceipt system at <u>https://cdmrp.org</u> will be accepted.

Several steps are critical to successful proposal submission:

- The Proposal Information must be "Finalized for CR Approval" before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be "Finalized for CR Approval" before the proposal is submitted. The e-mail address of a Contract Representative at the applicant's institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant's institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, May 23, 2006 deadline.

- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g. Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Detailed Cost Estimate form and the Budget Justification form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers differ fundamentally. The first tier is a scientific peer review of proposals against established criteria for determining scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program.

2. Peer Review: Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Scientific reviewers are selected for their subject matter expertise and experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review process by bringing the patient perspective to the assessment of science and the relevance of the research.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. A function of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a

common pool. Integration Panel members base programmatic review primarily on the peer review summary statements and the proposal abstracts. The Integration Panel also may review SOWs and impact statements. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals are reviewed concurrently with others in the same research area during scientific peer review. However, they may be evaluated separately during programmatic review. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions are based on scientific excellence and program relevance.

B. Review Criteria

1. Peer Review: Predoctoral Traineeship Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- Applicant
 - How the applicant's achievements (as reflected by academic performance, awards, honors, and previous funding) indicate a potential for successful training in breast cancer research.
 - How the applicant's stated career goals demonstrate a commitment to pursuing a career as a breast cancer researcher or clinician.
 - How letters of recommendation from the mentor and others support the applicant's potential for productive breast cancer research.
 - Appropriateness of the proposed levels of effort for successful conduct of the proposed work.
 - Whether the applicant meets the appropriate eligibility requirements (see <u>Subsection IV.A</u>).

• 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 training achievements as reflected by his or her previous trainees' career achievements and areas of interest indicate the potential for successful training of the applicant 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.
- Whether the quality of the proposal suggests that the mentor provided appropriate guidance.
- Whether the mentor's letter of recommendation addresses each of the requested topics (see <u>Subsection V.L.7</u>).

• Training Program

• How the training focuses on breast cancer research.

- How well the applicant has outlined an individualized training program that augments his or her expertise.
- How the training will prepare the applicant 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 quality and extent of institutional support.

• Impact

- The impact the training program will have on the applicant's expertise in breast cancer research or patient care.
- How the project will train the applicant to make valuable contributions to the study or treatment of breast cancer.
- How the results of the research will advance breast cancer research or patient care if the aims of the project are achieved.

Research Project

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- If 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 applicant.
- The appropriateness of the expertise of the dissertation committee members.
- **Innovation:** How the training environment is innovative in its activities to train breast cancer researchers.
- **Budget:** If the budget is appropriate for the work proposed.

2. Programmatic Review: Criteria used by the Integration Panel to make funding recommendations that maintain the BCRP's broad portfolio include:

- Ratings and evaluations of the peer reviewers (scientific and consumer),
- 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 are selected by the Integration Panel and recommended for funding to the Commanding General, USAMRMC.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant will receive notification of the award status of his or her proposal. A copy of the peer review summary statement will be posted to the CDMRP eReceipt system. Applicants can expect to receive notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. An applicant must submit a proposal through, and be employed by or affiliated with, a university, college, nonprofit research institution, commercial firm, or Government agency (including military laboratories) to receive support. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110 and DOD Grant and Agreement Regulations) to be eligible for an award. Any organization requesting receipt of an award through this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

A change in Principal Investigator is not allowed for the BCRP Predoctoral Traineeship Award.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal.

2. Certificate of Environmental Compliance: The <u>Certificate of Environmental</u> <u>Compliance</u> must be submitted with the proposal. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents: The <u>Principal Investigator Safety Program Assurance</u> form must be submitted with the proposal.

A Facility Safety Plan is required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at <u>https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp</u>. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at <u>https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc</u>.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

4. Research Involving Animal Use: Not applicable for the BCRP Predoctoral Traineeship Award.

5. Research Involving Human Subjects/Biological Substances/Cadavers: Not Applicable for the BCRP Predoctoral Traineeship Award.

6. Award/Regulatory Approval: Not applicable for the BCRP Predoctoral Traineeship Award.

E. Reporting Requirements: The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full USAMRMC reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") *Failure to submit required reports by the required date may result in a delay in or termination of award funding.*

Reporting requirements include the following:

1. Progress Reports: Reporting requirements consist of an annual report (for each year of effort) that presents a detailed summary of training and scientific issues and accomplishments. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress report.

2. Fiscal Reports: Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

VIII. OTHER INFORMATION

A. Disclosure of Proprietary Information outside the Government: By submitting a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will be used only for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

B. Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

C. Information Service: Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161, 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.

D. Inquiry Review Panel: Applicants may submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

E. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.²), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

²Title 35 of the United States Code, section 200 et seq.

IX. ACRONYM LIST

AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
COI	Conflicts of Interest
CR	Contract Representative
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
Μ	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
PDF	Portable Document Format
SOW	Statement of Work
TIFF	Tagged Image File Format
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave