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FOREWORD

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

General information on the USAMRMC can be obtained from the USAMRMC website (*http://mrmc-www.army.mil*). Specific information on the DOD BCRP can be obtained from the USAMRMC Congressionally Directed Medical Research Programs (CDMRP) website (*http://cdmrp.army.mil*). A copy of this announcement and associated forms (except for the Proposal Cover Booklet) can also be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (*http://cdmrp.army.mil*).

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

Fax: (301) 619-7792
Phone: (301) 619-7079
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

Every effort will be made to answer questions within 10 working days of receipt. Inquiries should be restricted to format issues only; no questions relating to technical proposal content or reasonableness/allowability of costs will be answered. Applicants should submit any written questions regarding this program as early as possible.

Proposal Submission

The following information pertains except for submissions except those to the Clinical Translational Research (CTR) and Collaborative-CTR (C-CTR) categories. (See the following page for information on submission for these award mechanisms.)

To be considered for award, submit the following documentation to the address listed on the next page:

Proposal: 1 clearly labeled original (binder-clipped) and 30 collated photocopies (stapled or binder-clipped); please do not use rubber bands, or spiral or three-ring binders

Proposal Cover Booklet: 1 original (binder clipped to the original proposal) and 3 photocopies (***not*** binder-clipped to proposal copies)

Letters of Recommendation: If required, binder-clipped to the front of original proposal under the original Proposal Cover Booklet. See individual application instructions.

Abstract Pages: An additional 5 copies of both the technical and the public (non-technical) abstracts in a manila envelope along with a 3½" computer disk containing the abstract pages (clearly labeled with the name of the principal investigator (PI), institution, and word processing program). It is recommended that abstracts be formatted in Word, WordPerfect, or ASCII. Note: The abstracts are vital to the review of the proposal. Abstracts of all funded proposals will be reproduced in a BCRP abstract book and posted on the CDMRP website (http://cdmrp.army.mil).

Send the Proposal to:
Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702

Please package only **ONE** complete proposal submission per box. If an acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the proposal title and PI's name.

CTR and C-CTR Pre-Proposal Submissions

To be considered for full proposal submission, submit the following documentation to the address listed below:

Pre-Proposal: 1 clearly labeled original (binder-clipped) and 30 collated photocopies (stapled or binder-clipped, preferably on three-hole punched paper); please do not use rubber bands, or spiral or three-ring binders

Proposal Cover Booklet: 1 original (binder-clipped to the original pre-proposal) and 3 photocopies (***not*** binder-clipped to pre-proposal copies)

Send the Pre-Proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702

Please package only **ONE** complete pre-proposal submission per box. If an acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI's name.

Deadlines

The deadline for receipt of all submissions except CTR and C-CTR pre-proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

The deadline for receipt of CTR and C-CTR pre-proposals is April 7, 1999 at 4:00 p.m. Eastern Time.

The deadline for receipt of invited, full CTR and C-CTR proposals is July 28, 1999 at 4:00 p.m. Eastern Time.

Any proposal or pre-proposal received by the USAMRMC after the exact time specified for receipt shall not be considered unless it is received before award is made, and it:

1. was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or

2. was sent by U.S. Postal Service Express Mail Next Day Delivery (Post Office to Addressee: ***Do not use Second Day Delivery***) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline, or

3. was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline for delivery by 4:00 p.m. Eastern Time on the due date.

Investigators are advised that documentation of time of receipt by the delivery agent may be necessary if a problem should occur.

Driving Directions to Fort Detrick

Directions from Washington, DC

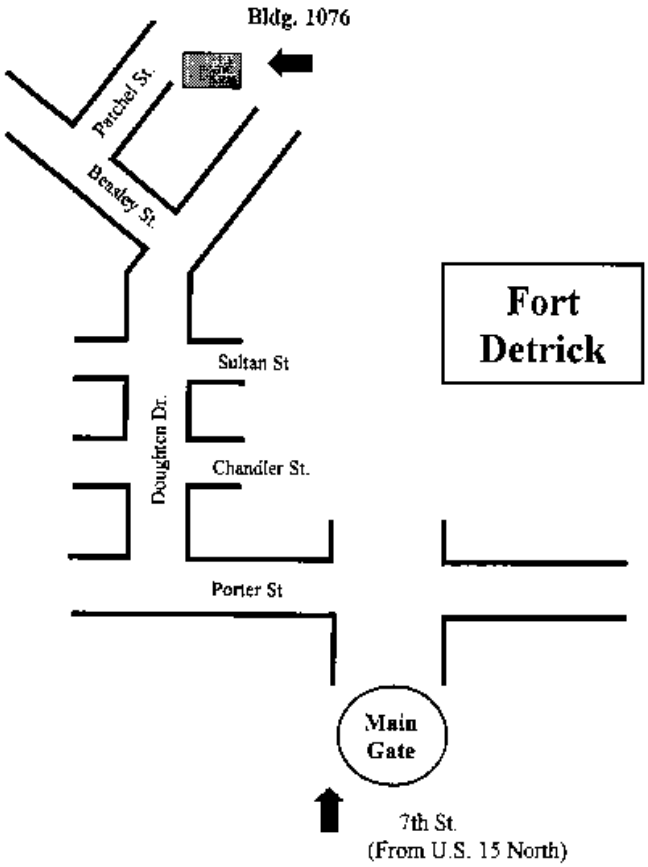
Take interstate 495 to Interstate 270 North (exit #38) toward Rockville, Maryland. At Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to 7th Street exit. Turn right on 7th Street and go four blocks to Fort Detrick's Main Gate.

Directions from Baltimore, MD

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

Map of Fort Detrick

Packages to be delivered to the Breast Cancer Research Program should be delivered to building 1076 as shown on the map below:



Breast Cancer Research Program
Bldg. 1076

Reference Table of Award Mechanisms and Submission Requirements

Award Mechanisms	Experience of PI	Key Category Elements	Dollars Available for Individual Awards	Proposal Submission Deadline	Instructions for Proposal Preparation
Career Development Award (CDA)	Assistant Professors or equivalent within 6 years of post-doctoral training, having their own, independent program of research	• To relieve applicants from academic responsibilities • Can be linked to Idea submissions	An average of $59,000/year inclusive of direct & indirect costs for up to 4 years for salary support	June 2, 1999 4:00 p.m. ET	Section VIII
Clinical Translational Research (CTR) Award	All levels of experience	• Research and clinical trial components • Must have a clinical trial within the lifetime of the award	No maximum dollar limit for up to 4 years	Pre-Proposal: April 7, 1999 4:00 p.m. ET Full Proposal: July 28, 1999 4:00 p.m. ET	Section IV
Clinical Translational Research (CTR) Career Development Award (CDA)	Clinicians with clinical trial experience; their own program of research; within 6 years of residency, fellowship, or equivalent; and rank of Assistant Professor or equivalent	• To train individuals in breast cancer related clinical translational research • Emphasis should be placed on clinical translational training • To relieve applicants from academic responsibilities	An average of $59,000/year inclusive of direct & indirect costs for up to 4 years for salary support	June 2, 1999 4:00 p.m. ET	Section XI
Clinical Translational Research (CTR) Fellowship Award	Recent medical degree graduates with less than 5 years of post-doctoral experience	• To train individuals in breast cancer related clinical translational research • Emphasis should be placed on clinical translational training	An average of $48,000/year inclusive of direct & indirect costs for up to 3 years	June 2, 1999 4:00 p.m. ET	Section X

Award Mechanisms	Experience of PI	Key Category Elements	Dollars Available for Individual Awards	Proposal Submission Deadline	Instructions for Proposal Preparation
Collaborative-Clinical Translational Research (C-CTR) Award	All levels of experience	• To (1) develop new models for performing clinical trials and (2) test new agents or technologies • Infrastructure support • To support collaborations among academia, community-based oncology clinics, and the private sector • Must contain clinical trials within the lifetime of the award	A maximum award limit of $400,000/year for direct costs for up to 3 years	Pre-Proposal: April 7, 1999 4:00 p.m. ET Full Proposal: July 28, 1999 4:00 p.m. ET	Section V
HBCU/MI*-Focused Training Awards	Faculty members (with doctoral degrees) working at an HBCU/MI with minimal or no research support and their own laboratory space; collaboration with an established investigator is required	• Collaborations between individual investigators at HBCU/MIs and investigators at another institution • To enable investigators at HBCU/MIs to better compete for breast cancer research funds in the future	Up to $150,000 for 18 months inclusive of direct & indirect costs; no more than 25% of the awarded funds should be directed toward the collaborating investigator	June 2, 1999 4:00 p.m. ET	Section XII
HBCU/MI* Partnership Training Awards	Faculty members (with doctoral degrees) working at an HBCU/MI	• Collaborations at an institutional level between an HBCU/MI and another institution • To develop a training program to increase the number of HBCU/MI investigators focused on breast cancer research	Up to $250,000/year inclusive of direct & indirect costs for up to 4 years; no more than 25% of the awarded funds should be directed toward the collaborating institution over the lifetime of the award	June 2, 1999 4:00 p.m. ET	Section XIII
Idea Awards	All levels of experience	• No preliminary data required • Reward innovative ideas and technology	An average of $75,000/year inclusive of direct costs for up to 3 years; population-based studies may request an average of $100,000/year inclusive of direct costs for up to 5 years	June 2, 1999 4:00 p.m. ET	Section III

Award Mechanisms	Experience of PI	Key Category Elements	Dollars Available for Individual Awards	Proposal Submission Deadline	Instructions for Proposal Preparation
Institutional Training Grants	All levels of experience	• To encourage the initiation of new training programs in breast cancer research for pre-doctoral and post-doctoral trainees	An average of $200,000/year inclusive of direct & indirect costs for up to 4 years	June 2, 1999 4:00 p.m. ET	Section IX
Post-doctoral Traineeships	Recent doctoral graduates with less than 5 years of post-doctoral experience	• Prepare new scientists for careers in breast cancer research	An average of $48,000/year inclusive of direct & indirect costs for up to 3 years	June 2, 1999 4:00 p.m. ET	Section VII
Pre-doctoral Traineeships	Pre-doctoral students	• Prepare new scientists for careers in breast cancer research	An average of $22,000/year inclusive of direct & indirect costs for up to 3 years	June 2, 1999 4:00 p.m. ET	Section VI

* HBCU/MI = Historically Black Colleges and Universities/Minority Institutions; Applicants from HBCU/MIs are encouraged to apply to all award mechanisms offered in this announcement.

I. Overview of the Congressionally Directed Medical Research Programs

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

In the past decade, the work of consumer advocacy organizations has dramatically influenced the way scientific research is funded in this country. Beginning in fiscal year 1992 (FY 92), the U.S. Congress has directed the Department of Defense (DOD) to manage various extramural and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) constituted the office of the Congressionally Directed Medical Research Programs (CDMRP) to administer these funds responsibly. To date, $1.1 billion has been targeted by Congress for research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense women's health, and osteoporosis. Together, these six programs comprise the CDMRP.

For each appropriation, the CDMRP has developed and refined a flexible 6-year 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 programs. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to their program, to establish an appropriate investment strategy, and to perform programmatic review as described in Section I-B.2. Based upon this investment strategy, each program then employs a variety of award mechanisms to address the most urgent needs of a research community.

Overall, the CDMRP exists to support research that will impact upon the health of all Americans. The CDMRP strives to identify gaps in funding and provide award opportunities that will enhance program research objectives without duplicating existing funding opportunities. In meeting their goals, the CDMRP has developed unique mechanisms to facilitate funding of quality research that addresses individual program objectives.

I-B. Proposal Evaluation

The CDMRP uses a two-tiered review system for proposal evaluation, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a 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-B.1. Scientific Peer Review

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

Each scientific review panel is composed of a chair, approximately 10-20 scientific reviewers, two consumer advocates, and a non-voting executive secretary. The chair and scientific reviewers are recognized leaders in their fields and are chosen on the basis of their scientific expertise. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their experience in scientific peer review. Consumer advocate reviewers are individuals who are affected by the disease, have been nominated by an advocacy organization, and have a demonstrated interest in and knowledge of the disease. The consumer advocates augment the scientific merit review by bringing the patient perspective to the assessment of science and relevance of the research.

Panel members rate each proposal based on the specific evaluation criteria developed for each award category. Two types of ratings are used. Each of the evaluation criteria, except for the budget, is rated on a scale of 1 (low merit) to 10 (high merit). The overall proposal is then given a global score using a scale of 1 (high merit) to 5 (low merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global score. A proposal may be disapproved at scientific peer review if it is so seriously flawed that its scientific merit review completion is impractical, or if gravely hazardous or unethical procedures are involved.

The proposal summary statement is a product of scientific peer review. Each statement includes an evaluation of the project as assessed by the peer reviewers with regard to evaluation criteria, the investigator's abstract (verbatim), and the global score. Summary statements not only assist investigators in assessing their research projects, but are forwarded to the next stage of the review process, programmatic review.

I-B.2. Programmatic Review

The second tier of the two-tiered review system is a programmatic review of the proposals considered eligible for funding. Programmatic review is accomplished by an IP composed of scientists and consumer advocates. The scientific 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. With their first-hand experience, the consumer advocates enhance the review process by focusing attention upon critical patient issues and outcomes. The function of the IP is to recommend an investment strategy for appropriated funds and conduct programmatic review to obtain a broad portfolio of grants across all disciplines.
Programmatic review is a comparison-based process in which proposals from multiple research

areas compete in a common pool. IP members use the proposal abstracts, summary statements, and scientific peer review scores when reviewing proposals. The statement of work may also be reviewed at this level. However, the full proposal is not forwarded for programmatic review.

Programmatic review balances the potential outcomes and risks of scientifically excellent proposals. The IP does not automatically recommend funding for all proposals highly scored by scientific peer review panels, nor does it re-review the scientific and technical merit. The criteria the IP uses to make funding recommendations are:

1. ratings and recommendations of the peer review panels;
2. programmatic relevance;
3. scientific innovation;
4. program portfolio balance with respect to research disciplines or specialty areas;
5. other equitable factors such as adequate support for young investigators, gender, minority status, and geographic distribution; and
6. research targeting special populations.

Scientifically excellent studies that directly address the unique focus and goals of the program are most likely to be recommended to the Commanding General (CG), USAMRMC, for funding.

II. Department of Defense Breast Cancer Research Program

II-A. History of the Breast Cancer Research Program

In 1993, a grassroots advocacy movement heightened political awareness of breast cancer as a major women's health issue. Federal budgetary opportunities spurred Congress to appropriate $210 M to the DOD budget for a peer reviewed breast cancer research program. Since then, Congress has continued to appropriate money for breast cancer research managed by the USAMRMC. To date, Congress has appropriated more than $840 M to the DOD through the Breast Cancer Research Program (BCRP), a multidisciplinary effort aimed at the eradication of breast cancer.

The program history for FYs 93 through 97 of the BCRP is shown in Table II-1 below.

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

	FY 93/94	**FY 95**	**FY 96**	**FY 97**	**FY 98[1]**
BCRP-Managed Appropriations for Peer Reviewed Research	$240 M	$150 M	$75 M	$108.3 M	$135 M
Number of full Proposals Received	2,678	2,209	2,509	1,938	1,322
Number of Proposals Funded	444	291	303	338	410
Percentage of Applications Recommended for Funding	17%	13%	12%	17%	31%
Number of Research/Infrastructure/ Cancer Center Awards[2]	308	202	153	217	261
Number of Training/Recruitment Awards	136	89	150	121	149
Number of CTR Proposals Received					
CTR pre-proposals	n/a	n/a	n/a	243	107
CTR full proposals	n/a	n/a	362[3]	64	45
Number of CTR Awards	n/a	n/a	8	11	8

[1]Final numbers for 1998 will be available after September 30, 1999.

[2]Includes Clinical Translational Research (CTR) Awards.

[3]Translational proposals were submitted to the Research with Translational Potential category in 1996; pre-proposals were not requested during this funding cycle.

II-B. Overview of the FY 99 BCRP

The USAMRMC, through this Program Announcement, is soliciting applications on breast cancer research. The overall goal of this funding effort 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 the prevention, detection, diagnosis, and treatment 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, socio-cultural, 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 under-represented and/or medically under-served 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. FY 99 Program Emphasis Areas

For the FY 99 BCRP, an estimated $110 M will be available to fund peer reviewed research. The programmatic strategy for FY 99 is to fund proposals in three categories: (1) Research Awards, (2) Infrastructure Awards, and (3) Training/Recruitment Awards. In addition, a percentage of the available monies will be set aside to fund Research, Infrastructure, and Training/Recruitment Awards at Historically Black Colleges and Universities/Minority Institutions (HBCU/MIs).

Prospective responders familiar with USAMRMC programs from previous years are urged to review this Program Announcement carefully, as revisions to award category definitions and submission requirements have been made.

II-C.1. Research Awards

Approximately $69 M will be allocated for Research Awards, which consist of Idea Awards (Section III) and Clinical Translational Research (CTR) Awards (Section IV). The intent of Idea Awards is to stimulate and reward creative research ideas that may be viewed as speculative, but with the potential for high payoff. CTR Awards are intended to support projects that apply promising, well-founded laboratory or other preclinical research to the clinical care of patients with, or populations at risk for, breast cancer.

II-C.2. Infrastructure Awards

Approximately $10 M will be allocated for Infrastructure Awards, which consist of Collaborative-CTR (C-CTR) Awards (Section V). The intent of C-CTR Awards is to foster the development of highly effective collaborative and consortia models to evaluate promising agents and technologies in well-designed clinical trials that utilize the combined resources of academia, the private sector, and community-based oncology clinics.

II-C.3. Training/Recruitment Awards

Approximately $25 M will be allocated for Training/Recruitment Awards: Pre-doctoral Traineeship Awards (Section VI), Post-doctoral Traineeship Awards (Section VII), Career Development Awards (CDAs) (Section VIII), Institutional Training Grants (ITGs) (Section IX), CTR Fellowship Awards (Section X), and CTR CDAs (Section XI). Pre-doctoral Traineeship Awards are direct individual awards to promising graduate students studying breast cancer under the guidance of a designated mentor. Post-doctoral Traineeship Awards should enable recent doctoral degree graduates with limited post-doctoral experience to gain additional experience in breast cancer research. CDAs are intended to free scientists at the Assistant Professor (or equivalent) level of academic responsibilities to allow them additional time to pursue breast cancer research. ITGs are intended to encourage the initiation of new pre-doctoral and/or post-doctoral training programs in breast cancer research. CTR Fellowship Awards and CDAs should enhance the education of individuals who wish to pursue a career in breast cancer clinical translational research.

Two additional training awards are targeted toward HBCU/MIs. These awards, which are not included in the $25 M allocation for Training/Recruitment Awards, will be supported with some of the funds from the HBCU/MI set aside described in the Section II.D (below) and Appendix B. HBCU/MI-Focused Training Awards are intended to enable individual investigators at HBCU/MIs to collaborate, train, and acquire the knowledge and experience needed to design fundable breast cancer research grants. HBCU/MI Partnership Training Awards are intended to provide assistance at an institutional level by forming collaborations between HBCU/MIs and other institutions.

II-D. Set Aside for Historically Black Colleges and Universities/Minority Institutions

Approximately $6 M will be set aside to support research at HBCU/MIs. This set aside is intended to "advance the development of human potential, to strengthen the capacity of Historically Black Colleges and Universities/Minority Institutions to provide quality education, and to increase opportunities to participate in and benefit from Federal programs."[1] Colleges and universities that qualify as HBCU/MIs, as determined by the Department of Education, are posted on the CDMRP website (http://cdmrp.army.mil).

[1]Executive Order 12876; see also Executive Orders 12900 and 13021.

Proposals are encouraged from minority investigators as well as investigators of any ethnicity working at an HBCU/MI. To apply for an HBCU/MI-Focused Training Award or an HBCU/MI Partnership Training Award, the PI must be appointed at an HBCU/MI. In addition, investigators at HBCU/MIs are encouraged to apply to all other Research, Infrastructure, and Training Awards offered in this announcement.

II-E. Breast Cancer Stamp

The Stamp Out Breast Cancer Act was legislation enacted in 1997 that authorized postal patrons to contribute funds for breast cancer research through the voluntary purchase of specially issued U.S. postage stamps (H.R. 1585). The Breast Cancer Stamp was released in August 1998. The dollars accrued for breast cancer research are divided between the National Institutes of Health (70%) and the DOD BCRP (30%). As of January 1999, the BCRP has received approximately $800,000. Additional payments are anticipated through July 2000. The DOD plans to use all Breast Cancer Stamp monies received prior to November 1999 to fund additional scientifically meritorious Idea proposals submitted in response to this Program Announcement.

III. Idea Awards

III-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 with 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 III-1. 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.

Table III-1: Differences between Traditional Research Proposals and Idea Research Proposals

Type of Proposal	Preliminary or Pilot Data	Research Approach
Traditional Research Proposal	Required	Expansion of well-established avenues of research
Idea Award Research Proposal	Not required (can be included if available)	Novel, challenging existing paradigms, high risk

Approximately $51 M will be available for Idea Awards. Funding for Idea Awards can be requested for an average of $75,000 per year in direct costs, for a maximum of $225,000 over 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 an average of $100,000 per year in direct costs for a maximum of $500,000 over 5 years, plus indirect costs as appropriate. Funds can be requested for salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

Additionally, Idea Award submissions can be linked with CDA proposals that focus on the same research. Linked CDA/Idea proposals will be reviewed as a single entity. During programmatic review, either both or neither proposal will be recommended for funding. Applicants who submit a CDA and Idea Award proposal that address the same research question must indicate on the title page that these submissions are linked.

III-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? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Preliminary data are not required but may be included. If included, do the preliminary data support the scientific rationale for the study?

- **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 under-explored or unexplored areas?

- **Scientific Relevance & 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 the scientific environment 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 reasonable for the research proposed?

III-C. Programmatic Review - Evaluation Criteria for Idea Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the biology, prevention, detection, diagnosis, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

III-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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

III-E. Proposal Preparation

The following proposal preparation information is specific for the Idea Award mechanism. Please note that the body of the proposal is limited to 10 pages and that the deadline for receipt is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents below in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

Idea Award
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Page Number

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, Idea Award applicants should state explicitly (within the 1 page limit) how the proposed work is innovative and relevant to breast cancer biology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of innovation and relevance in the proposal will have an impact upon and further the programmatic goals.

10. Proposal Body – See Appendix B, part 10

The body of Idea Award proposals is limited to 10 pages. The body of the proposal will consist of two parts. Both the overall page limit of 10 pages for the body and the page limit for each part of the proposal body must be followed.

A. Research Project - 5 page limit

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 <u>not</u> required for Idea Award proposals; 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:

(1) Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to the proposal. Cite relevant literature references.
(2) Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.
(3) Objectives: State concisely the specific aims of the study.
(4) 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. All figures, tables, and diagrams must be included within the proposal body (See B.- Figures/Tables below).

B. Figures/Tables - 5 page limit

Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketch.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15

16. Detailed Cost Estimate – See Appendix B, part 16

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of Idea Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

III-F. Reports

Idea Awards will require the timely delivery of several reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress.

The PIs of Idea Awards should plan on a requirement that consists of:

1. an **ANNUAL** report (for each year of research except the final year) that presents a detailed summary of findings (positive and negative), scientific issues, and accomplishments; and

2. a **FINAL** report (submitted in the last year of the grant period) that details the findings and accomplishments for the entire project.

The USAMRMC will notify PIs when these reports are due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the

USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

IV. Clinical Translational Research Awards

IV-A. Clinical Translational Research Awards

The intent of Clinical Translational Research (CTR) Awards is to extend recent findings in breast cancer research that offer the potential to revolutionize the practice of breast cancer care. CTR Awards support projects that are likely to have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer by applying promising and well-founded laboratory or other pre-clinical research findings to the care of patients with, or populations at risk for, breast cancer. Applicants must include preliminary data to support the feasibility of their hypotheses and approaches, along with a plan to conduct a prospective clinical trial or study during the course of the award. A requirement for consideration will be the inclusion of a clear experimental and appropriately powered statistical plan to perform a prospective clinical trial or study. Information should be provided to demonstrate that patients will be accrued for a minimum of 1 year in the proposed clinical trial during the lifetime of the award. These awards are intended to support both new and established scientists across a broad spectrum of disciplines. Ultimately, the goal of the CTR category is to sponsor novel research that will result in substantial improvements over today's approach to the prevention, detection, diagnosis, and/or treatment of breast cancer.

Approximately $18 M is available for CTR Awards. There are no dollar amount restrictions to these awards. Research should be completed in 4 years. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. As noted in Appendix E, it is the policy of the DOD that the equipment needed to support proposed research will be provided only in rare cases. The focus of the CTR Award should be on the clinical trial and work leading to the clinical trial. Therefore, in the rare cases that equipment/infrastructure costs can be justified, the total cost should be no more than 10% of the direct costs of the project. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

CTR submissions will be evaluated using the following review process:

1. A short pre-proposal, to be received no later than April 7, 1999 at 4:00 PM Eastern Time, will be screened. Selected investigators will be invited to submit a full proposal.

2. Invited, full proposals, to be received no later than July 28, 1999 at 4:00 PM Eastern Time, will be evaluated by the CDMRP two-tier review system described in Section I-B.

IV-B. Screening Criteria - Clinical Translational Research Award Pre-Proposals

Pre-proposals will be screened, and selected investigators will be invited to submit a full proposal based on the following criteria:

1. the application of well-founded laboratory or other preclinical insights that offer the potential to revolutionize the prevention, early detection, diagnosis, and/or treatment of breast cancer;

2. the outline of a clear experimental plan for a prospective human clinical study or trial that will be performed within the lifetime of the award;

3. the outline of a clear appropriately powered statistical plan to answer the research questions posed;

4. the likelihood of accruing patients in the proposed prospective trial for a minimum of 1 year; and

5. the project's potential to extend findings in breast cancer research that offer the potential to revolutionize breast cancer prevention, early detection, diagnosis, and/or treatment.

IV-C. Scientific Peer Review - Evaluation Criteria for Full, Invited Clinical Translational Research Award Proposals

Based upon the pre-proposal screening, selected investigators will be invited to submit a full CTR proposal. Invited, full CTR proposals will be evaluated in scientific peer review according to the following criteria:

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated, including laboratory and other preclinical evidence, to support the clinical feasibility and promise of the approach? Does the prospective clinical trial at least begin to investigate the impact on prevention, detection, diagnosis, and/or treatment within the lifetime of the grant? Does the applicant acknowledge potential problem areas and consider alternative approaches? Does the applicant demonstrate sufficient patient accural?

- **Translational Potential:** Is the project likely to result in patient accrual in the proposed prospective trial so that a minimum of 1 year of patient accrual can be achieved, presumably in the final year of the grant? Does the project apply promising and well-founded laboratory or other preclinical research findings to the care of patients with, or populations at risk for, breast cancer? Does the project form a bridge between laboratory

and other preclinical findings and a 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?

- **Clinical Relevance & Impact:** Is the project likely to extend recent findings in breast cancer research that offer the potential to revolutionize the practice of breast cancer care? Does the study address an important problem related to the prevention, detection, diagnosis, and/or treatment of human breast cancer? If the aims of the application are achieved, are they likely to have a substantial clinical impact?

- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new, under-explored, or unexplored areas?

- **Statistical Plan:** Is the design of the clinical trial sound and sufficiently well developed with the required statistical power to lead to significant results? Is there a clear statistical plan, including power analysis, outlined in the proposal? Is the appropriate statistical expertise represented on the research team?

- **Principal Investigator and Staff:** Is the PI appropriately trained and well suited to carry out this work? Are the other scientific personnel well qualified to participate in the project? Is there representation from all the areas of expertise needed to conduct the study successfully?

- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the preclinical and clinical requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?

- **Budget:** Is the budget reasonable for the research proposed?

IV-D. Programmatic Review - Evaluation Criteria for Full, Invited Clinical Translational Research Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

IV-E. Letter of Intent

All applicants considering submission of a pre-proposal in response to this Program Announcement are requested to submit a "Letter of Intent" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

IV-F. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for the CTR Award mechanism. Please note that the body of the pre-proposal is limited to 2 pages and that the deadline for receipt is April 7, 1999 at 4:00 p.m. Eastern Time. Investigators selected to submit a full proposal will be notified and sent CTR Supplemental Instructions no later than April 29, 1999. The full CTR proposal will be due no later than July 28, 1999 at 4:00 p.m. Eastern Time. Please note that the time table for the CTR and C-CTR pre-proposal and proposal submissions is different from the other proposal categories outlined in this announcement.

1. Who May Apply – See Appendix B, part 1

2. Pre-Proposal Acceptance Criteria – See Appendix B, part 2
   (Please note: The same acceptance criteria are applied to pre-proposals as full proposals.)

3. Pre-Proposal Cover Booklet – See Appendix B, part 3

4. The Pre-Proposal Title Page shall include the following information:
   A. Pre-Proposal Title
   B. Award Category; i.e., CTR
   C. PI's full name, including middle initial
   D. PI's phone and fax numbers
   E. Organization name and location (including city, state, zip or postal code, and country)

5. Pre-Proposal Translatability Statement – Limited to 1 page
   Applicants should state explicitly how the proposed work is translatable, i.e., how it will result in a prospective clinical trial during the lifetime of the award. Articulate how the proposed work will further the program's goals and meet the intent of the CTR Award mechanism.

6. Pre-Proposal Body – Limited to 2 pages
   It is the responsibility of the investigator to articulate clearly how the proposed research specifically addresses the screening criteria for pre-proposals.

7. References – Limited to 1 page
   List all relevant references using a standard reference format that includes the full citation (i.e., authors, year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

8. Biographical Sketches – Limited to 3 pages/investigator
   Investigators must include a description of their experience in breast cancer research. Biographical sketches should be prepared for key personnel, including collaborating investigators. Biographical sketches may not exceed 3 pages per investigator. The "Biographical Sketch" form can be found in Appendix D, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or their potential for contribution to the field of breast cancer research should be incorporated into the biographical sketches.

9. To be considered, submit the following documentation to the address listed below:

Pre-Proposal:	1 clearly labeled original (binder-clipped) and 30 collated photocopies (stapled or binder-clipped, preferably on three-hole punched paper); please do not use rubber bands, or spiral or three-ring binders
Proposal Cover Booklet:	1 original (binder-clipped to the original pre-proposal) and 3 photocopies (***not*** binder-clipped to pre-proposal copies)
Send the pre-proposal to:	Commander U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (BCRP99-Announcement) 1076 Patchel Street (Building 1076) Fort Detrick, MD 21702

Please package only **ONE** complete pre-proposal submission per box. If an acknowledgement of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI's

name.

10. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of CTR pre-proposals is April 7, 1999 at 4:00 p.m. Eastern Time. The deadline for receipt of invited, full CTR proposals is July 28, 1999 at 4:00 p.m. Eastern Time.

V. Collaborative-Clinical Translational Research Awards

V-A. Collaborative-Clinical Translational Research Awards

Note: The goals of this new award mechanism are (1) to support the infrastructure costs (personnel) required to develop new consortium models that include academic centers, community based oncology practices, and the private sector for the express purpose of performing clinical trials and (2) to test new agents or technologies to accelerate the eradication of breast cancer. Proposals that also include the participation of breast cancer consumer/survivor groups will receive special consideration.

The Collaborative-Clinical Translational Research (C-CTR) Awards are being offered specifically to support the development of the infrastructure required to facilitate the performance of well-designed clinical trials through new consortium models to evaluate promising drugs and technologies for the early detection, treatment, and prevention of breast cancer. These awards should clearly enhance patient participation in clinical trials by bringing together the resources of academia (i.e., medical centers), community-based oncology practices, and the private sector, to translate promising new agents and technologies to accelerate the eradication of breast cancer. This award is not intended to replace, supplement, duplicate, or compete with traditional academic/community research efforts such as the National Cancer Institute supported cooperative groups, CCOPs (Community Clinical Oncology Programs), or CGOPs (Cooperative Group Outreach Programs).

New models for performing breast cancer clinical trials through novel partnerships must be the focus of C-CTR Awards. These new models must specifically address the following needs: (1) decrease the time to perform a clinical trial; (2) increase the participation of patients with, and populations at risk for, breast cancer in clinical trials by making clinical trials more accessible through community oncologists; and (3) increase the number of drugs, modalities (including biological agents), or technologies tested for breast cancer. Also, applicants are encouraged to form collaborations with consumer/survivor organizations in the hope that this will increase patient accrual in the planned clinical trials. C-CTR Awards will provide funds to bring together all the necessary parties to develop and execute clinical trials that will be performed through the support for infrastructure. The proposal, in addition to providing a clear plan for the creation of the infrastructure to support the appropriate breast cancer clinical trials, must plan to test multiple novel drugs, modalities, or technologies during the award period. It is anticipated that most of these new approaches will be drugs, modalities, and technologies in development by industry, e.g., pharmaceutical, biotechnology, or other companies. Full proposals also must include a letter of intent that clearly demonstrates a commitment from an industrial partner (e.g., a pharmaceutical company providing access to new drugs/modalities/treatments/diagnostics).

Therefore, the following items are essential:

1. drugs, modalities, or technologies ready for clinical trials (phase I or II) with appropriate scientific hypothesis and plan

2. a central institution coordinating a program that will include community-based oncology practices, the private sector, and academic center(s)

3. community-based oncology practices with sufficient patient populations willing to participate

4. a clear plan to provide the required personnel, financial resources, and coordination at the level necessary to conduct the proposed trials

Proposals that include the participation of breast cancer consumer/survivor groups will receive special consideration.

At the completion of the funding period, the project must be able to demonstrate the following:

1. the testing of novel drugs, modalities, or technologies in well-designed prospective clinical trials with appropriate hypotheses that clearly demonstrates increased efficiency, patient enrollment, and participation of community-based oncologists and patients, over existing models for performing clinical trials

2. the successful development of a novel collaboration or consortium that includes academic center(s), community-based oncology practices, and the private sector, to execute clinical trials that can efficiently accrue patients

3. significant patient accrual and demonstrable results from clinical trials of multiple drugs, modalities, or technologies.

The following issues also should be considered when applying for C-CTR Awards.

1. Proposals should include data on pre-clinical results that clearly demonstrate that the drugs, modalities, or technologies are ready to be tested in clinical trials.

2. The C-CTR is not an appropriate funding mechanism for pre-clinical drug, modality, or technology development.

3. A requirement for consideration will be the inclusion of a clear experimental and statistical plan to perform prospective clinical trials.

Approximately $10 M is available to support C-CTR awards. Support can be requested for up to $400,000 per year in direct costs, for a maximum of $1,200,000 over 3 years, plus indirect costs as appropriate. Funds may be used to support clinical research nurses and/or data management personnel for clinical data management and clinical outreach. Funds are not intended to support direct patient costs. Applicants are encouraged to increase the effective resource base for these studies by developing partnerships with private industry for additional funding support. As noted in Appendix E, it is the policy of the DOD that the equipment needed to support the proposed

research should be provided only in rare cases. Therefore, in the rare cases that equipment costs can be justified, the total cost should be no more than 5% of the direct costs of the project. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, funding also 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 2 of the "Detailed Cost Estimate."

V-B. Screening Criteria - Collaborative-Clinical Translational Research Award Pre-Proposals

Pre-proposals will be screened, and selected investigators will be invited to submit a full proposal based on the following criteria:

1. evidence to clearly show that the drugs, modalities, or technologies are ready for clinical trials;

2. the application of well-founded laboratory or other pre-clinical findings to the prevention, detection, diagnosis, or treatment of patients with, or populations at risk for, breast cancer;

3. the development of a clear collaboration among academic medical center(s), community-based oncology practices, the private sector, and possibly consumer/survivor organizations with one organization acting as the coordinating institution;

4. the outline of a clear experimental plan to perform peer reviewed prospective human clinical trials;

5. documentation of sufficient patient populations willing to participate in prospective clinical trials and potential for significant patient accrual;

6. the outline of a clear, appropriately powered statistical plan to answer the research questions posed;

7. the likelihood of obtaining initial clinical results within the lifetime of the award;

8. an explanation of why the proposed model is expected to accelerate the translation of new agents or technologies into clinical practice to support the eradication of breast cancer; and

9. the project's potential to have a major impact on breast cancer prevention, detection, diagnosis, and/or treatment.

V-C. Scientific Peer Review - Evaluation Criteria for Full, Invited Collaborative-Clinical Translational Research Award Proposals

Based upon the pre-proposal screening, selected investigators will be invited to submit a full C-CTR proposal. Invited, full C-CTR proposals will be evaluated in scientific peer review according to the criteria listed below.

- **Available Agents or Technology:** Does the applicant clearly demonstrate sufficient evidence that multiple drugs, modalities, or technologies are available for testing in clinical trials? Are the agents to be tested ones that would provide new insights into the prevention, detection, diagnosis, and/or treatment of breast cancer?

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated, including laboratory and other pre-clinical evidence to support the clinical feasibility and promise of the approach? Do the prospective clinical trials investigate the impact on prevention, detection, diagnosis, and/or treatment within the lifetime of the grant? Does the applicant acknowledge potential problem areas and consider alternative approaches? Has a plan been developed to test multiple agents in prospective clinical trials within the lifetime of the award?

- **Collaborations:** Has an outline for outreach collaboration been developed? Are these community collaborations likely to lead to increased patient accrual? Are the collaborations with community-based oncology practices likely to be successful? Does the collaboration offer the opportunity to provide additional experience and training for practioners at community oncology clinics? Have new networks for testing new and/or innovative models for early clinical trials been developed? Is the private sector an active participant in this effort as demonstrated by the letter of intent? Is the application further strengthened by the involvement of consumer/survivor organization collaboration?

- **Patient Populations:** Are there sufficient documented patient populations available to perform the prospective clinical trials successfully? Has the ethnic diversity of the patient population been considered appropriately in developing community collaborations?

- **Translational Potential:** Is the project likely to produce statistically significant clinical results within the lifetime of the award? Does the project apply promising and well-founded laboratory or other pre-clinical research findings to the care of patients with, or populations at risk for, breast cancer? Does the collaborative model have the potential to result in substantial improvements over today's approaches to translating new agents and technologies into new strategies for the prevention, detection, diagnosis, and/or treatment of breast cancer?

- **Clinical Relevance & Impact:** Does this study address an important problem related to the prevention, detection, diagnosis, and/or treatment of human breast cancer? If the aims of the application are achieved, are they likely to have a significant impact on the prevention, early detection, and/or treatment of breast cancer?

- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Are the proposed collaborations a novel way to perform clinical trials? Does the project challenge existing paradigms or develop new, under-explored, or unexplored areas?

- **Statistical Plan:** Is the design of the clinical trials sound and sufficiently well developed with the required statistical power to lead to significant results? Is there a clear statistical plan including power analysis outlined in the proposals? Is the appropriate statistical expertise represented in the research team?

- **Principal Investigator and Staff:** Is the PI appropriately trained and well suited to carry out this work? Are the other scientific personnel well qualified to participate in the project? Is there representation from all the areas of expertise needed to conduct the study successfully? Does the supporting documentation demonstrate the ability of all participants to execute the project goals successfully?

- **Environment:** Are the scientific environments and community-based oncology practices appropriate settings for the proposed research? Are the collaborators appropriate to test whether the proposed model can be extended to other institutions to test other agents ready for clinical trials? Are the pre-clinical and clinical requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?

- **Budget:** Is the budget reasonable for the research proposed?

V-D. Programmatic Review - Evaluation Criteria for Full, Invited Collaborative-Clinical Translational Research Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

V-E. Letter of Intent

All applicants considering submission of a pre-proposal in response to this Program Announcement are requested to submit a "Letter of Intent" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

V-F. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for the C-CTR Award mechanism. Please note that the body of the pre-proposal is limited to 3 pages and that the deadline for submission is April 7, 1999 at 4:00 p.m. Eastern Time. Investigators selected to submit a full proposal will be notified and sent C-CTR Supplemental Instructions no later than April 29, 1999. The full C-CTR proposal will be due no later than July 28, 1999 at 4:00 p.m Eastern Time. Please note that the time table for C-CTR pre-proposal and proposal submissions is different from other proposal categories outlined in this announcement.

1. Who May Apply – See Appendix B, part 1

2. Pre-Proposal Acceptance Criteria – See Appendix B, part 2
   (Please note: The same acceptance criteria are applied to pre-proposals as full proposals)

3. Pre-Proposal Cover Booklet – See Appendix B, part 3

4. The Pre-Proposal Title Page should include the following information:
   A. Pre-Proposal Title
   B. Award Category; i.e., C-CTR
   C. PI's full name, including middle initial
   D. PI's phone and fax numbers
   E. Organization name and location (including city, state, zip or postal code, and country)

5. Pre-Proposal Body – Limited to 3 pages
   It is the responsibility of the investigator to clearly articulate how the proposed research meets the pre-screening criteria. At least 1 page should be dedicated to outlining the community clinic design.

6. References – Limited to 1 page
   List all relevant references using a standard reference format that includes the full citation (i.e., authors, year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

7. Biographical Sketches – Limited to 3 pages/investigator
   Biographical sketches should be prepared for key personnel, including a collaborating investigator at each community clinic. Biographical sketches may not exceed 3 pages per investigator. The "Biographical Sketch" form can be found in Appendix D, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or their potential for contribution to the field of breast cancer research should be incorporated into the biographical sketches.

8. To be considered, submit the following documentation to the address listed below:

   Pre-Proposal: 1 clearly labeled original (binder-clipped) and 30 collated photocopies (stapled or binder-clipped, preferably on three-hole punched paper); please do not use rubber bands, or spiral or three-ring binders

   Proposal Cover Booklet: 1 original (binder-clipped to the original pre-proposal) and 3 photocopies (***not*** binder-clipped to pre-proposal copies)

   Send the pre-proposal to: Commander
   U.S. Army Medical Research and Materiel Command
   ATTN: MCMR-PLF (BCRP99-Announcement)
   1076 Patchel Street (Building 1076)
   Fort Detrick, MD 21702

   Please package only **ONE** complete pre-proposal submission per box. If an acknowledgement of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI's name.

9. Submission Deadlines – See Appendix B, part 20
   The deadline for receipt of C-CTR pre-proposals is April 7, 1999 at 4:00 p.m. Eastern Time. The deadline for receipt of invited, full C-CTR proposals is July 28, 1999 at 4:00 p.m. Eastern Time.

VI. Pre-doctoral Traineeship Awards

VI-A. Pre-doctoral Traineeship Award Category

The intent of Pre-doctoral Traineeship Awards is to make direct individual awards to promising graduate students studying breast cancer under the guidance of a designated mentor. The overall goal of Pre-doctoral Traineeship Awards is to prepare individuals for a career in breast cancer research. Individuals enrolled in an M.D./Ph.D. program are encouraged to apply. The important components of these applications are:

1. mentor and training environment,
2. the applicant's interim plans after the completion of the proposed project, and
3. supporting documentation:
   A. the applicant's biographical sketch,
   B. the mentor's biographical sketch including his/her qualifications and previous training experience,
   C. official copies of the trainee's undergraduate and graduate transcripts,
   D. a letter of support from the mentor, and
   E. 2-3 letters of recommendation.

Pre-doctoral Traineeship proposals shall be written and signed by the trainee as the PI and author of the proposal. Proposals will not be evaluated, nor will awards be made, for "to be named" trainees. Pre-doctoral Traineeship applicants must describe both the training program and their career goals in the body of the proposal.

Approximately $3 M will be available for Pre-doctoral Traineeship Awards. Pre-doctoral 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. These funds 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. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

VI-B. Scientific Peer Review - Evaluation Criteria for Pre-doctoral Traineeship Proposals

Pre-doctoral Traineeship proposals will be evaluated according to the criteria listed below.

- **Candidate:** Do the candidate's achievements to date (as measured by background, academic performance, awards, and honors) make him or her qualified for pre-doctoral training? What are the candidate's stated career goals? What are the applicant'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 the trainee will acquire the necessary skills and knowledge about the scientific area being studied? Is the research proposed likely to give the applicant 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 to accomplishing the candidate's goals? Are the research and training requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?

- **Relevance:** Does the pre-doctoral 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 reasonable for the work proposed? Are there sufficient overall financial resources to support the proposed research?

VI-C. Programmatic Review - Evaluation Criteria for Pre-doctoral Traineeship Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

VI-E. Proposal Preparation

The following proposal preparation information is specific for Pre-doctoral Traineeships. Please note that the body of the proposal is limited to 6 pages and that the deadline for submission is June 2, 1999 at 4:00 p.m. Eastern Time.

1. Who May Apply – See Appendix B, part 1
   Pre-doctoral 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. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

Pre-doctoral Traineeship Award
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9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, pre-doctoral 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, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the applicant for a career in the battle against breast cancer.

10. Proposal Body – See Appendix B, part 10
    The body of Pre-doctoral Traineeship proposals is limited to 6 pages. The body of the proposal should consist of three parts. Both the overall page limit of 6 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Research Project/Training Plans - Prepared by the applicant - 3 page limit.
       (1) Description of Research Project: Describe the proposed project using the **general** outline provided below.
           (a) Background: Briefly describe the ideas behind the proposed work and 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 of the project.

(d) Methods: Give details about the experimental design and methodology.

(2) Description of the Research Training: Describe the research training in which the applicant will participate such as coursework, laboratory techniques, conferences, and journal clubs.

(3) Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development. Discuss the applicant's research plans after the completion of this award.

B. Figures/Tables - 2 page limit

Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

C. 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 pre-doctoral students should also 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 13 on the following page.)

Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

For Pre-doctoral Traineeship proposals, biographical sketches should be prepared for the applicant, collaborating investigators, and the mentor. The mentor's biographical sketch should include his/her qualifications, especially in breast cancer research, and previous experience in training students and pre-doctoral trainees. A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13
    For Pre-doctoral Traineeships, it is especially important to provide documentation of existing/pending support involving the mentor to show that there is adequate support in the training environment for the pre-doctoral trainee.

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    The following support documentation shall be provided in the proposal submission:

    A. Official transcripts from undergraduate institutions and graduate-level courses completed to date.

    B. 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 relationship with the trainee. This letter is to be sent from the mentor to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that the mentor's letter of support is not misplaced, the sealed envelope should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support <u>will not</u> be accepted separately from the application.

    C. Two additional letters of recommendation are to be sent from the references to the applicant in **sealed** envelopes for forwarding, unopened, with the application. To ensure that the letters of reference are not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of recommendation <u>will not</u> be accepted separately from the application.

    To document the sources of these letters, please include in the Support Documentation section of the application a list of the names, positions, and grant function (e.g., mentor, recommender) of authors of the letters. However, please attach the letters in sealed envelopes with a binder clip to the original proposal underneath the Proposal Cover Booklet.

    Finally, the Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of Pre-doctoral Traineeship Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

VI-F. Reports

Pre-doctoral Traineeship Awards will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress.

The PIs of Pre-doctoral Traineeships will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

VII. Post-doctoral Traineeship Awards

VII-A. Post-doctoral Traineeship Award Category

The intent of Post-doctoral Traineeship Awards is to enable recent doctoral degree graduates with limited post-doctoral experience (i.e., less than 5 years) to either extend ongoing research related to breast cancer or broaden the scope of their research to include work relevant to breast cancer, under the guidance of a designated mentor. 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. Individuals with a Ph.D., M.D., D.V.M., D.D.S./D.M.D., or other equivalent degree are encouraged to apply. The research focus of Post-doctoral Traineeships should address an issue relevant to breast cancer biology, prevention, detection, diagnosis, and/or therapy.

The overall goal of Post-doctoral Traineeship Awards is to prepare individuals for a career in breast cancer research. Therefore, important components of these applications are:

1. mentor and training environment,
2. the applicant's plans after completion of the proposed project, and
3. supporting documentation:
   A. the applicant's biographical sketch,
   B. the mentor's biographical sketch including his/her qualifications and previous training experience,
   C. official copies of the trainee's undergraduate and graduate transcripts,
   D. a letter of support from the mentor, and
   E. 2-3 letters of recommendation.

Post-doctoral Traineeship proposals shall be written and signed by the trainee as the PI and author of the proposal. Proposals will not be evaluated, nor will awards be made for "to be named" trainees. Post-doctoral Traineeship applicants must describe both the training program and their goals in the body of the proposal.

Approximately $6 M will be available for Post-doctoral Traineeship Awards. Post-doctoral Traineeships can be requested for an average of $48,000 per year, inclusive of direct and indirect costs, for a maximum of $144,000 over 3 years. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

VII-B. Scientific Peer Review - Evaluation Criteria for Post-doctoral Traineeship Proposals

Post-doctoral 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 a well-qualified candidate for post-doctoral training? Does the candidate have a record of previous research experience, publications, and/or related professional training that indicates suitability for a research career? What are the applicant'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 is the mentor's previous research training experience with post-doctoral trainees?

- **Research 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 post-doctoral training take place in an environment that is appropriate to accomplishing the candidate's goals? Are the research requirements 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 post-doctoral training relate to an important problem in breast cancer research? Is the proposed research likely to train and encourage the trainee to pursue a career in breast cancer research? Does the application make a convincing case for the relevance of the research to breast cancer?

- **Budget:** Is the budget reasonable for the work proposed? Are there sufficient overall financial resources to support the proposed research?

VII-C. Programmatic Review - Evaluation Criteria for Post-doctoral Traineeship Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

VII-E. Proposal Preparation

The following proposal preparation information is specific for Post-doctoral Traineeships. Please note that the body of the proposal is limited to 8 pages and that the deadline for receipt is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

Post-doctoral Traineeship Award
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9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, Post-doctoral applicants should describe explicitly (within the 1 page limit) the training value of the proposed research concept relative to the applicant's career goals in breast cancer research and how the proposed research is pertinent to one or more critical issues in breast cancer biology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the applicant for a career in the battle against breast cancer.

10. Proposal Body – See Appendix B, part 10
    The body of Post-doctoral Traineeship proposals is limited to 8 pages. The body of the proposal should consist of three parts. Both the overall page limit of 8 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Research Project/Training Plans - Prepared by the applicant - 4 page limit.
       (1) Description of Research Project: Describe the proposed project using the **general** outline provided on the following page.

(a) Background: Briefly describe the ideas behind the proposed work and 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 of the project.
(d) Methods: Give details about the experimental design and methodology.

(2) Description of the Research Training: Describe the research training in which the applicant will participate such as coursework, laboratory techniques, conferences, and journal clubs.

(3) 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.

B. Figures/Tables - 3 page limit

Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

C. 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 pre-doctoral students should also 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 13 on the following page.)

Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

For Post-doctoral Traineeship proposals, biographical sketches should be prepared for the applicant, collaborating investigators, and the mentor. The mentor's biographical sketch should include his/her qualifications, especially in breast cancer research, and previous experience in training students and post-doctoral fellows. A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13
    For Post-doctoral Traineeships, it is especially important to provide documentation of existing/pending support involving the mentor to show that there is adequate support in the training environment for the post-doctoral trainee.

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    The following support documentation shall be provided in the proposal submission:

    A. A letter signed by the Department Chair, Dean, or equivalent official verifying the applicant has completed a doctoral degree and has less than 5 years of post-doctoral training. This letter is to be sent to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that this letter is not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Support documentation will not be accepted separately from the application.

    B. A letter of support from the mentor describing his or 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 to become a future breast cancer researcher and the mentor's relationship with the trainee. This letter is to be sent from the mentor to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that the mentor's letter of support is not misplaced, the sealed envelope should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support will not be accepted separately from the application.

    C. Two additional letters of recommendation shall accompany the application. These letters are to be sent from the references to the applicant in **sealed** envelopes for forwarding, unopened, with the application. To ensure that the letters of reference are not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of recommendation will not be accepted separately from the application.

    To document the sources of these letters, please include in the Support Documentation section of the application a list of the names, positions, and grant functions (e.g., mentor, recommender) of authors of the letters. However, attach the letters in sealed envelopes with a binder clip to the original proposal underneath the Proposal Cover Booklet.

Finally, the Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of Post-doctoral Traineeship Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

VII-F. Reports

Post-doctoral Traineeship Awards will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress.

The PIs of Post-doctoral Traineeships will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

VIII. Career Development Awards

VIII-A. Career Development Award Category

Career Development Awards (CDAs) are designed to encourage (1) scientists who have post-doctoral training, but are not yet established investigators, to pursue a breast cancer-related research career, as well as (2) established scientists 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 accumulate the data and experience to compete for traditional awards later in their careers. For the purpose of this program, a CDA is intended for an individual who has their own, independent program of research; is within 6 years of post-doctoral, residency, fellowship, or equivalent training; and holds a position as an Assistant Professor or equivalent.

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 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 shall be included as part of the proposal.**

Approximately $6 M will be available for CDAs. CDAs can be requested for an average of $59,000 per year inclusive of direct and indirect costs for a maximum of $236,000 over 4 years. Funds can be requested only for salary support and travel to scientific meetings. Funds for research must be provided from another resource. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

Additional money for research can be awarded by linking a CDA with an Idea Award submission that focuses on the same research. Linked CDA/Idea proposals will be reviewed as a single package. During programmatic review, either both proposals or neither proposal will be recommended for funding. Applicants who submit CDA and Idea Award proposals that address the same research question must indicate on the proposal title page that these submissions are linked. Applicants should consider the unique nature of Idea Award proposals (i.e., they are not for traditional research) when submitting linked applications.

Applicants may submit only one individual proposal for a CDA or an HBCU/MI-Focused Training Award (Section XII).

VIII-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?

- **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? Will the research offer a valuable opportunity to further develop research experience to advance and develop the candidate's independent research career?

- **Innovation:** Does the research to be pursued during the period of this award employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies, or address under- explored or unexplored areas?

- **Scientific Relevance & 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 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 reasonable?

VIII-C. Programmatic Review - Evaluation Criteria for Career Development Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

VIII-E. Proposal Preparation

The following proposal preparation information is specific for Career Development Awards. Please note that the body of the proposal is limited to 8 pages and that the deadline for receipt is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents outlined below in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, CDA applicants should describe (within the 1 page limit) explicitly the training value of the proposed research concept relative to the applicant's career goals in breast cancer research. Articulate how the combination of training value and relevance to breast cancer biology, prevention, detection, diagnosis, and/or therapy will catalyze the applicant's development as an independent breast cancer investigator.

10. Proposal Body – See Appendix B, part 10
    The body of CDA proposals is limited to 8 pages. The body of the proposal should consist of two parts. Both the overall page limit of 8 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Research Project/Career Development Plans - 4 page limit
       For CDA proposals, the body of the proposal shall 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 or her academic 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.

       Additionally, applicants should provide an overview of how their time will be spent once relieved from other academic responsibilities. If the applicant will be devoting time to a research project, the following **general** outline should be used to describe the project.

       (1) Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.
       (2) Hypothesis/Purpose: State the hypothesis to be tested and the expected results.
       (3) Objectives: State concisely the specific aims of the project.
       (4) Methods: Give details about the experimental design and methodology.

    B. Figures/Tables - 4 page limit
       Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

    Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12
    A list of significant publications and a succinct summary of the investigator's experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketch.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15

    A letter of institutional commitment is required. This letter should state that the candidate meets the award requirements (i.e., the candidate has their own, independent program of research; is within 6 years of post-doctoral, residency, fellowship, or equivalent training; and holds a position as an Assistant Professor or equivalent). This letter should describe the level of institutional commitment to fostering the applicant's research career, as reflected by the extent to which the applicant will be relieved of other academic responsibilities to have additional time for research and by the provision of adequate laboratory facilities, equipment, and opportunities for critical professional interaction with senior colleagues.

    Finally, the Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application. Support documentation will not be accepted separately from the proposal submission.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of CDA proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

VIII-F. Reports

CDAs will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress.

The PIs of CDAs will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

IX. Institutional Training Grants

IX-A. Institutional Training Grants

Institutional Training Grants (ITGs) are intended to encourage the initiation of new training programs in breast cancer. These awards should draw pre- and/or post-doctoral students focused on breast cancer research together in a common research and training environment. These grants may emphasize the training of students from different disciplines (e.g., basic cancer biology, epidemiology, health services research, and clinical, behavioral, and social sciences) who have an underlying interest in breast cancer research.

ITG proposals should address the following key aspects of the proposed training program: (1) the program vision and goals, (2) the program faculty, and (3) the training program and trainees. As part of the discussion of each of these key aspects, the body of the proposal should address the scientific emphasis of the program, the structure of the training program to integrate multi-disciplinary specialties into breast cancer research, the training environment and history, the physical environment, the qualifications of the program director, the training faculty for both the pre- and post-doctoral programs, the proposed curriculum for both pre- and post-doctoral programs, the selection criteria for students, the recruitment of students into the program, and the method of assigning students to a faculty mentor.

As part of the proposal, the following training support documentation shall be included in the appropriate proposal sections to provide greater detail on selected requirements discussed in the body of the submission:

1. faculty biographical sketches with a section describing previous training experiences and mentoring,
2. expanded description of the training environment and facilities, and
3. letter of support from the institution.

Approximately $7 M will be available for ITGs. ITGs can be requested for an average of $200,000 per year inclusive of direct and indirect costs for a maximum of $800,000 over 4 years. A maximum of 6 trainees (pre-doctoral and post-doctoral) is recommended. With clear and compelling justification, funds may be requested for student tuition and stipends, faculty salary, seminars and courses, administrative support (e.g., photocopying charges, telephone and fax services, secretarial support, etc.), and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

IX-B. Scientific Peer Review - Evaluation Criteria for Institutional Training Grant Proposals

ITG proposals will be evaluated according to the criteria listed below.

- **Training Program:** Does the training program offer a structured, well-rounded, focused experience in breast cancer research? Does the program support opportunities for collaboration and communication with various members of the training faculty, and involvement in other institutional research activities?

- **Program Director:** Does the Program Director have the background, research qualifications, and ability to lead and manage the training program successfully? Is there a record of past experience in training pre- and post-doctoral students? Is there sufficient research support available for the training needs outlined in the proposal?

- **Training Faculty:** Is there a diverse, well-qualified faculty available to provide multiple, suitable training opportunities for students in the program? What are the research interests and the past training records of the individual faculty members? Do the faculty members have sufficient research support available to conduct their own research programs? How will interaction and communication between the trainees and the faculty be optimized?

- **Trainees:** What methods are used to recruit trainees? Are the selection criteria for admitting students into the program appropriate to select highly qualified trainees? What is the overall quality of present and former students? Have former trainees made significant contributions to cancer research and, more specifically, to breast cancer research?

- **Relevance:** Does the institution make a convincing case for its commitment to develop a training program focused on breast cancer research?

- **Institutional Environment:** Is there a strong institutional commitment to research training in breast cancer? Does the institution provide an intellectually stimulating environment and facilitate interaction among faculty and trainees? Does the institution provide adequate laboratory facilities, equipment, and other relevant resources to support the research and training activities?

- **Budget:** Is the budget reasonable for the work proposed?

IX-C. Programmatic Review - Evaluation Criteria for Institutional Training Grants

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

IX-E. Proposal Preparation

The following proposal preparation information is specific for ITGs. Please note that the body of the proposal is limited to 10 pages and that the deadline for receipt is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents below in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

Institutional Training Grants
Table of Contents

Page Number

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, ITG proposals shall describe (within the 1 page limit) how the training program will be designed to offer a structured, well-rounded, focused experience in breast cancer biology, prevention, detection, diagnosis, and/or therapy. Include how the training program will foster the likelihood of its trainees pursuing a career in breast cancer research. Indicate how the training program will foster opportunities for collaboration and communication with various members of the training faculty and involvement in other institutional research activities.

10. Proposal Body – See Appendix B, part 10
    The body of ITG proposals is limited to 10 pages. The body of the proposal should consist of two parts. Both the overall page limit of 10 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Overview of Training Program - 8 page limit
       The body shall include a clear description of how the training program will draw pre- and post-doctoral students from different disciplines, all with an underlying interest in breast cancer, together into a common environment. The proposal should clearly demonstrate how the training program is different from a mere collection of pre-and/or post-doctoral students. ITG proposals should address the following key aspects of the proposed training program: (1) the program vision and goals, (2) the program faculty, and (3) the training program and trainees. As part of the discussion of each of these key aspects, the body of the proposal should address the scientific emphasis of the program, how the training program will be structured to integrate multidisciplinary specialties into breast cancer research, the training environment and history, the physical environment, the qualifications of the program director, the training faculty for both the pre- and post-doctoral programs, the proposed curricula for both pre- and post-doctoral programs, the recruitment of students into the program, and the methods of assigning students to a faculty mentor.

    B. Figures/Tables - 2 page limit
       Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

    Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12
    For ITG proposals, biographical sketches should include a section describing the faculty members' previous training experiences and mentoring, including experience in the field of breast cancer research. A list of significant publications in breast cancer research should be incorporated into the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    A letter of support from the institution indicating a commitment to the training program shall be included.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of ITG proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

IX-F. Reports

ITG Awards will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress.

The PIs of ITGs will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

X. Clinical Translational Research Fellowship Awards

X-A. Clinical Translational Research Fellowship Awards

The intent of the Clinical Translational Research (CTR) Fellowship Awards is to train clinically oriented physicians and clinical investigators to serve as a dynamic bridge between the laboratory and the clinic. An overall goal of CTR Fellowship Awards is to encourage interested physicians to undertake clinical translational research in breast cancer. The research focus of CTR Fellowship Awards is on clinical translational research that is directly relevant to the prevention, detection, diagnosis, or treatment of breast cancer.

CTR Fellowship Awards are intended to enable recent medical degree graduates to obtain the necessary experience to pursue a career in clinical translational breast cancer research. Applicants should be medical degree graduates with less than 5 years post-doctoral experience. Additionally, applicants should have worked in the laboratory in which the research will be performed for no more than 2 years at the time of submission; thus allowing applicants an opportunity to perform 3 years of research with this award. Individuals applying for this award should be able to demonstrate their interest in, and commitment to, pursuing a career in clinical translational breast cancer research.

The overall goal of CTR Fellowship Awards is to prepare individuals for a career in breast cancer clinical translational research. Therefore, important components of these applications are: the mentor and training environment, the applicant's plans after the completion of the proposed project, and supporting documentation (i.e., the applicant's biographical sketch, the mentor's biographical sketch including his/her qualifications and previous training experience, official copies of the trainee's undergraduate and graduate transcripts, a letter of support from the mentor, and 2-3 letters of recommendation). CTR Fellowship proposals shall be written and signed by the trainee as the PI and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees.

Approximately $3 M will be available for CTR Training Awards, i.e., CTR Fellowships and CDAs (Section XI). CTR Fellowship Awards can be requested for an average of $48,000 per year, inclusive of direct and indirect costs, for a maximum of $144,000 over 3 years. Funds for CTR Fellowship Awards can cover salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

Applicants should be cautioned that proposals submitted into the CTR Fellowship Award mechanism can <u>not</u> be evaluated by reviewers under another award mechanism, i.e., a CTR Fellowship can not be reviewed as a Post-doctoral Traineeship. Therefore, applicants applying

for CTR Fellowship Awards should consider the intent and review criteria of CTR Fellowship Awards carefully when submitting proposals.

Applicants may submit only one individual proposal to either of the following categories: Post-doctoral Traineeship Awards (Section VII) or CTR Fellowship Awards.

X-B. Scientific Peer Review - Evaluation Criteria for Clinical Translational Research Fellowship Award Proposals

CTR Fellowship Award proposals will be evaluated according to the following peer review criteria.

- **Candidate:** Do the candidate's achievements to date (as assessed by background, academic performance, awards, and honors) make him/her a well-qualified candidate for this fellowship? Has the candidate demonstrated a personal commitment to pursuing a career in clinical translational breast cancer research? Has the candidate demonstrated that his/her experience has provided him/her with the foundation for pursuing a career in clinical translational breast cancer research? Do the letters of recommendation support the candidate's abilities and potential for a productive research career?

- **Potential for a Career in Translational Research:** Has the candidate demonstrated how their qualifications, mentor, training environment, quality of research training, and project's scientific relevance will lead to a career in clinical translational research?

- **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.?

- **Training Plans and Environment:** Is there a clearly proposed formal training program in breast cancer clinical and/or translational research? Does the training take place in an environment that is appropriate to accomplishing the candidate's goals? Are the research requirements 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?

- **Quality of the Research Training:** Will the training result in a valuable experience for the trainee in preparing him/her for an independent research career? Is the proposed training appropriate for the trainee? Would the described training further the trainee's goals to become an independent clinical translational researcher?

- **Scientific Relevance:** Does the training relate to an important problem in breast cancer clinical translational 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 reasonable for the work proposed? Are there sufficient overall financial resources to support the proposed research?

X-C. Programmatic Review - Evaluation Criteria for Clinical Translational Research Fellowship Awards

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

Additionally, programmatic reviewers will consider how well CTR Fellowship submissions meet the intent of this award mechanism. Since reviewers can not move applications to another award mechanism, applicants should consider the intent of these awards seriously when submitting proposals.

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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

X-E. Proposal Preparation

The following proposal preparation information is specific for CTR Fellowship Awards. The body of the proposal is limited to 8 pages for CTR Fellowships. The deadline for submission for CTR Fellowship Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents on the below in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

CTR Fellowship Award
Table of Contents

Page Number

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, CTR Fellowship Award applicants should describe explicitly the training/potential of the proposed research and/or program. Articulate how the combination of training value and relevance to breast cancer biology, prevention, detection, diagnosis, and/or therapy will prepare trainees for a career in translational breast cancer research.

10. Proposal Body – See Appendix B, part 10

Applicants should emphasize the translational components of the training in this section. The body of the proposal is limited to 8 pages. The body of the proposal should consist of three parts. Both the overall page limit of 8 pages for the body and the page limit for each part of the proposal body shall be followed.

A. Research Project/Training Plans - Prepared by the applicant - 4 page limit.

(1) Description of Research Project: Describe the proposed project using the **general** outline provided below.

(a) Background: Briefly describe the ideas behind the proposed work and 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 of the project.

(d) Methods: Give details about the experimental design and methodology.

(2) Description of the Research Training: Describe the translational research training in which the applicant will participate such as coursework, laboratory techniques, conferences, and journal clubs. Describe explicitly the training value/potential of the proposed research and/or program. Articulate how the combination of training value and relevance to breast cancer will prepare the applicant for a career in clinical breast cancer research.

(3) Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development. Discuss the applicant's plans after the completion of this award.

B. Figures/Tables - 3 page limit

Figures, tables, and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

C. 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 clinical translational research training should also 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 13 on the following page.)

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

For CTR Fellowship proposals, biographical sketches should be prepared for the applicant, collaborating investigators, and the mentor. The mentor's biographical sketch should include his or her qualifications, especially in breast cancer research, and previous experience in training students and post-doctoral fellows. A list of significant publications in breast cancer research should be incorporated into the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    The following support documentation should be provided in the proposal submission:

    A. A letter signed by the Department Chair, Dean, or equivalent official verifying the applicant has completed a medical degree (M.D. or equivalent) and has no more than 2 years of research training at the institution. This letter is to be sent to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that this letter is not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support <u>will not</u> be accepted separately from the application.

    B. 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 to become a future breast cancer clinical translational researcher and the mentor's relationship with the trainee. This letter is to be sent from the mentor to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that the mentor's letter of support is not misplaced, the sealed envelope should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support <u>will not</u> be accepted separately from the application.

    C. Two additional letters of recommendation should accompany the application. These letters are to be sent from the references to the applicant in **sealed** envelopes for forwarding, unopened, with the application. To ensure that the letters of reference are not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of recommendation <u>will not</u> be accepted separately from the application.

To document the sources of these letters, please include in the Support Documentation section of the application a list of the names, positions, and grant functions (e.g., mentor, recommender) of authors of the letters. However, please attach the letters in sealed envelopes with a binder clip to the original proposal underneath the Proposal Cover Booklet.

Finally, the Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    Please note that the deadline for receipt of CTR Fellowship Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

X-F. Reports

CTR Fellowship Awards will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress. However, a particular research project may require some variation.

The PIs of CTR Fellowship Awards will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent

applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

XI. Clinical Translational Research Career Development Awards

XI-A. Clinical Translational Research Career Development Awards

The intent of the Clinical Translational Research (CTR) Career Development Awards (CDAs) is to train clinically oriented physicians and clinical investigators to serve as a dynamic bridge between the laboratory and the clinic. An overall goal of CTR CDAs is to encourage interested physicians to undertake clinical translational research in breast cancer. The research focus of CTR CDAs is on clinical translational research that is directly relevant to the prevention, detection, diagnosis, or treatment of breast cancer.

CTR CDAs are designed to encourage (1) physicians who have prior fellowship training, but are not yet established clinical investigators, to pursue a career in clinical translational breast cancer research, as well as (2) established research physicians who are currently working in other areas to shift their focus to clinical translational breast cancer research. Such awards will provide physicians who are new to breast cancer clinical translational research the opportunity to accumulate the training, data, and experience to eventually compete for traditional clinical translational research awards later in their careers. For the purpose of this program, a CTR CDA is intended for an individual who has their own, independent program of research; is within 6 years of residency, fellowship, or equivalent training; and holds a position as an Assistant Professor or equivalent. Applicants for this award mechanism should also have some experience in conducting clinical trials. Individuals applying for this award should be able to demonstrate their commitment to pursuing a career in clinical breast cancer research.

CTR 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 the applicant will be relieved of his or her academic 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 $3 M will be available for CTR Training Awards, i.e., CTR Fellowships (Section X) and CDAs. CTR CDAs can be requested for an average of $59,000 per year, inclusive of direct and indirect costs for a maximum of $236,000 over 4 years. Funds can be requested only for salary support and travel to scientific meetings. Funds for research must be provided from another resource. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 2 of the "Detailed Cost Estimate."

Applicants should be cautioned that proposals submitted into the CTR CDA mechanism can <u>not</u> be evaluated by reviewers under another award mechanism, i.e., a CTR CDA can not be reviewed

as a CDA. Therefore, applicants applying for CTR CDAs should consider the intent and review criteria of CTR CDAs carefully when submitting proposals.

Applicants may submit only one individual proposal to either of the following categories: CDAs (Section VIII) or CTR CDAs.

XI-B. Scientific Peer Review - Evaluation Criteria for Clinical Translational Research Career Development Award Proposals

CTR CDA proposals will be evaluated according to the following peer review criteria.

- **Candidate:** Does the candidate have the appropriate background to pursue a career in clinical translational breast cancer research? Does 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 clinical translational breast cancer research? Does the applicant have experience in conducting clinical trials?

- **Potential for a Career in Translational Research:** Has the candidate demonstrated how his/her qualifications, the mentor, the training environment, the quality of research training, and the project's scientific relevance will lead to a career in clinical translational research?

- **Research Program:** Is there a clearly proposed formal training program in breast cancer clinical and/or translational research? 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? Will the research offer a valuable opportunity to further develop research experience to advance and develop the candidate's independent research career?

- **Scientific Relevance & 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 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 reasonable?

XI-C. Programmatic Review - Evaluation Criteria for Clinical Translational Research Career Development Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. In other words, how will the proposal contribute to the program's goal of eradicating breast cancer and will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

Additionally, programmatic reviewers will consider how well CTR CDA submissions meet the intent of this award mechanism. Since reviewers can not move applications to another award mechanism, applicants should consider the intent of these awards seriously when submitting proposals.

XI-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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

XI-E. Proposal Preparation

The following proposal preparation information is specific for CTR CDAs. The body of the proposal is limited to 8 pages for CTR CDAs. The deadline for submission for CTR CDA proposals is June 2, 1999 at 4:00 p.m. Eastern Time. The proposed start date should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents outlined below in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.

CTR CDA
Table of Contents

Page Number

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, CTR CDA applicants should describe explicitly the training/potential of the proposed research and/or program. Articulate how the combination of training value and relevance to breast cancer biology,

prevention, detection, diagnosis, and/or therapy will prepare trainees for careers in translational breast cancer research.

10. Proposal Body – See Appendix B, part 10
    Applicants should emphasize the translational components of the training in this section. The body of CTR CDA proposals is limited to 8 pages. The body of the proposal should consist of two parts. Both the overall page limit of 8 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Research Project/Career Development Plans - 4 page limit
       For CTR CDA proposals, the body of the proposal 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 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.

       Additionally, applicants should provide an overview of how their time will be spent once relieved from other academic responsibilities. The following **general** outline should be used to describe the research project.
       (1) Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.
       (2) Hypothesis/Rationale/Purpose: State the hypothesis that will be tested in an appropriately designed clinical trial and the expected results.
       (3) Objectives: State concisely the specific aims of the project.
       (4) Methods: Give details about the experimental design and methodology.

    B. Figures/Tables - 4 page limit
       Figures, tables, and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

    Applicants should consider the peer and programmatic review evaluation criteria when writing the body of the proposal.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12
    A list of significant publications in breast cancer research should be incorporated into the biographical sketch.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    A letter of institutional commitment should be provided in the proposal submission. This letter should state that the candidate meets the award requirements (i.e., the candidate has their own, independent program of clinical research; is within 6 years of residency, fellowship, or equivalent training; and holds a position as an Assistant Professor or equivalent). This letter should describe the level of institutional commitment to fostering the applicant's research career, as reflected (1) by the extent to which the applicant will be relieved of other academic responsibilities to have additional time for research, and (2) by the provision of adequate laboratory facilities, equipment, and opportunities for critical professional interaction with senior colleagues.

    The Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    Please note that the deadline for receipt of CTR CDA proposals is June 2,1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

XI-F. Reports

CTR CDA Awards will require the timely delivery of reports during the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress. However, a particular research project may require some variation.

The PIs of CTR CDAs will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

XII. Historically Black Colleges and Universities/ Minority Institutions-Focused Training Awards

XII-A. Historically Black Colleges and Universities/Minority Institutions-Focused Training Awards

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI)-Focused Training Awards are intended to enable investigators at HBCU/MIs to collaborate, train, and acquire the knowledge and experience needed to prepare and submit a high quality proposal(s) for breast cancer research. Major goals of this award are to attract new investigators to this research area and to establish collaborations between applicant investigators and established investigators in breast cancer research.

The PI and established collaborating investigators need not be of an ethnic minority. The collaborating investigators must have a strong track record in acquiring funding in breast cancer research. The applicant/proposal submission must be from an HBCU/MI, and **applications are required to include a collaboration between the applicant investigator and an established investigator.** Although they may be from different institutions, both investigators must contribute to the planned project.

Applicants must have their own research space, have minimal or no other research support, hold a faculty position, and possess a doctoral level degree. Initially, the designated location for the effort can be a senior investigator or mentor's laboratory for bench researchers and/or assigned office space for others.

Concept development proposals are encouraged in the following areas of research, but may be targeted on any aspect of breast cancer biology, prevention, detection, diagnosis, and/or treatment:

- Disparity in Morbidity and 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-Focused Training Awards will be funded out of the HBCU/MI set aside (see Appendix B-1), which is approximately $6 M in FY 99. HBCU/MI-Focused Training Awards can be requested for up to $100,000 per year for up to 18 months (i.e., up to $150,000/award), inclusive of direct and indirect costs. No more than 25% of the awarded funds should be directed toward the collaborator. Funds can be requested for salary support, tuition for special training and/or education, consultation with an established investigator, consultation with scientific and/or technical experts (e.g., statisticians, editors, etc.), administrative and technical

assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. No more than one trip to a scientific meeting per award per year is funded. In addition to these meetings, 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 the "Detailed Cost Estimate."

Only one HBCU/MI-Focused Training Award proposal may be submitted from any one investigator.

XII-B. Scientific Peer Review - Evaluation Criteria for HBCU/MI-Focused Training Award Proposals

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

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- **Applicant:** Do the applicant's previous training, prior research experience, and publication record indicate promising achievements to date? Will the training/collaboration offer a valuable opportunity to further develop the experience necessary to advance the applicant's research career in breast cancer?

- **Collaborating Investigator:** Does the collaborating investigator have the background, qualifications, and time to develop a productive collaboration with the applicant? Is the collaborating investigator committed to the applicant's career development? Does the collaborating investigator have a strong track record of funding in breast cancer research? Does the collaborating investigator have experience in training of individuals from diverse backgrounds?

- **Training Plan:** Will the proposed training increase the applicant's likelihood of submitting a high quality breast cancer research proposal? Will the collaboration support the applicant's planned program of research? Do both the applicant and the collaborating investigator contribute to the planned project? How do the collaborating investigator and applicant propose to sustain an interactive, ongoing partnership?

- **Scientific Relevance:** Is the proposed concept and research likely to be developed into a clear focused project on breast cancer biology, prevention, detection, diagnosis, and/or treatment? Does the application make a convincing case for the potential to develop a concept that is relevant to breast cancer?

- **Resources/Environment:** Is the applicant adequately supported by the scientific environment, necessary resources, and collaborative arrangements (of both the collaborator and the applicant)? Is there a sufficient demonstration of a strong institutional commitment to relieve the applicant of other academic or clinical

responsibilities in order to permit time for collaboration and concept development? Is there a strong institutional commitment to the applicant's career development?

- **Budget:** Is the budget reasonable for the work proposed? Does the HBCU/MI applicant secure 75% of the total requested funds?

XII-C. Programmatic Review - Evaluation Criteria for HBCU/MI-Focused Training Award Proposals

All proposals have the potential of being programmatically reviewed. Funding recommendations are based on a comparative process. Thus, the demonstrated need of HBCU/MI applicants may be taken into consideration in making recommendations. Applicants are reminded of the importance of programmatic relevance. In other words, will the award enable an HBCU/MI investigator to pursue a productive career in breast cancer research? Additional details on programmatic review procedures and evaluation criteria are included in Section I-B.

XII-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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

XII-E. Proposal Preparation

The following proposal preparation information is specific for the HBCU/MI-Focused Training Award category. Please note that the body of the proposal is limited to 7 pages and that the deadline for submission is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1
   The list of HBCU/MIs as recognized by the Department of Education is available on the World Wide Web at http://cdmrp.army.mil.

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents, outlined below, in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

HBCU/MI-Focused Training Award
Table of Contents

Page Number

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7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8
   A sample HBCU/MI-Focused Training Award Statement of Work is provided on page XII-9.

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, HBCU/MI-Focused Training 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. Articulate how the proposal's combination of training and relevance to breast cancer biology, prevention, detection, diagnosis, and/or therapy will prepare the applicant for a career in the battle against breast cancer.

10. Proposal Body – See Appendix B, part 10
    The body of HBCU/MI-Focused Training Awards proposals is limited to 7 pages. The body of the proposal should consist of two parts. Both the overall page limit of 7 pages for the body and the page limit for each part of the proposal body shall be followed.

    A. Collaboration Plans/Career Development/Proposed Project - 4 page limit
       Describe the proposed research concept using the **general** outline provided below:

       (1) Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the established investigator and the applicant should be articulated. Qualifications and facilities of the established investigator should be addressed. Document the experience of the collaborating investigator in training breast cancer researchers and include information on training/collaborations with minority investigators.

       (2) Career Development: Explain how the proposed training will increase the applicant's ability to prepare a high quality grant application for breast cancer research within the lifetime of the award. Describe explicitly the value of the proposed training as it relates to the applicant's career goals. Articulate how the combination of training and relevance to breast cancer in the proposal will catalyze the applicant's development as an independent breast cancer investigator.

       (3) Project Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Proposals must present a clearly articulated plan for research concept development that focuses on the biology, prevention, detection, diagnosis, and/or treatment of breast cancer. State the specific aims of the study. Briefly describe the methods to be used. Cite relevant literature references.

    B. Figures/Tables - 3 page limit
       Figures, tables, and graphs should be included within this section. Submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12
    For HBCU/MI-Focused Training Award proposals, biographical sketches should be prepared for the applicant, established investigator, and each of the key personnel, including collaborating investigators listed on the budget page for the initial budget period. A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be included in the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
    The following support documentation is to be contained within the HBCU/MI-Focused Training Award proposal submission:

    A. A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution describing the commitment of the institution to the applicant's research career, as reflected by the extent to which the applicant will be relieved of his or her academic and/or clinical responsibilities to have additional time for collaboration and training, access to appropriate facilities, and opportunities for professional interactions with senior colleagues.

    B. A form signed by the Department Chair, Program Director, or Dean indicating that the PI holds a faculty position and possesses a doctoral level degree and, therefore, is an eligible applicant for this award type. The form on page XII-8 should be used.

    C. A letter from the collaborating established investigator describing his/her commitment to the training/career development/mentorship of the applicant, and the nature of the proposed collaboration/training.

    D. Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project describing their role in the concept development.

    Support documentation <u>will not</u> be accepted separately from the proposal submission.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of HBCU/MI-Focused Training Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

XII-F. Reports

HBCU/MI-Focused Training Awards will require a timely reporting of the research and collaborative efforts. The PIs of HBCU/MI-Focused Training Awards will be required to submit a 2-5 page **FINAL** summary. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must site the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

STATEMENT OF ELIGIBILITY

Applicant's Name_____

Title of Proposal_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of Applicant:_____

STATEMENT OF ELIGIBILITY

For the purposes of the Department of Defense Congressionally Directed Medical Research Program's Breast Cancer Research Program Historically Black Colleges and Universities/ Minority Institutions (HBCU/MI)-Focused Training Award mechanism as outlined in the Program Announcement, the applicant fulfills all of the following criteria:

- holds a faculty position at an HBCU/MI,
- has their own research space, **AND**
- holds a doctoral degree (M.D., Ph.D., D.V.M., or equivalent).

I, _____of
(printed name of Department Chair, Dean, or equivalent official)

_____
(printed name of institution)

affirm that the above-named investigator fulfills the requirements for HBCU/MI-Focused Training Award.

Signature of Official:_____ Date:_____

Sample Statement of Work
HBCU/MI-Focused Training Award

Smith, Mary E.

Statement of Work

Correlating Dietary Intake with Breast Cancer Incidence in African American Women

Phase 1: Project Startup and Parameter Development (Months 1-6)

- Meet with collaborating, established investigator – set up schedule for regular meetings
- Hire a biostatistician for statistical analyses of data
- Purchase computer to assist in information processing
- Review current databases for parameters relating to dietary intake and breast specific antigen measurements

Phase 2: Information Consolidation and Project Development (Months 7-12)

- Conduct a preliminary analysis of information obtained from databases
- Consult an epidemiologist to determine appropriate research design for a clinical trial
- Determine methods to recruit subjects
- Continue to consult with collaborating, established investigator

Phase 3: Formulation of Research Questions for Idea Award proposal in response to the DOD BCRP Announcement (Months 13-18)

- Consolidate information obtained during Phase 2 for another funding opportunity
- Prepare grant application
- Have grant application reviewed and critiqued by the collaborating, established investigator
- Prepare and submit reports summarizing the accomplishments of the collaborative and research efforts

XIII. Historically Black Colleges and Universities/Minority Institutions Partnership Training Award

XIII-A. Historically Black Colleges and Universities/Minority Institutions Partnership Training Award

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 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 fundable breast cancer research proposals. Established investigators from collaborating institutions need not be of an ethnic minority. However, the established investigators must have a strong track record in acquiring funding in breast cancer research. The applicant/proposal submission must be from an HBCU/MI.

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 fundable 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. Concept development proposals are encouraged for training programs in the following areas of research, but may be targeted on any aspect of breast cancer biology, prevention, detection, diagnosis, and/or treatment:

- Disparity of Morbidity and 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 out of the HBCU/MI set aside, which is approximately $6 M in FY 99. These awards can be requested for up to $250,000 per year for up to 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. Funds 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, etc.), 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.

Only one HBCU/MI Partnership Training proposal may be submitted from any one HBCU/MI.

XIII-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:

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- **Applicant Institution:** Does 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?

- **Collaborating Partner:** Does the collaborating institution have the background, qualifications, experience, and track 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 track record of developing institutional training programs and 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 at the HBCU/MI by the end of the award period?

- **Scientific Relevance:** Does the proposed collaboration and training concept clearly focus on breast cancer biology, 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 the applicant 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?

- **Potential Impact:** What impact would this training/collaboration have on producing well-trained breast cancer researchers?

- **Budget:** Is the budget reasonable 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?

XIII-C. Programmatic Review - Evaluation Criteria for HBCU/MI Partnership Training Award Proposals

Scientifically meritorious proposals will be programmatically reviewed. Funding recommendations are based on a comparative process. Thus, the demonstrated need of HBCU/MI applicants may be taken into consideration in making recommendations. Applicants are reminded of the importance of programmatic relevance. In other words, is the award likely to train investigators at an HBCU/MI to perform high quality research and become successful, independent researchers? Additional details on programmatic review evaluation criteria are included in Section I-B.

XIII-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" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the CDMRP website (*http://cdmrp.army.mil*). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

XIII-E. Proposal Preparation

The following proposal preparation information is specific for HBCU/MI Partnership Training Awards. Please note that the body of the proposal is limited to 10 pages and that the deadline for submission is June 2, 1999 at 4:00 p.m. Eastern Time. Proposed start dates should be no earlier than March 1, 2000 and no later than October 1, 2000.

1. Who May Apply – See Appendix B, part 1
   The list of HBCU/MIs as recognized by the Department of Education is available on the World Wide Web at http://cdmrp.army.mil.

2. Proposal Acceptance Criteria – See Appendix B, part 2

3. Proposal Cover Booklet – See Appendix B, part 3

4. Peer Review Referral Page – See Appendix B, part 4

5. Proposal Title Page – See Appendix B, part 5

6. Table of Contents – Use the table of contents on the next page in your proposal submission. As listed, number all pages consecutively at the bottom center, beginning with the Proposal Title Page.

7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8
   A sample HBCU/MI Partnership Training Award Statement of Work is provided on page XIII-10.

9. Proposal Relevance and Impact Statement – See Appendix B, part 9
   In addition to the instructions found in Appendix B, part 9, 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, prevention, detection, diagnosis, and/or therapy in the proposal will prepare the HBCU/MI participants for successful experiences as breast cancer researchers.

HBCU/MI Partnership Training Award
Table of Contents

10. Proposal Body – See Appendix B, part 10
    The body of HBCU/MI Partnership Training Awards is limited to 10 pages. Figures, tables, and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2). Describe the proposed research concept using the **general** outline provided below:

    A. Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the established collaborating institution and the HBCU/MI should be articulated. Qualifications and facilities of the established 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.

    B. Career Development: Describe explicitly the value of the proposed training as it relates to the applicant institution's plans for development of 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.

C. Background: Provide a brief statement of the ideas and reasoning behind the proposed collaboration. Describe previous experience of the collaborating institution most pertinent to this proposal. Proposals must present a clearly articulated plan for training program development that focuses on the biology, prevention, detection, diagnosis, and/or treatment of breast cancer. State the specific aims of the study. Briefly describe the methods to be used. Cite relevant literature references.

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" can not be used in lieu of actual meetings and the communications between the institutions' faculties. They also can not be substituted for the contractually required annual and final reports, but can be supplied in annual/final reports as supplemental information (see section XIII-F).

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12
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. A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketches.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15
The following support documentation is to be contained within the HBCU/MI Partnership Training Award proposal submission, as follows:

A. 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.

B. A form signed by the Department Chair, Program Director, or Dean indicating that the investigators on this project hold faculty positions and possess doctoral level degrees and, therefore, are an eligible applicant for this award type. The form on page XIII-9 should be used.

C. 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.

D. Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project describing their role in the concept development.

Support documentation will not be accepted separately from the proposal submission.

16. Detailed Cost Estimate – See Appendix B, part 16
    Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Submission Address – See Appendix B, part 19

20. Submission Deadlines – See Appendix B, part 20
    The deadline for receipt of HBCU/MI Partnership Training Award proposals is June 2, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

XIII-F. Reports

HBCU/MI Partnership Training Awards will require the timely delivery of reports summarizing the research effort. The recipient organization and the PI should realize that these reports are necessary for the USAMRMC to monitor progress. The PIs of HBCU/MI Partnership Training

Awards will be required to submit 2-5 page **ANNUAL** and **FINAL** reports. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by the DOD must contact their USAMRMC contract specialist for guidance.

STATEMENT OF ELIGIBILITY

Applicant's Name_____

Title of Proposal_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of Applicant:_____

STATEMENT OF ELIGIBILITY

For the purposes of the Department of Defense Congressionally Directed Medical Research Program's Breast Cancer Research Program Historically Black Colleges and Universities/Minority Institutions (HBCU/MI)-Partnership Training Award category as outlined in the Announcement, the applicant fulfills all of the following criteria:

- holds a faculty position at an HBCU/MI; **AND**
- holds a doctoral degree (M.D., Ph.D., D.V.M., or equivalent).

I, _____of
(printed name of Department Chair, Dean, or equivalent official)

_____,
(printed name of institution)

affirm that the above-named investigator fulfills the requirements for HBCU/MI Partnership Training Award.

Signature of Official:_____ Date:_____

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 (established) 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
- 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