

CENTER OF EXCELLENCE PILOT AWARD

Partnering to accelerate discovery and eradicate 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 Center of Excellence (CoE) Pilot Award encourages the formation of a multidisciplinary, multi-institutional research program encompassing exceptional scientists, clinicians, and consumer advocates.

The intent of the CoE Pilot Award is to support the recruitment of an integrated, synergistic, multi-institutional team of world-renowned investigators working together to develop the preliminary infrastructure that will provide a foundation for a Breast Cancer Center of Excellence. Essential to this award is the identification of a single, unifying question critical to the prevention, detection, diagnosis, and/or treatment of breast cancer.

Proposals for the CoE Pilot Awards should include plans for the establishment of the research team, the development of tools for data management and research administration, and the resolution of intellectual property and material rights between institutions. Recipients of the Center of Excellence Pilot Award will be required to submit a Breast Cancer Center of Excellence proposal in FY05. Awardees may receive up to \$150,000 (direct and indirect costs) for 1 year.

PROPOSALS ARE DUE BY MARCH 24, 2004

This document is a synopsis of details specific to the Breast Cancer Research Program (BCRP) Center of Excellence Pilot 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 Center of Excellence (CoE) Pilot Award encourages the formation of a multidisciplinary, multi-institutional research program encompassing exceptional scientists, clinicians and consumer advocates.

The intent of CoE Pilot Award is to support the recruitment of an integrated, synergistic, multi-institutional team of world-renowned investigators working together to develop the preliminary infrastructure that will provide a foundation for a Breast Cancer Center of Excellence. Essential to this award is the identification of a single, unifying question critical to the prevention, detection, diagnosis, and/or treatment of breast cancer.

Proposals for CoE Pilot Awards should include plans for the establishment of the research team, the development of tools for data management and research administration, and the resolution of intellectual property and material rights between institutions. ***Recipients of the Center of Excellence Pilot Award will be required to submit a compliant Breast Cancer Center of Excellence proposal in the following year.*** CoE Pilot Award recipients may receive up to \$150,000 (direct and indirect costs) for 1 year.

A. Title of Award: Center of Excellence Pilot Award (COEP).

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

C. Funding Opportunity Number: BC04-COEP.

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-COEP)
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(s): 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 Program Announcement for details pertaining to this award mechanism.

Funds from this award may not be used to support laboratory or preclinical research.

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the CoE Pilot Award is to provide support for the recruitment of an integrated, synergistic, multi-institutional team of exceptional investigators that will work together to develop the preliminary infrastructure that will provide a foundation for a Breast Cancer Center of Excellence. Pivotal to this award is the identification of a single, unifying question *critical* to the prevention, detection, diagnosis, and/or treatment of breast cancer. Proposals for the CoE Pilot Awards should include plans for the establishment of the research team, the development of tools for data management and research administration, and the resolution of intellectual property and material rights between institutions.

A CoE Pilot proposal must endeavor to obtain the most exceptional investigators and consumer/survivor groups to accomplish the proposed work, regardless of their location. ***It is a requirement that breast cancer consumer/survivor groups be active participants in the development and execution of the CoE Pilot Award.*** The unifying question identified in the CoE Pilot Award will be the cornerstone of the proposed Breast Cancer Center of Excellence proposal. Recipients of this award will be required to submit a compliant Breast Cancer Center of Excellence proposal in FY05, pending Congressional appropriation of funds.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately \$1 million will be available for the CoE Pilot Award mechanism.
- It is anticipated that approximately seven CoE Pilot Award proposals will be funded.
- Submission to the FY04 Breast Cancer Center of Excellence Award may be executed through either of two separate tracks: (1) the Breast CoE Pilot Award, or (2) the Breast Cancer Center of Excellence Awards. Proposals for the CoE Pilot Award are being requested through this program announcement. Details pertaining to the Breast Cancer Center of Excellence Award can be found in a separate program announcement at <https://cdmrp.org/proposals>.

- Funding for CoE Pilot Awards can be requested for up to \$150,000 per award inclusive of both direct and indirect costs, for up to an 12-month performance period. Funding will be disbursed in two equal installments, one installment at the time of award and the second installment contingent upon submission of a compliant FY05 Breast Cancer Center of Excellence proposal.
- Please note that it is anticipated that full Breast Cancer Center of Excellence Award proposals may be submitted in FY05 without prior submission or receipt of a FY04 CoE Pilot Award proposal.
- **Please note that there is no guarantee that funds will be available for Breast Cancer Center of Excellence Awards in FY05.**

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 V.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. 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. Proposal Preparation: Investigators interested in applying for the CoE Pilot Award must submit the Proposal Information. See Section V of the Full Text of Program Announcement for preparation instructions.

C. Proposal Submission Dates and Times: Deadline Date: March 24, 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).

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

VI. PROPOSAL REVIEW INFORMATION

CoE Pilot Award proposals will be scientifically and programmatically reviewed by the BCRP Integration Panel (IP), which is composed of scientific experts, clinicians, and consumer advocates. The IP will determine which proposals best fulfill the intent of the award mechanism.

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 Center of Excellence (CoE) Pilot Award encourages the formation of a multidisciplinary, multi-institutional research program encompassing exceptional scientists, clinicians, and consumer advocates.

The intent of CoE Pilot Award is to support the recruitment of an integrated, synergistic, multi-institutional team of world-renowned investigators working together to develop the preliminary infrastructure that will provide a foundation for a Breast Cancer Center of Excellence. Essential to this award is the identification of a single, unifying question critical to the prevention, detection, diagnosis, and/or treatment of breast cancer.

Proposals for CoE Pilot Awards should include plans for the establishment of the research team, the development of tools for data management and research administration, and the resolution of intellectual property and material rights between institutions. ***Recipients of the Center of Excellence Pilot Award will be required to submit a compliant Breast Cancer Center of Excellence proposal in the following year.*** CoE Pilot Award recipients may receive up to \$150,000 (direct and indirect costs) for 1 year.

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

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

C. Funding Opportunity Number: BC04-COEP.

D. Agency Name: 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-COEP)
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: qa.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.

Funds from this award may not be used to support laboratory or preclinical research.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The CoE Pilot 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). The CoE Pilot Award is a new award mechanism for the BCRP and is being offered for the first time in FY04.

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

Program History	FY92-02	FY03 ¹
Congressional Appropriations for the BCRP	\$1.38B	\$150M
Total Proposals Received	19,840	1,543
Total Proposals Funded	3,671	240

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 or novel applications of existing technologies are highly sought. Although the BCRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

C. Award Mechanism Description: Due to the scope and magnitude of the Breast Cancer Center of Excellence Awards, the CoE Pilot Award has been instituted to provide support to form the necessary collaborations and develop the preliminary infrastructure that will provide a sound foundation for a multi-institutional, synergistic research consortium. The intent of CoE Pilot Award is to provide support for the recruitment of an integrated, synergistic, multi-institutional team of highly qualified investigators and consumer advocates that will work together to develop a Breast Cancer Center of Excellence.

The CoE Pilot Award proposal should identify a single, unifying question critical to the prevention, detection, diagnosis, and/or treatment of breast cancer that will be the focus of the proposed Breast Cancer Center of Excellence Award. In addition, the CoE Pilot proposal must endeavor to obtain the most highly qualified investigators to accomplish the proposed work, regardless of their location. It is anticipated that in order to meet this requirement, the CoE Pilot Award and the proposed Breast Cancer Center of Excellence Award will be multi-institutional, and will include the most qualified scientists, clinicians, and consumer advocates as members of a synergistic, multidisciplinary team.

Please note that 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 V.E.14).

All proposals submitted to the CoE Pilot Award should define the major, overarching question that will be the focus of the CoE Pilot and proposed Breast Cancer Center of Excellence.

In addition, the proposal should outline a plan to:

- ***Recruit and assemble a team of preeminent investigators from appropriate disciplines and institutions to form an integrated team.*** Highly accomplished scientists complementary to the proposed areas of research and promising young investigators that can provide fresh insight must be brought together to develop and address the central, overarching research problem. Collaborations with scientists from nontraditional disciplines such as computer sciences, mathematics, economics, physics, bioengineering, or other quantitative disciplines are highly encouraged. The CoE Pilot Award is intended to provide for the recruitment of these personnel *regardless of their location* under the support of a single “virtual” center.
- ***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 CoE Pilot and proposed Center of Excellence’s conceptual design, program development, and relevance to the community.

- ***Provide for effective, coordinated communication that integrates and optimizes the research and collaborations.*** The CoE Pilot Award proposal must provide a plan for communication between the proposed collaborators for the purpose of developing the Center of Excellence proposal. In addition, include preliminary plans for real-time sharing of data and the use of information technologies to facilitate timely and effective communication and cooperation among investigators for the proposed Center of Excellence.
- ***Provide for an effective, coordinated administrative management that integrates and optimizes the research and collaborations.*** A preliminary administrative management plan should provide the basis for organizing and managing the CoE Pilot Award and provide a framework for the administration of the proposed FY05 Breast Cancer of Excellence Center Award. The Center of Excellence Director, i.e., the Principal Investigator (PI) on the proposal, should be involved in the development of the CoE Pilot Award proposal and should play a significant role in assembling/recruiting of the research team. In addition, the preliminary administrative management component should include provisions for maximizing the utilization of resources, eliminating unnecessary duplication, data management, and development of the Breast Cancer Center of Excellence proposal in FY05.

III. AWARD INFORMATION

Funding for the CoE Pilot Awards in FY04 is for up to \$150,000 per award inclusive of both direct and indirect costs for up to 12 months. Funds will be disbursed in two equal installments. The first installment will be made at the time of the award; the second installment will be made after the submission of a compliant FY05 Breast Cancer Center of Excellence Award proposal. *Failure to submit a compliant Breast Cancer Center of Excellence Award proposal in FY05 after receipt of a FY04 CoE Pilot Award will result in a forfeit of the second installment of the CoE Pilot Award funding.*

Funds from both installments of the CoE Pilot Award can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning, and development of the proposed Center of Excellence proposal. ***Funds from this award may not be used to support laboratory or preclinical research.***

The nature of this Program does not allow for renewal of grants or supplementation of existing grants. Approximately \$1M is available for CoE Pilot Awards. It is anticipated that approximately seven proposals will be funded.

Please note that there is no guarantee that funds will be available for Breast Cancer Center of Excellence Awards in FY05.

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 V.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. 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.

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

- Proposal body exceeds page limit.
- Proposal body is missing.
- 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 review.

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

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.

¹Executive Orders 12876, 12900, and 13021

- **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 institutions 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) March 24, 2004. 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.

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, and
- Identify outcomes, products, and deliverables for each phase of the project.

D. Proposal Abstracts – Abstracts are not required for the CoE Pilot Award application process, but the data fields must be completed for the final submission. Therefore, the applicant should type “Not applicable for the CoE Pilot Award” into both abstract data fields.

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?prg=BCRP&prg_fy=2004. 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 “Center of Excellence Pilot Award.”
- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate reviewers, 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. CoE Pilot Award applicants should state explicitly how the proposed work (1) will meet the intent of the CoE Pilot Award mechanism and (2) will lay the foundation for a Center of Excellence that will accelerate the solution of an overarching problem in breast cancer research.

5. Main Body: Start section on a new page; six-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 proposal body should consist of the following five parts. It is the responsibility of the investigator to clearly articulate how the proposed CoE Pilot plan meets the intent of the mechanism. The proposal should address the evaluation criteria as outlined in Subsection VI.B.

- a. Describe the central overarching question and its relevance to breast cancer.
- b. Outline the plan to recruit and assemble the team of investigators. Address the qualifications of the Center Director and the key participants and their proposed contributions to the Center of Excellence. (Additional information on collaborators can be included in the Biographical Sketch section; see Subsection V.E.9 below.)
- c. Describe how breast cancer consumer/survivor groups will be recruited and integrated into every aspect of the proposed effort.
- d. Provide an *outline* of a communication plan between and among the participants (for both the CoE Pilot Award and the proposed Center of Excellence).
- e. Provide an *outline* of an administrative management plan.

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. 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: Not applicable for this award mechanism.

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 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 CoE Pilot Award proposal submission:

- Letters from potential private sector and academic center collaborators, as appropriate, documenting an interest in participating.
- Letters from breast cancer consumer/survivor organizations documenting a willingness to participate.
- Letters of institutional commitment from all institutions represented.
- Documentation demonstrating that all participating institutions have a plan for 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 [COE Pilot Award 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 the CoE Pilot Awards in FY04 is for up to \$150,000 per award inclusive of both direct and indirect costs for up to 12 months. Funds will be disbursed in two equal installments. The first installment will be made at the time of the award; the second installment will be made after the submission of a compliant Breast Cancer Center of Excellence Award proposal in FY05. Funds for the CoE Pilot Award can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning and development of pilot/feasibility data for Breast Cancer Center of Excellence Award proposal in FY05. Funds from this award may not be used to support laboratory or preclinical research.

2. COE Pilot Award Cost Estimate Form and Justifications Instructions: Budget is an important consideration in 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 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 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. Travel Costs:** Funds from the CoE Pilot Award may be used for travel among participating investigators, as required for planning and development of the FY05 CoE proposal.
- e. 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.
- f. 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.
- g. 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://cdmrp.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.

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 March 24, 2004 deadline.

The timeline for CoE Pilot Awards is:

Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time March 24, 2004
Proposal Review:	April 2004
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	May 2004
Award Start Date:	As early as June 2004

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 March 24, 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.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: CoE Pilot Award proposals will be scientifically and programmatically reviewed by the BCRP Integration Panel (IP), which is composed of scientific experts, clinicians, and consumer advocates. The IP will determine which proposals best fulfill the intent of the award mechanism.

B. Review Criteria:

1. Proposal Review: CoE Pilot Award proposals will be evaluated according to the following criteria:

- **Overarching question:** Is the proposed question of paramount importance to the goal of eradicating breast cancer? Is the proposed central, unifying research question one that requires a multidisciplinary (generally multi-institutional) team of investigators?
- **Personnel:** Does the CoE Pilot Award proposal attempt to recruit the *most highly qualified individuals* to contribute to the project? Does the PI/Director have the appropriate qualifications and experience to oversee the proposed research and to coordinate and manage the proposed Center of Excellence?
- **Consumer Participation:** Is there evidence of substantive consumer participation at all levels of the CoE Pilot and proposed Center of Excellence?
- **Project Management:** Is there an outline of a plan for a multi-institutional, multidisciplinary consortium including a description of the individual components of the consortium and the resources available? Is there an outline for a preliminary administrative management plan that will integrate and optimize the proposed collaborations? Is there an outline of an effective communications plan to support the multi-institutional consortium, including real-time communication of results, issues, problems, and progress? Is there evidence of an intellectual property management plan that is agreed upon by all participating institutions?
- **Budget:** Is the budget appropriate for the proposed work?

2. Programmatic Review: The criteria the IP uses to make funding recommendations are:

- Evaluations of the reviewers;
- 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.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the 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 May 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 move to a new institution, the U.S. Army reserves the right to either 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/FY02FSPAappendix.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: Not applicable for this award mechanism.

5. Research Involving Human Subjects/Anatomical Substances: Not applicable for this award mechanism.

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

Funds from this award may not be used to support laboratory or preclinical research.

E. Reporting: All funded CoE Pilot Awards will require the timely delivery of a report during the development period. Reporting requirements for the CoE Pilot Award consist of an annual report that presents a detailed summary of issues and accomplishments for the funding period.

VIII. 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 the review process 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.

IX. 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	Center of Excellence
COEP	CoE Pilot Award
DOD	Department of Defense
FY	Fiscal Year
HBCU	Historically Black Colleges and Universities
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
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
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave