

CENTER OF EXCELLENCE AWARD

*A pioneering, multi-institutional approach to
eradicating breast cancer*

The BCRP believes that groundbreaking advances toward the eradication of breast cancer will be made by assembling the most gifted individuals into a multidisciplinary team to focus on a pivotal question in breast cancer research. Thus, the Breast Cancer Center of Excellence Award mechanism was established to encourage the formation of a multidisciplinary, multi-institutional research program that includes exceptional scientists, clinicians, and consumer advocates. Highly accomplished scientists renowned for their contributions to the proposed areas of research and promising young investigators that can provide fresh insight should be assembled to address the central, overarching research problem. In addition, the BCRP strongly encourages the integration of scientists from nontraditional disciplines such as computer sciences, mathematics, economics, physics, and other quantitative disciplines. Breast cancer consumer/survivor groups must be active participants in all aspects of these awards. Awardees may receive up to \$10 million (direct and indirect costs).

PRE-PROPOSALS ARE DUE BY MARCH 24, 2004

All investigators interested in applying for a Center of Excellence Award **must** submit a pre-proposal.

This document is a synopsis of details specific to the Breast Cancer Research Program (BCRP) Center of Excellence Award. Detailed descriptions of each BCRP FY04 mechanism with specific evaluation criteria, submission requirements, and deadlines are available in the FY04 BCRP Program Announcements.

BCRP

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Breast Cancer Research Program (BCRP) believes that groundbreaking advances toward the eradication of breast cancer will be made by assembling the most gifted individuals into a multidisciplinary team to focus on a pivotal question in breast cancer research. Thus, the Breast Cancer Center of Excellence Award mechanism was established to encourage multidisciplinary, multi-institutional research programs that includes exceptional scientists, clinicians, and consumer advocates. Highly accomplished scientists renowned for their contributions to the proposed areas of research and promising young investigators that can provide fresh insight should be assembled to address the central, overarching research problem. In addition, the BCRP strongly encourages the integration of scientists from nontraditional disciplines such as computer sciences, mathematics, economics, physics, and other quantitative disciplines. Breast cancer consumer/survivor groups must be active participants in all aspects of these awards. Recipients may receive up to \$10 million (M) (direct and indirect costs).

A. Title of Award: Breast Cancer Center of Excellence Award (COE).

B. Program Name: Department of Defense Fiscal Year 2004 BCRP.

C. Funding Opportunity Number: BC04-COE.

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

E. Agency Contact(s):

1. Questions related to the Program, proposal format, or required documentation may be addressed to the CDMRP at:

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BC04-COE)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: <https://cdmrp.org/proposals> (the proposal submission website)
E-mail: help-proposals-cdmrp@cdmrp.org

F. Anticipated Instrument Type(s): Grants/Cooperative Agreements.

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

H. Website Address to Access Application Package: Proposals must be submitted electronically at <https://cdmrp.org/proposals>. The website contains all the information, forms, documents, and links you will need to apply.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use. Please see the Full Text of Program Announcement for details pertaining to this award mechanism.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Breast Cancer Center of Excellence Awards is to accelerate the solution of a *major overarching problem* in breast cancer research. A Breast Cancer Center of Excellence proposal must address a single, unifying question critical to the prevention, detection, diagnosis, or treatment of breast cancer through a synergistic, multidisciplinary research program. ***Breast cancer consumer/survivor groups must be active participants at all levels in these multidisciplinary efforts.***

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$30M is available for this award mechanism.
- It is anticipated that two to three Breast Cancer Center of Excellence Award proposals will be funded.
- Funding for Breast Cancer Center of Excellence Awards can be requested for a maximum of \$10M, inclusive of both direct and indirect costs, for up to a 5-year performance period.

IV. ELIGIBILITY INFORMATION

A. Applicants: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" located in Subsection VI.F.2.c of the Full Text of Program Announcement for details.

D. Other Eligibility Criteria: Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

V. PRE-PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Information: Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at <https://cdmrp.org/proposals>.

B. Pre-proposal Preparation: Investigators interested in applying for the Breast Cancer Center of Excellence Award must submit the Proposal Information and a pre-proposal. See subsection V of the Full Text of Program Announcement for preparation instructions. Pre-proposals will be reviewed as described in the Full Text of Program Announcement.

All pre-proposals must be converted into an electronic PDF (Portable Document Format) file for electronic pre-proposal submission. Please see the Full Text of Program Announcement for details.

C. Pre-proposal Submission Date and Times: Deadline Date: **March 24, 2004**. Pre-proposals must be submitted through the CDMRP eReceipt system by 5:00 p.m. (Eastern time).

Invitations to prepare a full Breast Cancer Center of Excellence proposal will be sent to selected investigators no later than May 2004.

D. Invited Proposal Preparation: All proposals must be converted into an electronic PDF file for electronic proposal submission. Please see the Full Text of Program Announcement for details.

E. Proposal Submission Dates and Times: Deadline Date: **July 27, 2004**. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

F. Proposal Electronic Submission Requirements: Electronic submission is required. No paper copy submissions will be accepted. Proposals must be submitted electronically at <http://cdmrp.org/proposals>. Please see the Full Text of Program Announcement for details.

G. Invited Proposal Preparation and Submission Information: *Do not submit a full Breast Cancer Center of Excellence proposal unless you receive a letter of invitation.*

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tier review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures, and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

The Breast Cancer Research Program (BCRP) believes that groundbreaking advances toward the eradication of breast cancer will be made by assembling the most gifted individuals into a multidisciplinary team to focus on a pivotal question in breast cancer research. Thus, the Breast Cancer Center of Excellence Award mechanism was established to encourage multidisciplinary, multi-institutional research programs that includes exceptional scientists, clinicians, and consumer advocates. Highly accomplished scientists renowned for their contributions to the proposed areas of research and promising young investigators that can provide fresh insight should be assembled to address the central, overarching research problem. In addition, the BCRP strongly encourages the integration of scientists from nontraditional disciplines such as computer sciences, mathematics, economics, physics, and other quantitative disciplines. Breast cancer consumer/survivor groups must be active participants in all aspects of these awards. Recipients may receive up to \$10 million (M) (direct and indirect costs).

A. Title of Award: Breast Cancer Center of Excellence Award (COE).

B. Program Name: Department of Defense (DOD) Fiscal Year 2004 (FY04) BCRP.

C. Funding Opportunity Number: BC04-COE.

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

E. Agency Contact(s):

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

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BC04-COE)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission or the process of electronic submission. The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: <https://cdmrp.org/proposals> (the proposal submission website)
E-mail: help-proposals-cdmrp@cdmrp.org

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

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

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

H. Website to Access Application Package: Proposals must be submitted electronically at <https://cdmrp.org/proposals>. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.1 above.

I. Award/Regulatory Approval: Please note, each award mechanism has specific requirements regarding human subjects and animal use.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Breast Cancer Center of Excellence Award is part of the DOD BCRP, which was established in FY92 to promote innovative research directed toward the eradication of breast cancer. Appropriations for the BCRP since FY92 total \$1.53 billion (B). The program history of the FY92-03 BCRP is shown in Table 1. The FY04 appropriation is \$150 million (M).

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

Program History	FY92-02	FY03¹
Congressional Appropriations for the BCRP	\$1.38B	\$150M
Total Proposals Received	19,840	1,543
Total Proposals Funded	3,671	240
Breast Cancer Center of Excellence Award Proposals Received	29	12
Breast Cancer Center of Excellence Award Proposals Funded	8	1

¹Award negotiations will be finalized by September 2004.

B. Program Objectives: The overall goal of the FY04 BCRP is to promote research directed toward eradicating breast cancer. Within this context, an objective of the BCRP is to fund a broad portfolio of

scientifically meritorious research related to all aspects of breast cancer. Thus, 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 BCRP is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research are highly sought.

C. Award Mechanism Description: The intent of the Breast Cancer Center of Excellence Award is to optimize research and accelerate the solution of a *major overarching problem* in breast cancer research within an integrated consortium of the most highly qualified investigators. Each Breast Cancer Center of Excellence Award proposal must address a single, critical question relevant to the prevention, detection, diagnosis, and/or treatment of breast cancer through a synergistic, multidisciplinary research program. The central problem addressed by the Breast Cancer Center of Excellence should (1) solve a major problem(s) in basic, translational, population-based and/or clinical breast cancer research; (2) develop critically needed resources (e.g., databases to address specific problems); and/or (3) create a unique, new approach or infrastructure to focus on a critical research problem. The Breast Cancer Center of Excellence may include Phase I or Phase II clinical trials, and collaborations with pharmaceutical or biotechnology industry scientists are welcome.

It is anticipated that the Breast Cancer Center of Excellence will be multi-institutional and will include the best scientists, clinicians, and consumer advocates as members of a synergistic, multidisciplinary team, ***unless a compelling justification is provided that a single institution can best address the focus of the Breast Cancer Center of Excellence Award.***

Participating institutions must be willing to resolve potential intellectual property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful establishment and maintenance of the multidisciplinary, synergistic research consortium. An intellectual property plan agreed upon by all participating institutions is required as part of the administrative documentation of this proposal (see Subsection VI.E.14).

All proposals submitted to the Breast Cancer Center of Excellence Award should:

- ***Focus on the solution of a critical question in breast cancer research using research strategies that optimize the Breast Cancer Center of Excellence Award's comprehensive array of personnel and resources.*** The project designed for the Breast Cancer Center of Excellence must be founded on sound research and must be critical to the detection, prevention, and/or treatment of breast cancer. In addition, the question should be of sufficient breadth to require a multidisciplinary approach. Applicants *must* include published or preliminary data in both the pre-proposal and the invited proposal to support the feasibility of their hypotheses and/or approaches, along with a description of the proposed team of investigators and the anticipated research.
- ***Integrate a team of preeminent investigators from appropriate disciplines and institutions.*** Emphasis should be placed on integrating the most highly qualified investigators to focus on the research problem, *regardless of their location*. This includes highly accomplished scientists and promising young investigators in the targeted areas of research that collectively represent the best

team to solve the problem(s) identified. *Inclusion of scientists from nontraditional disciplines such as computer sciences, mathematics, economics, physics, technology development, bioengineering, or other quantitative disciplines is encouraged.*

- ***Incorporate breast cancer consumer/survivor groups into every aspect of the proposed consortium.*** Breast cancer consumer/survivor groups must have active roles in every aspect of the proposed Center of Excellence including program conception and design, discussions, recruitment of research participants, program evaluation, and dissemination of information to the public.
- ***Optimize, facilitate, and accelerate research progress through real-time communication.*** Communication between and among Breast Cancer Center of Excellence team members is essential to the success of the Center's goals and should be addressed, including a strategy for sharing data in real time and the use of information technologies to facilitate timely and effective communication and cooperation. It is expected that the Breast Cancer Center of Excellence will take full advantage of current Internet and electronic communication tools, as well as formal and informal meetings. Collaborators also must plan to meet in person two to four times per year to assess research progress, address problems, and define future directions.
- ***Provide an effective, coordinated administrative management plan that integrates and optimizes the research and collaborations.*** The day-to-day management of the Breast Cancer Center of Excellence Award is provided by the Center of Excellence Director, i.e., the Principal Investigator (PI) on the proposal. Due to the intricate nature of administrating the Center, the Center Director is expected to make a commitment of time and effort commensurate with directing and managing an initiative of this magnitude; at least 30% of his or her time is to be committed to this award. He or she should have a proven record of leadership and the scientific ability to direct and oversee large research programs, including experience in the effective use of communication tools and management of multifaceted and multidisciplinary projects. The administrative management component should provide the basis for organizing and managing the Breast Cancer Center of Excellence, including regulating the processes and tools for regular and structured communication, data management, scheduling project meetings, reviewing research report findings, and other issues of common concern for the Center and its investigators. As a part of the administrative management plan, the Center of Excellence Director is also expected to develop procedures that maximize the utilization of resources and eliminate unnecessary duplication; e.g., experimental techniques, databases, models (including animal models), antibodies, etc., should be shared resources for all Breast Cancer Center of Excellence Award participants. The Center of Excellence Director will also assure that publications arising from the Center's work are given multidisciplinary authorship.

This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts such as the National Cancer Institute-supported Specialized Programs of Research Excellence (SPORE) nor should it represent a collection of related Program Project grants or sub-projects.

III. AWARD INFORMATION

Funding for Breast Cancer Center of Excellence Awards can be requested for up to a maximum of \$10M inclusive of both direct and indirect costs for up to a 5-year performance period. The amount allotted for travel is \$1,800 per year per investigator to attend scientific/technical meetings. In addition, travel funding of \$1,800 per investigator per meeting should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$30M of the \$150M FY04 BCRP appropriation to fund two to three Breast Cancer Center of Excellence Awards.

IV. ELIGIBILITY INFORMATION

A. Applicants: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below.

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under “Major Equipment” located in Subsection VI.F.2.c.

D. Other Eligibility Criteria:

1. Duplicate Submissions: Submission of the same research project to the FY04 BCRP under different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP’s peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.¹ Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website under Minority Institutions at <http://cdmrp.army.mil/funding/pdf/mibcrp120803.pdf>.

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

¹Executive Orders 12876, 12900, and 13021

The following will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages over the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the Government, any material submitted after the submission deadline will not be forwarded for peer review.

V. PRE-PROPOSAL PREPARATION AND SUBMISSION INFORMATION

Investigators interested in applying for the Breast Cancer Center of Excellence Awards must submit a pre-proposal. 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 to prepare a full Breast Cancer Center of Excellence proposal will be sent to selected investigators no later than May 2004. ***Do not submit a full Center of Excellence proposal unless you receive a letter of invitation.***

A. Pre-proposal Components Summary: This subsection summarizes submission requirements for the pre-proposal. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The Project Director (PI) is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields.
- **Pre-proposal:** The pre-proposal is uploaded as a PDF (Portable Document Format) file under the “Required Files” tab.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the pre-proposal. Complete the Proposal Information as described in <https://cdmrp.org/proposals>.

- **Letter of Intent:** A Letter of Intent is not required for this award mechanism.

C. Pre-proposal Preparation:

1. Format: All pre-proposals must be converted into an electronic PDF file for electronic submission. Pre-proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare pre-proposals for PDF submission, the instructions in this subsection must be followed carefully.

The pre-proposal must be clear and legible and conform to the following guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Color, Resolution, and Multimedia Objects: Pre-proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these items must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the pre-proposal directing the reviewer to the electronic file for parts of the pre-proposal that may be difficult to interpret when printed in black and white.
- Spell out all acronyms the first time they are used.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).

2. Pre-proposal Title/Referral Page: No page limit.

Complete the Title/Referral Page, which can be downloaded from the CDMRP website at <https://cdmrp.org/programAnnouncements.cfm>. Complete each section as described:

- a. Pre-proposal title (up to 160 characters).
- b. Pre-proposal log number (this will be automatically provided when a draft of the Proposal Information is completed and saved).
- c. PI's full name (first, middle initial, last).
- d. Submitting Institution.
- e. Award mechanism: Type in "Breast Cancer Center of Excellence Award."
- f. Keyword descriptive technical terms: To assist the staff in assigning pre-proposals to the appropriate reviewer, please specify the subject area of the pre-proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposed Center including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposed Center who may have a conflict of interest in review of this pre-proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

3. Pre-proposal Body: Start section on a new page; two-page limit. It is the responsibility of the investigator to articulate clearly how the proposed center specifically addresses each of the screening criteria for pre-proposals.

Pre-proposals should be written to address the follow pre-proposal screening criteria:

- a. Clearly state the overarching research question. Include a discussion of its suitability to be addressed in a multidisciplinary, multi-institutional consortium and its relevance to, and impact on, the prevention, detection, diagnosis, and/or treatment of breast cancer.
- b. Describe the *multi-institutional, multidisciplinary* team of investigators and consumer advocates that will address the major, overarching research question, including the identification and location of key personnel. In addition, this section should address the plan for consumer advocate involvement at every level of the Breast Cancer Center of Excellence.
- c. A description of how the interactions and collaborations established through the Breast Cancer Center of Excellence Award will result in a *synergistic* research effort that will substantively accelerate the research needed to lead to the solution of the central problem.
- d. A description of the Center of Excellence's director's qualifications and ability to organize, administer, and manage a well-qualified team of multidisciplinary, multi-institutional researchers and consumer advocates in a consortium to solve a critical problem in breast cancer research.
- e. The outline of a project management plan.
- f. The outline of a communications plan.
- g. The outline of an experimental strategy to address the specific research question.

4. References: Start section on a new page; one-page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

5. Biographical Sketches: Three-page limit per individual. Biographical sketches should be included for the key personnel listed on the budget page, including collaborating investigators, consumers, and support staff. These documents are a critical component of the review process. The [Biographical Sketch form](#) may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

D. Electronic Pre-proposal Submission Requirements: Electronic submission of the pre-proposal is required. Pre-proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at <https://cdmrp.org/proposals>. Pre-proposals must be submitted on the CDMRP eReceipt system by the by the 5:00 p.m. (Eastern time) March 24, 2004 deadline.

Several steps are critical to successful pre-proposal submission.

- The Proposal Information must be submitted prior to submission of the pre-proposal. Applicants are encouraged to begin this part of the submission process early. During the full proposal submission process you will have an opportunity to edit the Proposal Information as needed.
- While the applicant's Sponsored Program Office is not responsible for any part of pre-proposal submission, the Sponsored Program Office will be responsible for portions of the

full proposal submission. Therefore, applicants are encouraged to begin coordinating with their Sponsored Programs Office early, well in advance of full proposal submission.

- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time March 24, 2004 pre-proposal deadline. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time March 24, 2004 deadline.
- All components of the pre-proposal must be incorporated into one PDF file prior to upload.
- Some items to be included in the pre-proposal may need to be scanned. All scanned documents, including figures, should be scanned at a resolution of 300-400 dpi or less.

E. Pre-proposal Review Information: Pre-proposals will be screened according to the criteria listed in Subsection V.C.3. to determine which projects best fulfill the intent of the award mechanism. Following completion of the pre-proposal screening process, invitations to prepare a full Breast Cancer Center of Excellence proposal will be sent to selected investigators no later than May 2004.

VI. INVITED PROPOSAL PREPARATION AND SUBMISSION INFORMATION

Do not submit a full Breast Cancer Center of Excellence proposal unless you receive a letter of invitation.

A. Proposal Components Summary: This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the “Required Files” tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the “Required Files” tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the “Required Files” tab.

The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) from the applicant’s institution is responsible for the following:

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute’s currently negotiated “Rate Agreement,” “Certifications and Assurances for Assistance Agreements,” and the “Representations for Assistance Agreements” are to be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal

Information, SOW, Abstracts, Proposal, Budget Information, and Regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) July 27, 2004. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time July 27, 2004 deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described in <https://cdmrp.org/proposals>. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution.

- **Letter of Intent:** A Letter of Intent is not required for this award mechanism.

C. SOW – 11,400-character limit, including spaces (approximately two pages): The SOW is captured as a data field under the “SOW/Abstract” tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW or “cut and paste” it from a word processing application into the data field. Sample SOWs can be found at <https://cdmrp.org/samples.cfm>.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims),
- Identify the timeline and milestones for the work over the period of the proposed effort,
- Indicate the numbers of research subjects (animal or human) and/or anatomical samples projected or required for each task,
- Identify methods, and
- Identify outcomes, products, and deliverables for each phase of the project.

D. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to both the peer and programmatic review process.

Programmatic review is based upon the Integration Panel’s (IP’s) review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the “SOW/Abstracts” tab of the CDMRP eReceipt system. Applicants can either type in their abstracts, or “cut and paste” them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at <http://cdmrp.army.mil>. Thus, proprietary or confidential information should not be included in the abstracts.

1. Technical Abstract: Sample technical abstracts can be found at <https://cdmrp.org/samples.cfm>. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the Program's goals.

Use the outline below for preparing the structured technical abstract.

- Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State concisely the specific aims of the study.
- Study Design: Briefly describe the study design.
- Relevance: Provide a brief statement explaining the relevance of the proposed work to the Program's goals, for example, how the study will cure, prevent, or improve the detection or treatment of the disease.

2. Public Abstract: Sample public abstracts can be found at <https://cdmrp.org/samples.cfm>. The public abstract is intended to communicate the purpose of, and rationale for, the study to non-scientific audiences. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. **The public abstract should not be a duplicate of the technical abstract**, but should describe the goals and objectives of the research project, and its relevance to the Program.

In addition to describing the project, the public abstract must answer the following questions:

- (1) What will the ultimate applicability of the research be?
 - What types of patients will it help and how?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a consumer-related outcome?
- (2) If the research is too basic for clinical applicability, what are the interim outcomes?
 - What types of contributions will this study make to advance research?
 - How will the research enhance this or other studies being conducted?

E. Proposal:

1. Format: All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single PDF file for electronic submission. Proposals must be uploaded under the "Required Files" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these items must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).

2. Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded at <https://cdmrp.org/programAnnouncements.cfm>. Complete each section as described:

- a. Proposal title (up to 160 characters).
- b. Proposal log number (this will be automatically provided when the Proposal Information is completed and saved).
- c. PI's full name (first, middle initial, last).
- d. Submitting institution.
- e. Award mechanism: Type in "Breast Cancer Center of Excellence Award."
- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

3. Table of Contents/Checklist: Start section on a new page; one-page limit. Prepare a [Table of Contents/Checklist](#), with page numbers. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Please note that headers should not be included, as the proposal log number will be placed on each page of the proposal after receipt.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Breast Cancer Center of Excellence Award applicants should state explicitly how the proposed work (1) meets the intent of the Center of Excellence Award mechanism; (2) will accelerate the solution of an overarching, multidisciplinary problem in breast cancer research; and (3) will have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer. *Note that for Breast Cancer Center of Excellence Awards, the Proposal Relevance Statement will be available for programmatic review.*

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

6. Main Body: Start section on a new page; 25-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. The format of the proposal should reflect the integrated nature of the Center of Excellence. This award is not intended to replace, supplement, duplicate, or compete with other collaborative research efforts such as the National Cancer Institute-supported SPORE or Program Project grants. The submission of separate projects and cores is not recommended.

Describe the overall project using the outline provided below.

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed Center of Excellence. Describe the major, overarching question in breast cancer research that is the focus of this proposal. Include information on previous experience most pertinent to the proposal. Cite relevant literature references.
- b. **Purpose:** State the purpose of the Center of Excellence and the expected results and outcomes. Show how the Center of Excellence is a synergistic effort to solve the overarching problem, as opposed to being a collection of individual investigators pursuing their own interests.
- c. **Objectives:** State concisely the specific aims and research strategy of the study. Describe the expected measurable outcomes of the proposed Center of Excellence. Provide information as to how the Center of Excellence will address these objectives and why the approaches are better than traditional collaborations
- d. **Collaborators:** Provide information on the multidisciplinary, multi-institutional team of highly qualified researchers and consumer advocates participating in the project and how each will contribute. Describe how the team will be organized, administrated, and managed. If the proposed Center of Excellence does not involve a multi-institutional effort, provide justification that the Center of Excellence's focus can best be addressed within the single institution.
- e. **Data:** Provide information on well-founded research that supports this project. Include data to support the feasibility of the hypotheses and/or approaches.

- f. **Proposed Research and Methods:** Describe the experimental plan and methodology that will address the specific research question. Provide information on how the Center of Excellence will maximize the utilization of resources and minimize unnecessary duplication; e.g., experimental techniques, databases, models (including animal models), and antibodies.
 - g. **Communications:** Describe the key features of the communications plan that will help expedite the proposed research. Provide information on the availability of communication network resources and support for this research. State the specific features of this plan that facilitate and encourage the real-time exchange of research findings.
- 7. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used.
- 8. References: Start section on a new page; no page limit.** List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- 9. Biographical Sketches: Three-page limit per individual.** Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower priority scores. The [Biographical Sketch](#) form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.
- 10. Existing/Pending Support: Start section on a new page; no page limit.** List on a separate page the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel. If no support exists, state “none.” Proposals submitted under this program announcement should not duplicate other funded research projects.
- 11. Facilities/Equipment Description: No page limit.** Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use.
- 12. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit.** Include an appropriately titled page listing the documents you have included in this section.
- 13. Publications and/or Patent Abstracts: Five-document limit.** Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.
- 14. Administrative Documentation: No page limit.** Submit only material specifically requested or required in this program announcement. **This section is not for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other relevant information needed to judge the proposal.** Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

The first item in this section must be a list of all the items included in the Administrative Documentation section.

The following documentation must be included in the Breast Cancer Center of Excellence proposal submission:

- Letters from private sector and academic center collaborators, as appropriate, documenting a willingness to participate and demonstrating that (1) a multi-institutional, multidisciplinary team of investigators is participating in the project, (2) the necessary drugs, modalities, or technologies are available, and (3) there is no unnecessary duplication of resources.
- Letters from breast cancer consumer/survivor organizations documenting a willingness to participate and how they will contribute to the projects.
- Documentation that all participating institutions have an intellectual property plan and are willing to resolve intellectual property issues.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted proposal.

F. Budget Information: Budget Information includes the [Detailed Cost Estimate form and Budget Justification](#). Budget Information is uploaded under the “Required Files” tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for Breast Cancer Center of Excellence Awards can be requested for a maximum of \$10M, inclusive of both direct and indirect costs, for up to a 5-year performance period. The amount allotted for travel is \$1,800 per year per investigator to attend scientific/technical meetings. In addition, travel funding of \$1,800 per investigator per meeting should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

2. Detailed Cost Estimate Form and Justifications Instructions: Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. The Detailed Cost Estimate form and Justification for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the Detailed Cost Estimate form. All amounts entered should be in U.S. dollars.

a. Personnel:

i. Name: Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

- ii. Role on Project:** Identify the role of each individual listed on the project. Describe his or her specific functions in the “Justification” section of the Detailed Cost Estimate form.
- iii. Type of Appointment (Months):** List the number of months per year reflected in an individual’s contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the “Justification” section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- iv. Annual Base Salary:** Enter the annual institutional base salary for each individual listed for the project.
- v. Percentage of Effort on Project:** The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.
- vi. Salaries Requested:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual’s institutional base salary by the percentage of effort on the project.
- vii. Fringe Benefits:** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization for all sponsors. Documentation to support the fringe benefits should be provided.
- viii. Totals:** Calculate the totals for each position and enter these as subtotals in the columns indicated.
- b. Consultant Costs:** Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.
- c. Major Equipment:** It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed \$5,000.
- d. Materials, Supplies, and Consumables:** A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.
- e. Travel Costs:** Travel costs may not exceed \$1,800 per year per investigator to attend scientific/technical meetings. In addition, travel funding of \$1,800 per investigator per meeting

should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

f. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

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

h. Subaward Costs: A description of services or materials that are to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more, provide the following specific information:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.

i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should equal the amount previously entered online in the Proposal Information <https://cdmrip.org/proposals>.

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

G. Regulatory Requirements: Completed and signed copies of the "[Certificate of Environmental Compliance](#)" and "[Principal Investigator Safety Program Assurance Form](#)" must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other Regulatory Documents (Research Involving Human Subjects and/or Anatomical Substances; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

H. USAMRAA Documents: The most current version of the institution’s negotiated “Rate Agreement,” the “[Certifications and Assurances for Assistance Agreements](#),” and the “[Representations for Assistance Agreements](#)” must be uploaded by the Contract Representative from the Sponsored Programs Office (or equivalent). These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system prior to negotiations.

I. Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution’s Sponsored Programs Office (or equivalent) by the deadline. If your proposal is either incomplete or not approved electronically before the deadline, it will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time July 27, 2004 deadline.

The timeline for Breast Cancer Center of Excellence Awards is:

Pre-proposal Submission Deadline:	5:00 p.m. Eastern time March 24, 2004
Pre-proposal Screening:	April 2004
Full Proposal Invitations:	May 2004
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time July 27, 2004
Peer Review:	September 2004
Programmatic Review:	November 2004
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Between December 2004 and September 2005

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

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time July 27, 2004 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.

- Budget Information includes the Detailed Cost Estimate form and the Budget Justification form. Budget Information must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The Regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

VII. INVITED PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview:

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

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

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review 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 below). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

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

3. Programmatic Review: The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-

based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review summary statements and the proposal abstracts. *Note that for Breast Cancer Center of Excellence Awards, the Proposal Relevance and Center of Excellence Synergy Statements will be available for programmatic review.* SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

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

B. Review Criteria:

1. Peer Review: Breast Cancer Center of Excellence Award proposals will be evaluated according to the following criteria:

- **Disease Relevance and Impact:** Is the central, overarching question relevant to the prevention, detection, diagnosis, and/or treatment of breast cancer? Is the unifying research question one that would be best solved through a multidisciplinary (generally multi-institutional) approach? Will the Center of Excellence make an original and important contribution to (1) significantly advancing research to address the key breast cancer research problem/area identified, and (2) the goal of eradicating breast cancer?
- **Innovation:** Does this Breast Cancer Center of Excellence proposal represent more innovative and effective approaches to address the unifying research question(s) posed? For example, does the Center of Excellence draw on expertise from diverse fields, employ *novel* approaches or methods, and/or challenge existing assumptions and paradigms? Does the Center of Excellence eliminate duplication of effort?
- **Research Strategy:** Does the research question provide a real basis for a unified focus that will facilitate and accelerate progress? Are the conceptual framework, rationale, design, methods, and analyses adequately developed and well-integrated to support the feasibility and promise of the approach? Do the preliminary data cited support the rationale for the Breast Cancer Center of Excellence Award? Does the applicant acknowledge potential problem areas and consider alternative approaches? If needed, are statistical support services included in the Center of Excellence's design? Does each aim contribute to the solution of the overarching research question?
- **Center Structure:** Does the Center of Excellence proposal meet the criteria of a synergistic research program with a central unified theme that addresses a specific research question rather than an additive set of sub-projects? Is a management plan proposed that will integrate and optimize the research and collaborations and result in a synergistic research effort? Is there a plan to maximize utilization of resources and avoid unnecessary duplication of effort? Does the Center of Excellence director (i.e., PI) have a clear strategy and plan that will ensure cross-Center of Excellence participation and real-time communication of results, issues, problems, and progress? Does the proposal utilize state-of-the-art communication tools and is a plan for data management and statistical support presented?
- **Personnel:** Does the team assembled in the Breast Cancer Center of Excellence proposal represent the "critical mass" of talent required to solve the proposed problem? Does the Center of Excellence unite and integrate the *most highly qualified individuals* to contribute to the project? If the participants are from a single institution, is this justified? Does the Center of Excellence director have the appropriate qualifications and experience to oversee

the research that addresses the overarching breast cancer problem proposed and to coordinate and manage the proposed Center of Excellence? Is the Center of Excellence Director dedicating at least 30% effort to this award? Is there representation from all the areas of expertise needed to conduct the study successfully? Does the team also include members who will provide new perspectives and fresh insights? Is the contribution of each investigator clear?

- **Consumer Participation:** Are breast cancer consumer/survivor groups active participants at all levels? Are consumer advocates active participants in the project and are their roles clearly defined?
- **Environment:** Do the different institutions/organizations involved in this project strengthen the Center of Excellence? Is the appropriate support staff available for administering all of the Center of Excellence's functions (e.g., communications infrastructure, informatics, access to required databases)? Have the institutions/organizations demonstrated their clear commitment to the Center of Excellence? Is there evidence of an intellectual property management plan that is agreed upon by all participating institutions?
- **Budget:** Is the budget appropriate for the Breast Cancer Center of Excellence Award and the research proposed?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to structure the BCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation;
- Program portfolio balance; and
- Adherence to the intent of the award mechanism.

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

VIII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in December 2004.

B. Administrative Requirements: All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support. To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110 and DOD Grant and Agreement Regulations). Any organization requesting receipt of an award from this announcement must

be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at <http://www.ccr.gov/>.

It is anticipated that these awards will not transfer; however, should the PI transfer to a new institution during the tenure of this award, the US Army reserves the right to terminate the award or transfer the existing award to the new institution.

Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

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

D. Regulatory Review:

1. Overview: Concurrent with the USAMRAA negotiations, the office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance, and Principal Investigator Safety Program Assurance form submitted with the proposal. The USAMRMC RCQ office will review documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army regulations are met.

2. Certificate of Environmental Compliance: The [Certificate of Environmental Compliance](#) must be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.

3. Safety Program Documents: The [Principal Investigator Safety Program Assurance form](#) must be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at <http://mrmc-www.army.mil/crprcsohdfsplan.asp>. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at <http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc>.

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

4. Research Involving Animal Use: Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at <http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc>.

5. Research Involving Human Subjects/Anatomical Substances: Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be

requested at a later date. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC RCQ office. 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. For example:

- **Intent to Benefit.** In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at <http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf>. An informed consent form template can be located at http://mrmc-www.army.mil/docs/rcq/consentform_template.pdf.

6. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written approval from the applicable USAMRMC RCQ office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

E. Reporting: All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project.

IX. OTHER INFORMATION

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

B. Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other

commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

C. Information Service: Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.

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

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

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

²Title 35, United States Code, Section 200 et seq.

X. ACRONYM LIST

AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
COE	Breast Cancer Center of Excellence Award
DOD	Department of Defense
FY	Fiscal Year
HBCU	Historically Black Colleges and Universities
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
SPORE	Specialized Programs of Research Excellence
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave