

**DEPARTMENT OF DEFENSE**

**BREAST CANCER RESEARCH PROGRAM**

**FISCAL YEAR 2000**

**PROGRAM ANNOUNCEMENT**

**MARCH 10, 2000**

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 by the Secretary of the Army to continue the Department of Defense (DOD) Breast Cancer Research Program (BCRP). The deadline, format, and other criteria specified for proposals in this BCRP fiscal year 2000 (FY00) Program Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC web site at <http://mrmc-www.army.mil>. Specific information on the DOD BCRP can be obtained from the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil>. A copy of this Program Announcement and associated forms (except for the Proposal Cover Booklet; see item 4 on the following page) also can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce> and <http://cdmrp.army.mil/?/announce/forms>, respectively.

### 1. Inquiries

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

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP00-Program Announcement)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

Applicants should submit any written questions regarding this program as early as possible. Every effort will be made to answer questions within 2 working days of receipt. Inquiries should be restricted to format issues only. Questions relating to technical proposal content or reasonableness/allowability of costs should be submitted in writing and will be forwarded to the U.S. Army Medical Research Acquisition Activity.

### 2. Research Involving Human Subjects and/or Anatomical Substances

All proposals submitted with research involving human subjects and/or anatomical substances must be approved by the appropriate local review board. Proposals must also be approved by the U.S. Army Human Subjects Research Review Board (HSRRB). The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and

will require information in addition to that supplied to the local review board. Therefore, all investigators submitting such proposals must comply with the requirements detailed in Appendix H **before funds can be awarded.**

### **3. Forms**

Associated forms (except for the Proposal Cover Booklet; see item 4 below) can be found in the Appendices of this Program Announcement and can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>.

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

A Proposal Cover Booklet must be completed for each proposal according to the instructions found in Appendix C.

Proposal Cover Booklets can be requested via phone, fax, e-mail, or mail at the following addresses/numbers. Please allow sufficient time for delivery by regular mail.

Phone: 301-682-5501  
Fax: 301-682-5521  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP00-Program Announcement)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

### **5. Proposal Submission**

To be considered for all awards **except** Clinical Translational Research (CTR), Collaborative-Clinical Translational Research (C-CTR), and Virtual Breast Cancer Center of Excellence (Virtual Center) Awards, submit the following documentation to the address at the end of this item. (See item 6 on the following page for requirements for pre-proposal submissions for CTR, C-CTR, and Virtual Center Awards.)

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

**Proposal Cover Booklet:** **ONE** original (binder clipped to the original proposal) and **THREE** photocopies (**not** binder-clipped to proposal copies).

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

**Abstract Pages:** **TWO** additional copies of both the technical and the public (nontechnical) abstracts in a manila clasp envelope along with a 3½" computer disk containing the abstract files (clearly labeled with the name of the principal investigator [PI], institution, and word processing program). Format abstracts in Word, WordPerfect, or ASCII.

**Statement of Work:** **TWO** additional copies of the Statement of Work in the same manila clasp envelope with abstract copies and disk.

**Packaging:** Package only **ONE** complete proposal submission (original plus all materials requested above) per box. If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard must state the 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 or proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals or proposals most frequently result from **failure to adhere to timelines, page limits, and font requirements.**

**Send the Proposal to:** Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BCRP00-Announcement)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

## **6. CTR, C-CTR, and Virtual Center Pre-Proposal Submissions**

To be considered for CTR, C-CTR, and Virtual Center Awards, pre-proposals are required. Submit the following documentation to the address listed at the end of this item:

**Pre-Proposal:** **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated 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 thirty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI's name.

**Noncompliance:** Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal or proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals or 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 (BCRP00-Announcement)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

## 7. Receipt Deadlines

Deadlines for individual award mechanisms are provided in item 9 (Timelines) starting on the following page and in the Reference Tables of Award Mechanisms and Submission Requirements found on pages viii-xi.

Any proposal received by the USAMRMC after the exact time specified for receipt shall **not** be considered unless it is received before FY00 award negotiations have been completed, and:

1. It was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. It was sent by U.S. Postal Service Express Mail Next Day Delivery, Post Office to the address listed in item 5 (Proposal Submissions) on page ii (**do not use Second Day Delivery**) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline, or
3. It was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline for delivery by 4:00 p.m. Eastern Time on the due date, or
4. The Government, in its sole discretion, decides to accept the late proposal if it determines that no competitive advantage has been conferred and that the integrity of the competitive grants process will not be compromised.

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

## 8. Duplicate Submissions

Duplicate submissions of the same research project under different award mechanisms will **not** be allowed unless one of the following three exceptions applies.

1. An Idea Award proposal (Section III) may address the same research question proposed in a Career Development Award (CDA) proposal (see Section XII). Both proposals must specify the same PI. If a submitted Idea Award proposal is listed as the source of research support in a CDA proposal, the CDA can only be recommended for funding if the Idea Award is recommended for funding. However, the Idea Award may be recommended for funding even if the corresponding CDA proposal is not.
2. A Clinical Bridge Award proposal (Section IV) may address the same research question proposed in a CDA proposal (Section XII). Both proposals must specify the same PI. If a submitted Clinical Bridge Award proposal is listed as the source of research support in a CDA proposal, the CDA can only be recommended for funding if the Clinical Bridge Award is recommended for funding. However, the Clinical Bridge Award may be recommended for funding even if the corresponding CDA proposal is not.
3. A research project proposal submitted as part of a Behavioral Center of Excellence Award (Section VIII) proposal may address the same research question as an Idea Award (Section III). If both the research project proposal and Idea Award proposal are favorably reviewed, then the research project proposal will be funded as part of the Behavioral Center of Excellence Award.

## 9. Timelines

**The timeline for Idea, Clinical Bridge, Undergraduate Summer Training Program, Predoctoral or Postdoctoral Fellowship, and Career Development Awards is:**

Letter of Intent (requested):	As soon as possible but no later than May 24, 2000
Proposal Receipt Deadline:	<b>June 7, 2000</b>
Peer Review:	August-September 2000
Request for RCQ <sup>1</sup> Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2000
Notification:	Approximately 2 weeks after the completion of programmatic review
Award Date:	No earlier than March 1, 2001 and no later than September 30, 2001

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

**The timeline for CTR , C-CTR, and Virtual Center Awards is:**

Pre-proposal receipt:	<b>April 19, 2000</b>
Pre-proposal screening:	May 2000
Invitations for full proposals:	June 2000
Full proposal receipt:	<b>August 2, 2000</b>
Peer Review:	September 2000
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2000
Notification:	Approximately 2 weeks after the completion of programmatic review
Award Date:	No earlier than March 1, 2001 and no later than September 30, 2001

**The timeline for Behavioral Centers of Excellence Awards is:**

<b>Required</b> Letter of Intent:	<b>July 19, 2000</b>
Proposal Receipt Deadline:	<b>August 2, 2000</b>
Peer Review:	September 2000
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2000
Notification:	Approximately 2 weeks after the completion of programmatic review
Award Date:	No earlier than March 1, 2001 and no later than September 30, 2001

**The timeline for Historically Black Colleges and Universities/Minority (HBCU/MI) Institutions Focused Training or HBCU/MI Partnership Training Awards is:**

Letter of Intent (requested):	As soon as possible but no later than July 19, 2000
Proposal Receipt Deadline:	<b>August 2, 2000</b>
Peer Review:	September 2000
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2000
Notification:	Approximately 2 weeks after the completion of programmatic review
Award Date:	No earlier than March 1, 2001 and no later than September 30, 2001

## Directions to Fort Detrick

### From Washington, DC

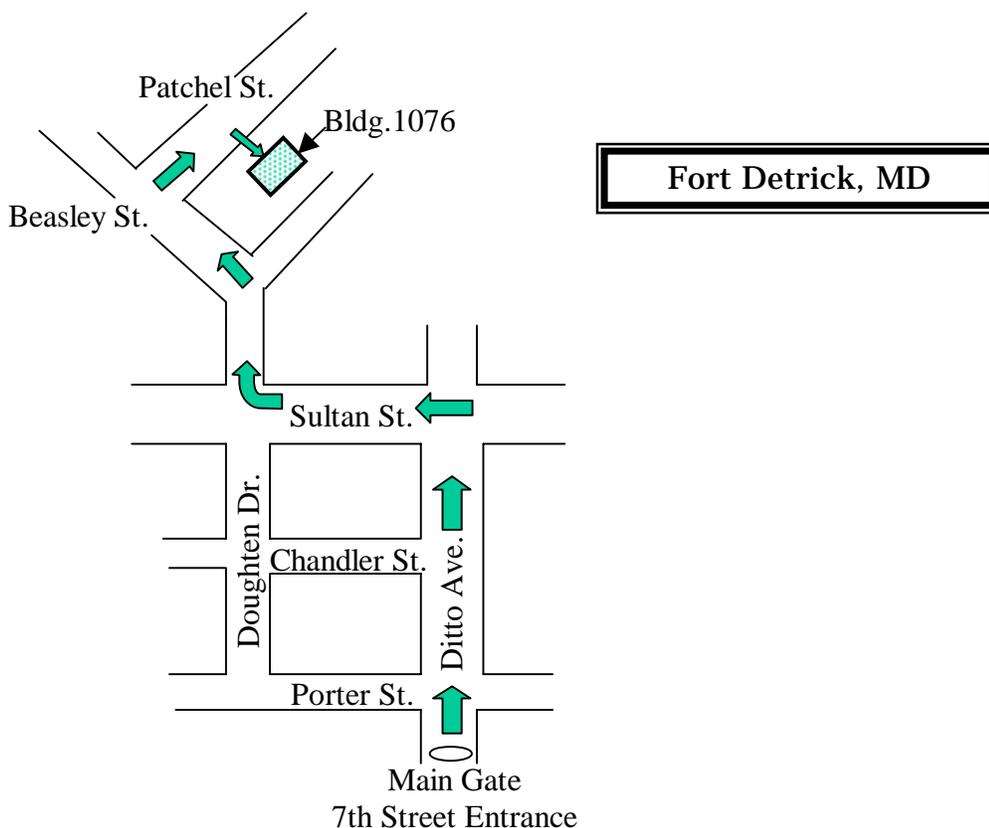
Take Interstate 495 to Interstate 270 North (exit #38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

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



## Reference Tables of Award Mechanisms and Submission Requirements

**Table 1: Research Awards**

Award Mechanisms	Experience of PI	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
Idea Awards	All levels of experience	<ul style="list-style-type: none"> <li>• No preliminary data required</li> <li>• Reward innovative ideas and technology</li> </ul>	An average of \$100,000/year for direct costs for up to 3 years; population-based studies may request an average of \$125,000/year for direct costs for up to 5 years	June 7, 2000 4:00 p.m. ET*	Section III
Clinical Bridge Awards	All levels of experience	<ul style="list-style-type: none"> <li>• To support pre-clinical or post-clinical research, building toward (but not including) a clinical trial</li> <li>• To facilitate development of <i>novel</i> agents, model systems, or markers with clinical potential</li> <li>• Preliminary data required</li> </ul>	An average of \$100,000/year for direct costs for up to 3 years	June 7, 2000 4:00 p.m. ET	Section IV
Clinical Translational Research (CTR) Award	All levels of experience	<ul style="list-style-type: none"> <li>• Research and clinical trial components</li> <li>• Proposals sought in the areas of target-based chemoprevention and therapeutics</li> <li>• Must have a clinical trial, with at least 1 year of patient accrual within the lifetime of the award</li> </ul>	No maximum dollar limit for up to 4 years	<u>Pre-Proposal:</u> April 19, 2000 4:00 p.m. ET  <u>Full Proposal:</u> August 2, 2000 4:00 p.m. ET	Section V

\*Eastern Time

**Table 2: Infrastructure Awards**

Award Mechanisms	Experience of PI	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
Collaborative-Clinical Translational Research (C-CTR) Award	All levels of experience	<ul style="list-style-type: none"> <li>• To (1) develop new models for performing clinical trials and (2) test new agents or technologies</li> <li>• Infrastructure support</li> <li>• To support collaborations among academia, community-based oncology clinics, and the private sector</li> <li>• Must contain prospective clinical trials within the lifetime of the award</li> </ul>	An average of \$400,000/year for direct costs for up to 3 years for a maximum award limit of \$1,200,000	<p><u>Pre-Proposal:</u> April 19, 2000 4:00 p.m. ET</p> <p><u>Full Proposal:</u> August 2, 2000 4:00 p.m. ET</p>	Section VI
Virtual Breast Cancer Center of Excellence Awards	Established investigator with a record of leadership and scientific ability	<ul style="list-style-type: none"> <li>• To establish virtual, <i>electronic</i> centers to address an overarching and/or multidisciplinary problem in breast cancer research</li> <li>• To support electronic-network collaborations among accomplished scientists from diverse backgrounds and areas of expertise, who will communicate and share data in “real time”</li> </ul>	No maximum dollar limit for up to 4 years	<p><u>Pre-Proposal:</u> April 19, 2000 4:00 p.m. ET</p> <p><u>Full Proposal:</u> August 2, 2000 4:00 p.m. ET</p>	Section VII
Behavioral Center of Excellence Awards	Established investigator with a record of leadership and scientific ability	<ul style="list-style-type: none"> <li>• To establish multidisciplinary behavioral science centers</li> <li>• <i>Synergistic</i> program incorporating multiple research projects and a core facility(ies)</li> <li>• Two to five nested trainees</li> </ul>	An average of \$1M/year for direct costs for up to 4 years for a maximum award limit of \$4M in direct costs	<p><u>Required Letter of intent:</u> July 19, 2000</p> <p><u>Full Proposal:</u> August 2, 2000</p>	Section VIII

**Table 3: Training/Recruitment Awards**

<b>Award Mechanisms</b>	<b>Experience of PI</b>	<b>Key Mechanism Elements</b>	<b>Dollars Available for Individual Awards</b>	<b>Proposal Receipt Deadline</b>	<b>Instructions for Proposal Preparation</b>
Undergraduate Summer Training Program Awards	All levels of experience	<ul style="list-style-type: none"> <li>• Supports 2-8 students for summer internships</li> <li>• To encourage undergraduate students to pursue careers in breast cancer research</li> </ul>	An award of \$4,000/student per summer and up to \$10,000/year for administrative costs for up to 3 years	June 7, 2000 4:00 p.m. ET	Section IX
Predocutorial Fellowships	Predocutorial students	<ul style="list-style-type: none"> <li>• Prepare new scientists for careers in breast cancer research</li> </ul>	An average of \$22,000/year for direct and indirect costs for up to 3 years	June 7, 2000 4:00 p.m. ET	Section X
Postdoctoral Fellowships	Recent doctoral graduates with less than 5 years of postdoctoral research experience	<ul style="list-style-type: none"> <li>• Prepare new scientists for careers in breast cancer research</li> </ul>	An average of \$50,000/year for direct and indirect costs for up to 3 years	June 7, 2000 4:00 p.m. ET	Section XI
Clinical Translational Research (CTR) Postdoctoral Fellowship Award	Recent medical degree graduates with less than 5 years of postdoctoral research experience	<ul style="list-style-type: none"> <li>• To train individuals in breast cancer-related clinical translational research</li> <li>• Emphasis should be placed on clinical translational training</li> </ul>	An average of \$50,000/year for direct and indirect costs for up to 3 years	June 7, 2000 4:00 p.m. ET	Section XI
Career Development Award (CDA)	Assistant Professors or equivalent within 6 years of postdoctoral training, having their own, independent program of research	<ul style="list-style-type: none"> <li>• To relieve applicants from academic responsibilities</li> <li>• Provides salary support</li> <li>• Requires separate source of research support</li> </ul>	An average of \$59,000/year for direct costs for upto4years for salarysupport	June 7, 2000 4:00 p.m. ET	Section XII
CTR CDA	Clinicians at the Assistant Professor level or equivalent within 6 years of residency, fellowship, or equivalent, having their own, independent program of research	<ul style="list-style-type: none"> <li>• To train individuals in breast cancer-related clinical translational research</li> <li>• Emphasis should be placed on clinical translational training</li> <li>• To relieve applicants from academic responsibilities</li> <li>• Provides salary support</li> <li>• Requires separate source of research support</li> </ul>	An average of \$59,000/year for direct costs for up to 4 years for salary support	June 7, 2000 4:00 p.m. ET	Section XII

(Table 3 continued on next page)

**Table 3: Training/Recruitment Awards (cont'd)**

Award Mechanisms	Experience of PI	Key Mechanism Elements	Dollars Available for Individual Awards	Proposal Receipt Deadline	Instructions for Proposal Preparation
HBCU/MI* Focused Training Awards	Faculty members (with doctoral degrees) working at an HBCU/MI with minimal or no research support and their own laboratory space; collaboration with an established investigator is required	<ul style="list-style-type: none"> <li>• Collaborations between individual investigators at HBCU/MI and established breast cancer researchers</li> <li>• To enable investigators at HBCU/MI to better compete for breast cancer research funds in the future</li> </ul>	Up to \$150,000 for 18 months for direct and indirect costs; no more than 25% of the awarded funds may be directed toward the collaborating investigator	August 2, 2000 4:00 p.m. ET	Section XIII
HBCU/MI* Partnership Training Awards	Faculty members (with doctoral degrees) working at an HBCU/MI	<ul style="list-style-type: none"> <li>• Collaborations at an institutional level between an HBCU/MI and another institution</li> <li>• To provide training for HBCU/MI faculty toward establishing successful breast cancer research careers</li> </ul>	Up to \$250,000/year for direct and indirect costs for up to 4 years; no more than 25% of the awarded funds may be directed toward the collaborating institution over the lifetime of the award	August 2, 2000 4:00 p.m. ET	Section XIV

\* HBCU/MI = Historically Black Colleges and Universities/Minority Institutions; applicants from HBCU/MI are encouraged to apply to all award mechanisms offered in this Program Announcement.

## **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 directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage various extra- and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, \$1.5 billion has been targeted by Congress for research on breast, prostate, and 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 award opportunities that will enhance program research objectives without duplicating existing funding opportunities. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that address individual program objectives.

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

For each program, the CDMRP has developed and refined a flexible 7-year execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. 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, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals.

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

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

Each scientific review panel is composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. The chair and scientific reviewers are recognized leaders in their fields. 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 merit 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 “Scientific Peer Review – Evaluation Criteria” within each award mechanism section). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed as to make its completion implausible.

The peer review summary statement is a product of scientific peer review. Each statement includes the investigator’s technical and public (nontechnical) abstracts (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 assist investigators in assessing research projects and are forwarded to the next stage of the review process, programmatic review.

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

The second tier of the two-tiered review process is programmatic review. Programmatic review is accomplished by the IP, composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. With firsthand experience, consumer

advocates enhance the review process. One of the functions of the IP is to conduct programmatic review to obtain a broad portfolio of grants across all disciplines and recommend an investment strategy for appropriated funds.

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 for programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and recommendations of 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 recommendations of the peer review panels;
- Programmatic relevance;
- Relative innovation;
- Program portfolio balance with respect to research disciplines or specialty areas; and
- Other equitable factors, e.g., geographic distribution and adequate support for new investigators.

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

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

Following completion of the two-tiered evaluation process, every applicant will receive a letter indicating the funding status of their proposal, along with a scientific summary critique. The peer review summary statements will contain the criteria scores, the global score, and detailed comments that address the proposal's strengths and weaknesses with respect to each evaluation criterion. Notification letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

#### **I-E. 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.

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 grant period) that details the findings and issues for the entire project.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of 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 to the CDMRP. In accordance with the Bayh-Dole Act (35 USC<sup>1</sup> 200 et seq.), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must contact the contract specialist and follow the instructions in the contract concerning license agreements and patents.

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<sup>1</sup> United States Code

## II. Department of Defense Breast Cancer Research Program

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

Grass roots advocacy organizations provided the impetus that led to the fiscal year 1993 (FY93) Congressional appropriations to the Department of Defense (DOD) for \$210M targeted toward breast cancer research. Since then, due to the ongoing efforts of advocacy groups and increased public awareness on health issues, Congress has continued to appropriate money for breast cancer research managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the office of the Congressionally Directed Medical Research Programs (CDMRP). To date, Congress has appropriated more than \$1 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 FY92-99 appropriations of the BCRP is shown in Table II-1 below.

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

<b>Program History</b>	<b>FY92<sup>1</sup>-97</b>	<b>FY98</b>	<b>FY99<sup>2</sup></b>
BCRP-Managed Appropriations for Peer-Reviewed Research	\$598.3M	\$135M	\$135M <sup>3</sup>
Number of Full Proposals Received	9,406	1,322	1,281
Number of Proposals Funded	1,403	403	~397
Percentage of Applications Recommended for Funding	15%	30%	31%
Number of Research/Infrastructure Awards <sup>4</sup>	906	260	~227
Number of Training/Recruitment Awards	497	143	~170
Number of CTR and C-CTR Proposals Received			
CTR and C-CTR pre-proposals	243	107	87
CTR and C-CTR full proposals	64 <sup>5</sup>	45	22
Number of CTR and C-CTR Awards	10 <sup>6</sup>	8	~3 <sup>3</sup>

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

<sup>2</sup> The number of proposals received and recommended for funding do not include Concept Award proposals; final numbers for FY99 will be available after September 30, 2000.

<sup>3</sup> An additional \$1.8M was received in FY99 as a result of the Stamp Out Breast Cancer Act.

<sup>4</sup> Includes Clinical Translational Research (CTR) and Collaborative-CTR (C-CTR) Awards.

<sup>5</sup> The pre-proposal strategy was implemented in FY97; the eight translational awards made in FY96 are not included in these numbers.

<sup>6</sup> Does not include the eight Translational proposals that were funded in FY96, prior to the implementation of pre-proposals.

## **II-B. Overview of the FY00 BCRP**

The USAMRMC, through this Program Announcement, is soliciting applications on breast cancer research. The overall goal of this funding effort is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research on 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.

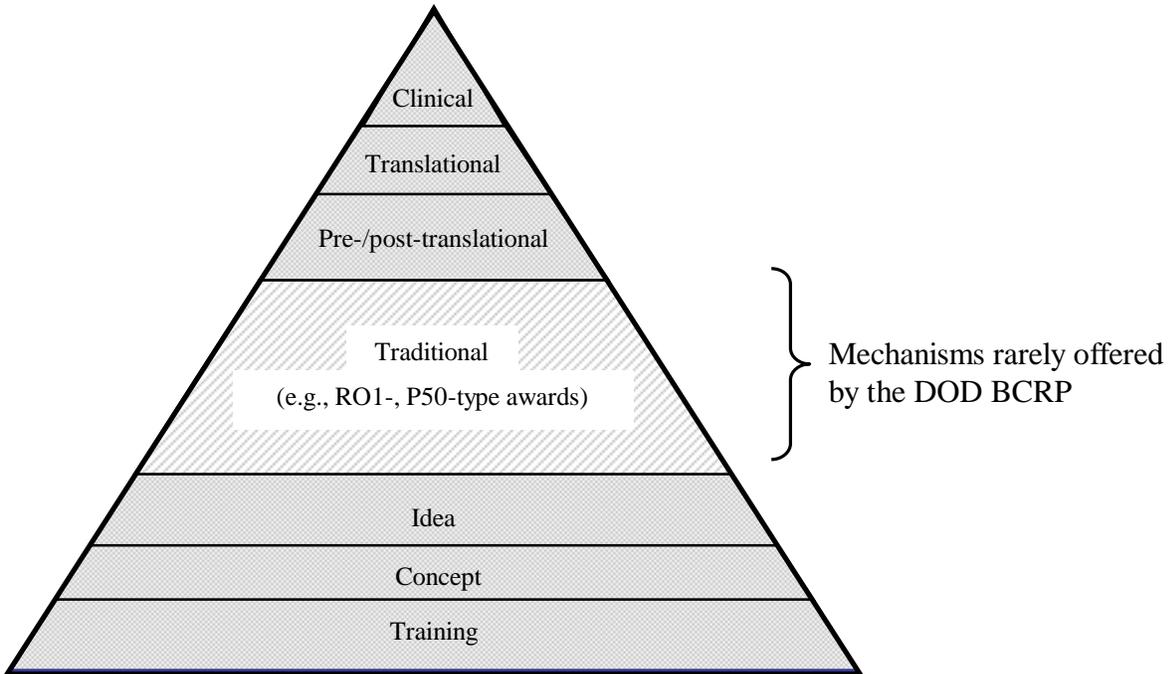
The USAMRMC is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures 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 CDMRP Staff and 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 BCRP offers several training/recruitment awards (Sections II-E.3 and IX-XIV).
- The next level of the pyramid is concepts that, when developed, can lead to testable hypotheses. On February 17, 2000 the BCRP published a Program Announcement soliciting 1-page electronic submissions for Concept Awards. The receipt deadline for these proposals is April 12, 2000. For additional information on Concept Awards, see the CDMRP web site at <http://cdmrp.army.mil>.
- The third 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 (Sections II-E.1 and III).

**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. 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 solicited only in rare cases when there is a particular need. For example, the FY00 BCRP is soliciting behavioral science research through the establishment of Behavioral Centers of Excellence (Sections II-E.2 and VIII). In addition, critical problems in breast cancer research can be pursued through collaborations within a Virtual Breast Cancer Center of Excellence (Sections II-E.2 and VII).
- Approaching the pyramid’s summit are Translational Awards. The BCRP focuses efforts at the critical juncture between bench and bedside research. Two mechanisms support these types of studies. Clinical Bridge Awards (Sections II-E.1 and IV) support research that is directly proximal to a clinical study. CTR Awards (Sections II-E.1 and V) support research projects that move bench research into a clinical trial during the life of the award.
- The pinnacle of the pyramid represents the very few research studies that make it to a clinical trial. The BCRP supports the infrastructure for developing new means to perform clinical trials through C-CTR Awards (Sections II-E.2 and VI).

## II-E. FY00 Award Opportunities

The programmatic strategy for FY00 is to fund proposals in three categories: (1) Research Awards, (2) Infrastructure Awards, and (3) Training/Recruitment Awards. For the FY00 BCRP, an estimated \$147M<sup>1</sup> will be available to fund competitive peer-reviewed breast cancer research. A percentage of the available monies will be set aside to fund Research, Infrastructure, and Training/Recruitment Awards at Historically Black Colleges and Universities/Minority Institutions (HBCU/MI). (Applicants from HBCU/MI should see Appendix B, part 1 for additional information.) In addition, as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585), the DOD BCRP expects to receive additional monies in 2000 for breast cancer research. The DOD plans to use all Breast Cancer Stamp monies received prior to November 2000 to fund additional scientifically meritorious Idea proposals submitted in response to this Program Announcement.

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

### II-E.1. Research Awards

Approximately \$87M will be allocated for Research Awards, which consist of Idea Awards (Section III), Clinical Bridge Awards (Section IV), and CTR Awards (Section V). The intent of *Idea Awards* is to stimulate and reward creative research ideas that may be viewed as speculative, but have potential for high payoff. *Clinical Bridge Awards* are for the support of research that is either pre- or post-CTR. CTR Awards support projects that apply promising, well-founded laboratory or other pre-clinical research to the clinical care of patients with, or populations at risk for, breast cancer.

In an effort to efficiently use the BCRP appropriation for research and to facilitate the scientific merit review of proposals that focus on detection-based computer-aided diagnosis (CAD) in mammography, investigators submitting CAD research projects are encouraged to use a common set of digitized film screen mammography images. The use of a common set of images will allow the scientific merit review of proposals to focus on detection performance, a key element in CAD research. See Appendix L for additional information on CAD submissions.

### II-E.2. Infrastructure Awards

Approximately \$40M will be allocated for Infrastructure Awards, which consist of C-CTR Awards (Section VI), Virtual Breast Cancer Center of Excellence Awards (Section VII), and

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<sup>1</sup>A total of \$175M was appropriated by Congress in FY00 to the DOD to continue the BCRP. Prior to receipt of these funds by the CDMRP, the DOD withholds approximately 8.5% for Congressionally mandated and DOD initiatives. Of that, an additional 8% is set aside to manage the program, including costs for peer and programmatic review of proposals and the administration of grants/contracts throughout their entire period of performance (up to 7 years).

Behavioral Center of Excellence Awards (Section VIII). The intent of *C-CTR Awards* is to foster the development of highly effective collaborative and consortia models to evaluate promising agents and technologies in well-designed clinical trials that utilize the combined resources of academia, the private sector, and community-based oncology clinics. The intent of *Virtual Breast Cancer Center of Excellence (Virtual Center) Awards* is to establish virtual, electronic centers to address an overarching problem in breast cancer research. *Behavioral Center of Excellence Awards* (Section VIII) are intended to establish research centers that address behavioral breast cancer research.

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

Approximately \$20M will be allocated for Training/Recruitment Awards: Undergraduate Summer Training Program Awards (Section IX), Predoctoral Fellowship Awards (Section X), Postdoctoral Fellowship Awards (Section XI), CTR Fellowship Awards (Section XI), Career Development Awards (CDAs) (Section XII), CTR CDAs (Section XII), HBCU/MI Focused Training Awards (Section XIII) and HBCU/MI Partnership Training Awards (Section XIV). *Undergraduate Summer Training Program Awards* are for the establishment of summer undergraduate training programs in breast cancer research. *Predoctoral Fellowship Awards* are direct individual awards to promising graduate students studying breast cancer under the guidance of a designated mentor. *Postdoctoral Fellowship Awards* should enable recent doctoral degree graduates with limited postdoctoral experience to gain additional experience in breast cancer research. *CTR Fellowship Awards* should enhance the education of clinicians who wish to pursue a career in breast cancer clinical translational research. CDAs are intended to free scientists at the Assistant Professor (or equivalent) level of academic responsibilities to allow them additional time to pursue breast cancer research. CTR CDAs will free clinicians at the Assistant Professor (or equivalent) level of academic responsibilities to allow them additional time to pursue translational breast cancer research. *HBCU/MI Focused Training Awards* are intended to enable individual investigators at HBCU/MI to collaborate, train, and acquire the knowledge and experience needed to design fundable breast cancer research grants. *HBCU/MI Partnership Training Awards* are intended to provide assistance at an institutional level by forming collaborations between HBCU/MI and other institutions. Both HBCU/MI training award mechanisms will be funded with some of the monies set aside to support research performed at HBCU/MI.

### III. Idea Awards

#### III-A. Idea Awards

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

Idea Award proposals are qualitatively different from traditional research proposals as outlined in Table III-1. Although Idea Award proposals do not require preliminary or pilot data, they should be based on a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning.

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

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

Approximately \$72M will be available for Idea Awards. Funding for Idea Awards can be requested for an average of \$100,000 per year for direct costs for a maximum of \$300,000 over 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request an average of \$125,000 per year in direct costs for a maximum of \$625,000 over 5 years, plus indirect costs as appropriate. A population-based study is one that requires extra time and resources due to the participation of human subjects. Direct costs can cover salary, expenses (including research supplies), equipment, and travel to scientific meetings.

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

In general, the Department of Defense (DOD) Breast Cancer Research Program (BCRP) does not accept duplicate submissions addressing the same research question. However, two exceptions exist for applicants submitting Idea Award proposals.

1. An Idea Award proposal may address the same research question proposed in a Career Development Award (CDA) proposal (see Section XII). Both proposals must be prepared by and specify the same principal investigator (PI). If a submitted Idea Award proposal is listed as the source of research support in a CDA proposal, the CDA can only be recommended for funding if the Idea Award is recommended for funding. However, the Idea Award may be recommended for funding even if the corresponding CDA proposal is not.
2. A research project proposal submitted as part of a Behavioral Center of Excellence Award (Section VIII) proposal may address the same research question as an Idea Award. If both projects are favorably reviewed, then the proposal will be funded as part of the Behavioral Center of Excellence Award.

Please refer to the Foreword, item 8 (Duplicate Submissions) on page v for additional details on duplicate submissions.

### ***Research Studies Encouraged***

In addition to requesting submissions across all aspects of breast cancer research, the fiscal year 2000 BCRP encourages investigators to submit Idea Award proposals that address epidemiological questions in breast cancer patients postdiagnosis; e.g., studies on molecular, behavioral, environmental, or lifestyle factors that may alter response to treatment, recurrence, or survival. Please note that population-based studies can request up to 5 years of support at a higher maximum direct cost limit (see page III-1).

### ***Additional Information for Computer-Aided Diagnosis (CAD) Proposals***

In an effort to efficiently use the fiscal year 2000 BCRP appropriation for research and to facilitate the scientific merit review of proposals that focus on detection-based CAD in mammography, investigators submitting CAD research projects are encouraged to use a common set of digitized film screening images. The use of a common set of images will allow the scientific merit review of proposals to focus on detection performance, a key element in CAD research. Since budget is a key consideration in peer review, investigators should consider using this common set of digitized film screen mammography images in the execution of their proposed research and limiting budget requests for additional data acquisition. See Appendix L for additional information on CAD submissions.

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

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

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

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

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, How will the proposal contribute to the program's goal of eradicating breast cancer? Will the project lead to new insights into the biology, etiology, prevention, detection, diagnosis, and/or treatment of breast cancer? Does the proposal meet the intent of the Idea Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

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

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” no later than 2 weeks prior to the proposal receipt deadline. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/?/announce/forms>.

### **III-E. Proposal Preparation**

Instructions for proposal preparation are found in Appendix B of this Program Announcement. The following proposal preparation information is specific for Idea Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of figures, tables, and graphs and that the **receipt deadline is June 7, 2000 at 4:00 p.m. Eastern Time**.

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
4. Peer Review Referral Page – See Appendix B, part 4.
5. Proposal Title 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. Number all pages consecutively at the bottom center, beginning with the Proposal Title Page. The DOD BCRP recommends that PIs use this table of contents as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance and Impact Statement – See Appendix B, part 10.  
In addition to the instructions found in Appendix B, part 10, Idea Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of innovation and relevance in the proposal will impact and further programmatic goals.

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

The body of Idea Award proposals is limited to **6 pages**. Figures, tables, and graphs, if used, must be included within this section. If color figures are submitted, it is recommended that they be provided in all copies to ensure their availability to all peer reviewers.

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

Describe the proposed project using the general outline provided below:

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

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

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

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

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

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

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

Funding for Idea Awards can be requested for an average of \$100,000 per year in direct costs for a maximum of \$300,000 over 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request an average of \$125,000 per year in direct costs for a maximum of \$625,000 over 5 years, plus indirect costs as appropriate.

*Idea Awards*

Direct costs can cover salary, expenses including research supplies, equipment, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to be held in the Baltimore, Maryland/Washington, DC area to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

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

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

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

Please note that the **receipt deadline for Idea Award proposals is June 7, 2000 at 4:00 p.m. Eastern Time.**

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

**Principal Investigator:** \_\_\_\_\_

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

\_\_\_\_\_

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**Idea Award Proposal  
Table of Contents**

	Page Number
Proposal Cover Booklet (12 pages)	
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Checklist for Proposal Submission (1 page).....	3
Technical Abstract (1-page limit).....	4
Public Abstract (1-page limit).....	5
Statement of Work (2-page limit) .....	6
Proposal Relevance and Impact Statement (1-page limit).....	___
Proposal Body (6-page limit).....	___
Abbreviations (1-page limit) .....	___
References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
PI.....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff).....	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit) .....	___
Administrative Documentation (no page limit)	
Letters of support from collaborating individuals and/or institutions .....	___
Detailed Cost Estimate (no page limit).....	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (5-document limit) .....	___

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## IV. Clinical Bridge Awards

### IV-A. Clinical Bridge Awards

The intent of Clinical Bridge (Bridge) Awards is to sponsor novel research that can lead to a clinical trial and that will ultimately lead to new translational paradigms for the prevention, detection, diagnosis, and/or treatment of breast cancer. This award is intended to support critical, hypothesis-driven research projects that are either (1) Pre-Clinical Lead-Up or (2) Post-Clinical Trial Follow-Up studies. A goal of the Bridge Awards is to support research that will have clinical applications during or shortly after the completion of the funding period. Unlike Clinical Translational Research Awards, Bridge Awards do not need to include a clinical trial within the lifetime of the award. Bridge Awards should support research that (1) approaches or follows and (2) is proximal to a clinical trial. Two general types of studies are envisioned:

1. Pre-Clinical Lead-Up studies must include the advanced phases in the development of a lead agent for a breast cancer prevention, detection, diagnostic, or therapeutic clinical trial. Projects must focus on the final stages of pre-clinical development/testing of a lead agent(s) that already has demonstrable activity *in vitro* and in animal models. At the time of proposal submission, these projects do not need to demonstrate sufficient progress to ensure the execution of a clinical trial within the timeline of the award. The goal of Pre-Clinical Lead-Up studies is to provide support for the generation of sufficient data within the award period to allow the investigator to justify inclusion of the lead agent in a clinical trial and/or to subsequently apply for a clinical award. Examples of topics that the Breast Cancer Research Program (BCRP) considers well-suited to be addressed by this mechanism include *in vivo* testing of a lead agent for efficacy in breast cancer model systems, *in vitro* studies on materials obtained from *in vivo* experiments, pharmacokinetic and/or toxicological studies, and structural optimization investigations.
2. Post-Clinical Trial Follow-Up studies should involve laboratory investigations to test new hypotheses that are based upon clinical observations and/or findings that emanated directly from a prospective clinical trial. These projects must utilize materials or data from a prospective clinical trial to investigate questions that may lead to a new understanding of the clinical data or the development of new clinical hypotheses. These projects are not Phase IV studies. The goal of Post-Clinical Trial Follow-Up studies is to provide data that will result in new clinical paradigms or applications upon completion of the proposed work. Topics that the BCRP considers well-suited to be addressed by this mechanism should involve diagnostic, prognostic, or predictive factors explored in the context of prospective clinical trials (either therapeutic or epidemiological). In these projects, clinical material (e.g., radiographs, serum, plasma, peripheral mononuclear cells, tumor tissue, normal breast tissue) should be tied to a defined patient database. Studies should be hypothesis-driven but may involve a hypothesis developed after trial completion as a result of new technology and/or availability of new markers.

Though the techniques proposed for these studies may be standard, innovation of the agent, model system, or diagnostic/prognostic marker under study is a criterion of this award. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative and will advance breast cancer interventions leading to or leading from the clinic. All Bridge Award proposals must include preliminary data supporting the rationale for the proposed study. A clear statistical plan with power analysis must be included in the proposal.

Approximately \$5M will be available for Bridge Awards. Funding for Bridge Awards can be requested for an average of \$100,000 per year for direct costs for a maximum of \$300,000 over 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, animal studies, and travel to scientific meetings.

For Pre-Clinical Lead-Up proposals, documentation of the availability and quality control for all critical reagents, including lead agents, to be supplied by an industrial partner or collaborator is required. For Post-Clinical Trial Follow-Up proposals, documentation of the availability of materials or data from the prospective clinical trial, including the timeline of availability is required. For complete proposal requirements, please refer to Section IV-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

In general, the Department of Defense (DOD) BCRP does not accept duplicate submissions addressing the same research question. However, a Clinical Bridge Award proposal may address the same research question proposed in a Career Development Award (CDA) proposal (see Section XII). If a submitted Bridge Award proposal is listed as the source of research support in a CDA proposal, the CDA can only be recommended for funding if the Bridge Award is recommended for funding. However, the Bridge Award may be recommend for funding even if the corresponding CDA proposal is not. Please refer to the Foreword, item 8 (Duplicate Submissions) on page v for additional details on duplicate submissions.

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

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

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well-integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Do the preliminary data support the scientific rationale for the study? Are *in vivo* model systems (if included) relevant to clinical breast cancer in heterogeneity and progression, and do they utilize appropriate methodologies?
- **Clinical/Translational Relevance and Impact:** Does this study address a critical problem in breast cancer translational research? Is the work proposed proximal to a clinical trial? Does the proposal make a convincing case for the relevance of the research to breast cancer?

What is the likelihood that successful completion of the proposed studies will lead to the design of a new prospective clinical trial? Does the research have the potential to result in substantial improvements over today's approach to the prevention, detection, diagnosis, and/or treatment of breast cancer?

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

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

- **Statistical Plan:** Is the experimental design 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?
- **Innovation:** Are the overall translational objective and scientific hypothesis innovative? Though the techniques proposed for these studies may be standard, does the research employ novel agents, models systems, or markers? Does the project challenge existing paradigms, develop new methodologies or technologies, or address underexplored or unexplored areas? Are the *in vivo* model systems (if included) innovative?
- **Principal Investigator and Staff:** Is the PI appropriately trained and well-suited to carry out this work? Are other scientific personnel well-qualified to participate in the project? Is there appropriate representation from all areas of expertise needed to conduct the study successfully?
- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the basic and translational research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

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

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, How will the proposal contribute to the program's goal of eradicating breast cancer? Will the project lead to new insights into the biology, etiology, prevention, detection, diagnosis, and/or treatment of

breast cancer? Does the proposal meet the intent of the Bridge Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

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

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” no later than 2 weeks prior to the proposal receipt deadline. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/?/announce/forms>.

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

Instructions for proposal preparation are found in Appendix B of this Program Announcement. The following proposal preparation information is specific for Bridge Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of figures, tables, and graphs and that the **receipt deadline is June 7, 2000 at 4:00 p.m. Eastern Time**.

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
4. Peer Review Referral Page – See Appendix B, part 4.
5. Proposal Title Page – See Appendix B, part 5.  
On the title page, indicate whether the proposal is a Pre-Clinical Lead-Up or a Post-Clinical Trial Follow-Up Clinical Bridge Award.
6. Table of Contents – See Appendix B, part 6.  
Use the table of contents at the end of this section in your proposal submission. Number all pages consecutively at the bottom center, beginning with the Proposal Title Page. The DOD BCRP recommends that PIs use this table of contents as a guide for assembling all required components of the proposal.
7. Checklist for Proposal Submission – See Appendix B, part 7.
8. Proposal Abstracts – See Appendix B, part 8.
9. Statement of Work – See Appendix B, part 9 and Appendix D.

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

In addition to the instructions found in Appendix B, part 10, Bridge Award applicants should state explicitly (within the 1-page limit) the significance and innovation of the translational hypothesis to be tested. Also, describe how, if the aims are achieved, the proposed work will lead to significant, novel clinical strategies for the prevention, detection, diagnosis and/or treatment of breast cancer.

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

The body of Bridge Award proposals is limited to **10 pages**. Figures, tables, and graphs, if used, must be included within this section. If color figures are submitted, it is recommended that they be provided in all copies to ensure their availability to all peer reviewers. The inclusion of preliminary data is required for Bridge proposals; investigators must submit promising and well-founded preliminary data relevant to breast cancer research and the proposed project.

Describe the proposed project using the general outline provided below:

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

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

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

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

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

For proposals including animal experiments, document the availability of space, support personnel, and regulatory mechanisms.

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

Provide the following administrative documentation, as applicable, in the proposal submission:

- Letters of support from industrial partners or collaborators documenting availability and quality control for all critical reagents, including all lead agents.
- Letters of support documenting the availability of materials or data from the prospective clinical trial, including the timeline of availability.

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

Funding for Bridge Awards can be requested for an average of \$100,000 per year in direct costs for a maximum of \$300,000 over 3 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, animal studies, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year to attend scientific/technical meetings. In addition, funding should also be requested for a one-time, 3½-day meeting to be held in the Baltimore, Maryland/Washington, DC area to disseminate the results of DOD-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate form.

19. Instruments – See Appendix B, part 19.

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

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

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

Please note that the **receipt deadline for Bridge Award proposals is June 7, 2000 at 4:00 p.m. Eastern Time.**

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

**Principal Investigator:** \_\_\_\_\_

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

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**Clinical Bridge Award Proposal  
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Proposal Cover Booklet (12 pages)	
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Checklist for Proposal Submission (1 page).....	3
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Statement of Work (2-page limit) .....	6
Proposal Relevance and Impact Statement (1-page limit).....	___
Proposal Body (10-page limit).....	___
Abbreviations (1-page limit) .....	___
References (no page limit).....	___
Biographical Sketches (3-page limit each)	
PI.....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff).....	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit) .....	___
Administrative Documentation (no page limit).....	___
Letters of support from industrial partners or collaborators documenting availability and quality control for all critical reagents, including all lead agents .....	___
Letters of support documenting the availability of materials or data from the prospective clinical trial, including the timeline of availability .....	___
Letters of support from other collaborating individuals and/or institutions .....	___
Detailed Cost Estimate (no page limit).....	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (5-document limit) .....	___

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## V. Clinical Translational Research Awards

### V-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. Unlike previous Breast Cancer Research Program solicitations, **CTR proposals are only being sought in the areas of target-based 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 pre-clinical research findings to the care of patients with, or populations at risk for, breast cancer. *Applicants must include preliminary data to support the feasibility of their hypotheses and approaches, along with a plan to conduct a prospective clinical trial or study during the course of the award.* 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 the target-based chemoprevention and/or therapy of breast cancer.

Approximately \$10M is available for CTR Awards. There are no dollar amount restrictions to these awards. Research should be completed in 4 years. As noted in Appendix F, it is the policy of the Department of Defense 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 short pre-proposal to be received **no later than April 19, 2000 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 and Supplemental Instructions for preparing a full CTR proposal will be mailed to selected investigators no later than June 15, 2000. The receipt deadline for the invited, full proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Section I-C, V-C, and V-D.

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

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

- The application of well-founded laboratory or other pre-clinical insights that offer the potential to revolutionize the target-based 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;
- 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; and
- The project's potential to extend findings in breast cancer research that offer the potential to revolutionize breast cancer target-based chemoprevention and/or therapy.

### **V-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 pre-clinical 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, presumably in the final year of the grant?* Does the project apply promising and well-founded laboratory or other pre-clinical research findings to the care of patients with or populations at risk for breast cancer? Does the project form a bridge between laboratory and other pre-clinical 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?
- **Principal Investigator and Staff:** Is the PI appropriately trained and well-suited to carry out this work? Are the other scientific personnel well-qualified to participate in the project? Is there representation from all the areas of expertise needed to conduct the study successfully?
- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the pre-clinical and clinical requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

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

Funding recommendations are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, How will the proposal contribute to the program's goal of eradicating breast cancer? Will the project lead to new insights into the chemoprevention and/or therapy of breast cancer? Does the proposal meet the intent of the CTR Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

#### **V-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 19, 2000 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 and sent CTR Supplemental Instructions no later than June 15, 2000. The receipt deadline for the invited, full CTR proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Please note that the timeline for the CTR, Collaborative-CTR, and Virtual Center pre-proposal and proposal submissions is different from those of the other proposal categories outlined in this Program Announcement.

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. Pre-Proposal Cover Booklet – **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 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 investigator. The “Biographical Sketch” form can be found in Appendix E, or downloaded from the CDMRP

web site at <http://cdmrp.army.mil/?/announce/forms>. A list of significant publications and a succinct summary of the investigator's professional experience in breast cancer research and/or their potential for contribution to the field of breast cancer research should be incorporated into the biographical sketch.

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

**Pre-Proposal:** **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated 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 thirty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI's name.

**Noncompliance:** Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal or proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals or 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 (BCRP00-Announcement)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

10. Receipt Deadlines

Please note that the **receipt deadline for CTR Award pre-proposals is April 19, 2000 at 4:00 p.m. Eastern Time.** The receipt deadline for invited, full CTR Award proposals is August 2, 2000 at 4:00 p.m. Eastern Time.

## VI. Collaborative-Clinical Translational Research Awards

### VI-A. Collaborative-Clinical Translational Research Awards

**The goals of this award mechanism are (1) to support the infrastructure costs (primarily personnel) required to develop new consortium models 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 new consortium models to evaluate promising drugs and technologies for the early detection, treatment, and prevention of breast cancer. These awards should clearly enhance patient participation in clinical trials by bringing together the resources of academia (i.e., medical centers), community-based oncology practices, and the private sector to translate promising new agents and technologies to accelerate the eradication of breast cancer. *This award is not intended to replace, supplement, duplicate, or compete with traditional academic/community research efforts such as the National Cancer Institute-supported cooperative groups, CCOPs (Community Clinical Oncology Programs), or CGOPs (Cooperative Group Outreach Programs).* Funds from C-CTR Awards are not intended to replace funds provided by industry to support clinical trials of new agents.

New models for performing breast cancer clinical trials through novel partnerships are the focus of C-CTR Awards. These new models must specifically address the following needs: (1) decrease the time to perform a clinical trial; (2) increase the participation of patients with, and populations at risk for, breast cancer in clinical trials by making clinical trials more accessible through community oncologists; and (3) increase the number of drugs, modalities (including biological agents), or technologies tested for breast cancer. Also, applicants are encouraged to form collaborations with consumer/survivor organizations in the hope that this will increase patient accrual in the planned clinical trials. Please note that breast cancer consumer/survivor groups should be active participants in these efforts. Whenever possible, 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 for infrastructure. The proposal, in addition to providing a clear plan for the creation of the infrastructure to support the appropriate breast cancer clinical trials, must plan to test multiple novel drugs, modalities, or technologies during the award period. It is anticipated that these new 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 intent 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 I or II) with appropriate scientific hypothesis and plan;
2. A central institution coordinating a program that will include community-based oncology practices, the private sector, and academic center(s);
3. Community-based oncology practices with sufficient patient populations willing to participate; and
4. 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, and the private sector to execute clinical trials that can efficiently accrue patients; and
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 pre-clinical drug, modality, or technology development.
2. Proposals should include data on pre-clinical results that clearly demonstrate that the drugs, modalities, or technologies are ready to be tested in clinical trials.
3. A requirement for consideration will be the inclusion of a clear experimental and statistical plan to perform **prospective** clinical trials.

Approximately \$5M is available to support C-CTR awards. Support can be requested for an average of \$400,000 per year in direct costs, for a maximum of \$1,200,000 over 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 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.

Investigators interested in applying for a C-CTR Award must submit a short pre-proposal to be received **no later than April 19, 2000 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 and Supplemental Instructions for preparing a full C-CTR proposal will be mailed to selected investigators no later than June 15, 2000. The receipt deadline for the invited, full proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Full proposals will be evaluated in accordance with the two-tier review system and criteria described in Section I-C, VI-C, and VI-D.

## **VI-B. Screening Criteria – 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 are ready for clinical trials;
- The application of well-founded laboratory or other pre-clinical findings to the prevention, detection, diagnosis, or treatment of patients with, or populations at risk for, breast cancer;
- 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 outline of a *clear, appropriately powered* statistical plan to answer the research questions posed;
- 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.

## **VI-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.

- **Available Agents or Technology:** Does the applicant **clearly** demonstrate sufficient evidence that multiple drugs, modalities, or technologies are available for testing in clinical trials? Are the agents to be tested ones that would provide new insights into the prevention, detection, diagnosis, and/or treatment of breast cancer?
- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well-integrated, including laboratory and other pre-clinical evidence to support the clinical feasibility and promise of the approach? Do the prospective clinical trials investigate the impact on prevention, detection, diagnosis, and/or treatment within the lifetime of the grant? Does the applicant acknowledge potential problem areas and consider alternative approaches? ***Has a plan been developed to test multiple agents in prospective clinical trials within the lifetime of the award?***
- **Collaborations:** Are the essential partners capable and committed? Has an outline for outreach collaboration been developed? Are these community collaborations likely to lead to increased patient accrual? Are the collaborations with community-based oncology practices likely to be successful? Does the collaboration offer the opportunity to provide additional experience and training for practitioners at community oncology clinics? Have new networks for testing new and/or innovative models for early clinical trials been developed? Is the private sector an active participant in this effort as demonstrated by the private sector's letter of intent? Is the application further strengthened by the involvement of consumer/survivor organization collaboration?
- **Patient Populations:** Are there sufficient documented patient populations available to perform the prospective clinical trials successfully? Are the plans for patient accrual realistic? Has the ethnic diversity of the patient population been considered appropriately in developing community collaborations?
- **Translational Potential:** ***Is the project likely to produce meaningful clinical results within the course of the award?*** Does the project apply promising and well-founded laboratory or other pre-clinical research findings to the care of patients with, or populations at risk for, breast cancer? Does the collaborative model have the potential to result in substantial

improvements over today's approaches to translating new agents and technologies into new strategies for the prevention, detection, diagnosis, and/or treatment of breast cancer?

- **Clinical Relevance 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*?
- **Innovation:** Does the research employ *novel* concepts, approaches, or methods? Are the aims original and innovative? Are the proposed collaborations a novel way to perform clinical trials? Does the project challenge existing paradigms or develop new, underexplored, or unexplored areas?
- **Statistical Plan:** Is the design of the clinical trials sound and sufficiently well-developed with the *required statistical power* to lead to 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?
- **Principal Investigator and Staff:** 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?
- **Environment:** Are the scientific environments and community-based oncology practices appropriate settings for the proposed research? Are the collaborators appropriate to test whether the proposed model can be extended to other institutions to test other agents ready for clinical trials? Are the pre-clinical and clinical requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Does the supporting documentation demonstrate the commitment of all participants to execute the project goals? Is there evidence of institutional support for the establishment of the consortium?
- **Budget:** Is the budget reasonable for the research proposed?

#### **VI-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. For example, how will the proposal contribute to the program's goal of eradicating breast cancer? Will the project lead to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Does

the proposal meet the intent of the C-CTR Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

## **VI-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 19, 2000 at 4:00 p.m. Eastern Time**. Investigators selected to submit a full proposal will be notified and sent C-CTR Supplemental Instructions no later than June 15, 2000. The receipt deadline for the full C-CTR proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Please note that the timeline for C-CTR pre-proposal and proposal submissions is different from those of other proposal categories outlined in this announcement.

1. Who May Apply – See Appendix B, part 1.
2. Pre-Proposal Acceptance Criteria – See Appendix B, part 2.  
Please note that the same acceptance criteria are applied to pre-proposals as full proposals.
3. Pre-Proposal Cover Booklet – **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 the pre-screening criteria. 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 CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>. A list of significant publications and a succinct summary of the investigator’s professional experience in breast cancer research and/or his/her potential for contribution to the field of breast cancer research should be incorporated into the biographical sketch.

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

**Pre-Proposal:** **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated 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 thirty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI’s name.

**Noncompliance:** Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal or proposal rejection. Administrative reasons for **rejection** of all or part of pre-proposals or 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 (BCRP00-Announcement)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

9. Receipt Deadlines

Please note that the **receipt deadline for C-CTR Award pre-proposals is April 19, 2000 at 4:00 p.m. Eastern Time.** The receipt deadline for invited, full C-CTR Award proposals is August 2, 2000 at 4:00 p.m. Eastern Time.

## **VII. Virtual Breast Cancer Center of Excellence Awards**

### **VII-A. Virtual Breast Cancer Center of Excellence Awards**

The intent of Virtual Breast Cancer Center of Excellence (Virtual Center) Awards is to establish virtual, electronic centers to accelerate the solution of overarching and/or multidisciplinary problems in breast cancer research. Virtual Center Awards are intended to support the establishment of state-of-the-art electronic network (e-network) collaborations among accomplished scientists from different institutions and diverse backgrounds and areas of expertise, who will communicate and share data in real time to solve pivotal breast cancer research problems. Virtual Centers should have a unified focus on a single research project or a set of closely related, overlapping projects. The overall goals of these awards are to accelerate advances in breast cancer research and support the Breast Cancer Research Program's (BCRP's) goal of eradicating of breast cancer. The results generated from these awards should have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer.

Proposals for Virtual Center Awards should be designed using the power of a real-time, e-based communication infrastructure as a foundation for the choice of research problems and investigators. Emphasis should be placed on the development of virtual networks of diverse, accomplished investigators and consumer advocates to focus on specific research problems that will be facilitated by such an approach. These awards should bring together individuals from different disciplines and institutes, reduce the time required to communicate research results, attack complex problems using a more comprehensive array of personnel and resources, and generally accelerate research progress through real-time communication and problem solving. Collaborations established through Virtual Centers should result in a synergistic research project rather than an additive set of subprojects (i.e., the combined efforts in the whole center project provides greater benefit than the sum of individual research initiatives). Collaborators may plan to meet in person two to four times per year to assess research progress, address problems, and define future directions. Breast cancer consumer/survivor groups should be active participants in these multidisciplinary efforts. Whenever possible, consumers should be involved in program conception and design, e-network discussions, recruitment of research participants, and/or program evaluation and dissemination of information to the public.

Virtual Center proposals should address an overarching problem that is relevant to the prevention and cure of breast cancer. The problem can be a major question(s) in breast cancer research or the development of a valuable on-line breast cancer research database(s) that may play a significant role in the cure and prevention of breast cancer. Virtual Center Award proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiological research, including basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. The following list illustrates topics that the BCRP believes may be appropriate for the focus of Virtual Center 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 area. Pertinent topics might include:

- A consortium of basic and clinical scientists devoted to accelerate the development of specific therapies (e.g., immunotherapies, small molecule therapies, gene therapies). Problems that such a group might address include the development of acceptable array(s) of breast cancer markers for use as surrogate endpoints in clinical trials of new therapeutic agents or new, innovative pre-clinical and/or clinical models.
- Determining the potential role of specific environmental factors in breast cancer etiology (e.g., studying and categorizing interactions of environmental factors with specific breast cancer genes and/or molecular pathways).
- A common basic or translational research problem pursued in several laboratories that has reached a stage where linking the participants through a virtual network will avoid unnecessary duplication, resolve discrepancies, and accelerate and facilitate progress in areas relevant to breast cancer (e.g., erbB/erbB receptor family signaling, BRCA1/II action, relative contribution of proteolytic enzymes of different classes, steroid hormone co-stimulators).
- Epidemiological studies that link population data to generate large or diverse databases to determine risk factors or evaluate outcomes in breast cancer (e.g., dietary contributions, interactions of genes with known risk factors, quality of life assessment of therapies).
- Breast cancer detection studies that extend across scientific disciplines, such as breast cancer detection aids (computer or human), development of detection performance metrics, lesion characterization, individualized risk assessment, and development of management strategies for patients in different risk categories.

An Informatics Resource Center and the investigator/staff responsible for the managing the e-network are essential parts of Virtual Center proposals. The e-network that will be set up as part of this award should take advantage of powerful Internet and current electronic communication tools. The e-network should not simply be standard e-mail communications that occur among traditional collaborations. The new e-network should provide the basis for organizing and managing the project, establish the process and tools for data management and project meetings, encourage a real-time exchange of research findings through open discussions, meetings, etc. of all participants.

The topic chosen should be one that is best addressed by a multidisciplinary, multi-institutional team of experts. Virtual Centers should maximize the utilization of resources and minimize unnecessary duplication; e.g., experimental techniques, databases, models, animal models, antibodies, etc. should be shared resources in a Virtual Center. These awards should lead to publications with multidisciplinary, multi-institutional authorship. The Virtual Center Project Director, i.e., the principal investigator (PI) on the proposal, should have a proven track record of leadership and scientific ability to direct and oversee the overall research effort, ensure the use of the e-network Informatics Resource Center to its fullest potential, and have experience in managing multifaceted projects.

Projects should be based on well-founded research findings. Applicants must include preliminary data to support the feasibility of their hypotheses and/or approaches, along with a plan to conduct the proposed research.

Approximately \$17M is available to support Virtual Center Awards. There are no dollar amount restrictions to these awards. Research should be completed in 4 years. Investigators interested in applying for a Virtual Center Award should submit a short pre-proposal **no later than April 19, 2000 at 4:00 p.m. Eastern Time**. Pre-proposals will be screened to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations and Supplemental Instructions for preparing a full Virtual Center proposal will be mailed to invited investigators no later than June 15, 2000. The receipt deadline for the invited, full proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Full proposals will be evaluated in accordance with the two-tier review system described and criteria in Sections I-C, VII-C, and VII-D.

## **VII-B. Screening Criteria – Virtual Breast Cancer Center of Excellence Awards Pre-Proposals**

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

### *Relevance/Impact:*

- The specific research question's or database development's relevance and impact to the prevention, detection, diagnosis, and/or treatment of breast cancer; and
- The extent to which the proposed study addresses a critical issue in breast cancer research that would best be addressed and facilitated by a multidisciplinary, multi-institutional team of scientists and consumer advocates working together virtually through an e-network.

### *Project Management and Experimental Plan:*

- The outline of a plan for a multi-institutional, multidisciplinary consortium to address an appropriate problem;
- The PI's qualifications and ability to organize, administer, and manage a well-qualified team of multidisciplinary, multi-institutional researchers and consumer advocates in a virtual center to solve a critical problem in breast cancer research;
- The outline of a project management plan, including the identification of key personnel, for the development of an Informatics Resource Center and e-network(s) that will lead to real-time communication to synergistically expedite research and to attain the project goals; and
- The outline of a *clear* experimental plan to address the specific research question or development of the proposed database.

*Informatics and e-Network Resources and Management:*

- The demonstration of the availability of resources and support for this research through an e-network; and
- The demonstration that the proposed Informatics Resource Center and e-network will provide a critical benefit to attaining the projects goals.

### **VII-C. Scientific Peer Review – Evaluation Criteria for Invited, Full Virtual Breast Cancer Center of Excellence Award Proposals**

Invited, full Virtual Center proposals will be evaluated in scientific peer review according to the criteria listed below:

- **Scientific Relevance and Impact:** Is the project likely to extend recent findings in breast cancer research? Does it offer the potential to revolutionize an aspect of breast cancer research? What will be the effect of these studies on the concepts or methods that drive this field? To what extent will the project, if successful, make an original and important contribution to the goal of eradicating breast cancer and/or advancing research in the field?
- **Research Strategy:** Is the problem that is being addressed in this project one that will be better solved through the use of an e-network, as opposed to more traditional forms of communication? Is the proposed project multi-institutional and multidisciplinary? Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well-integrated into the aims of the project? Is the project synergistic, i.e., are the combined efforts in the Virtual Center of greater benefit than the sum of individual research initiatives? Do the preliminary data support the rationale for this project? Does the applicant acknowledge potential problem areas and consider alternative approaches? Has an analysis of the risk factors and how they will be anticipated, e.g., that the speed of results may dictate changes in direction, been taken into consideration? Is there a clear statistical plan with power analysis included in the proposal?
- **Project Director and Project Management:** Does the Project Director have the appropriate qualifications and experience to coordinate and manage this project? Does the Project Director have the training and expertise to oversee the research that addresses the overarching breast cancer problem proposed? Has a management plan been outlined to coordinate and optimize the work/collaborations covered in this project? Has the Project Director demonstrated that he/she can efficiently visualize, implement and utilize the e-network and informatics core resource to accomplish the project's goals? Has a project management plan been presented for how this project will be directed and managed to insure real-time communication of results, issues, problems, and progress?

- **E-Network and Communications Plan:** Has it been demonstrated that the establishment of an e-network will expedite this research? Has the e-network communication plan been clearly rationalized and planned? Does the proposal take advantage of current Internet and electronic communication tools? Have security issues been addressed? Is convincing evidence presented that the new e-network will facilitate and encourage the exchange of research findings in real time through the proposed communications plan?
- **Informatics Resource Center and Data Management:** Can the Informatics Resource Center be supported at the designated institution and by each participating institution as required? Is the Informatics Coordinator, i.e., the investigator who is responsible for coordinating the Informatics Resource Center, appropriately qualified? Has the Informatics Coordinator demonstrated his/her ability to manage web sites, arrange data communication/exchange, address security issues, and tie working groups together? Is the appropriate support staff available for administering the Informatics Resource Center and e-network? If required by the proposed problem, has a plan been developed to address data management? Does the data management plan encourage collaborative efforts? Are the models proposed for linking and analyzing information appropriate?
- **Collaborations and Environment:** Has the multi-institutional project team been carefully configured? Is the team appropriate for addressing the overarching problem? 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? Are consumer advocates active participants in the project? Have all participants demonstrated the skills and willingness to participate as part of the virtual team and utilize the e-network and other proposed tools? Are the scientific environments appropriate settings for the proposed research? Do the different institutions/organizations involved in this project strengthen this proposal? Is there evidence that the infrastructure required to support the e-network is available?
- **Innovation:** Does the research employ *novel* concepts, approaches, or methods, especially in the areas of e-communications, networks, and/or databases? Are the aims original and innovative? Are the proposed collaborations a novel way to address the specific research question or to develop a database? Does the project challenge existing paradigms or develop new, underexplored, or unexplored areas?
- **Budget:** Is the budget reasonable for the research proposed?

#### **VII-D. Programmatic Review – Evaluation Criteria for Full, Invited Virtual Breast Cancer Center of Excellence 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. For example, How will the proposal contribute to the program's goal of eradicating breast cancer? Will the project lead

to new insights into the prevention, diagnosis, detection, and/or treatment of breast cancer? Does the proposal meet the intent of the Virtual Center Award mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

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

The following pre-proposal preparation information is specific for the Virtual Center Award mechanism. Please note that the body of the pre-proposal is limited to **3 pages** and that the **receipt deadline is April 19, 2000 at 4:00 p.m. Eastern Time**. Investigators selected to submit a full proposal will be notified and sent Virtual Center Supplemental Instructions no later than June 15, 2000. The receipt deadline for the invited, full Virtual Center proposal is August 2, 2000 at 4:00 p.m. Eastern Time. Please note that the timeline for Virtual Center, CTR, and C-CTR pre-proposal and proposal submissions is different from those of other proposal categories outlined in this announcement.

1. Who May Apply – See Appendix B, part 1.
2. Pre-Proposal Acceptance Criteria – See Appendix B, part 2.  
Please note that the same acceptance criteria are applied to pre-proposals as full proposals.
3. Pre-Proposal Cover Booklet – **Not required** for pre-proposals.
4. The Pre-Proposal Title Page should include the following information:
  - a. Pre-Proposal title
  - b. Award Mechanism; i.e., Virtual Center
  - c. Project Director’s full name, including middle initial
  - d. Project 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” as a key word)
5. Pre-Proposal Body – Limited to **3 pages**.  
The pre-proposal body should consist of **three parts**, each with a **1-page** limit. It is the responsibility of the investigator to clearly articulate how the proposed research meets the screening criteria. Each page of the pre-proposal should address the evaluation criteria as outlined in Section VII-B.
  - a. Relevance/Impact

- b. Project Management and Experimental Plans
- c. Informatics and e-Network Resources and Management

Additional Information on collaborators can be included in items 7 and 8 below.

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. Project Director Biographical Sketch – See Appendix E.  
A biographical sketch for the Project Director not exceeding 3 pages should be submitted. The “Biographical Sketch” form can be found in Appendix E, or downloaded from the CDMRP web site at <http://cdmrp.army.mil/?/announce/forms>. A list of significant publications and a succinct summary of the investigator’s professional experience in breast cancer research and/or their potential for contribution to the field of breast cancer research should be incorporated into the biographical sketch.
8. Participating Investigators – Limited to 1 page.  
A 1-page summary of key personnel with brief summary information on their background should be provided. Emphasis should be placed on the qualifications of individuals who support essential elements of the project, including the Informatics Coordinator. Written descriptions of how those qualifications relate to the proposed duties in the Virtual Center are encouraged.
9. To be considered, submit the following documentation to the address listed below:

**Pre-Proposal:** **ONE** clearly labeled original (binder-clipped) and **THIRTY** collated 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 thirty copies) per box. If acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the pre-proposal title and PI’s name.

**Noncompliance:** Noncompliance to established guidelines may be perceived as an attempt to gain an unfair competitive advantage and therefore may result in pre-proposal or proposal rejection.

Administrative reasons for **rejection** of all or part of pre-proposals or 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 (BCRP00-Announcement)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

10. Receipt Deadlines

Please note that the **receipt deadline for Virtual Center Award pre-proposals is April 19, 2000 at 4:00 p.m. Eastern Time.** The receipt deadline for invited, full Virtual Center proposals is August 2, 2000 at 4:00 p.m. Eastern Time.