DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
BREAST CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT I

February 21, 2002

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

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Foreword

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed to continue the Department of Defense (DOD) Breast Cancer Research Program (BCRP). The deadline, format, and other criteria specified for proposals in this DOD fiscal year 2002 (FY02) BCRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

Please note that the signing of the FY02 appropriation was delayed until January 2002, which requires the announcement, evaluation and decision process to commence before the actual receipt of funding at this Command for these projects. However, this Command's study of the appropriation and its knowledge of the history of these programs lead it to believe that the DOD will provide the funds for these projects.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity (USAMRAA), the Congressionally Directed Medical Research Programs (CDMRP), and the DOD BCRP can be obtained from the CDMRP web site at http://cdmrp.army.mil. A copy of this program announcement and associated forms also can be downloaded from the CDMRP web site (for information on completing the Proposal Information, see Section 8, page iv of this Foreword).

1. Overview of the FY02 Program Announcements

- **Proposals for the FY02 BCRP will again be requested through the publication of two separate program announcements.**

- This program announcement (Program Announcement I) is requesting proposals in five award mechanisms, all of which require submission of a pre-proposal. Four of the Program Announcement I award mechanisms have been offered in previous years: Clinical Translational Research (CTR), Collaborative-CTR, Breast Cancer Center of Excellence, and Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Partnership Training Awards. Program Announcement I also requests proposals in a new award mechanism, Biotechnology Clinical Partnership Awards. Program Announcement II is anticipated to be released in March 2002 and will request proposals in five award mechanisms that have been requested in previous years: Idea, Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, and Innovator Awards. Program Announcement II will also include three new award mechanisms: Exploration, Physician-Scientist Training, and Clinical Research Nurse Awards.

2. Highlights of Changes from the FY01 Program Announcements

- All mechanisms in this program announcement require the submission of a paper pre-proposal. However, after a screening process, those applicants who are invited to submit a full proposal will be required to submit their proposals through an electronic process. An authorized Administrative Representative from the Sponsored Programs Office at the applicant's organization will be **required to submit one electronic version of the applicant's invited full proposal as a PDF (Portable Document Format) file through the Internet (electronic submission)**; the electronic PDF file will serve as the official proposal submission. Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

- Margins for proposal preparation and acceptance have been changed to a minimum of **0.5-inch top, bottom, right,** and **1-inch left**.

- The paper Proposal Cover Booklet has been replaced by Proposal Information found online at http://cdmrp.org/proposals.

- The Biotechnology Clinical Partnership Award is a new mechanism offered in this program announcement to fund prospective clinical trials in the areas of breast cancer therapeutics and chemoprevention through the establishment of partnerships between the biotechnology industry and academic institutions.

- Breast Cancer Center of Excellence Awards in the areas of prevention and tailored cancer therapeutics are encouraged.

- HBCU/MI Partnership Training Award applicants are required to submit a pre-proposal.

- Documentation related to Regulatory Compliance and Quality issues (RCQ) will be available on the CDMRP web site by April 2002. You will be notified if you need to submit these documents to support your submission.

- All submissions to the BCRP that involve human subjects should provide medical care for research-related injuries at no cost to the subject. Investigators should plan on budgeting for such costs.

3. Who May Apply

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

4. Receipt and Submission Deadlines

Investigators interested in applying for mechanisms in this program announcement must submit a paper pre-proposal to be received no later than **April 3, 2002 at 4:00 p.m. Eastern Time**. See Section E of each award mechanism section for additional details. An electronic PDF version of an invited, full proposal, which will serve as the official proposal submission, must be sent through the Internet by an authorized Administrative Representative of the Sponsored Programs office (or equivalent) of your organization no later than **11:59 p.m. (applicant's local time) August 21, 2002**. See Appendix B, part 22, and Appendix C for additional details.

5. Timeline

The timeline for all Program Announcement I Awards is:

Pre-Proposal Submission:	**April 3, 2002 at 4:00 p.m. Eastern Time**
Pre-Proposal Screening:	May 2002
Invitation for Full Proposals:	May 2002
Full Proposal Submission:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002;** this must be accompanied by the Proposal Information.
Peer Review:	October 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	January 2003
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between February 2003 and September 2003

6. Inquiries

Questions concerning the proposal format or required documentation can be addressed to the CDMRP at:

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP02)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

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

Help lines will be available by May 7, 2002 to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (http://cdmrp.army.mil) and the proposal submission web site (http://cdmrp.org/proposals). Alternately, help can be obtained by e-mail at help-proposals-cdmrp@cdmrp.org.

7. Pre-Proposal Submission

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

Send the Pre-Proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP02)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

For driving directions to Fort Detrick, please refer to page vi of this Foreword. However, the use of commercial carriers is encouraged due to enhanced security measures at Fort Detrick.

8. Proposal Submission

Applicants should refer to sections on individual award mechanisms and Appendix B for appropriate submission requirements. Effective with this program cycle, electronic submission of full proposals is required.

Proposals will be submitted electronically at http://cdmrp.org/proposals. The web site will be available for proposal submission by May 7, 2002. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must submit one electronic PDF version of the applicant's proposal, which will count as the official proposal submission.

Several steps are critical for successful electronic submission of the applicant's proposal:

1. The applicant is required to submit Proposal Information (referred to in previous years as the Proposal Cover Booklet) online at http://cdmrp.org/proposals, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf. **The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.**

2. Once the applicant has submitted the Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.

3. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Applicants are encouraged to coordinate early with their Sponsored Programs Office.

4. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. The Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the web site (http://cdmrp.org/proposals) no later than **11:59 p.m. (applicant's local time) August 21, 2002.** Detailed instructions for electronic submission will be available at http://cdmrp.org/proposals by May 7, 2002.

Driving Directions to Fort Detrick

From Washington, DC

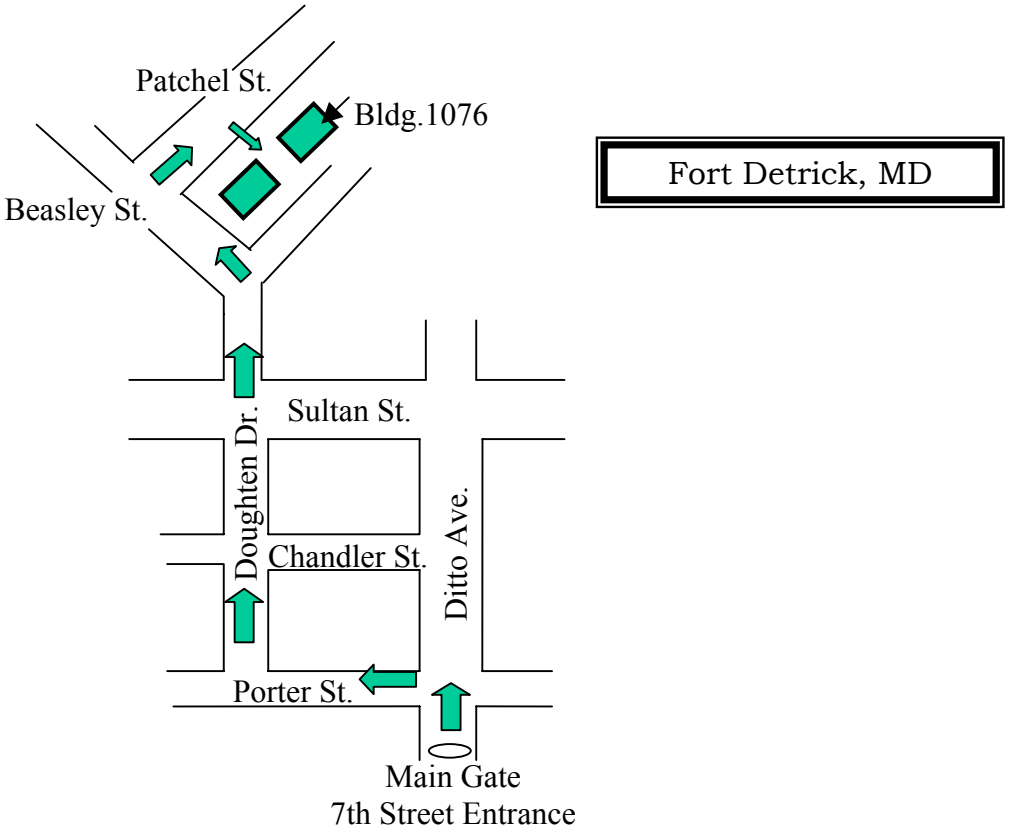
Take Interstate 495 to Interstate 270 North (exit 38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

From Baltimore, MD

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

Map of Fort Detrick

Packages to be delivered to the BCRP must be delivered to building 1076 as shown on the map below. To gain entry to Fort Detrick, you will be required to show 2 forms of photo identification at the Main Gate. **Please allow at least 45 minutes to pass through the gate area.**



I. Overview of the Congressionally Directed Medical Research Programs

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

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received more than $2.2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense Women's Health, osteoporosis, and other specified areas.

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

I-B. Investment Strategy

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

I-C. Proposal Evaluation

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

I-C.1. Scientific Peer Review

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

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

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

The peer review summary statement is a product of scientific peer review. Each summary statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement. Summary statements are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. One of the functions of programmatic review is to select 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 peer review summary statements, which include the proposal abstracts, to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded to programmatic review.

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

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation; and
- Program portfolio balance with respect to research disciplines or specialty areas.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

I-D. Notification

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

I-E. Negotiation of the Award

Please note that the signing of the FY02 appropriation was delayed until January 2002, which requires the announcement, evaluation, and decision process to commence before the actual receipt of funding at this Command for these projects. However, this Command's study of the appropriation and its knowledge of the history of these programs lead it to believe that the DOD will provide the funds for these projects.

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving the U.S. Army Medical Research Acquisition Activity (USAMRAA) and Regulatory Compliance and Quality (RCQ). A Contract Specialist from USAMRAA will contact the Administrative Representative who is authorized to negotiate contracts and grants at

the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

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

Concurrent with the USAMRAA discussions, RCQ will review the environmental compliance, safety plan, animal use, and human subjects/anatomical substance use documents to ensure that Army regulations are met. All documents related to RCQ will be requested in the applicant's notification letter and will be reviewed by RCQ staff. All documents related to RCQ should be available on the CDMRP web site by April 2002.

I-F. Human Use Requirements Unique to Department of Defense-Funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects, a second, DOD review and approval is also required. The Human Subjects Research Review Board (HSRRB), administered by the USAMRMC RCQ Office, is responsible for conducting this second level of review. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. **All research protocols involving human subjects and/or anatomical substances must be approved by both the appropriate local review board and by the HSRRB before awards are made and prior to initiation of the research protocol.**

Two requirements specific to DOD-funded research that the applicant must specifically address, if applicable, in the development of a research proposal for submission to the DOD are outlined below.

- Medical Care for Research-Related Injuries. For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, Part 7 for more details.

- Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally

authorized representative. Therefore, applicants should be able to articulate how the research intends to benefit minors or others who cannot legally consent who will be in the placebo arm of the study.

More information regarding research involving human subjects can be found in the RCQ Document, "Research Involving Human Subjects and/or Anatomical Substances," which will be available on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

I-G. Annual and Final Reports

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

- An **annual** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and

- A **final** report (submitted in the last year of the award period) that details the findings and issues for the entire project.

I-H. Publications and Patents

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

In accordance with the Bayh-Dole Act (35 USC 200 et seq.[1]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

[1] Title 35, United States Code, Section 200 et seq.

II. Department of Defense Breast Cancer Research Program

II-A. History of the Breast Cancer Research Program

Grass roots advocacy organizations provided the impetus that led to the fiscal year 1993 (FY93) Congressional appropriations to the Department of Defense (DOD) for $210M targeted toward breast cancer research. Since then, due to the ongoing efforts of advocacy groups and increased public awareness on health issues, Congress has continued to appropriate money for breast cancer research managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the office of the Congressionally Directed Medical Research Programs (CDMRP). To date, Congress has appropriated more than $1.3 billion to the DOD, through the Breast Cancer Research Program (BCRP), a multidisciplinary effort aimed at the eradication of breast cancer.

A summary program history for FY92-01 appropriations of the BCRP is shown in Tables II-1 and II-2.

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

Program History	FY92[1]-99[2]	FY00	FY01[3]
BCRP-Managed Appropriations for Peer-Reviewed Research	$868.3M	$175.0M	$175.0M
Breast Cancer Stamp[4]	$1.8M	$1.3M	$2.4M
Number of Full Proposals Received	12,009	1,234	1,500
Number of Proposals Funded	2,192	344	371
Percentage of Applications Recommended for Funding	18%	28%	25%
Number of Research Awards[5]	1,331	180	171
Number of Infrastructure Awards[6]	56	6	1
Number of Training/Recruitment Awards	805	158	194
Number of Innovator Awards	-	-	5

[1]Upon establishment of the BCRP in FY93, the CDMRP assumed responsibility for managing the $25M appropriation made in FY92 for breast cancer research that was being administered by the USAMRMC.
[2]Does not include 1,774 FY99 Concept proposals, 98 of which were awarded with FY99 funds and 203 of which were awarded with FY00 funds.
[3]Final numbers for FY01 will be available after September 30, 2002.
[4]Funds received as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585) are also managed under the BCRP.
[5]Includes Clinical Translational Research (CTR) Awards.
[6]Includes Collaborative-CTR (C-CTR) Awards.

Table II-2: Number of Proposals Received and Number of Awards Made for CTR and C-CTR Awards in FY97-01

Program History	FY97-99[1]	FY00	FY01[2]
Number of CTR and C-CTR Proposals Received			
CTR and C-CTR pre-proposals	437	40	46
CTR and C-CTR full proposals	131	20	16
Number of CTR and C-CTR Awards	21	7	1

[1] The pre-proposal strategy was implemented in FY97.
[2] Final numbers for FY01 will be available after September 30, 2002.

II-B. Overview of the FY02 Breast Cancer Research Program: Two Program Announcements

The CDMRP is requesting proposals on breast cancer research in two separate program announcements. This program announcement (Program Announcement I) is requesting proposals in the following five award mechanisms: CTR, Biotechnology Clinical Partnership, C-CTR, Breast Cancer Center of Excellence, and Historically Black Colleges/Minority Institutions (HBCU/MI) Partnership Training Awards. Program Announcement II is anticipated to be released in March 2002 and will request proposals in eight award mechanisms: Innovator, Exploration, Idea, Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, Physician-Scientist Training, and Clinical Research Nurse Awards.

The overall goal of the FY02 BCRP is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research on all aspects of breast cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

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

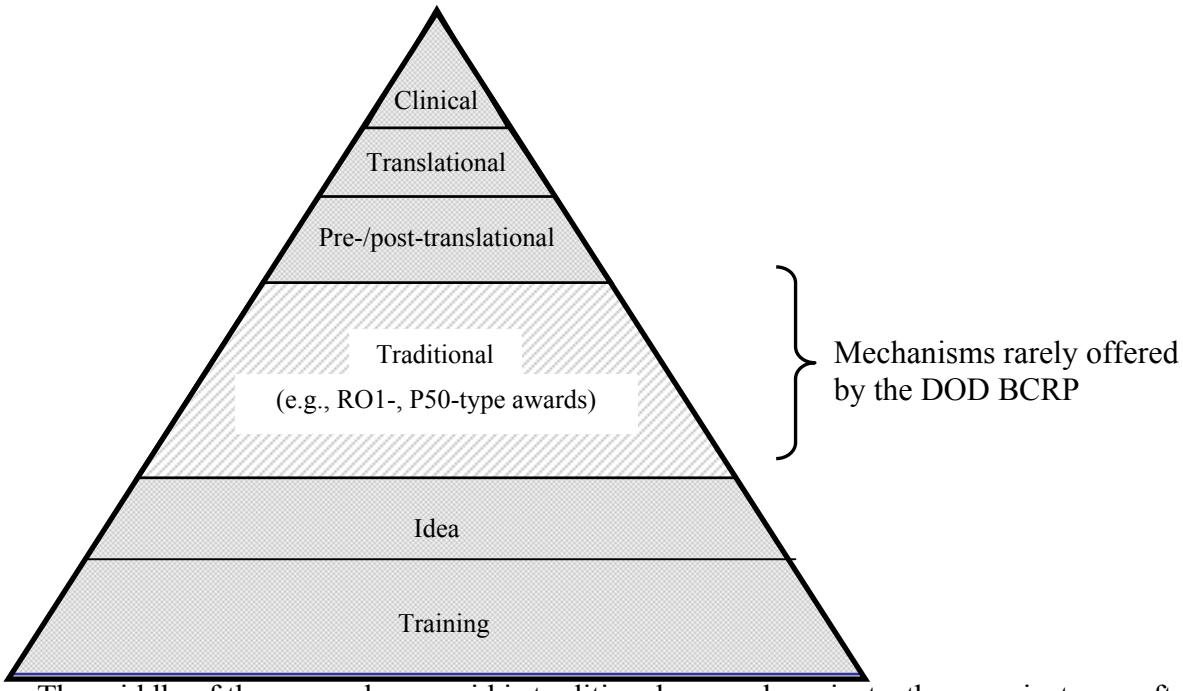
II-C. BCRP Emphasis Areas

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

- The foundation of the pyramid is the training of investigators in breast cancer research. The FY02 BCRP will offer several training/recruitment awards (see Section VII of this program announcement and FY02 Program Announcement II, anticipated to be released in March 2002). New training awards will be offered in Program Announcement II for physicians and nurses who want to pursue clinical research careers; these awards will also directly impact translational and clinical research.

- The second level of the pyramid is ideas; research starts with thousands of ideas, not all of which will lead to fruitful areas of investigation. Idea Awards have been and continue to be a major emphasis of the BCRP; a new Exploration Award will also be offered to support the initial evaluation of a concept (FY02 BCRP Program Announcement II, anticipated to be released in March 2002).

Figure II-1. BCRP Funding Philosophy



- The middle of the research pyramid is traditional research projects; these projects are often

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

- Approaching the pyramid's summit are Translational Awards. The BCRP focuses efforts at the critical juncture between bench and bedside research. CTR Awards support research projects that move bench research into a clinical trial during the life of the award (see Section III).

- The pinnacle of the pyramid represents the very few research studies that make it to a clinical trial. Biotechnology Clinical Partnership Awards provide an impetus for biotechnology companies and academic institutions to work together to accelerate the delivery of novel breast cancer therapeutics by offering support for Phase 1/2 or Phase 2 clinical trials (see Section IV). The BCRP supports the infrastructure for developing new means to perform clinical trials through C-CTR Awards (see Section V).

Most awards offered by the BCRP fit into one level of the pyramid. However, in FY02, the BCRP is offering two awards that may either fit a single level or span multiple levels of the pyramid.

- Breast Cancer Center of Excellence Awards may focus on an overarching problem in breast cancer research at any level of this pyramid or may traverse several levels of the pyramid from training and basic research to the clinical use of information (see Section VI).

- Innovator Awards are intended to attract outstanding investigators from a diversity of fields to explore new avenues in breast cancer research (FY02 BCRP Program Announcement II, anticipated release in March 2002).

II-D. FY02 BCRP Program Announcement Award Opportunities

The programmatic strategy for BCRP Program Announcement I is to fund proposals in three categories: (1) Research Awards, (2) Infrastructure Awards, and (3) Training/Recruitment Awards. In addition, a unique award that does not fit into these categories, the Innovator Award, is included in Program Announcement II. This Command anticipates that an estimated $136M will be available for the FY02 BCRP to fund competitive, peer reviewed breast cancer research.

The DOD intends that 5.5% of the available monies be used to fund awards at HBCU/MI. (Applicants from HBCU/MI should see Appendix B, part 1 for additional information.) In addition, as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585), the

DOD BCRP expects to receive approximately $3M in 2002 for breast cancer research. The DOD plans to use all Breast Cancer Stamp monies received prior to November 2002 to fund additional scientifically meritorious Idea Award proposals submitted to the FY02 BCRP.

Additional details of the FY02 budget and the intended allocations for each mechanism are provided in Tables II-3 and II-4.

Table II-3: Estimated Budget for the FY02 BCRP

Congressional Appropriation	**$150.0M**
Less: Congressional/DOD Withholds[1]	($9.6M)
Appropriation Received	$140.4M
Less: Approximate BCRP Management Costs[2]	($7.7M)
Plus: Estimated Stamp Out Breast Cancer Act Proceeds	$3.0M
Amount Available for FY02 Research	**$135.7M**

[1] Withholds include Small Business Innovation Research (SBIR)/USAMRMC. For more information, refer to the Small Business Administration web site (http://www.sba.gov/SBIR).
[2] Any cost savings from management costs will be applied to research funding.

FY02 BCRP budget data are estimated based on prior year's experience and information available for the current year. The only data known at the time of publication of this program announcement is the congressional appropriation in the amount of $150M. Until funds are received by USAMRMC, a final budget for withholds, management costs, or research cannot be quantified nor can research funding availability be guaranteed.

Table II-4: Anticipated Investment by Award Category and Mechanism

Research Awards:	**$55.5M**
CTR Awards	$5.1M
Biotechnology Clinical Partnership Awards	$5.1M
Exploration Awards	$6.2M
Idea Awards	$39.1M
Infrastructure Awards:	**$33.9M**
C-CTR Awards	$3.1M
Center Awards	$30.8M
Training/Recruitment Awards:	**$37.0M**
HBCU/MI Partnership Training Awards	$6.2M
Undergraduate Summer Training Program Awards	$2.1M
Predoctoral Traineeship Awards	$5.1M
Postdoctoral Traineeship Awards	$10.3M
Clinical Research Nurse Awards	$5.1M
Physician-Scientist Training Award	$8.2M
Innovator Awards	**$9.3M**
Total	**$135.7M**

Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this program announcement carefully because revisions have been made.

Important note regarding duplicate submissions: Submission of the same research project to the FY02 BCRP under different award mechanisms is **not** allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms by different Principal Investigators. The Government reserves the right to reject any proposal.

Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available	Receipt and Submission Deadlines	Instructions for Proposal Preparation
Clinical Translational Research Awards	All levels of experience	• Research and clinical trial components • Chemoprevention and therapeutics • Preliminary data required • Must have a clinical trial, with at least 1 year of patient accrual within the lifetime of the award	No maximum dollar limit for a period of up to 4 years	Required Pre-Proposal: April 3, 2002 4:00 p.m. ET* Full Proposal: August 21, 2002 11:59 p.m. (applicant's local time)	Section III
Biotechnology Clinical Partnership Awards	All levels of experience	• Biotechnology company partnering with academic institution • Lead agent with some information regarding safety, toxicity, and efficacy in preclinical models • Must have a clinical trial, with at least 2 years of patient accrual within the lifetime of the award	No maximum dollar limit for a period of up to 4 years	Required Pre-Proposal: April 3, 2002 4:00 p.m. ET Full Proposal: August 21, 2002 11:59 p.m. (applicant's local time)	Section IV
Collaborative-Clinical Translational Research Awards	All levels of experience	• To (1) develop models for performing clinical trials and (2) test new agents or technologies • Infrastructure support • To support collaborations among academia, community-based oncology clinics, the private sector, and consumers • Must contain prospective clinical trials within the lifetime of the award	A maximum award of $1.2M in direct costs for a period of up to 3 years	Required Pre-Proposal: April 3, 2002 4:00 p.m. ET Full Proposal: August 21, 2002 11:59 p.m. (applicant's local time)	Section V

* Eastern Time.

Breast Cancer Center of Excellence Awards	Established investigators with experience in managing large research programs	• Team of preeminent individuals from different disciplines and institutions • Unified focus on overarching breast cancer problem using a comprehensive array of personnel and resources • Prevention and tailored cancer therapeutics encouraged	A maximum award of $5M in direct costs for a period of up to 4 years	Required Pre-Proposal: April 3, 2002 4:00 p.m. ET Full Proposal: August 21, 2002 11:59 p.m. (applicant's local time)	Section VI
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 provide faculty training toward developing a breast cancer research program at the HBCU/MI	Up to $250,000/year for direct and indirect costs for up to 4 years; no more than 25% of the awarded funds may be directed toward the collaborating institution over the lifetime of the award	Required Pre-Proposal: April 3, 2002 4:00 p.m. ET Full Proposal: August 21, 2002 11:59 p.m. (applicant's local time)	Section VII

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

III. Clinical Translational Research Awards

III-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 proposals are only being sought in the areas of chemoprevention and therapeutics.** CTR Awards are for the support of projects that are likely to have a major impact on the chemoprevention and/or therapy of breast cancer by applying promising and well-founded laboratory or other preclinical or clinical research findings to the care of patients with, or populations at risk for, breast cancer. Projects that would be advanced into clinical trial during this award may have been initiated in the applicant's laboratory. **Alternatively, projects may capitalize on independently published research if the applicant can demonstrate the ability to conduct the required preclinical and Phase 1 or 2 clinical trial aspects of the project**. ***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.*** The inclusion of a clear experimental and appropriately powered statistical plan to perform a prospective clinical trial or study is a requirement for consideration. 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 mechanism is to sponsor novel research that will result in substantial improvements over today's approach to chemoprevention and/or therapy of breast cancer.

It is anticipated that approximately $5M will be available for CTR Awards. There are no dollar amount restrictions to these awards. Research should be completed in within 4 years. As noted in Appendix F, it is the policy of the Department of Defense (DOD) that the Principal Investigator (PI) should possess the equipment needed to support the proposed research; requests for equipment in excess of 10% of the direct costs of the project will be considered only in rare cases. The focus of the CTR Award should be on the clinical trial and work leading to the clinical trial.

Investigators interested in applying for CTR Awards must submit a pre-proposal to be received **no later than April 3, 2002 at 4:00 p.m. Eastern Time** (see Section III-E for details of pre-proposal preparation). Pre-proposals will be screened according to the criteria in Section III-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full CTR proposal will be sent to selected investigators no later than May 2002 (see Section III-F for details of invited, full proposal preparation). The deadline for electronic submission of the invited, full proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)**. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Sections I-C, III-C, and III-D.

III-B. Screening Criteria for Clinical Translational Research Award Pre-Proposals

Pre-proposals will be screened based on the following criteria:

- The application of well-founded laboratory or other preclinical insights that justify the progression of a project into clinical trial, with emphasis on the potential to revolutionize chemoprevention and/or therapy of breast cancer.

- The outline of a ***clear*** experimental plan for a prospective human clinical study or trial that will be conducted during the course of the award. Clinical research funded by this award can result from:

  - the development in the investigator's laboratory of a new compound that can proceed to Phase 1 testing, or

  - independently published preclinical and/or clinical data to support the conduct of a Phase 1 or 2 breast cancer trial. In this case, the investigator must present sufficient preliminary data to ensure his or her ability to conduct the required preclinical and clinical studies.

- The outline of a ***clear,*** appropriately powered statistical plan to answer the research questions posed.

- The likelihood of accruing study subjects in the proposed prospective trial for a minimum of 1 year.

- The project's potential to extend findings in breast cancer research that offer the potential to revolutionize breast cancer chemoprevention and/or therapy.

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

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 chemoprevention and/or therapy within the lifetime of the grant? Does the applicant acknowledge potential problem areas and consider alternative approaches? Does the applicant demonstrate the ability to accrue a sufficient number of subjects?

- **Translational Potential:** ***Is the project likely to result in subject accrual in the proposed prospective trial so that a minimum of 1 year of subject accrual can be achieved?*** Does the project clinically evaluate promising and well-founded laboratory or other preclinical research findings for 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 chemoprevention and/or therapy of breast cancer?

- **Clinical Relevance and 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 chemoprevention and/or therapy 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, underexplored, 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 meaningful results? Is there a clear statistical plan, including power analysis, outlined in the proposal? Is the appropriate statistical expertise represented on the research team?

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

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

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

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

III-E. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for CTR Awards. Please note that the body of the pre-proposal is limited to **2 pages** and that the **receipt deadline is April 3, 2002 at 4:00 p.m. Eastern Time**. Following completion of the pre-proposal screening process, investigators selected to submit a full proposal will be notified no later than May 2002. The submission deadline for the invited, full CTR proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)** (see Section III-F for details on invited, full CTR proposal preparation).

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

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

3. Proposal Information – **Not required** for pre-proposals.

4. The Pre-Proposal Title Page should 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 number, fax number, and e-mail address.

   e. Organization name and location (including city, state, zip or postal code, and country).

   f. Three key words that describe the research (please do not use "breast cancer," "clinical trial," or "translational" as key words).

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 with at least 1 year of patient accrual during the course 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 each of 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 – See Appendix E.
   Biographical sketches should be prepared for key personnel, including collaborating investigators. Biographical sketches may not exceed 3 pages per individual. The Biographical Sketch form can be found in Appendix E, or downloaded from the Congressionally Directed Medical Research Programs web site at http://cdmrp.army.mil/funding/default

9. Submit the following documentation to the address listed below:

Pre-Proposal:	**ONE** clearly labeled original (binder-clipped) and **TWENTY** collated, three-hole-punched photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original.** Do not use rubber bands, or spiral or three-ring binders.
Packaging:	Package only **ONE** complete pre-proposal submission (original plus twenty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. The postcard should state the pre-proposal title and PI's name.
Noncompliance:	Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**
Send the pre-proposal to:	Commander U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (BCRP-02) 1076 Patchel Street (Building 1076) Fort Detrick, MD 21702-5024

10. Receipt Deadline.
    Please note that the **receipt deadline for CTR Award pre-proposals is April 3, 2002 at 4:00 p.m. Eastern Time.**

III-F. Invited, Full CTR Proposal Preparation

Investigators interested in applying for CTR Awards must submit a pre-proposal (see Section III-E). Pre-proposals will be screened according to the criteria in Section III-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full CTR proposal will be sent to selected investigators no later than May 2002. ***Do not submit a full CTR proposal unless you receive a letter of invitation.*** (For the funding history of CTR proposals for fiscal years 1997-2001, please see Section II, Table II-2.)

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for ***invited*** CTR Award proposals. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections III-C and III-D, respectively. Please note that the body of the proposal is limited to **15 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

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

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

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number (assigned after pre-proposal receipt).

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

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

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

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, CTR Award applicants should state explicitly (within the 1-page limit) how the proposed work is translational, meets the intent of the CTR Award mechanism, and is relevant to breast cancer chemoprevention and/or therapeutics.

11. Proposal Body – See Appendix B, part 11.
    The body of CTR Award proposals is limited to **15 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    Describe the overall project using the general outline provided below.

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to the proposal. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the specific aims and research strategy of the study.

    d. Preliminary Data: Provide pertinent data to support the hypothesis to be tested.

    e. Proposed Research and Methods: Provide details about the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Describe the plans for the prospective human clinical trial. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

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

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

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

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, include letters of support documenting availability and quality control for all critical reagents.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. There are no dollar amount restrictions for CTR Awards. Funding is to support research for up to 4 years. As noted in Appendix F, it is the policy of the DOD that the PI possess the equipment needed to support the proposed research. Requests for equipment in excess of 10% of the direct costs of the project will be considered only in rare cases. The amount allotted for travel is $1,800 per year per PI to attend scientific/technical meetings. In addition, funding should also be requested for a one-time, 3½-day meeting to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate form.

    For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, part 7 for more details.

19. Instruments – See Appendix B, part 19.

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

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

22. Submission Deadline – See Appendix B, part 22.
    Do not submit a full CTR proposal unless you receive a letter of invitation following the pre-proposal screening process. Please note that one electronic PDF version of your proposal must be uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

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

Principal Investigator:_____
Last Name *First Name* *MI*

Proposal Title:_____

_____

Clinical Translational Research Award Proposal
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Table of Contents (1-page limit)	1
Checklist for Proposal Submission (1 page)	2
Technical Abstract (1-page limit)	3
Lay Abstract (1-page limit)	4
Statement of Work (2-page limit)	5
Proposal Relevance Statement (1-page limit)	___
Proposal Body (15-page limit)	___
Abbreviations (1-page limit)	___
References (no page limit)	___
Biographical Sketches (3-page limit each)	
PI (CTR Applicant)	___
Key Personnel (including collaborating investigators, individuals in training, and support staff)	___
Existing/Pending Support (no page limit)	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
List of all items included in this section	___
Letters of support documenting availability and quality control for all critical reagents	___
Letter(s) of support from collaborating individuals and/or institutions	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and/or Patent Abstracts (5-document limit)	___

IV. Biotechnology Clinical Partnership Awards

IV-A. Biotechnology Clinical Partnership Awards

The intent of Biotechnology Clinical Partnership Awards is to fund prospective clinical trials in the areas of breast cancer therapeutics and chemoprevention. The major goal of this award is to establish partnerships between the biotechnology industry and academic institutions that will reduce the drug development challenges faced by many biotechnology companies, and accelerate the delivery of novel breast cancer therapeutics and chemopreventives.

These awards are designed to support Phase 1/2 or Phase 2 clinical trials. One partner must have expertise in drug development and must have a potential breast cancer drug/chemopreventive, with the means to produce sufficient quantities of appropriate quality for clinical trials. The other partner should have the expertise and the means to direct a clinical trial and accrue an appropriate number of breast cancer patients to demonstrate efficacy of the agent. The lead agent of the clinical trial may include a newly discovered breast cancer therapeutic/chemopreventive or a therapeutic/chemopreventive originally designed for the treatment of other diseases or conditions that has promise for the treatment or prevention of breast cancer. **This award is not intended to support the study of new combinations of standard breast cancer therapies.** For lead agents developed for other diseases, the safety of the agent and preliminary dose proportionality information should already be available. Investigational use rules will apply for these agents [see 21 CFR 312.3(b)[1]]. Optimally, all lead agents should already be on file with the Food and Drug Administration (FDA) as an investigational new drug (IND) prior to proposal submission. However, proposals that include limited, clearly defined preclinical work to further define or clarify specific antitumor activity will be considered.

Biotechnology Clinical Partnership Awards are designed for the support of projects that are likely to have a major impact on treatment or prevention of breast cancer by applying promising and well-founded preclinical findings to the care of patients with, or populations at risk for, breast cancer. ***Applicants must include data to support the feasibility of their hypotheses and approaches, along with a plan to conduct a prospective clinical trial with a minimum of 2 years of patient accrual during the lifetime of the award.*** The inclusion of a clear experimental and appropriately powered statistical plan to perform a prospective clinical trial is a requirement for consideration.

In accordance with the Bayh-Dole Act (35 USC 200 et seq.[2]), title to inventions and patents resulting from federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents. However, because this research would involve both a private

[1] Title 21, Code of Federal Regulations, Part 312, Section 3(b).
[2] Title 35, United States Code, Section 200, et seq.

biotechnology company and an academic institution, an intellectual property rights agreement between the two parties should be developed. This agreement should be included with the submission of the Biotechnology Clinical Partnership Awards proposal (see Section IV-F.17).

It is anticipated that approximately $5M will be available for Biotechnology Clinical Partnership Awards. There are no dollar amount restrictions to these awards. Research should be completed in 4 years. The focus of the award should be the clinical trial.

Investigators interested in applying for Biotechnology Clinical Partnership Awards must submit a pre-proposal to be received **no later than April 3, 2002 at 4:00 p.m. Eastern Time** (see Section IV-E for details of pre-proposal preparation). Pre-proposals will be screened according to the criteria in Section IV-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Biotechnology Clinical Partnership Award proposal will be sent to selected investigators no later than May 2002 (see Section IV-F for details of invited, full proposal preparation). The deadline for electronic submission of the invited, full proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)**. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Sections I-C, IV-C, and IV-D.

IV-B. Screening Criteria for Biotechnology Clinical Partnership Awards Pre-Proposals

Pre-proposals will be screened based on the following criteria:

- The selection and specific identification of a novel *molecule* or *compound* that offers the potential to revolutionize breast cancer therapeutics or chemoprevention.

- The establishment of a clear *partnership* between a biotechnology or pharmaceutical company and an academic institution, with each collaborator complementing the core competency of the other.

- The demonstration of an existing IND application or exemption that includes *laboratory data* or other *preclinical insights* for the proposed agent, that include safety and activity data; and specific reference/data to show that the agent has shown activity in animal models and is a rational choice to evaluate in breast cancer clinical trials (or, if an IND application has not already been filed, a clear plan to complete necessary preclinical work and to submit an IND application).

- The outline of a ***clear*** experimental plan with appropriate statistical power for a prospective human clinical trial that will be conducted during the course of the award.

- The likelihood of accruing study subjects in the proposed prospective trial for a minimum of 2 years during the course of the award.

- The project's potential relevance to an important problem in the area of breast cancer therapeutics or chemoprevention.

IV-C. Scientific Peer Review Evaluation Criteria for Biotechnology Clinical Partnership Award Proposals

- **Lead Agent:** Is there adequate laboratory and other preclinical evidence to support the clinical feasibility and promise of the agent? Is documentation provided that the therapy to be evaluated will be available in the required quality and sufficient quantity to permit a clinical trial? Has IND exemption been received or has an IND application been filed? If not, can IND exemption be obtained in time to accrue patients to test the agent? If the agent has been clinically tested in a disease other than breast cancer, are there sufficient data to rationalize the testing of this agent as a breast cancer therapeutic or chemopreventive?

- **Clinical Relevance and Impact:** Does the study address an important problem in the area of breast cancer therapy or chemoprevention? If the aims of the application are achieved, are they likely to have a ***substantial clinical impact***?

- **Trial Design:** 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? Do the applicants acknowledge potential problem areas and consider alternative approaches? Have the availability of subjects for the trial and the likelihood of subject attrition been addressed? Is the recruitment schedule reasonable and does it provide for at least 2 years of patient accrual within the lifetime of the award?

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

- **Personnel:** Is there appropriate representation of breast cancer research expertise and clinical trial experience to complete the study? 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? Is there a clear description of the expectations of both the biotechnology company and the academic institution?

- **Environment:** Does the proposed partnership create 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? Are letters of commitment included from the participating biotechnology company and academic institution(s)? Has an equitable intellectual property agreement been described?

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

IV-D. Programmatic Review Evaluation Criteria for Biotechnology Clinical Partnership Awards

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

IV-E. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for Biotechnology Clinical Partnership Awards. Please note that the body of the pre-proposal is limited to **3 pages** and that the **receipt deadline is April 3, 2002 at 4:00 p.m. Eastern Time**. Following completion of the pre-proposal screening process, investigators selected to submit a full proposal will be notified no later than May 2002. The receipt deadline for the invited, full Biotechnology Clinical Partnership Awards proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)** (see Section IV-F for details on invited, full Biotechnology Clinical Partnership Awards proposal preparation).

1. Who May Apply – See Appendix B, part 1.
   In addition to the criteria described in Appendix B, part 1, this mechanism is specific for application of a private company and academic institution(s) collaboration.

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

3. Proposal Information – **Not required** for pre-proposals.

4. The Pre-Proposal Title Page should include the following information:

   a. Pre-Proposal title.

   b. Award Category; i.e., Biotechnology Clinical Partnership Awards.

   c. Principal Investigator's (PI's) full name, including middle initial.

   d. PI's phone number, fax number, and e-mail address.

   e. Organization name and location (including city, state, zip or postal code, and country).

   f. Three key words that describe the research (please do not use "breast cancer," "clinical trial," or "translational" as key words).

5. Pre-Proposal Body – Limited to **3 pages**.
   It is the responsibility of the applicant to ***articulate clearly how the proposed research specifically addresses each of the Biotechnology Clinical Partnership Awards screening criteria for pre-proposals***.

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 – See Appendix E.
   Biographical sketches should be prepared for key personnel, including collaborating investigators. Biographical sketches may not exceed 3 pages per individual. The Biographical Sketch form can be found in Appendix E, or downloaded from the Congressionally Directed Medical Research Programs web site at http://cdmrp.army.mil/funding/default

8. Submit the following documentation to the address listed below:

Pre-Proposal:	**ONE** clearly labeled original (binder-clipped) and **TWENTY** collated, three-hole-punched photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original.** Do not use rubber bands, or spiral or three-ring binders.
Packaging:	Package only **ONE** complete pre-proposal submission (original plus twenty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. The postcard should state the pre-proposal title and PI's name.
Noncompliance:	Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**
Send the pre-proposal to:	Commander U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (BCRP-02) 1076 Patchel Street (Building 1076) Fort Detrick, MD 21702-5024

9. Receipt Deadline.
   Please note that the **receipt deadline for Biotechnology Clinical Partnership Awards pre-proposals is April 3, 2002 at 4:00 p.m. Eastern Time.**

IV-F. Invited, Full Biotechnology Clinical Partnership Proposal Preparation

Investigators interested in applying for Biotechnology Clinical Partnership Awards must submit a pre-proposal (see Section IV-E). Pre-proposals will be screened according to the criteria in Section IV-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Biotechnology Clinical Partnership proposal will be sent to selected investigators no later than May 2002. ***Do not submit a full Biotechnology Clinical Partnership proposal unless you receive a letter of invitation.***

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for ***invited*** Biotechnology Clinical Partnership Awards proposals. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-C and IV-D, respectively. Please note that the body of the proposal is limited to **25 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

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

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

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number (assigned after pre-proposal receipt).

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

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

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

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Biotechnology Clinical Partnership Awards applicants should state explicitly (within the 1-page limit) how the proposed work meets the intent of the Biotechnology Clinical Partnership Award mechanism.

11. Proposal Body – See Appendix B, part 11.
    The body of the Biotechnology Clinical Partnership Award proposals is limited to **25 pages**, inclusive of figures, tables, and graphs, if used.

    Describe the proposed project using the general outline below:

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to the proposal; provide an overview of the state of the science, and the relevance of the trial. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the specific aims of the study.

    d. Preliminary Studies: A presentation of the studies that led to the proposed clinical trial is required. Data from pilot studies and additional supporting data from other research that support the necessity, feasibility, and potential of the trial should also be provided. Safety and preliminary dosage data should be supplied.

    e. Preclinical Studies Proposed: Provide details about the experimental design and methodology. Include steps to be followed to obtain IND exemption if needed.

f. Clinical Trial Design: Include a discussion of the following topics.

- Study design for the intervention to be used.
- Potential biases in the research protocol and how they will be addressed.
- Clinical, behavioral, laboratory, and physiological tests and protocols.
- Availability of the lead agent, including (1) the amount presently on hand, (2) the means to obtain additional amounts, and (3) the total amount estimated to be needed for the clinical trial.
- Patient recruitment, including (1) patient availability; (2) inclusion and exclusion criteria; (3) methods for recruiting, retention, and follow-up; (4) data to support recruitment/retention estimates; (5) patient assignment to experimental groups and methods of randomization (if any); and (6) study endpoints.
- Data management, including the (1) overall approach to data management, (2) a statistical plan that includes sample size calculations and methods to monitor quality and consistency of both the intervention and data collection, and (3) data security measures.
- Methods of analysis (primary and secondary endpoints should be clearly defined and related to the power calculation).
- Any issues that may lead to concern for the welfare of human subjects and confidentiality.
- A study organization and management plan, including an organizational chart and timetable.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

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

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

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

17. Administrative Documentation – See Appendix B, part 17.
    Include the following items in this section of the proposal submission.

    - Letters of commitment from the collaborating biotechnology company and academic institution confirming collaborative efforts that are necessary for the project's success. These letters should include documentation of support by the collaborating groups (e.g., the provision of a proposed therapeutic, patient availability).

    - Documentation of IND application or exemption for the agent to be tested (unless a clear plan to complete necessary preclinical work and to submit an IND application is presented).

    - A copy of the intellectual property agreement between the collaborating biotechnology company and academic institution, and assurances that the individuals and their organizations are willing to resolve intellectual property issues.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. There are no dollar amount restrictions for Biotechnology Clinical Partnership Awards. Funding is to support research for up to 4 years. As noted in Appendix F, it is the policy of the Department of Defense (DOD) that the PI possess the equipment needed to support the proposed research. Requests for equipment in excess of 10% of the direct costs of the project will be considered only in rare cases. A budget for the entire trial and data analysis period must be provided. If some costs of the trial are to be funded through other sources, provide detailed information about these sources. Budgets should clearly delineate which portions are being requested for support by this program and which are to be supported by other sources. A total overall budget as well as itemized, individual budgets for each year of support requested must be prepared. If multiple centers are proposed or if any subcontract(s) for personnel or facilities exist, separate itemized budgets must be prepared for each year of the study. The amount allotted for travel is $1,800 per year per collaborator to attend scientific/technical meetings. In addition, funding should also be requested for the PI for a one-time, 3½-day meeting to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

    For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F for more details.

19. Instruments – See Appendix B, part 19.

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

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

22. Submission Deadline – See Appendix B, part 22.
    Do not submit a full Biotechnology Clinical Partnership Award proposal unless you receive a letter of invitation following the pre-proposal screening process. Please note that one electronic PDF version of your proposal must be uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

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

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

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Abbreviations (1-page limit)	___
References (no page limit)	___
Biographical Sketches (3-page limit each)	
PI (Biotechnology Clinical Partnership Applicant)	___
Key Personnel (including collaborating investigators, individuals in training, and support staff)	___
Existing/Pending Support (no page limit)	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
List of all items included in this section	___
Letters of commitment from private and academic partners	___
Documentation of IND application or exemption	___
Intellectual property agreement between partners	___
Letters of support from collaborating individuals or institutions	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
Publications and/or Patent Abstracts (5-document limit)	___

V. Collaborative-Clinical Translational Research Awards

V-A. Collaborative-Clinical Translational Research Awards

The goals of this award mechanism are (1) to support the infrastructure costs (primarily personnel) required to develop consortium models based on new or existing networks that include academic centers, community-based oncology practices, consumer/survivor groups, 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.

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 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).*** Funds from C-CTR Awards are not intended to replace funds provided by industry to support clinical trials of new agents.

Models for performing breast cancer clinical trials through novel partnerships are the focus of C-CTR Awards. These 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 the involvement of consumer/survivor organizations; and (3) increase the number of drugs, modalities (including biological agents), or technologies tested for breast cancer. Also, applicants should form collaborations with consumer/survivor organizations in the hope that this will increase patient accrual in the planned clinical trials. Please note that breast cancer consumer/survivor groups should be active participants in these efforts. Consumers should be involved in program conception and design, recruitment of research participants, and/or in program evaluation and dissemination of information to the public. 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 of 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 these approaches will involve drugs, modalities, and technologies in development by the private sector (e.g., pharmaceutical, biotechnology, or other companies). Full proposals must include a letter of support that clearly demonstrates a commitment from any such partner (e.g., a pharmaceutical company providing access to new drugs/modalities/treatments/diagnostics).

The following items are essential for a C-CTR Award:

1. Drugs, modalities, or technologies ready for clinical trials (Phase 1 or 2) with appropriate scientific hypothesis and plan.

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

3. Consumer involvement in program conception and design, recruitment of research participants, and/or in program evaluation and dissemination of information to the public.

4. Community-based oncology practices with sufficient patient populations willing to participate.

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

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, the outcomes of which clearly demonstrate 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, consumer/survivor organizations, 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. The C-CTR is not an appropriate funding mechanism for preclinical drug, modality, or technology development.

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

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

It is anticipated that approximately $3M will be available to support C-CTR awards. Support can be requested for a maximum of $1.2M in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can 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 F, it is the policy of the Department of Defense (DOD) that the Principal Investigator (PI) should possess the equipment needed to support the proposed research; requests for equipment in excess of 5% of the direct costs of the project will be considered only in rare cases.

Investigators interested in applying for a C-CTR Award must submit a pre-proposal to be received **no later than April 3, 2002 at 4:00 p.m. Eastern Time** (see Section V-E for details of pre-proposal preparation). Pre-proposals will be screened according to the criteria in Section V-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full C-CTR proposal will be sent to selected investigators no later than May 2002 (see Section V-F for details of invited, full proposal preparation). The deadline for electronic submission of the invited, full proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)**. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Sections I-C, V-C, and V-D.

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

Pre-proposals will be screened based on the following criteria.

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

- Evidence to clearly show that the drugs, modalities, or technologies will be available in the required quality and sufficient quantity for breast cancer clinical trials.

- The outline of a ***clear*** experimental plan to perform peer-reviewed prospective human clinical trials.

- Documentation of sufficient patient populations willing to participate in prospective clinical trials and potential for significant patient accrual.

- The identification of appropriate statistical support.

- The likelihood of obtaining initial clinical results within the lifetime of the award.

- 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 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 Invited, Full Collaborative-Clinical Translational Research Award Proposals

Invited, full C-CTR proposals will be evaluated in scientific peer review according to the criteria listed below.

- **Consortium Model:** Are the partners capable and committed? Are the collaborations likely to lead to increased patient accrual? Does the proposed network of collaborations represent an innovative model for early clinical trials? Are the private sector, community-based oncology practices, and consumer/survivor organizations active participants in this effort as demonstrated by letters of commitment? Is there evidence of institutional support for the establishment of the consortium? Are the plans for patient accrual realistic, including demonstration of the availability of sufficient patient populations? Has the ethnic diversity of the patient population been considered appropriately in developing community collaborations?

- **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?

- **Clinical Relevance and 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***?

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

- **Personnel:** Is the PI appropriately trained and well suited to carry out and coordinate this work? Are the other 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? Has a plan been presented for how this project will be managed and coordinated?

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

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

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

V-E. 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 **receipt deadline is April 3, 2002 at 4:00 p.m. Eastern Time**. Following completion of the pre-proposal screening process, investigators selected to submit a full proposal will be notified no later than May 2002. The deadline for the invited, full C-CTR proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)** (see Section V-F for details on invited, full C-CTR proposal preparation).

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

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

3. Proposal Information – **Not required** for pre-proposals.

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 number, fax number, and e-mail address.

   e. Organization name and location (including city, state, zip or postal code, and country).

   f. Three key words that describe the research (please do not use "breast cancer," "clinical trial," or "translational" as key words).

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

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 – See Appendix E.
   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 E, or it can be downloaded from the Congressionally Directed Medical Research Programs web site at http://cdmrp.army.mil/funding/default

8. Submit the following documentation to the address listed below:

Pre-Proposal:	**ONE** clearly labeled original (binder-clipped) and **TWENTY** collated, three-hole-punched photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original.** Do not use rubber bands, or spiral or three-ring binders.
Packaging:	Package only **ONE** complete pre-proposal submission (original plus twenty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. The postcard should state the pre-proposal title and PI's name.
Noncompliance:	Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**
Send the pre-proposal to:	Commander U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (BCRP-02) 1076 Patchel Street (Building 1076) Fort Detrick, MD 21702-5024

9. Receipt Deadline.
   Please note that the **receipt deadline for C-CTR Award pre-proposals is April 3, 2002 at 4:00 p.m. Eastern Time.**

V-F. Invited, Full C-CTR Proposal Preparation

Investigators interested in applying for C-CTR Awards must submit a pre-proposal (see Section V-E). Pre-proposals will be screened according to the criteria in Section V-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full C-CTR proposal will be sent to selected investigators no later than May 2002. ***Do not submit a full CTR proposal unless you receive a letter of invitation.*** (For the funding history of C-CTR proposals for fiscal years 1997-2001, please see Section II, Table II-2.)

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for ***invited*** C-CTR Award proposals. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections V-C and V-D, respectively. Please note that the body of the proposal is limited to **15 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

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

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

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number (assigned after pre-proposal receipt).

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

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

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

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, C-CTR Award applicants should state explicitly (within the 1-page limit) how the model specifically addresses 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 the involvement of consumer/survivor organizations; and (3) increase the number of drugs, modalities (including biological agents), or technologies tested for breast cancer.

11. Proposal Body – See Appendix B, part 11.
    The body of C-CTR Award proposals is limited to **15 pages,** inclusive of figures, tables, graphs, and photographs, if used**.**

    Describe the overall project using the general outline provided below.

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to the proposal. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the specific aims and research strategy of the study.

    d. Preliminary Data: Proposals should include data on preclinical results that clearly demonstrate that the drugs, modalities, or technologies are ready to be tested in clinical trials (Phase 1 or 2).

    e. Proposed Research and Methods: This section should include, but is not limited to,

        i. A description of collaboration among community-based oncology practices, the private sector, academic center(s), and consumer survivor group(s).

        ii. A description of how the central institution will coordinate the program.

        iii. Information on patient populations.

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

v. A plan to test multiple agents in *prospective* clinical trials within the lifetime of the award. Provide details about the statistical plan, experimental design, and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

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

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

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

17. Administrative Documentation – See Appendix B, part 17.
On the list of all items included in the Administrative Documentation section, (see Appendix B), include the names, position, and grant function (e.g., private sector collaborator, breast cancer consumer/survivor organizations) of the authors of all letters of support.

    In addition to the documentation described in Appendix B, the following documentation must also be included in the C-CTR Award proposal submission:

    - Letters from private sector collaborators documenting a willingness to participate and the availability of the necessary drugs, modalities, or technologies.

    - Letters from academic center collaborators, if any, documenting a willingness to participate and, if appropriate, access to patient populations and the availability of the necessary drugs, modalities, or technologies.

    - Letters from community-based oncology practices documenting a willingness to participate and access to patient populations.

    - Letters from breast cancer consumer/survivor organizations documenting a willingness to participate and how they will contribute to the projects, e.g., through increasing patient accrual, program conception and design, recruitment of research participants, and/or in program evaluation and dissemination of information to the public.

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. The cost of preparing proposals in response to these instructions is not considered an allowable direct charge to any resultant award. Support can be

requested for a maximum of $1.2M in direct costs for a period of up to 3 years, plus indirect costs as appropriate. Direct costs can support infrastructure costs (primarily personnel), including clinical research nurses and/or data management personnel for clinical data management and clinical outreach. Funds are not intended to replace funds provided by industry to support clinical trials of new patients or 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 F, it is the policy of the DOD that the PI should possess the equipment needed to support the proposed research; requests for equipment in excess of 5% of the direct costs of the project will be considered only in rare cases. The amount allotted for travel is $1,800 per year per collaborator to attend scientific/technical meetings. In addition, funding should also be requested for the PI for a one-time, 3½-day meeting to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate form.

For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F for more details.

19. Instruments – See Appendix B, part 19.

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

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

22. Submission Deadline – See Appendix B, part 22.
    Do not submit a full C-CTR proposal unless you receive a letter of invitation following the pre-proposal screening process. Please note that one electronic PDF version of your proposal must be uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

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

Principal Investigator:_____
Last Name *First Name* *MI*

Proposal Title:_____

_____

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VI. Breast Cancer Center of Excellence Awards

VI-A. Breast Cancer Center of Excellence Awards

The intent of the Breast Cancer Center of Excellence Awards (Center) is to unite, in a Center of Excellence environment, the most highly qualified investigators to accelerate the solution of a major overarching problem in breast cancer research. ***A Center must have a central, unified focus on an important question relevant to breast cancer that drives the establishment of a synergistic research program.*** The Center Awards are intended to support the establishment of a directed ***multi-institutional collaboration*** among highly accomplished scientists from diverse backgrounds and areas of expertise to create a critical mass of talent focused on a well-defined scientific problem. Centers are encouraged to take a transnational or multicultural approach. ***Breast cancer consumer/survivor groups should be active participants at all levels in these multidisciplinary efforts.*** The results generated from these awards should have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer. This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts such as the National Cancer Institute-supported Specialized Programs of Research Excellence (SPORE) or Program Project grants.

Proposals for the Center Award should (1) assemble and integrate a team of preeminent investigators from different disciplines and institutions; (2) focus on the solution of an important problem in breast cancer research using research strategies that optimize the Center's comprehensive array of personnel and resources; and (3) generally facilitate and accelerate research progress through real-time communication and team problem solving. In setting up a Center, emphasis should be placed on attracting the most highly qualified investigators to focus on the research problem, regardless of their current location. This includes highly accomplished scientists in the targeted areas of research, promising young investigators, and individuals from complementary fields who ultimately represent the best team to solve the problem(s) identified. Communication between Center team members should be addressed, including sharing data in real time and use of information technologies to facilitate timely and effective communication and cooperation. It is anticipated that in order to meet the requirement to bring together the most qualified team of investigators to address a specific problem, the Centers will be multi-institutional, unless a justification is provided that a single institution can best address the Center's focus. Consumers must be members of the collaborative team and must be involved in program conception and design, discussions, recruitment of research participants, and/or program evaluation and dissemination of information to the public. Collaborations established through the Center should result in a synergistic research program with a central, unified theme to address a specific research question rather than an additive set of sub-projects. Collaborators may plan to meet in person two to four times per year to assess research progress, address problems, and define future directions.

Center Award proposals should address an overarching problem that is relevant to the prevention, detection, diagnosis, and/or cure of breast cancer. The central problem addressed by the Center should (1) solve a major problem(s) in breast cancer research; (2) develop critically

needed resources (e.g., databases to address specific problems); and/or (3) create a unique, new approach or infrastructure to focus on a critical research problem.

It is anticipated that approximately $31M will be available to support Center Awards. The Breast Cancer Research Program (BCRP) intends to dedicate about one-third of that amount to proposals in prevention, one-third to proposals in tailored cancer therapeutics, and one-third to proposals in other relevant areas of breast cancer research.

Proposals in the area of prevention should accelerate the development of strategies to prevent the occurrence of breast cancer. The following list illustrates prevention topics that the BCRP believes may be appropriate for the focus of these awards. This list is meant only to provide examples and should not be considered either comprehensive or as examples of preferred or more desirable research questions.

- Determining the contributions and consequences of lifestyle and behavioral factors on primary prevention of breast cancer. Problems that such a Center might address include contributions and consequences of factors such as diet, nutrition, exercise, etc., on breast cancer risk, as well as developing and testing educational and lifestyle interventions to reduce or prevent breast cancer risk.

- Developing or accelerating the development of specific breast cancer preventive agents (e.g., new chemopreventive agents or natural products). The proposal could include the development and validation of preclinical models for the testing of novel chemopreventive agents.

- Determining the role of specific environmental factors in breast cancer etiology relevant to breast cancer prevention (e.g., studying and categorizing interactions of environmental factors with specific breast cancer genes and/or molecular pathways).

- Developing an acceptable array(s) of breast cancer markers for use as surrogate endpoints in clinical trials of new primary prevention agents.

- Generating large or diverse databases through epidemiological studies that link population data with gene composition and genetic mutations.

Proposals in the area of tailored cancer therapeutics should employ the tools from recent advances in genomics, proteomics, and bioinformatics to tailor breast cancer therapy for the individual patient and reduce the use of toxic therapies that can be predicted to be ineffective in a given patient. The Centers should focus on molecular classification of tumors and other relevant patient characteristics and the diagnostic/prognostic implications of these classifications that would lead to individualized patient treatment. The following list illustrates topics that the BCRP believes may be appropriate for inclusion in a tailored cancer therapeutics Center. This list is meant only to provide examples and should not be considered either comprehensive or as examples of preferred or more desirable research questions.

- Develop a tumor classification system based on molecular profile of genetic, mRNA expression, or protein expression variations rather than histopathology, and use these classifications as a basis for identifying and testing therapies.

- Develop methods to accurately establish the drug metabolism profile of a patient (and tumor) to assist with choice of drug and/or dose.

- Identify aberrant signal transduction pathways in breast cancer and use this information as a basis for choice of therapy.

Communication and the overall organization and management of the Centers are important aspects of Center Award proposals. The management and communication components should provide the basis for organizing and managing the Center, establish the processes and tools for regular and structured communication, data management, project meetings, and other issues of common concern. It is anticipated that the Center could take full advantage of current Internet and electronic communication tools, as well as formal and informal meetings.

The topic chosen should be one that is best addressed by a multidisciplinary team of experts and that could be solved most efficiently or effectively within a multi-institutional Center structure. The Center should maximize the utilization of resources and minimize unnecessary duplication; e.g., experimental techniques, databases, models (including animal models), antibodies, etc. should be shared resources for all Center participants. These awards should lead to publications with multidisciplinary authorship. The Center Director, i.e., the Principal Investigator (PI) on the proposal, should have a proven record of leadership and scientific ability to direct and oversee large research programs, including the effective use of communication tools and the management of multifaceted and multidisciplinary projects.

The Center project should be based on well-founded research findings. Applicants ***must*** include published or preliminary data to support the feasibility of their hypotheses and/or approaches, along with a plan to develop the proposed center and conduct the anticipated research.

Funding for Center Awards can be requested for a maximum of $5M in direct costs for a period of up to 4 years, plus indirect costs as appropriate.

Investigators interested in applying for a Center Award must submit a pre-proposal to be received **no later than April 3, 2002 at 4:00 p.m. Eastern Time** (see Section VI-E for details of pre-proposal preparation). Pre-proposals will be screened according to the criteria in Section VI-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Center Award proposal will be sent to selected investigators no later than May 2002 (see Section VI-F for details of invited, full proposal preparation). The deadline for electronic submission of the invited, full proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)**. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Sections I-C, VI-C, and VI-D.

VI-B. Screening Criteria for Breast Cancer Center of Excellence Award Pre-Proposals

Pre-proposals will be screened based on the following criteria:

- The specific research question's relevance and impact to the prevention, detection, diagnosis, and/or treatment of breast cancer and suitability to be addressed in a multidisciplinary, multi-institutional center.

- A description of how the interactions and collaborations established through the Center will result in a ***synergistic*** research effort that will substantively accelerate the solution of the central problem.

- The outline of a plan for a multi-institutional, multidisciplinary consortium to address an appropriate problem, including the identification of key personnel.

- The Center Director's qualifications and ability to organize, administer, and manage a well-qualified team of multidisciplinary, multi-institutional researchers and consumer advocates in a center to solve a critical problem in breast cancer research.

- The outline of a plan for consumer advocate involvement in the Center.

- The outline of a project management and communications plan.

- The outline of an experimental plan to address the specific research question.

VI-C. Scientific Peer Review Evaluation Criteria for Invited, Full Center Award Proposals

Breast Cancer Center of Excellence proposals will be evaluated in scientific peer review according to the criteria listed below:

- **Disease Relevance and Impact:** Is the unifying research problem(s) one that would be best solved through a multidisciplinary (generally multi-institutional) approach? Will the Center make an original and important contribution to (1) significantly advancing research to address the key breast cancer research problem/area identified and (2) the goal of eradicating breast cancer?

- **Innovation:** Does this Center represent potentially more effective and innovative approaches to better address the unifying research question(s) posed? For example, does the Center draw on expertise from diverse fields, employ ***novel*** approaches or methods, and/or challenge existing assumptions and paradigms?

- **Center Structure:** Is a management plan proposed to integrate and optimize the research and collaborations proposed that will result in a synergistic research effort? Is there a plan to maximize utilization of resources and avoid unnecessary duplication of effort? Does the Center Director (i.e., PI) have a clear strategy and plan that will ensure cross-Center participation and real-time communication of results, issues, problems, and progress? If appropriate, does the proposal utilize state-of-the-art communication tools and is a plan for data management and statistical support presented?

- **Research Strategy:** Does the research question provide a real basis for a unified focus that will facilitate and accelerate progress? Are the conceptual framework, hypothesis, design, methods, and analyses adequately developed and well-integrated to support the feasibility and promise of the approach? Do the preliminary data cited support the rationale for the Center? Does the applicant acknowledge potential problem areas and consider alternative approaches? If needed, are statistical support services included in the Center's design?

- **Personnel:** Does the team assembled in the Center represent a "critical mass" of talent? Does the Center unite and integrate the ***most highly qualified individuals*** to contribute to the project? Does the Center Director have the appropriate qualifications and experience to oversee the research that addresses the overarching breast cancer problem proposed and to coordinate and manage the proposed Center? Is there representation from all the areas of expertise needed to conduct the study successfully? Does the team also include members who will provide new perspectives and fresh insights? Are consumer advocates active participants in the project and are their roles clearly defined? Is the contribution of each investigator clear?

- **Environment:** Do the different institutions/organizations involved in this project strengthen the Center? Is the appropriate support staff available for administering all of the Center's functions (e.g., Communications infrastructure, informatics, access to required databases)? Have the institutions/organizations demonstrated their clear commitment to the Center?

- **Budget:** Is the budget appropriate for the Center and research proposed?

VI-D. Programmatic Review Evaluation Criteria for Invited, Full Center Award Proposals

Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Center Award mechanism. For example, is there an integrated and synergistic research program focused around a central, unifying theme? Does the Center optimize the utilization of resources? Is there substantive consumer involvement in the Center? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2. In addition, please note that for Center Award submissions, the Proposal Relevance and Center Synergy Statements (Section VI-F, parts 10-11) will also be available for programmatic review.

VI-E. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for Center Awards. Please note that the body of the pre-proposal is limited to **3 pages** and that the **receipt deadline is April 3, 2002 at 4:00 p.m. Eastern Time**. Following completion of the pre-proposal screening process, investigators selected to submit a full proposal will be notified no later than May 2002. The deadline for the invited, full Center Award proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)** (see Section VI-F for details on invited, full Center proposal preparation).

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

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

3. Proposal Information – **Not required** for pre-proposals.

4. The Pre-Proposal Title Page should include the following information:

   a. Pre-Proposal title.

   b. Award Category; i.e., Center.

   c. Center Director's full name, including middle initial.

   d. Center Director's phone number, fax number, and e-mail address.

   e. Organization name and location (including city, state, zip or postal code, and country).

   f. Three key words that describe the research (please do not use "breast cancer" or "center" as key words).

5. Pre-Proposal Body – Limited to **3 pages**.
   Include the following components in the pre-proposal.

   a. A description of the overarching research question. Include a discussion of its suitability to be addressed in a multidisciplinary, multi-institutional center and its relevance to and impact on the prevention, detection, diagnosis, and/or treatment of breast cancer.

   b. A description of how the interactions and collaborations established through the Center will result in a ***synergistic*** research effort that will substantively accelerate the solution of the central problem.

   c. The outline of a plan for a multi-institutional, multidisciplinary consortium to address an appropriate problem, including the identification of key personnel.

d. A description of the Center Director's qualifications and ability to organize, administer, and manage a well-qualified team of multidisciplinary, multi-institutional researchers and consumer advocates in a center to solve a critical problem in breast cancer research.

e. The outline of a plan for consumer advocate involvement in the Center.

f. The outline of a project management and communications plan.

g. The outline of an experimental plan to address the specific research question.

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 – See Appendix E.
   Biographical sketches should be prepared for key personnel, including collaborating investigators. Biographical sketches may not exceed 3 pages per individual. The Biographical Sketch form can be found in Appendix E, or downloaded from the Congressionally Directed Medical Research Programs web site at http://cdmrp.army.mil/funding/default

8. Submit the following documentation to the address listed below:

Pre-Proposal:	**ONE** clearly labeled original (binder-clipped) and **TWENTY** collated, three-hole-punched photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original.** Do not use rubber bands, or spiral or three-ring binders.
Packaging:	Package only **ONE** complete pre-proposal submission (original plus twenty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. The postcard should state the pre-proposal title and PI's name.
Noncompliance:	Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**

Send the pre-proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP-02)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

9. Receipt Deadline.
   Please note that the **receipt deadline for Center Award pre-proposals is April 3, 2002 at 4:00 p.m. Eastern Time.**

VI-F. Invited, Full Center Award Proposal Preparation

Investigators interested in applying for Center Awards must submit a pre-proposal (see Section VI-E). Pre-proposals will be screened according to the criteria in Section VI-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Center proposal will be sent to selected investigators no later than May 2002. ***Do not submit a full Center proposal unless you receive a letter of invitation.***

Instructions for proposal preparation are found in Appendix B. The following supplemental information is specific for ***invited*** Center Award proposals. Please note that the body of the proposal is limited to **25 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

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

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

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the

Title/Referral Page. Provide a header on every page of the proposal that includes the Center Director's name (last name, first name, middle initial) and the proposal log number (assigned after pre-proposal receipt).

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

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

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

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Center Award applicants should state explicitly (within the 1-page limit) how the proposed work (1) meets the intent of the Center Award mechanism; (2) will accelerate the solution of an overarching and/or multidisciplinary problem in breast cancer research; and (3) will have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer. Note that for Center Awards, the Proposal Relevance Statement will be available for programmatic review.

11. Center Synergy Statement – Limited to 1 page.
    Applicants should include (1) the key collaborators involved in the Center; (2) how there will be synergy among the collaborators within the Center that will accelerate the solution of the major problem to be addressed by the Center; and (3) the means of communication that will be employed to ensure real-time sharing of data and problem solving. Note that for Center Awards, the Center Synergy Statement will be available for programmatic review.

12. Proposal Body – See Appendix B, part 11.
    The body of Center Award proposals is limited to **25 pages,** inclusive of figures, tables, graphs, and photographs, if used**.**

    The format of the proposal should reflect the integrated nature of the Center. This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts such as the National Cancer Institute-supported SPORE or Program Project grants. The submission of separate projects and cores is not recommended.

    Describe the overall project using the outline provided below.

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed Center. Describe the major question(s) in breast cancer research that is the focus of this proposal. Include information on previous experience most pertinent to the proposal. Cite relevant literature references.

    b. Purpose: State the purpose of the Center and the expected results and outcomes. Indicate how the Center is synergistic.

c. Objectives: State concisely the specific aims and research strategy of the study. Describe the expected measurable outcomes of the proposed Center. Provide information as to how the Center will address these objectives and why the approaches are better than traditional collaborations.

d. Collaborators: Provide information on the team of multidisciplinary, multi-institutional researchers and consumer advocates participating in the project and how they will contribute to the project. Describe how the team of multi-institutional, multidisciplinary researchers and consumer advocates will be organized, administrated, and managed. If the proposed Center does not involve a multi-institutional effort, provide justification that the Center's focus can best be addressed within the single institution.

e. Data: Provide information on well-founded research that supports this project. Include data to support the feasibility of the hypotheses and/or approaches.

f. Proposed Research and Methods: Describe the experimental plan and methodology that will address the specific research question. Provide information on how the Center will maximize the utilization of resources and minimize unnecessary duplication; e.g., experimental techniques, databases, models (including animal models), antibodies.

g. Communications: Describe the key features of the communications plan that will help expedite the proposed research. Provide information on the availability of communication network resources and support for this research. State the specific features of this plan that facilitate and encourage the real-time exchange of research findings.

13. Abbreviations – See Appendix B, part 12.

14. References – See Appendix B, part 13.

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

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

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

18. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, the following documentation must be included in the Center proposal submission:

- Letters from private sector and academic center collaborators, as appropriate, documenting a willingness to participate and demonstrating that a multi-institutional, multidisciplinary team of investigators is participating in the project, that the necessary drugs, modalities, or technologies are available, and that there is no unnecessary duplication of resources.

- Letters from breast cancer consumer/survivor organizations documenting a willingness to participate and how they will contribute to the projects, e.g., through increasing patient accrual, program conception and design, recruitment of research participants, and/or in program evaluation and dissemination of information to the public.

19. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. The cost of preparing proposals in response to these instructions is not considered an allowable direct charge to any resultant award. Funding for Center Awards can be requested for a maximum of $5M in direct costs for a period of up to 4 years, plus indirect costs as appropriate. As noted in Appendix F, it is the policy of the Department of Defense (DOD) that the PI possess the equipment needed to support the proposed research. However, because the intent of this award mechanism is to establish Centers that expedite research in a critical area of breast cancer research through real-time exchange of results and information sharing, reasonable requests for funds to purchase necessary informatics equipment will be considered. In addition to the funds for internal center meetings, the amount allotted for travel is $1,800 per year per collaborator to attend scientific/technical meetings. Funding should also be requested for the Center Director for a one-time, 3½-day meeting to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 3 of the Detailed Cost Estimate form.

    For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F for more details.

20. Instruments – See Appendix B, part 19.

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

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

23. Submission Deadline – See Appendix B, part 22.
    Do not submit a full Center Award proposal unless you receive a letter of invitation following the pre-proposal screening process. Please note that one electronic PDF version of your proposal must be sent by your organization's sponsored programs office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

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

Principal Investigator:_____
Last Name *First Name* *MI*

Proposal Title:_____

_____

Breast Cancer Center of Excellence Award Proposal
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Proposal Body (25-page limit) .....___
Abbreviations (1-page limit) .....___
References (no page limit) .....___
Biographical Sketches (3-page limit each)
PI (Center Director) .....___
Key Personnel (including collaborating investigators, individuals in training, and support staff) .....___
Existing/Pending Support (no page limit) .....___
Facilities/Equipment Description (no page limit) .....___
Administrative Documentation (no page limit)
List of all items included in this section .....___
Letter(s) from collaborators demonstrating that a multidisciplinary team of investigators is participating .....___
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VII. Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards

VII-A. Historically Black Colleges and Universities/Minority Institutions Partnership Training Awards

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Partnership Training Awards are intended to provide assistance at an institutional level. A major goal of this award is to support collaborations between multiple investigators at an applicant HBCU/MI and a collaborating institution with established investigators in breast cancer research **for the purpose of creating an environment that fosters breast cancer research and in which HBCU/MI faculty investigators will receive training toward establishing successful breast cancer research careers**. A long-term goal is to assist HBCU/MI investigators in submitting competitive breast cancer research proposals. The applicant/proposal submission must be from an HBCU/MI. Established investigators from collaborating institutions must have a strong record in acquiring funding in breast cancer research.

This award provides support for concept development for faculty researchers with doctoral degrees with little or no resources. HBCU/MI Partnership Training Awards will provide investigators the opportunity to collaborate, train, and acquire the knowledge and experience needed to develop a competitive and successful 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. Research supported through an HBCU/MI Partnership Training Award may involve the development of initial concepts, laying the groundwork for further study. These concept development proposals are encouraged for partnerships in the following areas of research, but may target any aspect of breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment:

- Disparity of morbidity and/or mortality in underserved/minority populations
- Cell biology or molecular biology, including biomarkers
- Epidemiology, including molecular, nutrition, diet, and environmental
- Access to care
- Treatment and outcomes
- Social/behavioral sciences

It is anticipated that approximately $6M will be available for HBCU/MI Partnership Training Awards. These awards can be requested for an average of $250,000 per year, for a maximum of $1M over 4 years inclusive of direct and indirect costs. Collaborating institutions may receive up to 40% of total costs during the first year of an award. However, no more than 25% of total

costs for the full award can be granted to collaborating institutions during the lifetime of an award. Direct costs for HBCU/MI Partnership Training Awards can cover salary support, tuition for special training and/or education, consultation with established investigators, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs, in which experienced and well-funded investigators provide consultation and mentoring in grant writing and grantsmanship.

In contrast to previous years in which this award has been offered, investigators interested in applying for an HBCU/MI Partnership Training Award ***must* submit a pre-proposal to be received no later than April 3, 2002 at 4:00 p.m. Eastern Time** (see Section VII-E for details of pre-proposal preparation). Pre-proposals will be screened according to the criteria in Section VII-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full HBCU/MI Partnership Training Awards proposal will be sent to selected investigators no later than May 2002 (see Section VII-F for details of invited, full proposal preparation). The deadline for electronic submission of the invited, full proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)**. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Sections I-C, VII-C, and VII-D.

VII-B. Screening Criteria for HBCU/MI Partnership Training Awards Award Pre-Proposals

Pre-proposals will be screened based on the following criteria:

- The identification of a clear and meaningful collaboration throughout the term of the award between multiple investigators at an applicant HBCU/MI and **established** investigators with a strong track record in acquiring funding in breast cancer research.

- The development of a concept in any aspect of breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment. Topics of particular interest for concept development include:

  - disparity of morbidity and/or mortality in underserved/minority populations;

  - cell biology or molecular biology, including biomarkers;

  - epidemiology, including molecular, nutrition, diet, and environmental;

  - access to care;

  - treatment and outcomes; and

  - social/behavioral sciences.

- An explanation of how this award will provide investigators the opportunity to collaborate, train, and acquire the knowledge and experience needed to develop a competitive and successful program in breast cancer research.

VII-C. Scientific Peer Review Evaluation Criteria for Invited, Full HBCU/MI Partnership Training Award Proposals

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

- **Applicant Institution:** Do the HBCU/MI's previous training history, prior research experience, and publication record indicate promising achievements to date? Will the training/collaboration offer a valuable opportunity to further develop necessary experience to advance the institution's capability to develop research programs in breast cancer? Are appropriate management and leadership of the partnership present at the HBCU/MI?

- **Collaborating Institution:** Does the collaborating institution have the background, qualifications, experience, and record to develop a productive collaboration with the applicant institution? Is the collaborating institution committed to the applicant institution's development? What are the qualifications of the collaborating investigators as established breast cancer researchers? Does the collaborating institution have a strong record of developing institutional training programs and acquiring funding in breast cancer research? Do the collaborating and applicant institutions propose to sustain an interactive, ongoing partnership?

- **Training Plan:** Will the proposed training plan and research environment increase the numbers of independent breast cancer researchers at the applicant HBCU/MI? Do both the applicant and the collaborating institutions contribute to the planned project? Is the project of sufficient depth and duration to foster the development of independent breast cancer research careers? How do the collaborating and applicant institutions propose to sustain the interactive environment necessary for the development of an effective training program? What are the plans to develop an independent program in breast cancer research at the HBCU/MI by the end of the award period? What impact would this training/collaboration have on producing well-trained breast cancer researchers?

- **Disease Relevance:** Do the proposed collaboration and training concept clearly focus on breast cancer biology, etiology, prevention, detection, diagnosis, and/or treatment? Does the applicant institution make a convincing case for its commitment to develop a program focused on breast cancer research?

- **Resources/Environment:** Will the collaboration support the development of the applicant institution's program of breast cancer research? Is there evidence that the applicant institution has the appropriate scientific environment, necessary resources, and collaborative arrangements to develop and sustain a breast cancer research program? Is there a strong institutional commitment at the HBCU/MI to support the development of the breast cancer research program by relieving participants of some of their academic or clinical responsibilities in order to have additional time for the collaboration and training?

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

VII-D. Programmatic Review Evaluation Criteria for Invited, Full HBCU/MI Partnership Training Award Proposals

Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the HBCU/MI Partnership Training Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VII-E. Pre-Proposal Preparation

The following pre-proposal preparation information is specific for HBCU/MI Partnership Training Awards. Please note that the body of the pre-proposal is limited to **5 pages** and that the **receipt deadline is April 3, 2002 at 4:00 p.m. Eastern Time**. Following completion of the pre-proposal screening process, investigators selected to submit a full proposal will be notified no later than May 2002. The submission deadline for the invited, full HBCU/MI Partnership Training Award proposal is **August 21, 2002 at 11:59 p.m. (applicant's local time)** (see Section VII-F for details on invited, full HBCU/MI Partnership Training Award proposal preparation).

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

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

3. Proposal Information– **Not required** for pre-proposals.

4. The Pre-Proposal Title Page should include the following information:

   a. Pre-Proposal title.

   b. Award Category; i.e., HBCU/MI Partnership.

c. Principal Investigator's (PI's) full name, including middle initial.

d. PI's phone number, fax number, and e-mail address.

e. Organization name and location (including city, state, zip or postal code, and country).

f. Three key words that describe the research (please do not use "breast cancer," "HBCU/MI," "partnership," or "training" as key words).

5. Pre-Proposal Body – Limited to **5 pages**.
It is the responsibility of the investigator to ***articulate clearly how the proposed research specifically addresses each of the screening criteria for pre-proposals***.

Describe the proposed partnership using the general outline provided below, which is the same as that for the full proposal body (see Section VII-F, part 11):

a. Background

b. Collaborative Arrangement

c. Training Program

d. Communication

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 – See Appendix E.
Biographical sketches should be prepared for key personnel, including collaborating investigators. Biographical sketches may not exceed 3 pages per individual. The Biographical Sketch form can be found in Appendix E, or downloaded from the Congressionally Directed Medical Research Programs web site at http://cdmrp.army.mil/funding/default

8. Submit the following documentation to the address listed below:

Pre-Proposal: **ONE** clearly labeled original (binder-clipped) and **TWENTY** collated, three-hole-punched photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original.** Do not use rubber bands, or spiral or three-ring binders.

Packaging: Package only **ONE** complete pre-proposal submission (original plus twenty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. The postcard should state the pre-proposal title and PI's name.

Noncompliance: Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**

Send the pre-proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP-02)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

9. Submission Deadline.
Please note that the **receipt deadline for HBCU/MI Partnership Training Award pre-proposals is April 3, 2002 at 4:00 p.m. Eastern Time.**

VII-F. Invited, Full HBCU/MI Partnership Training Award Proposal Preparation

Investigators interested in applying for HBCU/MI Partnership Training Award must submit a pre-proposal (see Section VII-E). Pre-proposals will be screened according to the criteria in Section VII-B to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full HBCU/MI Partnership Training Award proposal will be sent to selected investigators no later than May 2002. ***Do not submit a full*** *HBCU/MI Partnership Training Award* ***proposal unless you receive a letter of invitation.***

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for ***invited*** HBCU/MI Partnership Training Award proposals. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VII-C and VII-D, respectively. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1.
   The list of HBCU/MI as recognized by the Department of Education is available at the CDMRP web site at http://cdmrp.army.mil/funding/pdf/2001_mi_list.pdf.

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

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents on page VII-11 in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and the proposal log number (assigned after pre-proposal receipt).

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

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

9. Statement of Work – See Appendix B, part 9 and Appendix D.
   A sample HBCU/MI Partnership Training Award Statement of Work is provided on page VII-12.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, HBCU/MI Partnership Training Award applicants should describe explicitly (within the 1-page limit) the plan for developing a program for faculty to carry out breast cancer research at the HBCU/MI. Articulate how the proposal's combination of training and relevance to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy in the proposal will prepare the HBCU/MI participants for successful experiences as breast cancer researchers.

11. Proposal Body – See Appendix B, part 11.
    The body of HBCU/MI Partnership Training Awards proposals is limited to **10 pages,** inclusive of figures, tables, graphs, and photographs, if used**.**

Describe the proposed partnership using the general outline provided below:

a. Background: Provide a brief statement of the ideas and reasoning behind the proposed collaboration(s). Proposals must present a clearly articulated plan for training program development that focuses on the biology, etiology, prevention, detection, diagnosis, and/or treatment of breast cancer. State the specific aims of the study (or studies). Briefly describe the methods to be used. Cite relevant literature references.

b. Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the collaborating institution and the HBCU/MI should be articulated. Qualifications and facilities of the collaborating institution should be addressed, including the record in acquiring funding in breast cancer research. Document the experience of the collaborating institution in training breast cancer researchers and include information on training/collaborations with minority investigators.

c. Training Program: Describe explicitly the value of the proposed training as it relates to the applicant institution's plans for developing a breast cancer research program. Articulate how the combination of collaboration and relevance to breast cancer in the proposal will catalyze the applicant institution's development of a successful breast cancer research program. Describe the PI's qualifications and role in management of the partnership training program. Describe any special seminar series, journal clubs, expert consultations, technical assistance programs, etc. planned.

d. Communication: Outline a plan for preparing reports on the status of how the collaboration is proceeding. These reports should be issued between the applicant and the collaborating institutions and should document progress, show how each institution is responding to problems, etc. Please note that these status reports cannot be used in lieu of actual meetings and the communications between the institutions' faculties.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
For HBCU/MI Partnership Training Award proposals, biographical sketches should be prepared for the participants at the applicant institution, participants at the established collaborating institution, and each of the key personnel, including collaborating investigators listed on the budget page for the initial budget period.

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

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

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

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

- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution assuring the commitment of the institution to the proposed training program. This letter should reflect the extent to which the institution will support the collaboration by relieving participants of their academic and/or clinical responsibilities to have additional time for collaboration and training, providing access to appropriate facilities, and providing opportunities for professional interactions with senior colleagues.

- A letter from the collaborating institution describing a commitment to the training/ development/mentorship of the applicant institution and the nature of the proposed collaboration/training.

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

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    HBCU/MI Partnership Training Awards can be requested for an average of $250,000 per year, for a maximum of $1M over 4 years inclusive of direct and indirect costs. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Collaborating institutions may receive up to 40% of total costs during the first year of an award. However, no more than 25% of total costs for the full award can be granted to collaborating institutions during the lifetime of an award. Direct costs for HBCU/MI Partnership Training Awards can cover salary support, tuition for special training and/or education, consultation with established investigators, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Funds also may be used to establish formal technical assistance programs in which experienced and well-funded investigators provide consultation and mentoring in grant writing and grantsmanship. It is the policy of the Department of Defense (DOD) that all commercial and nonprofit recipients provide the equipment needed to support proposed research (see Appendix F). However, the greater need for equipment support at an HBCU/MI institution is recognized by the DOD Breast Cancer Research Program and will be taken into consideration during the review process. The amount allotted for travel is $1,800 per year per investigator for up to five investigators from the HBCU/MI to attend scientific/technical meetings. In addition, funding should be requested for up to five investigators from the HBCU/MI for a one-time, 3½-day meeting to disseminate the results DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

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

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

22. Submission Deadline – See Appendix B, part 22.
    Do not submit a full *HBCU/MI Partnership Training* ***Award proposal unless you receive a letter of invitation following the pre-proposal screening process.*** Please note that one electronic PDF version of your proposal must be uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) August 21, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

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

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

HBCU/MI Partnership Training Award Proposal
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Proposal Body (10-page limit).....___
Abbreviations (1-page limit).....___
References (no page limit).....___
Biographical Sketches (3-page limit each)
Participating investigators at HBCU/MI.....___
Participating investigators at collaborating institution .....___
Key personnel .....___
Existing/Pending Support (no page limit).....___
Facilities/Equipment Description (no page limit).....___
Administrative Documentation (no page limit)
List of all items included in this section .....___
Letter of commitment from HBCU/MI.....___
Letter of commitment from collaborating institution .....___
Letters of support from other collaborating individuals and/or institutions .....___
Detailed Cost Estimate (no page limit).....___
Instruments (no page limit).....___
Publications and/or Patent Abstracts (5-document limit) .....___

Sample Statement of Work

HBCU/MI Partnership Training Award

Smith, Mary E.

Statement of Work

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

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

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

Phase 2: Project Development (Years 2-3)

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

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

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