



**DEPARTMENT OF DEFENSE**

**FISCAL YEAR 2001  
BREAST CANCER RESEARCH PROGRAM  
PROGRAM ANNOUNCEMENT II**

*March 19, 2001*



Headquarters, U.S. Army Medical Research and Materiel Command  
MCMR-PLF, 1077 Patchel Street  
Fort Detrick, Maryland 21702-5024



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Headquarters, U.S. Army Medical Research and Materiel Command  
MCMR-PLF, 1077 Patchel Street  
Fort Detrick, Maryland 21702-5024

## Foreword

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed to continue the Department of Defense (DOD) Breast Cancer Research Program (BCRP). The deadline, format, and other criteria specified for proposals in this BCRP fiscal year 2001 (FY01) Program Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC web site at <http://mrmc-www.army.mil>. Specific information on the DOD BCRP can be obtained from the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil>. A copy of this program announcement and associated forms (except for the Proposal Cover Booklet; see Section 6 on page iii of this Foreword) also can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/default.htm>. Information on this program announcement, other program announcements, and the U.S. Army Medical Research Acquisition Activity can be obtained at <http://www-usamraa.army.mil>.

### 1. Highlights of Changes from the FY00 Program Announcement

- Proposals for the FY01 BCRP will be requested through the publication of two separate program announcements.
- Program Announcement I was released February 16, 2001, and requested proposals in the following three BCRP award mechanisms: Clinical Translational Research (CTR), Collaborative-CTR, and Breast Cancer Center of Excellence Awards.
- The Innovator Award is a new award mechanism offered in this Program Announcement to provide outstanding and visionary scholars/investigators with the freedom to pursue creative and innovative breast cancer research with the potential to lead to successful prevention, diagnosis, treatment, and/or management of this disease.
- A structured technical abstract using the headings in Appendix B, part 8, is required for all proposals.
- All foreign language transcripts submitted as part of a training proposal must be accompanied by an English translation.
- Appendices related to Regulatory Compliance and Quality (Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) have been extensively revised.

## 2. Who May Apply

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit, nonprofit, public, or private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. Please refer to sections on individual mechanisms for additional eligibility criteria.

## 3. Receipt Deadline

The receipt deadline for all proposals requested in this program announcement (Program Announcement II) is **June 13, 2001 at 4:00 p.m. Eastern Time**. See Appendix B, part 22 for additional details.

## 4. Timeline

**The timeline for proposals requested in this program announcement is:**

Letter of Intent:	As soon as possible but no later than May 30, 2001
Proposal Receipt:	<b>June 13, 2001 at 4:00 p.m. Eastern Time</b>
Peer Review:	August 2001
Request for RCQ <sup>1</sup> Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2001
Notification:	Approximately 2 weeks after programmatic review
Award Negotiations:	Between January 2002 and September 2002

## 5. Inquiries

Questions concerning the preparation of proposals, formats, or required documentation can be addressed to the CDMRP at:

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP01)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

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<sup>1</sup> Regulatory Compliance and Quality

Applicants should submit questions regarding this program announcement via e-mail or in writing as early as possible. Every effort will be made to answer questions within 5 working days of receipt.

## **6. Proposal Cover Booklet (Bubble Sheet)**

A Proposal Cover Booklet must be completed for each proposal according to the instructions found in Appendix C. Proposal Cover Booklets can be requested via phone, fax, e-mail, or mail at the following addresses/numbers. Please allow sufficient time for delivery by regular mail.

Phone: 301-682-5501 (8:00 a.m.-5:00 p.m. Eastern Time)  
Fax: 301-682-5521  
E-mail: prequest@unitedis.com  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP01)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

## **7. Proposal Submission**

Applicants should refer to sections on individual award mechanisms and Appendix B for appropriate submission requirements.

**Send the Proposal to:** Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP01)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

## Driving Directions to Fort Detrick

### From Washington, DC

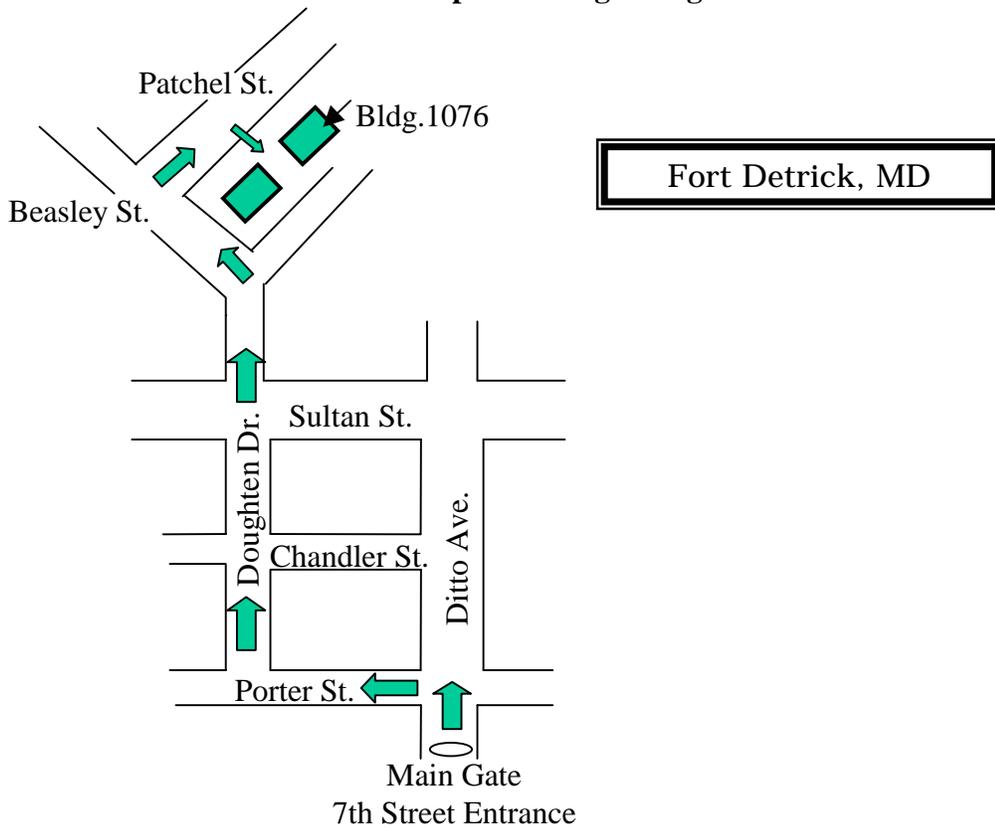
Take Interstate 495 to Interstate 270 North (exit 38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

### From Baltimore, MD

Take Interstate 695 to Interstate 70 West. In Frederick, take exit 53, Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

## Map of Fort Detrick

Packages to be delivered to the BCRP must be delivered to building 1076 as shown on the map below. To gain entry to Fort Detrick, you will be required to show your driver's license at the Main Gate. **Please allow at least 15 minutes to pass through the gate area.**



## **I. Overview of the Congressionally Directed Medical Research Programs**

### **I-A. History of the Congressionally Directed Medical Research Programs**

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received almost \$2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense Women's Health, osteoporosis, and other specified areas.

The CDMRP exists to support research that will positively impact the health of all Americans. The CDMRP strives to identify gaps in funding and provide opportunities that will enhance program research objectives without duplicating existing funding. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that addresses individual program objectives.

### **I-B. Investment Strategy**

For each program, the CDMRP has developed and refined a flexible execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to the program, establish an appropriate investment strategy, and perform programmatic review as described in Section I-C.2. Based upon this investment strategy, each program then uses a variety of award mechanisms to address the most urgent needs of the research community.

### **I-C. Proposal Evaluation**

The CDMRP uses a two-tiered review process for proposal evaluation as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals.

### **I-C.1. Scientific Peer Review**

Scientific peer review is conducted by panels organized by scientific discipline, specialty area, or award mechanism. The primary responsibility of the scientific peer review panels is to provide unbiased, expert advice on the scientific and technical merit of proposals, based upon the review criteria published for each award mechanism.

Scientific peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. For the breast, prostate, and ovarian cancer research programs, consumer reviewers are cancer survivors and representatives of consumer advocacy organizations. For the neurofibromatosis research program, consumer reviewers are individuals with neurofibromatosis or their family members and representatives of consumer advocacy organizations. Consumer reviewers are nominated by an advocacy organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the scientific peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see Section B of each award mechanism section). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed as to make its completion implausible.

The peer review summary statement is a product of scientific peer review. Each statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), 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. Summary statements are forwarded to the next stage of the review process, programmatic review.

### **I-C.2. Programmatic Review**

The second tier is programmatic review, which is accomplished by the IP. The members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. One of the functions of programmatic review is to recommend for funding a broad portfolio of proposals across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP

members use the peer review summary statements, which include the proposal abstracts, to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded to programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and evaluations of scientific peer review panels are primary factors in programmatic review; the IP also must consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation;
- Program portfolio balance with respect to research disciplines or specialty areas; and
- Other equitable factors, e.g., adequate support for new investigators.

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 IP and recommended to the Commanding General, USAMRMC, for funding.

#### **I-D. Notification**

Following completion of the two-tiered evaluation process, every applicant will receive a letter indicating the funding status of his/her proposal, along with the peer review summary statement. Letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

#### **I-E. Negotiation of the Award**

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving Regulatory Compliance and Quality (RCQ), budget, and Statement of Work. All documents related to RCQ (environmental compliance, human subjects/anatomical substance use, animal use, and safety plan documents) will be requested in the applicant's notification letter and reviewed by RCQ staff. All proposals submitted with research involving human subjects and/or anatomical substances must be approved by the appropriate local review board. Proposals must also be approved by the U.S. Army Human Subjects Research Review Board (HSRRB). The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. Therefore, all investigators submitting such proposals must comply with the requirements detailed in the RCQ documents dealing with research

involving laboratory animals, and human subjects and/or anatomical substances **before funded research can begin.**

Concurrent with the RCQ review, a Contract Specialist from the U.S. Army Medical Research Acquisition Activity will contact the administrative representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

**Please note that the award start date will be determined during the negotiation process.**

## **I-F. Annual and Final Reports**

All awards will require the timely delivery of several reports during the research effort. These reports are necessary for the CDMRP to monitor progress and evaluate program outcomes. The Principal Investigator (PI) should plan on a reporting requirement consisting of:

- An **annual** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and
- A **final** report (submitted in the last year of the award period) that details the findings and issues for the entire project.

## **I-G. Publications and Patents**

All investigators are strongly encouraged to publish their results in the scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. For example, "This research, under Award Number DAMD..., was supported by the Department of Defense Breast Cancer Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI must submit to the CDMRP a copy of any manuscript or publication resulting from research funded under the award.

In accordance with the Bayh-Dole Act (35 USC<sup>1</sup> 200 et seq.), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. 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.

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<sup>1</sup> United States Code

## II. Department of Defense Breast Cancer Research Program

### II-A. History of the Breast Cancer Research Program

Grass roots advocacy organizations provided the impetus that led to the fiscal year 1993 (FY93) Congressional appropriations to the Department of Defense (DOD) for \$210M targeted toward breast cancer research. Since then, due to the ongoing efforts of advocacy groups and increased public awareness on health issues, Congress has continued to appropriate money for breast cancer research managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the office of the Congressionally Directed Medical Research Programs (CDMRP). To date, Congress has appropriated more than \$1.2 billion to the DOD through the Breast Cancer Research Program (BCRP), a multidisciplinary effort aimed at the eradication of breast cancer.

A summary program history for FY92-00 appropriations of the BCRP is shown in Tables II-1 and II-2 below.

**Table II-1: History of the DOD's Peer Reviewed BCRP**

<b>Program History</b>	<b>FY92<sup>1</sup>-98</b>	<b>FY99<sup>2</sup></b>	<b>FY00<sup>3</sup></b>
BCRP-Managed Appropriations for Peer-Reviewed Research	\$733.3M	\$135M	\$175M
Breast Cancer Stamp <sup>4</sup>	-	\$1.8M	\$1.3M
Number of Full Proposals Received	10,728	1,281	1,234
Number of Proposals Funded	1,806	386	~346
Percentage of Applications Recommended for Funding	17%	30%	28%
Number of Research/Infrastructure Awards <sup>5</sup>	1,166	221	~186
Number of Training/Recruitment Awards	640	165	~160

<sup>1</sup>Upon establishment of the BCRP in FY93, the CDMRP assumed responsibility for managing the \$25M appropriation made in FY92 for breast cancer research that was being administered by the USAMRMC.

<sup>2</sup>Does not include 1,772 FY99 concept proposals, 98 of which were awarded with FY99 funds and 206 of which are currently under negotiation with FY00 funds.

<sup>3</sup>Final numbers for FY00 will be available after September 30, 2001.

<sup>4</sup>Funds received as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585) are also managed under the BCRP.

<sup>5</sup>Includes Clinical Translational Research (CTR) and Collaborative-CTR (C-CTR) Awards.

**Table II-2: Number of Proposals Received and Number of Awards Made for CTR and C-CTR Awards in FY98-00**

<b>Program History</b>	<b>FY98</b>	<b>FY99</b>	<b>FY00<sup>1</sup></b>
Number of CTR and C-CTR Proposals Received			
CTR and C-CTR pre-proposals	107	87	40
CTR and C-CTR full proposals	45	22	20
Number of CTR and C-CTR Awards	8	3	~7

<sup>1</sup>Final numbers for FY00 will be available after September 30, 2001.

## **II-B. Overview of FY01 Breast Cancer Research Program: Two Program Announcements**

The CDMRP is requesting proposals on breast cancer research in two separate program announcements. This program announcement (Program Announcement II) is requesting proposals in the following eight award mechanisms: Innovator, Idea, Clinical Bridge, Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, Career Development, and Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards. Program Announcement I, released February 16, 2001, requests proposals in the following three award mechanisms: CTR, C-CTR, and Breast Cancer Center of Excellence Awards.

The overall goal of the FY01 BCRP is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research on 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; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

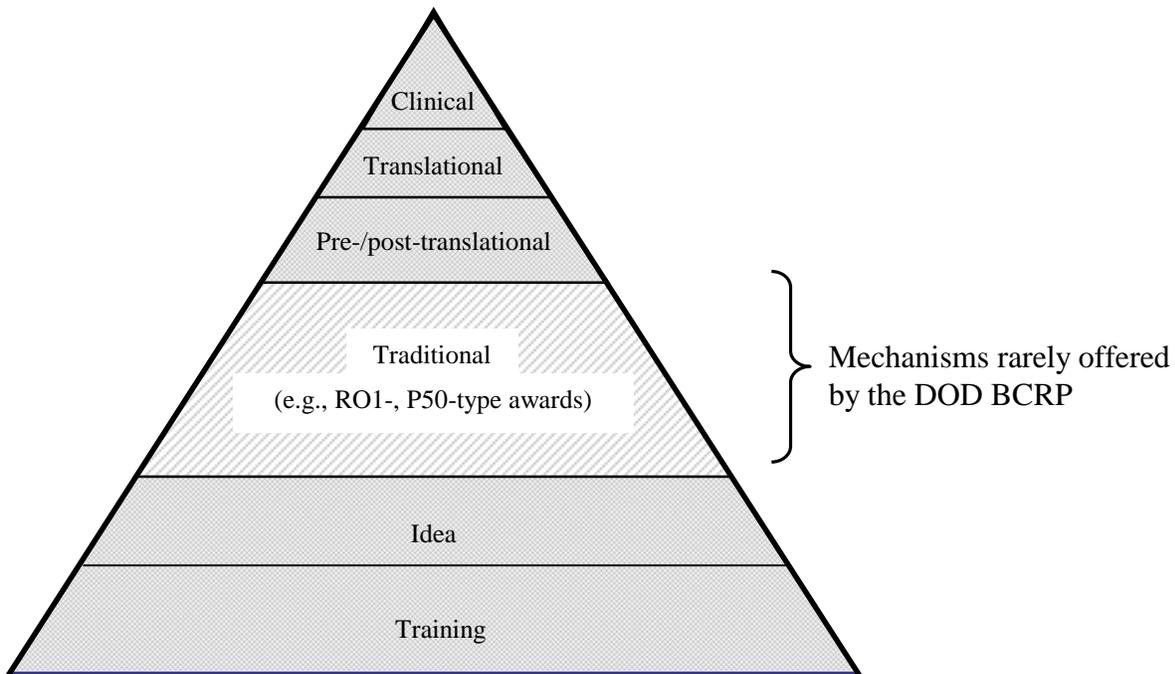
The USAMRMC is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the CDMRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

## II-C. BCRP Emphasis Areas

The BCRP adapts the types of award mechanisms it offers each year to meet the current needs in breast cancer research and treatment. Mechanisms are developed based upon recommendations of the Integration Panel, an expert panel of scientists, clinicians, and consumer advocates (see Section I-B). Multiple factors are taken into consideration when designing and offering award mechanisms for each fiscal year. In particular, the BCRP factors in funding opportunities that are offered by other agencies. Award mechanisms offered each year complement and fill niches in research that are not offered/emphasized by other agencies. The BCRP funding mechanism philosophy is illustrated by the pyramid depicted in Figure II-1.

- The foundation of the pyramid is the training of investigators in breast cancer research. The FY01 BCRP offers several training/recruitment awards (see Sections VI-X).
- The second level of the pyramid is ideas; research starts with thousands of ideas, not all of which will lead to fruitful areas of investigation. Idea Awards have been and continue to be a major emphasis of the BCRP (see Section IV).

**Figure II-1. BCRP Funding Philosophy**



- The middle of the research pyramid is traditional research projects; these projects are often the major emphasis of a laboratory or research program. Traditional research studies are long-range and typically include studies that can be projected over several years. Traditional research projects have not been emphasized by the DOD BCRP and are requested only in cases when there is a particular need.

- Approaching the pyramid's summit are Translational Awards. The BCRP focuses efforts at the critical juncture between bench and bedside research. Two mechanisms support these types of studies. Clinical Bridge Awards support research that is pre- or post-clinical trial (see Section V). CTR Awards support research projects that move bench research into a clinical trial during the life of the award (offered in Program Announcement I).
- The pinnacle of the pyramid represents the very few research studies that make it to a clinical trial. The BCRP supports the infrastructure for developing new means to perform clinical trials through C-CTR Awards (offered in Program Announcement I).

Most awards offered by the BCRP fit into one level of the pyramid. However, in FY01, the BCRP is offering two new awards that may either fit a single level or span multiple levels of the pyramid.

- Innovator Awards are intended to attract outstanding investigators from a diversity of fields to explore new avenues in breast cancer research (see Section III).
- Breast Cancer Center of Excellence Awards may focus on an overarching problem in breast cancer research at any level of this pyramid or may traverse several levels of the pyramid from ideas to the clinic (offered in Program Announcement I).

## **II-D. FY01 BCRP Program Announcement Award Opportunities**

For the FY01 BCRP, an estimated \$152M will be available to fund competitive peer-reviewed breast cancer research. Approximately \$50M will be used to fund proposals requested in response to BCRP Program Announcement I, released February 16, 2001, while the remaining \$102M will be used to fund proposals requested in response to this program announcement.

The programmatic strategy for BCRP Program Announcement II is to fund proposals in two categories: (1) Research Awards and (2) Training/Recruitment Awards. In addition, a unique award that does not fit into these categories, the Innovator Award, is included in Program Announcement II. The DOD intends that 5.5% of the available monies be used to fund awards at HBCU/MI. (Applicants from HBCU/MI should see Appendix B, part 1 for additional information.) In addition, as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585), the DOD BCRP expects to receive additional monies in 2001 for breast cancer research. The DOD plans to use all Breast Cancer Stamp monies received prior to November 2001 to fund additional scientifically meritorious proposals submitted to the FY01 BCRP.

**Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this program announcement carefully, as revisions to award mechanism definitions and requirements have been made.**

### **II-D.1. Innovator Award**

For BCRP Program Announcement II, approximately \$12M will be allocated for a new award mechanism that does not fit into any of the award categories of the BCRP, Innovator Awards (see Section III). The Innovator Award mechanism is designed to encourage the most talented individuals in any area of endeavor to pursue their own creative approaches that may significantly contribute to the conquest of breast cancer.

### **II-D.2. Research Awards**

For BCRP Program Announcement II, approximately \$55M will be allocated for Research Awards, which consist of Idea Awards (see Section IV) and Clinical Bridge Awards (see Section V). The intent of Idea Awards is to stimulate and reward creative research ideas that may be viewed as speculative, but have potential for high payoff. Clinical Bridge Awards are for the support of research that is either pre- or post-clinical trial.

### **II-D.3. Training/Recruitment Awards**

For BCRP Program Announcement II, approximately \$35M will be allocated for Training/Recruitment Awards: Undergraduate Summer Training Program Awards (Section VI), Predoctoral Traineeship Awards (Section VII), Postdoctoral Traineeship Awards (Section VIII), Career Development Awards (CDAs) (Section IX), and HBCU/MI Partnership Training Awards (Section X). Undergraduate Summer Training Program Awards are for the establishment of summer undergraduate training programs in breast cancer research. Predoctoral Traineeship Awards are individual awards to promising graduate students studying breast cancer under the guidance of a designated mentor. Postdoctoral Traineeship Awards should enable recent doctoral degree graduates (research scientists and clinicians) with limited postdoctoral experience to gain additional experience in breast cancer research. CDAs are intended to relieve scientists and clinicians of academic and clinical responsibilities to allow them additional time to pursue breast cancer research. HBCU/MI Partnership Training Awards are intended to provide assistance at an institutional level by forming collaborations between HBCU/MI and other institutions. HBCU/MI Partnership Training Awards will be funded with some of the monies allocated to support research performed at HBCU/MI.

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## Reference Table of Award Mechanisms and Submission Requirements

Award Mechanisms	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
Innovator Awards	Scholars from any field with outstanding record of creative accomplishments	<ul style="list-style-type: none"> <li>• Encourage creative and visionary breast cancer research</li> <li>• Primary award basis is individual's talent and potential</li> <li>• Traditional research proposal not required</li> </ul>	A maximum award of \$3M for direct and indirect costs for a period of up to 4 years	<u>Required letter of intent:</u> May 30, 2001  <u>Application:</u> June 13, 2001 4:00 p.m. ET*	Section III
Idea Awards	All levels of experience	<ul style="list-style-type: none"> <li>• No preliminary data required</li> <li>• Reward innovative ideas and technology</li> </ul>	A maximum award of \$300,000 in direct costs for a period of up to 3 years; population-based studies may request a maximum award limit of \$625,000 in direct costs for a period of up to 5 years	June 13, 2001 4:00 p.m. ET	Section IV
Clinical Bridge Awards	All levels of experience	<ul style="list-style-type: none"> <li>• To support pre-clinical or post-clinical research</li> <li>• To facilitate development of agents, model systems, or markers with clinical potential</li> <li>• Preliminary data required</li> </ul>	A maximum award of \$300,000 in direct costs for a period of up to 3 years	June 13, 2001 4:00 p.m. ET	Section V
Undergraduate Summer Training Program Awards	All levels of experience	<ul style="list-style-type: none"> <li>• Supports 2-8 students for summer internships</li> <li>• To encourage undergraduate students to pursue careers in breast cancer research</li> </ul>	An award of \$4,000/student per summer and up to \$10,000/year for administrative costs for up to 3 years	June 13, 2001 4:00 p.m. ET	Section VI
Predocutorial Traineeships	Predocutorial students	<ul style="list-style-type: none"> <li>• Prepare new scientists for careers in breast cancer research</li> </ul>	An average of \$22,000/year for direct and indirect costs for up to 3 years	June 13, 2001 4:00 p.m. ET	Section VII

\* Eastern Time

(Reference table continued on next page)

## Reference Table of Award Mechanisms and Submission Requirements (cont'd)

Award Mechanisms	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
Postdoctoral Traineeships	Recent doctoral graduates with less than 5 years of postdoctoral research experience	<ul style="list-style-type: none"> <li>• Prepare new scientists and clinicians for careers in breast cancer research</li> </ul>	An average of \$50,000/year for direct and indirect costs for up to 3 years	June 13, 2001 4:00 p.m. ET	Section VIII
Career Development Awards	Independent scientists or clinicians	<ul style="list-style-type: none"> <li>• To relieve applicants from academic or clinical responsibilities</li> <li>• Provides salary support</li> <li>• Requires separate source of research support</li> </ul>	An average of \$59,000/year for direct costs for up to 4 years for salary support	June 13, 2001 4:00 p.m. ET	Section IX
HBCU/MI** Partnership Training Awards	Faculty members (with doctoral degrees) working at an HBCU/MI	<ul style="list-style-type: none"> <li>• Collaborations at an institutional level between an HBCU/MI and another institution</li> <li>• To provide training for HBCU/MI faculty toward establishing successful breast cancer research careers</li> </ul>	Up to \$250,000/year for direct and indirect costs for up to 4 years; no more than 25% of the awarded funds may be directed toward the collaborating institution over the lifetime of the award	June 13, 2001 4:00 p.m. ET	Section X

\*\* Applicants from HBCU/MI are encouraged to apply to all award mechanisms offered in this program announcement.

**Important note regarding duplicate submissions:** Submission of the same research project to the FY01 BCRP under different award mechanisms will **not** be allowed. This includes submission of the identical research project to both a Research and a Training award mechanism. All such duplicate submissions may be administratively withdrawn by the Government. The Government reserves the right to reject any proposal. Exceptions apply for CDA applicants; see Appendix B, part 3 for more details.

### III. Innovator Awards

#### III-A. Innovator Awards

The Breast Cancer Research Program (BCRP) is establishing a new award in its battle against breast cancer, the Innovator Award. The intent of this award is to provide accomplished and visionary scholars/investigators from the academic, government, and private sectors with the funding and freedom to pursue creative, potentially breakthrough research that could ultimately accelerate the eradication of breast cancer.

*This award is designed to encourage the most creative individuals in all areas of research to pursue innovative and novel approaches that may significantly contribute to the conquest of breast cancer.* The primary criteria for making these awards will be the record and potential for accomplishment of the applicant rather than the merits of a specific research project. Experience in breast cancer research is not required; applicants can be either established breast cancer investigators or new to the field of breast cancer research.

Recipients of the Innovator Award may be scholars in all areas of investigation including the biological and physical sciences, computer sciences, social sciences, philosophy, economics, the humanities, and engineering. The BCRP's goal is to recognize talented individuals rather than projects, and the central feature of the award is the singular contribution(s) that the recipient will make to the cure and/or prevention of breast cancer.

The Innovator Award will provide recipients with the flexibility to explore new directions in breast cancer research. For example, recipients may use the award to establish multidisciplinary collaborations, redirect their careers to innovative breast cancer research, and/or establish research efforts at new, intellectually stimulating environments. The preceding list is meant only to provide examples for use of the award and should not be considered comprehensive. A traditional research proposal is not expected; however, the candidate is required to submit an essay that addresses several areas including his/her area(s) of focus and how he/she will use the award to pursue creative breast cancer investigations.

This award is designed to facilitate creative thinking and imaginative application of ideas to the field of breast cancer by investigators who have a prior history of creativity and innovation in their respective fields and careers. It is expected that the candidate will commit a minimum of 50% of his/her full-time professional effort to breast cancer research during the period of this award. Innovator Award recipients will meet annually with the Integration Panel (IP) and Program Staff for the purpose of open communication and mutual benefit and will report progress as an oral presentation and/or written summary.

Approximately \$12M will be available for Innovator Awards, but this could be increased depending on the quality of the applications. Funding for Innovator Awards can be requested for a maximum of \$3M for a period of up to 4 years, inclusive of direct and indirect costs. Examples

of possible uses for the award include project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies.

For complete application requirements, please refer to Section III-D. Additional guidance for application preparation may be gained by reviewing the review criteria listed in Section III-B.1.

## **III-B. Application Evaluation**

Due to the unique nature of the award, the review process described in Section I-C will be modified for the Innovator Award. Applications will be evaluated using a two-tiered process.

### **III-B.1. Peer Review**

The first tier peer review will be conducted by a multidisciplinary panel of knowledgeable and visionary scholars and researchers who are representatives from academia, government, industry, and breast cancer consumer organizations. The primary responsibility of the first tier reviewers will be to rank the applications received and make recommendations for awards to the IP.

The following criteria will be used to evaluate and compare the applications during the first tier of review:

- **Candidate:** Have the candidate's past and current endeavors had groundbreaking impact in his/her field? Does the application reflect creativity and innovative thinking and support the likelihood that the candidate would have a significant impact on breast cancer? Does the candidate's record of accomplishment demonstrate outstanding ability as an independent and visionary scholar/investigator?
- **Relevance and Impact:** Does the applicant's vision for the tenure of the award address an important problem(s) in breast cancer? Is the work demonstrably creative and does it have the potential to significantly impact the prevention, detection, diagnosis, treatment, and/or management of breast cancer?
- **Vision and Ideas:** Does the candidate communicate a clear vision of what he/she hopes to accomplish during the tenure of the award? Are the concepts and ideas original and innovative? Do the candidate's ideas reflect innovative thinking and does he/she present a clear and compelling argument for how this award will be used to pursue creative (potentially groundbreaking) breast cancer research?
- **Environment:** Is there evidence that the environment will facilitate and encourage the proposed work? Are the necessary resources available, or does the candidate have a plan for access to or creation of the needed resources?

### **III-B.2. Programmatic Review**

The second tier will be programmatic review. Programmatic review will be accomplished by members of the IP, composed of scientists, clinicians, and consumer advocates who are expert in the area of breast cancer research and/or advocacy (see Sections I-B and I-C.2). The complete award application will be forwarded for second tier review. The second tier of review will take programmatic relevance and program portfolio balance into consideration.

### **III-C. Letter of Intent**

All applicants considering submission of an Innovator Award application in response to this program announcement are **required to submit a Letter of Intent by May 30, 2001 at 4:00 p.m. Eastern Time**. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **III-D. Application Preparation**

Please use the following information specific for Innovator Awards in the preparation of your application and refer to Appendix B as appropriate. Please note that the required essay is limited to **5 pages**, inclusive of any figures, tables, graphs, and photographs. **Applications exceeding specified page limits may be administratively withdrawn by the Government prior to peer review**. Ensure that the application is received by **June 13, 2001 at 4:00 p.m. Eastern Time**.

#### **1. Who May Apply**

Eligible institutions include for-profit, nonprofit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, publicly or privately held companies, and agencies of local, state, and federal governments. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by or affiliated with an eligible institution.

Individuals not affiliated with an institution may apply for the Innovator Award; however, if the application is recommended for funding, they will be required to submit documentation for a determination of responsibility to be made by the USAMRMC. Such documentation may include, but is not limited to, information on time management, project management, and financial accountability.

Due to the unique nature of the award, if an Innovator Awardee should move to a new institution during the tenure of the award, the new institution will be designated as the recipient institution for the remaining award amount.

2. Application Acceptance Criteria – See Appendix B, part 2.  
Please note that the same acceptance criteria are applied to Innovator Award applications as to proposals for other award mechanisms.
3. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
4. Title/Referral Page – See Appendix B, part 5.
5. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your application submission. This table of contents should be used as a guide for assembling all required components of the application. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the application that includes the Principal Investigator's (PI's) name (last name, first name, middle initial).
6. Checklist for Application Submission – See Appendix B, part 7.

7. Application Abstracts

Both a 1-page technical abstract and a 1-page lay (nontechnical) abstract summarizing the application essay (see item 8 below) are required. Each application abstract page should contain the title of the application and the name of the PI. Abstracts must be submitted as part of the application and on disk. **Do not include figures or tables in either abstract.**

Sample abstracts for other award mechanisms are included in Appendix D. Please note that the technical abstract for Innovator Award applications is not required to follow the structured format described in Appendix B, part 8.

The lay abstract is intended to communicate the purpose of and rationale for the study to the nonscientific community. It should be composed in a way to make the objectives of and rationale for the application understandable to lay readers. The lay abstract should not duplicate the technical abstract.

In addition to the abstract pages contained within the application, submit a 3½" disk, zip disk, or CD containing the abstract files (clearly labeled with the name of the PI, institution, and word processing program). Submit abstracts in Word, WordPerfect, or ASCII format. **It is paramount that the investigator submit abstracts on disk that are identical to the versions contained in the application.**

8. Application Essay

The candidate must submit an essay that is limited to **5 pages**.

The content of the essay should address the following points:

- **Current Status of Breast Cancer Research:** Describe your views of the major research problems/barriers in breast cancer research that must be solved to accelerate progress and hasten the eradication of breast cancer.
- **Your Vision of the Future:** What do you see as the critical approaches, discipline combinations, etc., that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems/barriers that you have defined?
- **Your Specific Ideas:** Summarize some of the key examples of specific innovative ideas, hypotheses, research programs, etc. that you envision pursuing under the auspices of this award. Explain why/how your ideas may challenge current assumptions and ultimately produce significant progress.
- **Preparation for This Award:** Explain why/how your past training and experience qualifies you to receive this award. Give some examples of breakthrough creative thinking and/or experimentation in your past work that demonstrates your abilities as an innovator. How do you think your past publications, patents, other achievements, etc., reflect your capabilities as an innovator?

9. Abbreviations – See Appendix B, part 12.

10. References – See Appendix B, part 13.

11. Curriculum Vitae

Applicants should submit their complete curriculum vitae including employment, experience, honors, and a list of publications and patents. The publication list should exclude abstracts and should distinguish which publications are peer reviewed. On the curriculum vitae, the candidate should indicate up to three publications he/she considers most significant to the proposed work. Please note that the acceptance criteria in Appendix B, part 2 will apply to the curriculum vitae. There is no page limit for the curriculum vitae.

12. Existing/Pending Support – See Appendix B, part 15.

13. Facilities/Equipment Description – See Appendix B, part 16.

14. Administrative Documentation – See Appendix B, part 17.

In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the application submission:

- Letter of institutional support for the candidate's receipt of an Innovator Award, if applicable, as reflected by (1) the extent to which the applicant will be relieved of academic or administrative responsibilities and (2) permission to use institutional resources as needed.

- Three letters of nomination addressing the past and current creativity and innovation of the applicant should be provided.

15. Cost Estimate – See Appendix F.

Please complete the second page of the Detailed Cost Estimate form (Budget for Entire Proposed Period of Support) from Appendix F. The Detailed Budget for Initial Budget Period (page 1) and the Budget Justification (page 3) are not required with the application. Funding for Innovator Awards can be requested for a maximum of \$3M for a period of up to 4 years, inclusive of direct and indirect costs. Direct costs can include (but are not limited to) any project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies. Funds for the support of “to be named” trainees may be requested. Funds should be requested for an annual meeting of recipients of the Innovator Award with the IP and Program Staff. In addition, funding should also be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

16. Instruments – See Appendix B, part 19.

17. Publications and Patent Abstracts – See Appendix B, part 20.

18. Application Submission – See Appendix B, part 21.

19. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Innovator Award applications is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of an application after the deadline may be grounds for application rejection.**

20. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

Please note that any research involving human or animal use must be approved if the application is recommended for funding.

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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*Innovator Awards*

## IV. Idea Awards

### IV-A. Idea Awards

The intent of Idea Awards is to encourage innovative approaches to breast cancer research. These proposals may represent a new paradigm in the study of breast cancer, challenge existing paradigms, or look at an existing problem from a new perspective. The proposed studies may be untested, but should have a high probability of revealing new avenues of investigation. Although this research is inherently risky in nature, the research plan must demonstrate solid scientific judgment and rationale. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Idea Award proposals are qualitatively different from traditional research proposals as outlined in Table IV-1 below. Although Idea Award proposals do not require preliminary or pilot data, they should be based on a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning. Idea Awards are not intended to continue avenues of research already established. The incremental advancement of a hypothesis, the exploration of a hypothesis in a different cell line, or the use of a published series of in vitro assays to further characterize a model system are examples of aims appropriate for other funding mechanisms. The Breast Cancer Research Program (BCRP) recognizes that the incorporation of true innovation renders the proposal high risk/high impact.

**Table IV-1: Differences between Traditional Research Proposals and Idea Research Proposals**

<b>Type of Proposal</b>	<b>Preliminary or Pilot Data</b>	<b>Research Approach</b>
Traditional Research Proposal	Required	Continues established avenues of research
Idea Award Research Proposal	Not required (can be included if available)	Challenges existing paradigms; novel, high risk, potential for high gain

Approximately \$50M will be available for Idea Awards. Funding for Idea Awards can be requested for a maximum of \$300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request a maximum of \$625,000 in direct costs for a period of up to 5 years, plus indirect costs as appropriate. (A population-based study requires extra time and resources due to the participation of human subjects.) Direct costs can cover salary, expenses (including research supplies), equipment, and travel to scientific meetings.

For complete proposal requirements, please refer to Section IV-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

An Idea Award proposal may address the same research question proposed in a Career Development Award (CDA) proposal (see Section IX). Both proposals must be prepared by and specify the same Principal Investigator (PI). In addition, each proposal must reference the other in the Existing/Pending Support section.

## **IV-B. Scientific Peer Review Evaluation Criteria for Idea Award Proposals**

Idea Award proposals will be evaluated according to the criteria listed below:

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Preliminary data are **not** required but may be included. Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics?
- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms, develop new methodologies or technologies, or address underexplored or unexplored areas?
- **Scientific Relevance and Impact:** Does this study address a critical problem in breast cancer research? What will be the effect of these studies on the concepts or methods that drive this field? Does the proposal make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of eradicating breast cancer and/or advancing research in the field?
- **Principal Investigator:** Is the PI appropriately trained and well-suited to carry out this work? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?
- **Environment:** Is there evidence that the scientific environment is an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget appropriate for the research proposed?

### **IV-C. Programmatic Review Evaluation Criteria for Idea Award Proposals**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Idea Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

### **IV-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **IV-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.

In addition to the instructions found in Appendix B, part 10, Idea Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of innovation and relevance in the proposal will impact and further programmatic goals.

11. Proposal Body – See Appendix B, part 11.

The body of Idea Award proposals is limited to **6 pages**.

For Idea Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. The inclusion of preliminary data is **not** required; however, investigators must demonstrate a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning.

Describe the proposed project using the general outline provided below:

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- b. **Hypothesis/Rationale/Purpose:** State the hypothesis to be tested and the expected results.
- c. **Objectives:** State concisely the specific aims and the research strategy of the study.
- d. **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.
- e. **Innovation:** State concisely how the proposed research uses innovative hypotheses or methods to advance the prevention, detection, diagnosis, and/or treatment of breast cancer.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Funding for Idea Awards can be requested for a maximum of \$300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request a maximum of \$625,000 in direct costs for a period of up to 5 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Idea Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

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**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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Abbreviations (1-page limit).....	___
References (no page limit).....	___
Biographical Sketches (3-page limit each)	
PI.....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff).....	___
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## V. Clinical Bridge Awards

### V-A. Clinical Bridge Awards

The intent of Clinical Bridge (Bridge) Awards is to sponsor translational research that will ultimately lead to new strategies for the prevention, detection, diagnosis, and/or treatment of breast cancer. Two types of studies are envisioned: (1) Pre-Clinical Lead-Up or (2) Post-Clinical Trial Follow-Up. Unlike Clinical Translational Research Awards offered in Program Announcement I, Bridge Awards do not need to include a clinical trial within the lifetime of the award.

Translational studies, although hypothesis-driven, often involve work that appears to lack novelty such as in vivo testing, structural optimization or toxicology of a lead agent, or immunohistochemistry on tissues collected in a clinical trial. The Breast Cancer Research Program (BCRP) considers these translational projects a high priority, and the Bridge Award is designed to address this need. This award is not meant to fund basic research questions or behavioral research. The proposal must delineate clear end points for the work.

- **Pre-Clinical Lead-Up:** Pre-Clinical Lead-Up studies include translational research on a lead agent for a breast cancer prevention, detection, diagnostic, or therapeutic clinical trial. **Lead agents are defined as drugs, modalities (including biological agents), devices, or technologies with potential clinical application and demonstrated efficacy in a model system.** Examples of a lead agent include: a novel chemotherapeutic, hormonal, antibody, or other targeted therapy for breast cancer; a novel surrogate marker of disease or diagnostic reagent specific to breast cancer; and a new detector for digital mammography or a promising computer-aided diagnosis scheme. The lead agent must have demonstrable in vitro activity, except for radiological studies, and, at a minimum, data on in vivo efficacy. Consideration will be given to the novel use of an established agent. Lead agents do not have to be provided in Good Manufacturing Practice (GMP) form for all studies proposed. This award can be used in conjunction with other awards or programs that support the GMP production of a lead agent (e.g., Rapid Access to Intervention Development [RAID]). The goal of the Pre-Clinical Lead-Up study is to provide support for the generation of sufficient data within the award period to allow the investigator to submit an Investigational New Drug application to the Food and Drug Administration, to justify inclusion of the lead agent in a clinical trial, and/or to subsequently apply for a clinical translational award. Examples of topics that the BCRP considers well-suited to be addressed by this mechanism include: (1) in vivo testing of a lead agent for efficacy in breast cancer model systems, particularly ones that address novel and relevant aspects of the disease, such as bone metastasis formation or immunologic approaches to diagnosis or therapy; (2) in vitro studies on materials obtained from in vivo experiments; (3) pharmacokinetic, toxicological, and structural optimization of lead agents; (4) scale-up of production of lead agents.

- **Post-Clinical Trial Follow-Up:** Post-Clinical Trial Follow-Up studies should involve laboratory investigations to test new hypotheses that are based upon clinical observations and/or findings that emanated directly from a prospective clinical trial. These projects must utilize materials or data from a prospective clinical trial to investigate questions that may lead to a new understanding of the clinical data or the development of new clinical hypotheses. These projects are not Phase IV studies. The goal of Post-Clinical Trial Follow-Up studies is to provide data that will result in new clinical paradigms or applications upon completion of the proposed work. Topics that the BCRP considers well-suited to be addressed by this mechanism should involve diagnostic, prognostic, or predictive factors explored in the context of prospective clinical trials (either therapeutic or epidemiological). In these projects, clinical material (e.g., radiographs, serum, plasma, peripheral mononuclear cells, tumor tissue, normal breast tissue) should be tied to a defined patient database. Studies should be hypothesis-driven but may involve a hypothesis developed after trial completion as a result of new technology and/or availability of new markers.

Though the techniques proposed for these studies may be standard, either the agent, model system, or diagnostic/prognostic marker under study should be novel or an innovative use of an established agent should be proposed. It is the responsibility of the investigator to clearly articulate how the proposed research will advance breast cancer interventions leading to or from the clinic. All Bridge Award proposals must include preliminary data supporting the rationale for the proposed study. A clear statistical plan must be included in the proposal.

Approximately \$5M will be available for Bridge Awards. Funding for Bridge Awards can be requested for a maximum of \$300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, animal studies, and travel to scientific meetings.

For complete proposal requirements, please refer to Section V-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections V-B and V-C.

A Clinical Bridge Award proposal may address the same research question proposed in a Career Development Award proposal (see Section IX). Both proposals must be prepared by and specify the same Principal Investigator (PI). In addition, each proposal must reference the other in the Existing/Pending Support section.

## **V-B. Scientific Peer Review Evaluation Criteria for Clinical Bridge Award Proposals**

Bridge Award proposals will be evaluated according to the criteria listed below:

- **Research Strategy:** Are the conceptual framework, hypothesis, design, method, analyses, and statistical plans adequately developed? Does the proposal delineate clear end points for the work? Does the applicant acknowledge potential problem areas and consider alternative

methods/tactics? Do the preliminary data support the scientific rationale for the study? Though the techniques proposed for these studies may be standard, does the research employ novel agents, model systems, markers, or novel uses of established agents?

*For Pre-Clinical Lead-Up proposals:* Is this a well-defined agent of translational significance?

- **Clinical/Translational Relevance and Impact:** Does this study address a critical problem in breast cancer translational research? What is the likelihood that successful completion of the proposed studies will ultimately lead to the submission of an Investigational New Drug application to the Food and Drug Administration and the design of a new prospective clinical trial? Does the research have the potential to result in substantial improvements over today's approach to the prevention, detection, diagnosis, and/or treatment of breast cancer?

*For Pre-Clinical Lead-Up proposals:* Has a lead agent of significant translational potential been identified? Do the preliminary data for this agent justify additional investigation?

*For Post-Clinical Trial Follow-Up proposals:* Are the original aims of the trial, its progress, and its potential impact adequately described, so that the proposed investigations are scientifically justified?

- **Principal Investigator and Staff:** Is the PI appropriately trained and well-suited to carry out this work? Are other scientific personnel well-qualified to participate in the project? Is there appropriate representation from all areas of expertise needed to conduct the study successfully?
- **Environment:** Is there evidence that the scientific environment is an appropriate setting for the proposed research? Are the basic and translational research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget appropriate for the research proposed?

### **V-C. Programmatic Review Evaluation Criteria for Bridge Award Proposals**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Clinical Bridge Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

## **V-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

## **V-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Bridge Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs.

**Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.  
In the “Award mechanism” section of the Title/Referral Page, indicate whether the proposal is a Pre-Clinical Lead-Up or a Post-Clinical Trial Follow-Up Clinical Bridge Award.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI’s name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.  
In addition to the instructions found in Appendix B, part 10, Bridge Award applicants should

state explicitly (within the 1-page limit) the significance of the translational hypothesis to be tested. Also, describe how, if the aims are achieved, the proposed work will lead to significant, novel clinical strategies for the prevention, detection, diagnosis, and/or treatment of breast cancer.

11. Proposal Body – See Appendix B, part 11.

The body of Bridge Award proposals is limited to **10 pages**.

Describe the proposed project using the general outline provided below:

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal and how the proposed studies are directly proximal to a clinical trial. Cite relevant literature references.
- b. **Hypothesis/Rationale/Purpose:** State the hypothesis to be tested and the expected results.
- c. **Objectives:** State concisely the specific aims and research strategy of the study.
- d. **Preliminary Data:** The inclusion of preliminary data is required for Bridge proposals; investigators must submit promising and well-founded preliminary data relevant to breast cancer research and the proposed project. For Lead-Up studies, provide pertinent information on in vitro and in vivo data concerning the lead agent. For Follow-Up studies, provide information on the prospective clinical trial (including the aims, progress, and potential impact) and other information to support the hypothesis to be tested.
- e. **Proposed Research and Methods:** Provide details about the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Funding for Bridge Awards can be requested for a maximum of \$300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, animal studies, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year to attend scientific/technical meetings. In addition, funding should also be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Bridge Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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Abbreviations (1-page limit) .....	___
References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
PI .....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff) .....	___
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*Clinical Bridge Awards*

## **VI. Undergraduate Summer Training Program Awards**

### **VI-A. Undergraduate Summer Training Program Awards**

The intent of the Undergraduate Summer Training Program Awards (Undergraduate Awards) is to establish summer breast cancer training programs that will provide meaningful research experiences for undergraduate students. A goal of the Undergraduate Award is to attract talented students to careers that focus on breast cancer research. It is anticipated that these awards will provide educational and training opportunities for undergraduate students at an important career decision-making point.

Undergraduate Award proposals must have a minimum of two and a maximum of eight undergraduate students per year. Students should spend 8-12 weeks of the summer participating in the program. The undergraduate students in this program can be named or designated “to be named” (TBN) at the time of proposal submission.

One or more mentors may be involved in the training program. When a proposal includes multiple staff, a single individual should be clearly designated as the Program Director, i.e., the Principal Investigator (PI) for the proposal.

Applications are solicited from all eligible institutions. Eligible institutions include for-profit, nonprofit, public, or private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The Congressionally Directed Medical Research Programs (CDMRP) encourages proposals from Historically Black Colleges and Universities/Minority Institutions for Undergraduate Awards (see Appendix B, part 1).

Undergraduate Award proposals should address the following key aspects for the proposed breast cancer undergraduate training program: (1) the program vision and goals, particularly as they relate to breast cancer; (2) the program faculty/staff; (3) the training program; and (4) the trainee recruitment plans. In the development of recruitment plans, methods to encourage the participation of women and minority students should be considered. For complete proposal requirements, please refer to Section VI-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VI-B and VI-C.

Approximately \$4M will be available for Undergraduate Awards. Funding for these awards can be requested for a \$4,000 stipend per student per summer and \$10,000 per year for administrative costs over a 3-year performance period for a maximum total of \$126,000 in direct costs. Direct costs can cover tuition, student stipends, faculty salary, and expenses including research supplies.

## **VI-B. Scientific Peer Review Evaluation Criteria for Undergraduate Summer Training Award Proposals**

Undergraduate Award proposals will be evaluated according to the criteria listed below:

- **Training Program:** Does the training program offer a structured, focused experience in breast cancer research? Does the program ensure direct, structured interaction between mentor and student? Have plans been developed to provide students with a stimulating, problem-solving research experience? Does the program provide mechanisms for students to summarize and present their work? Does the training program provide opportunities for students to interact with other program mentors outside the laboratory in which they are working? Has a plan been developed to track the students' future careers and the effectiveness of the program for initiating careers in breast cancer research?
- **Program Director and Training Staff:** Does the Program Director (the PI) have the background, research qualifications, and ability to lead and successfully manage an undergraduate breast cancer training program? What are the research interests and records of past experience in training and mentoring undergraduates of the participating mentors? Is there a sufficient number of mentors participating in the program to ensure adequate mentoring and supervision for the number of student trainees?
- **Trainees:** What methods are used to recruit trainees? Are the selection criteria for admitting students into the program appropriate? Are the recruitment methods likely to attract students with a high likelihood of pursuing a career in breast cancer research? What is the overall quality of present and former students, if applicable? Have former undergraduate trainees (if any) gone on to pursue careers in breast cancer research? Is the size, i.e., number of trainees, appropriate for the available faculty/resources?
- **Relevance:** Does the institution make a convincing case for its commitment to develop an undergraduate summer training program focused on breast cancer research?
- **Institutional Environment:** Is there evidence of a strong institutional commitment to research training in breast cancer? Does the institution have other undergraduate research opportunities? Does the institution provide an intellectually stimulating environment and facilitate interaction among mentors and trainees? Does the institution provide adequate laboratory facilities, equipment, and other relevant resources to support these training activities?
- **Budget:** Is the budget appropriate for the proposal?

## **VI-C. Programmatic Review Evaluation Criteria for Undergraduate Summer Training Program Awards**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Undergraduate Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

## **VI-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed, or completed and submitted via the CDMRP web site at <http://cdmrp.army.mil/funding/default.htm>.

## **VI-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Undergraduate Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.  
The first summer training program should be planned for summer 2002.

10. Proposal Relevance Statement – See Appendix B, part 10.

In addition to the instructions found in Appendix B, part 10, Undergraduate Award proposals should describe (within the 1-page limit) how the training program will be designed to offer a structured, well-rounded, focused experience in breast cancer research. Include how the training program will foster the likelihood of its trainees pursuing a career in breast cancer research.

11. Proposal Body – See Appendix B, part 11.

The body of Undergraduate Award proposals is limited to **6 pages**.

Undergraduate Award proposals should address the following key aspects of the proposed training program: (1) the program vision and goals, particularly as they relate to breast cancer; (2) the program faculty/staff; (3) the training program; and (4) the trainee recruitment plans. As part of the discussion of each of these key aspects, the body of the proposal should address the breast cancer emphasis of the program; the qualifications of the Program Director and any additional participating mentors; a description of the training environment and facilities; the proposed research opportunities available for trainees; the recruitment of students into the program; the selection criteria for students; the method of assigning students to a mentor; and the plan for tracking students after participation in the program to determine how many go on to pursue careers involving breast cancer research. In the development of recruitment plans, methods to encourage the participation of female and minority students should be considered. An outline of any course or seminar series that might be available as part of the training program could be included. Additional information on the participating mentors/trainees and institutional support is to be described in items 14 and 17 in this section.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

a. Mentor Biographical Sketches

Biographical sketches should include a section describing the Program Director's (the PI's) and training staff members' experience in the field of breast cancer research and previous experience training and mentoring students, particularly undergraduates. A list of significant publications in breast cancer research should be incorporated into the biographical sketches.

b. Trainee Biographical Sketches

A biographical sketch of no more than 3 pages must be included in this section for **named** trainees. The biographical sketch form in Appendix E should be used, but emphasis should be placed on the trainee's interests and career goals, relevant coursework and extracurricular activities, and any past experience in scientific research. When TBN trainees are ultimately selected, the CDMRP must be notified, and the name and biographical sketch of each trainee must be provided.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:

- A letter of support from the institution indicating a strong commitment to the summer training program.
- Letters of support from all collaborating mentors demonstrating their commitment to support the breast cancer Undergraduate Summer Training Program.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Funding for these awards can be requested for a \$4,000 stipend per student per summer and \$10,000 per year for administrative costs over a 3-year performance period for a maximum total of \$126,000 in direct costs. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Direct costs can cover tuition, student stipends, faculty salary, and expenses including research supplies. Funding should be requested for the Program Director to attend a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Undergraduate Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

\_\_\_\_\_

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Abbreviations (1-page limit) .....	___
References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
Program Director (PI) .....	___
Participating Staff .....	___
Named Trainees .....	___
Existing/Pending Support (no page limit) .....	___
Facilities/Equipment Description (no page limit) .....	___
Administrative Documentation (no page limit)	
List of all items included in Administrative Documentation section .....	___
Letter of institutional support .....	___
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*Undergraduate Summer Training Program Awards*

## **VII. Predoctoral Traineeship Awards**

### **VII-A. Predoctoral Traineeship Awards**

The intent of Predoctoral Traineeship Awards is to support promising graduate students studying breast cancer under the guidance of a designated mentor. The overall goal of Predoctoral Traineeship Awards is to prepare individuals for careers in breast cancer research. Individuals enrolled in an M.D./Ph.D. program are encouraged to apply. Important aspects of these applications include (1) the mentor and the training environment, (2) the candidate's qualifications, and (3) the candidate's plans after the completion of the proposed project.

Predoctoral Traineeship proposals, with appropriate direction from the mentor, should be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees. Predoctoral Traineeship applicants must describe the proposed research project, training program, and their career goals in the body of the proposal. The mentor is also responsible for preparing certain components of the proposal. For complete proposal requirements, please refer to Section VII-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VII-B and VII-C.

Approximately \$8M will be available for Predoctoral Traineeship Awards. Predoctoral Traineeship Awards can be requested for an average of \$22,000 per year, inclusive of direct and indirect costs for a maximum of \$66,000 over 3 years. Direct costs can cover tuition, stipend, expenses (including research supplies), and travel to scientific meetings. These awards are intended to support dissertation research rather than rotations or basic course work.

### **VII-B. Scientific Peer Review Evaluation Criteria for Predoctoral Traineeship Proposals**

Predoctoral Traineeship proposals will be evaluated according to the criteria listed below:

- **Candidate:** Do the candidate's achievements to date (as reflected by background, academic performance, awards, and honors) make him/her qualified for predoctoral training? What are the candidate's stated career goals? What are the candidate's research plans after the completion of this project? Do the letters of recommendation support the candidate's abilities and potential for a productive research career?
- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the candidate's training program? What has been the mentor's previous research training experience with candidates for advanced degrees?

- **Research Training and Environment:** Are the research and training programs properly structured and balanced to ensure that the trainee will acquire the necessary skills and knowledge about the scientific area being studied? Is the research proposed likely to provide the candidate with a strong foundation in breast cancer research that will prepare and encourage him/her to follow a career path in this area? Does the training take place in an environment that is appropriate for accomplishing the candidate's goals? Is there evidence that the research and training requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?
- **Relevance:** Does the predoctoral training relate to an important problem in breast cancer research? If the aims of the training are achieved, will there be potential benefits to patients with, or populations at risk for, breast cancer? Does the application make a convincing case for the relevance of the research and training to breast cancer?
- **Budget:** Is the budget appropriate for the work proposed? Are there sufficient overall financial resources to support the proposed research?

### **VII-C. Programmatic Review Evaluation Criteria for Predoctoral Traineeship Proposals**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Predoctoral Traineeship mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

### **VII-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **VII-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Predoctoral Traineeships. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.  
Predoctoral Traineeship awards are made to promising graduate students under the guidance of a designated mentor. Individuals enrolled in an M.D./Ph.D. program are encouraged to apply.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.  
In addition to the instructions found in Appendix B, part 10, predoctoral candidates should describe explicitly (within the 1-page limit) the training value of the proposed research concept relative to the applicant's career goals and how the proposed research is pertinent to one or more critical issues in breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the candidate for a career in the battle against breast cancer.
11. Proposal Body – See Appendix B, part 11.  
The body of Predoctoral Traineeship proposals is limited to **6 pages** and should include descriptions of the research project, and training and career plans as described below.  
  
Address the following in the body of the proposal:
  - a. Description of Research Project: Describe the proposed project using the general outline provided below:
    - i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

- ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.
  - iii. Objectives: State concisely the specific aims and research strategy of the project.
  - iv. Methods: Give details about the experimental design and methodology.
- b. Career/Research Plans: Briefly describe the candidate's career development plan and how the proposed training will promote the candidate's career development in the area of breast cancer research. Discuss the applicant's research plans after the completion of this award.
12. Abbreviations – See Appendix B, part 12.
13. References – See Appendix B, part 13.
14. Biographical Sketches – See Appendix B, part 14 and Appendix E.  
For Predoctoral Traineeship proposals, biographical sketches should be prepared for the candidate (the PI), the mentor, and collaborating investigators.
15. Existing/Pending Support – See Appendix B, part 15.  
It is especially important to list the mentor's existing/pending support as evidence that there is adequate support in the training environment for the predoctoral trainee.
16. Facilities/Equipment Description – See Appendix B, part 16.
17. Administrative Documentation – See Appendix B, part 17.  
In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:
- Official transcripts from undergraduate institutions and graduate-level courses completed to date. All foreign transcripts must be accompanied by an English translation.
  - A description of the training environment prepared by the mentor (1-page limit). Describe the research training in which the applicant will participate such as coursework, laboratory techniques, conferences, and journal clubs. The mentor should provide a brief overview of research being performed under his/her direction. Information should be provided on how the mentor can assist in training the applicant for a career in breast cancer research. The mentor's history in training other predoctoral students should also be outlined. A brief summary of the laboratory's resources should be outlined to demonstrate the adequacy of available support for the trainee's project. (Specific details on existing support should be covered in item 15 above.)

- A letter of support from the **mentor** describing his/her commitment to the training/career development/mentorship of the applicant and the nature of the proposed collaboration/training. Emphasis should be placed on the applicant's potential as a future breast cancer researcher and the mentor's degree of interaction in training the candidate.
- Two additional letters of recommendation.
- Letters of support from any other collaborating investigators.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Predoctoral Traineeship Awards can be requested for an average of \$22,000 per year inclusive of direct and indirect costs for a maximum of \$66,000 over 3 years. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Direct costs can cover tuition, stipend, expenses including research supplies, and travel to scientific meetings. These awards are intended to support dissertation research rather than rotations or basic course work. The amount allotted for travel is \$1,500 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadlines – See Appendix B, part 22.

Please note that the **receipt deadline for Predoctoral Traineeship Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

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**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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PI (Predocotrual Applicant).....	___
Mentor.....	___
Collaborating Investigators.....	___
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*Predoctoral Traineeship Awards*

## **VIII. Postdoctoral Traineeship Awards**

### **VIII-A. Postdoctoral Traineeship Awards**

The intent of Postdoctoral Traineeship Awards is to enable recent medical or other doctoral degree graduates to obtain the necessary experience to pursue a career in breast cancer research. Eligible applicants should have been in the laboratory in which this research is to be performed no more than 2 years at the time of submission and should have less than 5 years total of postdoctoral research experience (exclusive of clinical residency or fellowship training). Unlike previous Breast Cancer Research Program (BCRP) Program Announcements, for fiscal year 2001 (FY01) there is no separate mechanism or review criteria for Clinical Translational Research Postdoctoral Fellowship Awards; however, **clinically oriented physicians who wish to undertake clinical translational research in breast cancer are encouraged to submit Postdoctoral Traineeship Award proposals.**

Postdoctoral Traineeship proposals should either extend the candidate's ongoing research related to breast cancer or broaden the scope of his/her research to include work relevant to breast cancer, under the guidance of a designated mentor. The research focus of the proposal should address an issue relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Individuals with a Ph.D., M.D., D.O., D.V.M., D.D.S./D.M.D., D.N.Sc., Sc.D., or other equivalent degree are encouraged to apply.

The overall goal of Postdoctoral Traineeship Awards is to prepare individuals for careers in breast cancer research. Important aspects of these applications include (1) the mentor and the training environment, (2) the candidate's qualifications, and (3) the candidate's plans after the completion of the proposed project.

Postdoctoral Traineeship proposals, with appropriate direction from the mentor, should be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees. Postdoctoral Traineeship applicants must describe their research project, training program, and goals in the body of the proposal. The mentor is also responsible for preparing certain components of the proposal. For complete proposal requirements, please refer to Section VIII-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VIII-B and VIII-C.

Approximately \$15M will be available for Postdoctoral Traineeship Awards. Traineeships can be requested for an average of \$50,000 per year, inclusive of direct and indirect costs, for a maximum of \$150,000 over 3 years. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings.

## **VIII-B. Scientific Peer Review Evaluation Criteria for Postdoctoral Traineeship Proposals**

Postdoctoral Traineeship proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's achievements to date (as assessed by background, academic performance, awards, and honors) make him/her well-qualified for postdoctoral training? Does the candidate have a record of previous research experience, publications, and/or related professional training that indicates suitability for a career in breast cancer research? What are the candidate's research plans after the completion of this project? Has the candidate demonstrated a personal commitment to pursuing a career in breast cancer research? Do the letters of recommendation support the candidate's abilities and potential for a productive research career?
- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the candidate's training program? What is the mentor's previous research training experience with doctoral students, fellows, residents, etc.?
- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal?
- **Training and Environment:** Will the training result in a valuable experience for the trainee in preparing him/her for an independent career in breast cancer research? Does the postdoctoral training take place in an environment that is appropriate to accomplishing the candidate's goals? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to research training in breast cancer?
- **Relevance:** Does the training relate to an important problem in breast cancer research? Is the proposed research likely to train and encourage the candidate to pursue a career in breast cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to breast cancer research? Does the application make a convincing case for the relevance of the research to breast cancer?
- **Budget:** Is the budget appropriate for the work proposed? Are there sufficient overall financial resources to support the proposed research?

### **VIII-C. Programmatic Review Evaluation Criteria for Postdoctoral Traineeship Proposals**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Postdoctoral Traineeship Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

### **VIII-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **VIII-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Postdoctoral Traineeships. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1 and item 17 on page VIII-5.

Eligible applicants should have been in the laboratory in which the research is to be performed no more than 2 years at the time of submission and should have less than 5 years total of postdoctoral research experience (exclusive of clinical residency or fellowship training). Individuals who will have received a Ph.D., M.D., D.O., D.V.M., D.D.S./D.M.D., D.N.Sc., Sc.D., or other equivalent degree by the time of award negotiation may apply.

2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10.  
In addition to the instructions found in Appendix B, part 10, Postdoctoral Traineeship Award applicants should describe explicitly (within the 1-page limit) the training value of the proposed research concept relative to the applicant's career goals and how the proposed research is pertinent to one or more critical issues in breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the candidate for a career in the battle against breast cancer.
11. Proposal Body – See Appendix B, part 11.  
The body of Postdoctoral Traineeship proposals is limited to **6 pages** and should include descriptions of the research project, and training and career plans as described below.
  - a. Description of the Research Training: Describe the research training in which the candidate will participate such as coursework, laboratory techniques, conferences, and journal clubs.
  - b. Description of Research Project: Describe the proposed project using the general outline provided below:
    - i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.
    - ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.
    - iii. Objectives: State concisely the specific aims and the research strategy of the project.
    - iv. Methods: Give details about the experimental design and methodology.

- c. Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development in the area of breast cancer research. Discuss the applicant's research plans after the completion of this award.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

For Postdoctoral Traineeship proposals, biographical sketches should be prepared for the applicant, the mentor, and collaborating investigators.

15. Existing/Pending Support – See Appendix B, part 15.

It is especially important to list the mentor's existing/pending support as evidence that there is adequate support in the training environment for the postdoctoral trainee.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:

- Official transcripts from undergraduate and graduate institutions. All foreign language transcripts must be accompanied by an English translation.
- A form signed by the Department Chair, Dean, or equivalent official verifying that the applicant (1) has or will have successfully completed a doctoral or medical degree at the time of award negotiation, (2) has been in the laboratory in which this research is to be performed no more than 2 years at the time of submission, and (3) has less than 5 years total of postdoctoral research experience (exclusive of clinical residency or fellowship training) and therefore is an eligible applicant for this award type. Use the Statement of Eligibility Form on page VIII-7.
- A description of the training environment prepared by the mentor (1-page limit). The mentor should provide a brief overview of other research being performed under his/her direction. Information should be provided on how the mentor can assist in training the applicant for a career in breast cancer research. The mentor's history in training other postdoctoral fellows should be outlined. A brief description of the laboratory's funds should be outlined to demonstrate the adequacy of available resources to support the trainee's project. (Specific details on existing support should be covered in item 15 above.)

- A letter of support from the **mentor** describing his/her commitment to the training/career development/mentorship of the applicant and the nature of the proposed collaboration/training. Emphasis should be placed on the applicant's potential as a future breast cancer researcher and the degree of interaction in training the candidate.
- Two additional letters of recommendation.
- Letters of support from any other collaborating investigators.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Postdoctoral Traineeships can be requested for an average of \$50,000 per year, inclusive of direct and indirect costs, for a maximum of \$150,000 over 3 years. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,500 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadlines – See Appendix B, part 22.

Please note that the **receipt deadline for Postdoctoral Traineeship Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**STATEMENT OF ELIGIBILITY**  
**FY01 BCRP Postdoctoral Traineeship**

Applicant's Name: \_\_\_\_\_

Title of Proposal: \_\_\_\_\_

Applicant's Organization Name: \_\_\_\_\_

Applicant's Organization Location: \_\_\_\_\_

Signature of Applicant: \_\_\_\_\_

I certify that the above-named investigator fulfills the following requirements to be considered for a Postdoctoral Traineeship Award and specifically meets all of the following criteria:

- Has or will have successfully completed a doctoral thesis or medical degree at the time of award negotiation;
- Has 2 years or less of postdoctoral experience in the laboratory in which the proposed research will be performed; and
- Has less than 5 total years of postdoctoral research experience (exclusive of clinical residency or fellowship training at the time of proposal submission).

Name of Official (*please print*): \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Signature of Official: \_\_\_\_\_ Date: \_\_\_\_\_

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**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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Mentor.....	___
Collaborating Investigators.....	___
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*Postdoctoral Traineeship Awards*

## **IX. Career Development Awards**

### **IX-A. Career Development Awards**

Career Development Awards (CDAs) are designed to encourage (1) scientists or clinicians who have postdoctoral and/or fellowship training, but are not yet established investigators, to pursue a breast cancer-related research career, as well as (2) established scientists or research clinicians who are currently working in areas other than breast cancer to shift their focus to breast cancer research. Such awards will provide investigators who are new to breast cancer research the opportunity to acquire the training, data, and experience to compete for traditional awards later in their careers. Unlike previous Breast Cancer Research Program (BCRP) Program Announcements, for fiscal year 2001 (FY01) there is no separate mechanism or review criteria for Clinical Translational Research CDAs; however, **clinically oriented physicians who wish to undertake clinical translational research in breast cancer are encouraged to submit CDA proposals.**

For the purpose of this program, a CDA is intended for an individual who (1) has his/her own independent program of research; is within 6 years of postdoctoral, residency, fellowship, or equivalent training; and holds a position as an Assistant Professor or equivalent; or (2) has his/her own established independent program of research with limited or no experience in the breast cancer field (as indicated by publications and research funding) and holds a position equivalent to or higher than the rank of Assistant Professor.

CDA proposals should include a discussion of the level of institutional commitment to fostering the applicant's research career as reflected by (1) the extent to which the applicant will be relieved of his/her academic or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) the opportunities for critical professional interaction with senior colleagues. A letter of support from the institution should be included as part of the proposal.

Approximately \$8M will be available for CDAs. CDAs can be requested for an average of \$59,000 per year in direct costs, for a maximum of \$236,000 over 4 years, plus indirect costs as appropriate. Direct costs can cover only salary support and travel to scientific meetings. Funds for research must be provided from another resource. **Evidence of either current or pending research support from any funding source or concomitant submission of a Department of Defense (DOD) BCRP Idea Award or Clinical Bridge Award proposal is a requirement of a CDA proposal** and should be noted in the Existing/Pending Support section.

A CDA proposal may address the same research question proposed in an Idea Award (Section IV) *or* a Clinical Bridge Award (Section V) proposal. Both proposals must be prepared by and specify the same Principal Investigator (PI). In addition, each proposal must reference the other in the Existing/Pending Support section.

## **IX-B. Scientific Peer Review Evaluation Criteria for Career Development Award Proposals**

CDA proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's previous training, prior research experience, and publication record indicate promising achievements to date? Is there a need for the proposed research experience and training in order for the candidate to develop into an independent breast cancer investigator? Has the candidate demonstrated a personal commitment to pursuing a career in breast cancer research, including an appropriate level of effort on this proposal? If appropriate, does the applicant have experience in conducting clinical trials?
- **Research Program:** Are the conceptual framework, hypotheses, design, methods, and analyses of the research adequately developed and well-integrated for the candidate's research program? Is the candidate appropriately trained and well-suited to carry out the proposed research? Is the candidate aware of potential problem areas and are potential solutions proposed? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal? Will the research offer a valuable opportunity to further develop research experience to advance and develop the candidate's independent research career?
- **Scientific Relevance and Impact:** Does the candidate's research program address a critical problem in breast cancer research? What will be the effect of these studies on the concepts or methods that drive this field? Does the application make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of preventing or eradicating breast cancer and/or advancing research in the field?
- **Institutional Commitment:** Is there a strong institutional commitment to relieve the candidate from other academic or clinical responsibilities in order to permit substantially increased time for research activities? Is the institution prepared to provide adequate laboratory facilities, equipment, and opportunities for critical professional interaction with senior colleagues? Is there a strong institutional commitment to the candidate's development?
- **Budget:** Is the budget appropriate?

### **IX-C. Programmatic Review Evaluation Criteria for Career Development Award Proposals**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the CDA mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

### **IX-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **IX-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for CDAs. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.

Applicants should articulate how the combination of training value and relevance to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy will catalyze the applicant's development as an independent breast cancer investigator.

11. Proposal Body – See Appendix B, part 11.

The body of CDA proposals is limited to **6 pages**.

a. Career Development Plans: Briefly describe the candidate's career development plan and how the proposed experience and training will promote the candidate's career development in the area of breast cancer research. Discuss the applicant's research plans after the completion of this award.

b. Description of Research Project: Applicants should provide an overview of how their time will be spent once relieved from other academic or clinical responsibilities. The following general outline should be used to describe the research project.

i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

ii. Hypothesis/Rationale/Purpose: State the hypothesis that will be tested (in an appropriately designed clinical trial, if applicable) and the expected results.

iii. Objectives: State concisely the specific aims of the project.

iv. Methods: Give details about the experimental design and methodology.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

Funds for research support are a requirement of the CDA proposal. The PI should clearly indicate (1) the titles, time commitments, supporting agencies, duration, and levels of funding for all existing and pending research grants involving the PI and key personnel and (2) the

level of support, source, and duration of any additional funds that would be applied to the CDA project (departmental funds, etc.). This support could come from a BCRP Idea or Bridge Award submitted at the same time as the CDA.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:

- A form signed by the Department Chair, Program Director, or Dean indicating that the PI is an eligible applicant for this award type. Use the Statement of Eligibility Form on page IX-7.
- A letter of institutional support the level of institutional commitment to fostering the applicant's research career, as reflected by (1) the extent to which the applicant will be relieved of other academic or clinical responsibilities to have additional time for research, and (2) the provision of adequate laboratory facilities, equipment, and (3) opportunities for critical professional interaction with senior colleagues.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

CDAs can be requested for an average of \$59,000 per year in direct costs, for a maximum of \$236,000 over 4 years, plus indirect costs as appropriate. Direct costs can cover only salary support and travel to scientific meetings. Funds for research must be provided from another resource and should be noted in the Existing/Pending Support section. The amount allotted for travel is \$1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to be held in the Baltimore, MD/ Washington, DC area to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for CDA proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

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**STATEMENT OF ELIGIBILITY**  
**FY01 BCRP Career Development Award**

Applicant's Name: \_\_\_\_\_

Title of Proposal: \_\_\_\_\_

Applicant's Organization Name: \_\_\_\_\_

Applicant's Organization Location: \_\_\_\_\_

Signature of Applicant: \_\_\_\_\_

I certify that the above-named investigator fulfills the requirements to be considered for a Career Development Award and specifically meets one of the following sets of criteria (please check the appropriate box):

- {
- Has his/her own independent research program;
  - Is within 6 years of residency, fellowship, or equivalent training; and
  - Holds a position as an Assistant Professor or equivalent

- {
- Has his/her own established independent program of research with limited or no experience in the breast cancer field, and
  - Holds a position as an Assistant Professor or equivalent or above

Name of Official (*please print*): \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Signature of Official: \_\_\_\_\_ Date: \_\_\_\_\_

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**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**Career Development Award Proposal  
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Proposal Body (6-page limit) .....	___
Abbreviations (1-page limit) .....	___
References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
PI .....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff) .....	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit) .....	___
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Detailed Cost Estimate (no page limit) .....	___
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*Career Development Awards*

## **X. Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards**

### **X-A. Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards**

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Partnership Training Awards are intended to provide assistance at an institutional level. A major goal of this award is to support collaborations between multiple investigators at an applicant HBCU/MI and a collaborating institution with established investigators in breast cancer research **for the purpose of developing a training program to increase the number of HBCU/MI investigators focused on breast cancer research.** A long-term goal is to assist HBCU/MI investigators in submitting competitive breast cancer research proposals. The applicant/proposal submission must be from an HBCU/MI. Established investigators from collaborating institutions need not be of an ethnic minority, but they must have a strong track record in acquiring funding in breast cancer research.

This award provides support for concept development for faculty researchers with doctoral degrees with little or no resources. HBCU/MI Partnership Training Awards will provide investigators the opportunity to collaborate, train, and acquire the knowledge and experience needed to develop a competitive and successful training program in breast cancer research. The focus of these awards should be on enhancing the HBCU/MI faculty's skills so they may become competitive breast cancer researchers and make significant contributions to the training program in breast cancer research to be developed by the institution. Research supported through an HBCU/MI Partnership Training Award may involve the development of initial concepts, laying the groundwork for further study. These concept development proposals are encouraged for training programs in the following areas of research, but may target any aspect of breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment:

- disparity of morbidity and/or mortality in underserved/minority populations
- cell biology or molecular biology, including biomarkers
- epidemiology, including molecular, nutrition, and diet
- access to care
- treatment and outcomes
- social/behavioral sciences

HBCU/MI Partnership Training Awards will be funded using the allocation for HBCU/MI (see Appendix B, part 1), which is approximately \$8M in fiscal year 2001. These awards can be requested for an average of \$250,000 per year, for a maximum of \$1M over 4 years inclusive of direct and indirect costs. Collaborating institutions may receive up to 40% of total costs during the first year of an award. However, no more than 25% of total costs for the full award can be granted to collaborating institutions during the lifetime of an award. Direct costs for HBCU/MI Partnership Training Awards can cover salary support, tuition for special training and/or education, consultation with established investigators, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of

essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs, in which experienced and well-funded investigators provide consultation and mentoring in grant writing and grantsmanship.

For complete proposal requirements, please refer to Section X-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections X-B and X-C.

## **X-B. Scientific Peer Review Evaluation Criteria for HBCU/MI Partnership Training Award Proposals**

HBCU/MI Partnership Training Award proposals will be evaluated according to the following criteria:

- **Applicant Institution:** Do the HBCU/MI's previous training history, prior research experience, and publication record indicate promising achievements to date? Will the training/collaboration offer a valuable opportunity to further develop necessary experience to advance the institution's capability to develop training programs in breast cancer? Are appropriate management and leadership of the partnership present at the HBCU/MI?
- **Collaborating Institution:** Does the collaborating institution have the background, qualifications, experience, and record to develop a productive collaboration with the applicant institution? Is the collaborating institution committed to the applicant institution's development? What are the qualifications of the collaborating investigators? Does the collaborating institution have a strong record of developing institutional training programs and acquiring funding in breast cancer research? How do the collaborating and applicant institutions propose to sustain an interactive, ongoing partnership?
- **Training Plan:** Does the proposed idea develop a credible training environment in the applicant institution to increase the numbers of HBCU/MI investigators focused on breast cancer research? Do both the applicant and the collaborating institutions contribute to the planned project? How do the collaborating and applicant institutions propose to sustain the interactive environment necessary for the development of an effective training program? What are the plans to develop an independent program in breast cancer research at the HBCU/MI by the end of the award period? What impact would this training/collaboration have on producing well-trained breast cancer researchers?
- **Scientific Relevance:** Do the proposed collaboration and training concept clearly focus on breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment? Does the applicant institution make a convincing case for its commitment to develop a training program focused on breast cancer research?
- **Resources/Environment:** Will the collaboration support the applicant institution's planned training program of breast cancer research? Is there evidence that the applicant is adequately

supported by the scientific environment, necessary resources, and collaborative arrangements? Is there a strong institutional commitment at the HBCU/MI to support the development of the breast cancer research training program?

- **Budget:** Is the budget appropriate for the work proposed? Does the HBCU/MI receive at least 75% of the intended funds over the lifetime of the award for use on projects directly related to building a breast cancer research training program? Does the collaborating institution receive 40% or less of the intended funds during the first year of the award?

### **X-C. Programmatic Review Evaluation Criteria for HBCU/MI Partnership Training Award Proposals**

Funding recommendations at this second tier of review are based on a comparative process. The demonstrated need of HBCU/MI applicants may be taken into consideration in making recommendations. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the HBCU/MI Partnership Training Award mechanism. Additional details on programmatic review evaluation criteria are included in Section I-C.

### **X-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than May 30, 2001 at 4:00 p.m. Eastern Time. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default.htm>.

### **X-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for HBCU/MI Partnership Training Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.** Ensure that the proposal is received by **June 13, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.  
The list of HBCU/MI as recognized by the Department of Education is available at the CDMRP web site at <http://cdmrp.army.mil/funding/minority.htm>.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Cover Booklet – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the Principal Investigator’s (PI’s) name (last name, first name, middle initial).
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.  
A sample HBCU/MI Partnership Training Award Statement of Work is provided on page X-7.
10. Proposal Relevance Statement – See Appendix B, part 10.  
In addition to the instructions found in Appendix B, part 10, HBCU/MI Partnership Training Award applicants should describe explicitly (within the 1-page limit) the plan for developing a breast cancer research training program at the HBCU/MI. Articulate how the proposal’s combination of training and relevance to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy in the proposal will prepare the HBCU/MI participants for successful experiences as breast cancer researchers.
11. Proposal Body – See Appendix B, part 11.  
The body of HBCU/MI Partnership Training Awards proposals is limited to **10 pages**.  
  
Describe the proposed partnership using the general outline provided below:
  - a. Background: Provide a brief statement of the ideas and reasoning behind the proposed collaboration(s). Proposals must present a clearly articulated plan for training program development that focuses on the biology, etiology, prevention, detection, diagnosis, and/or treatment of breast cancer. State the specific aims of the study (or studies). Briefly describe the methods to be used. Cite relevant literature references.
  - b. Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the collaborating institution and the HBCU/MI should be articulated. Qualifications and facilities of the collaborating institution should be addressed. Document the experience of the collaborating institution in training breast cancer researchers and include information on training/collaborations with minority investigators.

- c. **Training Program:** Describe explicitly the value of the proposed training as it relates to the applicant institution's plans for developing a breast cancer research training program. Articulate how the combination of collaboration and relevance to breast cancer in the proposal will catalyze the applicant institution's development of successful breast cancer research training programs. Describe the PI's qualifications and role in management of the partnership training program.
- d. **Communication:** Outline a plan for preparing reports on the status of how the collaboration is proceeding. These reports should be issued between the applicant and the collaborating institutions and should document progress, show how each institution is responding to problems, etc. Please note that these status reports cannot be used in lieu of actual meetings and the communications between the institutions' faculties.

12. **Abbreviations** – See Appendix B, part 12.

13. **References** – See Appendix B, part 13.

14. **Biographical Sketches** – See Appendix B, part 14 and Appendix E.

For HBCU/MI Partnership Training Award proposals, biographical sketches should be prepared for the participants at the applicant institution, participants at the established collaborating institution, and each of the key personnel, including collaborating investigators listed on the budget page for the initial budget period.

15. **Existing/Pending Support** – See Appendix B, part 15.

16. **Facilities/Equipment Description** – See Appendix B, part 16.

17. **Administrative Documentation** – See Appendix B, part 17.

In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:

- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution assuring the commitment of the institution to the proposed training program. This letter should reflect the extent to which the institution will support the collaboration by relieving participants of their academic and/or clinical responsibilities to have additional time for collaboration and training, providing access to appropriate facilities, and providing opportunities for professional interactions with senior colleagues.
- A letter from the collaborating institution describing a commitment to the training/development/mentorship of the applicant institution and the nature of the proposed collaboration/training.
- Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project describing their role in the research/training.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

HBCU/MI Partnership Training Awards can be requested for an average of \$250,000 per year, for a maximum of \$1M over 4 years inclusive of direct and indirect costs. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Collaborating institutions may receive up to 40% of total costs during the first year of an award. However, no more than 25% of total costs for the full award can be granted to collaborating institutions during the lifetime of an award. Direct costs for HBCU/MI Partnership Training Awards can cover salary support, tuition for special training and/or education, consultation with established investigators, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs in which experienced and well-funded investigators provide consultation and mentoring in grant writing and grantsmanship. It is the policy of the Department of Defense (DOD) that all commercial and nonprofit recipients provide the equipment needed to support proposed research (see Appendix F). However, the greater need for equipment support at an HBCU/MI institution is recognized by the DOD BCRP and will be taken into consideration during the review process. The amount allotted for travel is \$1,800 per year per investigator for up to five investigators from the HBCU/MI to attend scientific/technical meetings. In addition, funding should be requested for up to five investigators from the HBCU/MI for a one-time, 3½-day meeting to be held in the Baltimore, MD/Washington, DC area to disseminate the results DOD-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for HBCU/MI Partnership Training Award proposals is June 13, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**Sample Statement of Work  
HBCU/MI Partnership Training Award**

**Smith, Mary E.**

**Statement of Work**

**Training Program in the Epidemiological Basis of Breast Cancer Research at the  
University of Somewhere**

Phase 1: Project Startup and Parameter Development (Year 1)

- Meet with investigators at collaborating institution
- Begin training of faculty at HBCU/MI in epidemiological methodology
- Hire a biostatistician for statistical analyses of data
- Purchase equipment to assist in information processing

Phase 2: Project Development (Years 2-3)

- Train faculty at HBCU/MI on specific epidemiological aspects relevant to breast cancer
- Collect preliminary data on pilot projects
- Continue meetings and reports with collaborating institution
- Send faculty to workshops and appropriate courses
- Prepare grant applications
- Have grant application reviewed by collaborating, established investigator
- Submit grant applications

Phase 3: Analysis and interpretation of data gathered during Phase 2 (Year 4)

- Consolidate information obtained during Phase 2
- Prepare and submit additional proposals
- Prepare and submit reports summarizing the accomplishments of the collaborative and research efforts

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**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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**HBCU/MI Partnership Training Award Proposal  
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Proposal Relevance Statement (1-page limit).....	___
Proposal Body (10-page limit).....	___
Abbreviations (1-page limit).....	___
References (no page limit).....	___
Biographical Sketches (3-page limit each)	
Participating investigators at HBCU/MI.....	___
Participating investigators at collaborating institution.....	___
Key personnel.....	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit).....	___
Administrative Documentation (no page limit)	
List of all items included in Administrative Documentation section.....	___
Letter of Commitment from HBCU/MI.....	___
Letter of Commitment from collaborating institution.....	___
Letters of support from other collaborating individuals and/or institutions.....	___
Detailed Cost Estimate (no page limit).....	___
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