

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

The Breast Cancer Center of Excellence Award mechanism supports multidisciplinary, multi-institutional teams of gifted scientists, clinicians, and consumer advocates in making groundbreaking advances toward the eradication of breast cancer. The Breast Cancer Research Program (BCRP) encourages highly accomplished scientists renowned for their contributions to the proposed areas of research and promising young investigators who can provide fresh insight to work together to accelerate the solution of a central, overarching research problem in a way that could not be accomplished by a single investigator or group. In addition, the BCRP strongly endorses the integration of scientists from nontraditional disciplines such as computer science, mathematics, economics, physics, and other quantitative disciplines. The BCRP also encourages Centers of Excellence to incorporate study components addressing ethical issues in breast cancer research. Breast cancer consumer/survivor groups must be active participants in all aspects of these awards. Centers may receive up to \$20 million (M), including direct and indirect costs.

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

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: BC05-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-ZB-C (BC05-COE)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

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

Website: <https://cdmrp.org/> (User's Guide located in upper right corner of 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/>. The website contains all the information, forms, documents, and links needed to apply.

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

The Breast Cancer Center of Excellence Awards are designed to accelerate the solution of a *major overarching problem* in breast cancer research. Proposals for these awards must address a single, unifying question critical to the prevention, detection, diagnosis, or treatment of breast cancer through a synergistic, multidisciplinary research program in a way that could not be accomplished by a single investigator or group. ***Breast cancer consumer/survivor groups must be active participants at all levels of these multidisciplinary efforts.***

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$60 M is available to fund FY05 Breast Cancer Center of Excellence Awards.
- It is anticipated that up 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 \$20M, including direct and indirect costs, for up to a 5-year performance period.
- No more than \$5M will be granted within any single year during the lifetime of the award.
- Investigators funded by the Center of Excellence Award mechanism will be required to meet with USAMRMC contracting and grants officers during award negotiations to develop a timeline covering the full period of performance. Continued funding under this award

mechanism will be contingent upon achievement of study milestones in accordance with this timeline.

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. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see “Major Equipment” located in Subsection VII.G.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 HBCU/MI, and administrative compliance issues.

V. PRE-PROPOSAL PREPARATION, PROPOSAL PREPARATION, AND SUBMISSION INFORMATION

A. Proposal Information: Applicants are required to complete the Proposal Information as described at <https://cdmrp.org/> prior to uploading the pre-proposal.

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

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

C. Pre-proposal Submission Date and Time: Pre-proposal Deadline: April 5, 2005, 5:00 p.m. Eastern time. Pre-proposals must be submitted through the CDMRP eReceipt system.

D. Proposal Contacts: The Proposal Contacts **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. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

E. Invited Proposal Preparation: Pre-proposals will be screened by the BCRP Integration Panel to determine those projects that best fulfill the intent of the award mechanism. Invitations to submit full proposals will be sent to selected applicants no later than May 2005. **Do not**

submit a full Center of Excellence Award proposal unless you receive a letter of invitation or you are the recipient of a FY04 BCRP Center of Excellence Pilot Award.

Note that recipients of the FY04 BCRP Center of Excellence Pilot Award do not need to submit a pre-proposal for the FY05 Center of Excellence Award; however, a full proposal that adheres to all other FY05 Center of Excellence Award submission requirements must be submitted.

Each proposal must be converted into an electronic PDF file for electronic submission. Please see the Full Text of the Program Announcement for details.

F. Invited Proposal Submission Date and Time: Full Proposal Deadline: July 26, 2005. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the Sponsored Programs Office (or equivalent) of the applicant's institution by 5:00 p.m. Eastern time.

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

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 the Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements, including regulatory 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 the Program Announcement.

Funding for the Breast Cancer Center of Excellence Awards will be disbursed in installments. The first installment will be made at the time of the award; subsequent installments will be contingent upon the successful completion of milestones. Milestones from the approved Statement of Work will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of Center of Excellence Award funding.*

B. Reporting Requirements: Annual reporting requirements apply.

Full Text of Program Announcement

I. GENERAL INFORMATION

The Breast Cancer Center of Excellence Award mechanism supports multidisciplinary, multi-institutional teams of gifted scientists, clinicians, and consumer advocates in making groundbreaking advances toward the eradication of breast cancer. The Breast Cancer Research Program (BCRP) encourages highly accomplished scientists renowned for their contributions to the proposed areas of research and promising young investigators who can provide fresh insight to work together to accelerate the solution of a central, overarching research problem in a way that could not be accomplished by a single investigator or group. In addition, the BCRP strongly endorses the integration of scientists from nontraditional disciplines such as computer science, mathematics, economics, physics, and other quantitative disciplines. The BCRP also encourages Centers of Excellence to incorporate study components addressing ethical issues in breast cancer research. Breast cancer consumer/survivor groups must be active participants in all aspects of these awards. Centers may receive up to \$20 million (M), including direct and indirect costs.

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

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: BC05-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-ZB-C (BC05-COE)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

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

Website: <https://cdmrp.org/> (User's Guide located in upper right corner of 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-ZB-A
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/>. This website contains all the information, forms, documents, and links needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the requested written approvals directly to the applicant.

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 focused on eradicating breast cancer. Appropriations for the BCRP since FY92 total \$1.68 billion (B). The FY05 appropriation is \$150M. Approximately \$60M of the total appropriation will be available for Center of Excellence Awards.

B. Program Objectives: The overall goal of the FY05 BCRP is to promote research focused on eradicating breast cancer. Therefore, the BCRP challenges 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. The BCRP focuses its funding on innovative projects, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances, with the potential to make a significant impact on breast cancer. Under-investigated avenues of research and novel applications of existing technologies are strongly encouraged. The BCRP encourages risk-taking research; however, such projects must demonstrate solid scientific judgment and rationale.

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

C. Award Mechanism Description: The Breast Cancer Center of Excellence Award is designed to accelerate the solution of *major overarching questions* in breast cancer research by integrated consortia of the most highly qualified investigators. Each Breast Cancer Center of Excellence Award proposal must address a single, critical question whose solution will have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer. A synergistic, highly integrated, multidisciplinary research team must be assembled to address a central problem in a way that could not be accomplished by a single investigator or group.

The central question addressed by each 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 to a critical research problem. Breast Cancer Centers of Excellence may include Phase I or Phase II clinical trials and collaborations with pharmaceutical or biotechnology industry scientists and/or companies.

Breast Cancer Centers of Excellence must be multi-institutional, synergistic, highly integrated, multidisciplinary teams of the best scientists, clinicians, and consumer advocates *unless an exceptionally compelling case is made that a single institution can best address the aims of the Breast Cancer Center of Excellence Award.*

Participating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation to ensure the successful establishment and maintenance of the research consortium. An intellectual and material property plan agreed to by all participating institutions is required in the proposal's administrative documentation (see Subsection VII.E.13).

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

- ***Focus on solving a critical question in breast cancer research using strategies that optimize the Breast Cancer Center of Excellence Award's comprehensive array of personnel and resources.*** Projects must be founded on sound research and have the potential to make a significant impact on the detection, prevention, and/or treatment of breast cancer. The question should be broad enough to require a multidisciplinary approach. Applicants *must* include published or preliminary data that supports the feasibility of their hypotheses and/or approaches and a description of the proposed team of investigators and the anticipated research in both the pre-proposal and the invited proposal.
- ***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 who collectively represent the best team to solve the problem(s) identified. *Inclusion of scientists from nontraditional disciplines such as computer science, mathematics, economics, physics, technology development, bioengineering, or other quantitative disciplines is encouraged. In addition, applicants are urged to include plans for addressing ethical problems in breast cancer research in their proposals.*
- ***Incorporate breast cancer consumer/survivor groups into every aspect of the proposed consortium.*** Breast cancer consumer/survivor groups must have an active role in every aspect of the proposed Center of Excellence, including program conception and design, discussions, research participant recruitment, program evaluation, and dissemination of information to the public.
- ***Accelerate research progress through communication.*** Communication between and among Breast Cancer Center of Excellence team members is essential to the success of each Center's goals. Proposals should include a strategy for sharing data in real time and using information technologies to facilitate timely and effective communication and cooperation. Breast Cancer Centers of Excellence should 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 Center of Excellence Director, or Principal Investigator (PI) of the proposal, is responsible for the day-to-day management of the Center. Therefore, the Center Director is expected to commit an appropriate level of time and effort—at least 30%—to direct and manage an initiative of this magnitude. He or she must have the scientific ability to oversee large research programs and a proven record of leadership, including experience in the effective use of communication tools and the management of multifaceted and multidisciplinary projects. The administrative management plan should explain how the Breast Cancer Center of Excellence will be organized and managed; it should specify the processes and tools to be used for regular and structured communication, data management, project meeting scheduling, reviews of research report findings, and other issues of common concern to the Center and its

investigators. The administrative management plan also should describe procedures that maximize the use of resources and eliminate unnecessary duplication; for example, experimental techniques, databases, models (including animal models), and antibodies developed by each Center should be shared resources for all Breast Cancer Centers of Excellence. The Center Director will also ensure that publications arising from the Center's work have 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 (SPOREs) and it should not represent a collection of related Program Project grants or sub-projects.

Recipients of the Breast Cancer Center of Excellence Award will meet annually with each other, the BCRP Integration Panel (IP), and CDMRP Program Staff for the purpose of open communication and mutual benefit.

III. AWARD INFORMATION

Funding for Breast Cancer Center of Excellence Awards can be requested for a maximum of \$20M, including direct and indirect costs, for a maximum of 5 years. No more than \$5M will be granted in any single year during the lifetime of the award. Funding will be disbursed in installments. The first installment will be made at the time of the award; subsequent installments will be contingent upon the successful completion of specific milestones. Milestones from the approved Statement of Work will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of Breast Cancer Center of Excellence Award funding.*

The allotment for travel is \$1,800 per investigator per year to attend scientific/technical meetings. An additional \$1,800 per investigator should be requested for annual meetings with the other Breast Cancer Center of Excellence Award recipients, the IP, and CDMRP Staff. In addition, travel funding of \$1,800 per investigator should be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research during the award.

The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants. The CDMRP expects to allot approximately \$60M of the \$150M FY05 BCRP appropriation to fund up to three Breast Cancer Center of Excellence Awards depending on the quality and the number of proposals received.

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. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under “Major Equipment” in Subsection VII.G.2.c of the Full Text of the Program Announcement.

D. Other Eligibility Criteria

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

2. Historically Black Colleges and Universities/Minority Institutions (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 on 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 at <http://cdmrp.army.mil/spp> under “Minority Institutions.”

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. Non-adherence 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.

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

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inch on any side.
- Proposal body exceeds page limit.
- Proposal body is missing.
- A plan for substantive consumer advocate participation is missing.
- Required administrative documentation is missing.

¹Executive Orders 12876, 12900, and 13021

- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

For any other sections of a proposal with a defined page limit, any pages exceeding 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 Award must submit a pre-proposal. Pre-proposals will be screened to determine those projects that best fulfill the intent of the award mechanism. Invitations to prepare a full Center of Excellence Award proposal will be sent to selected investigators no later than May 2005. ***Do not submit a full Center of Excellence Award proposal unless you receive a letter of invitation or you are the recipient of a FY04 BCRP Center of Excellence Pilot Award.***

Note that recipients of the FY04 BCRP Center of Excellence Pilot Award do not need to submit a pre-proposal for the FY05 Center of Excellence Award; however, they must submit a full proposal that adheres to all other FY05 Center of Excellence submission requirements.

A. Pre-proposal Components Summary: This subsection is a summary of pre-proposal 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 Part 1 for which information is entered as data fields.
- **Pre-proposal:** The pre-proposal is uploaded as a PDF (Portable Document Format) file under the “Proposal Information” tab.

B. Proposal Information: Applicants are required to complete the Proposal Information (Part 1) as described in <https://cdmrp.org/> prior to uploading the pre-proposal. The Proposal Information must include the e-mail address of a representative from the applicant’s Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution.

- **Letter of Intent:** A Letter of Intent is not necessary for pre-proposal submission for the Center of Excellence Award.

C. Pre-proposal Preparation

1. Format: All pre-proposals must be converted into a single electronic PDF file for electronic submission. Pre-proposals must be uploaded under the “Proposal Information” 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. Please note that pre-proposals do not require approval by the Contract Representative of the applicant's institution's Sponsored Programs Office (or equivalent).

Please Note New Format Requirements

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

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inches in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

<p>Failure to follow the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire pre-proposal prior to pre-proposal screening.</p>

- **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, but applicants should keep in mind that 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.
- **Language:** English.

2. Pre-proposal Title/Referral Page: No page limit. Complete the [Title/Referral Page](#). Complete each section as described:

- a. Pre-proposal title (up to 160 characters).
- b. 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 reviewers, please specify the subject area of the pre-proposal. Also,

list specific keywords and descriptive technical terms that 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 pre-proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this pre-proposal who may have a conflict of interest in reviewing 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; three-page limit. The investigator is responsible for articulating clearly how the proposed center addresses each of the screening criteria for pre-proposals:

- a.** State the overarching research question clearly. Discuss the necessity of addressing this problem 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 who will address the major, overarching research question; provide names and locations for all key personnel. Describe how all participants will be interdependent upon each other and how they will create a team that is stronger than each individual participant.
- c.** Describe the plan for consumer advocate involvement at every level of the Breast Cancer Center of Excellence. Provide names and locations for all key personnel. Describe how the consumer advocates will be interdependent with other participants and how they will strengthen the team and the proposed research.
- d.** Describe how the interactions and collaborations established through the Breast Cancer Center of Excellence Award will result in a *synergistic* effort that will substantively accelerate the research needed to resolve the central problem. Describe the interdependence among participants in completing each aim of the study.
- e.** Describe the qualifications of the Center of Excellence director and his or her ability to organize, administer, and manage a qualified team of multidisciplinary, highly integrated, multi-institutional researchers and consumer advocates in a consortium to solve a critical problem in breast cancer research.
- f.** Provide a project management plan outline.
- g.** Provide a communications plan outline.
- h.** Outline an experimental strategy to address the specific research question.
- i.** Include a timeline for completing the proposed research.

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: Four-page limit per individual. Include biographical sketches for all participants at the applicant institution and the collaborating institution, as well as each of the proposed key personnel, including all collaborating investigators. These documents are a critical component of the screening process. Although use of the [Biographical Sketch form](#) is not mandatory, the information requested must 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 a single PDF file submitted through the CDMRP eReceipt system at <https://cdmrp.org/>. Pre-proposals must be submitted on the CDMRP eReceipt system by the 5:00 p.m. Eastern time April 5, 2005 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.
- Although the applicant's Sponsored Programs Office (or equivalent) is not responsible for any part of pre-proposal submission, the Sponsored Programs Office (or equivalent) will be responsible for portions of the full proposal submission. Therefore, applicants are encouraged to begin coordinating with their Sponsored Programs Office (or equivalent) 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 April 5, 2005 pre-proposal 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.

VI. PRE-PROPOSAL SCREENING 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 2005.

VII. INVITED 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. *Do not submit a full Breast Cancer Center of Excellence Award proposal unless you receive a letter of invitation or you are the recipient of a FY04 BCRP Center of Excellence Pilot Award.*

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 not required for the Center of Excellence Award.
- **Proposal Contacts:** Contact information for both the PI and the Contract Representative is required to complete the proposal submission process.
- **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 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 the sponsored program administration (or equivalent) from the applicant’s institution is responsible for the following:

- **The Contract Representative’s Contact Information Profile: This must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA) Required Documents:** The institution’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 (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, 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 26, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time 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>. The Proposal Information may be “Verified & Saved” for editing purposes until “Submit Final” for approval by their Sponsored Programs Office’s (or equivalent’s) representative.

- **Letter of Intent:** An electronic Letter of Intent is not required for the Breast Cancer Center of Excellence Award.

C. Proposal Contacts: The Proposal Contacts **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. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

D. 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 period for which the USAMRMC will provide financial support.

Specific milestones from the approved SOW will be determined during the negotiation process. Funding for the Breast Cancer Center of Excellence Awards will be disbursed in installments contingent upon the successful completion of these milestones. For this reason, applicants are encouraged to include specific and measurable goals in their SOW.

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;
- Allow an appropriate amount of time (at least six months) to obtain the required regulatory approvals (see Section IX.D);
- Indicate the numbers of research subjects (animal or human) projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

E. 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 on the IP's review of these two abstracts as part of the peer review summary statements; therefore it is paramount that the PI submit abstracts that describe the proposed work fully.

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 abstract.

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, describe how the study will cure, prevent, or improve the detection or treatment of breast cancer.

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 be the ultimate applicability of the research?
 - 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?

F. 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.

Please note that proposals not adhering to these regulations will be withdrawn prior to peer review.

Please Note New Format Requirements

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

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inches in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

<p>Failure to follow the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.</p>
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- **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, but applicants should keep in mind that 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.

- Language: English.

2. Title/Referral Page: No page limit. Complete the [Title/Referral Page](#). Please note that all forms are available on the “Summary Tab” of eReceipt. Complete each section as described:

- a. Proposal title (up to 160 characters).
- b. 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 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 best describe the project’s technical aspects.
- 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 reviewing this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, her or his 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 electronically captured on each page of the proposal after receipt.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. 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 critical to breast cancer research; and (3) will have a major impact on the prevention, detection, diagnosis, and/or treatment of breast cancer. *Note that the Proposal Relevance Statement will be available for programmatic review of the Breast Cancer Center of Excellence Awards.*

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 synergy and interdependence will occur among Center of Excellence collaborators to accelerate the solution of the major problem addressed by the proposed center in a way that could not be accomplished by any single investigator or group; and (3) the means of communication to be employed to ensure real-time sharing of data and problem solving. *Note that the Center of Excellence Synergy Statement will be available for programmatic review of the Breast Cancer Center of Excellence Awards.*

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. All aims/components of this proposal should be interdependent.

Describe the overall project using the following outline.

- 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 that is 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 contribution of each aim/project in answering or addressing the overarching question that is the focus of the proposal. Describe the expected measurable outcomes of the proposed Center of Excellence. Explain how the Center of Excellence will address these objectives and why these 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. Describe the team's interdependence and how it will create an entity that is greater than the sum of each individual component. If the proposed Center of Excellence does not involve two or more institutions, demonstrate that the focus of the Center of Excellence can be addressed best within the single institution.
- e. Data:** Provide information on substantive 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. Explain how the Center of Excellence will maximize the use of resources and minimize unnecessary duplication; for example, specify 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. Discuss 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: Four-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 global 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. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not intended 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, highly integrated, 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 details regarding their contributions to the project.
- Documented evidence that all participating institutions have an intellectual and material property plan and are willing to resolve intellectual and material 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.

14. 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.

G. Budget Information: Budget Information includes the [Detailed Cost Estimate form and Budget Justification form](#). 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 \$20M, including direct and indirect costs, for up to 5 years. No more than \$5M will be granted within any single year during the lifetime of the award.

The allotment for travel is \$1,800 per year per investigator to attend scientific/technical meetings. An additional \$1,800 per investigator should be requested for annual meetings with the other Breast Cancer Center of Excellence Award recipients, the IP, and CDMRP Staff. In addition, travel funding of \$1,800 per investigator must be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research.

Funding for the Breast Cancer Center of Excellence Awards will be disbursed in installments. The first installment will be made at the time of the award; subsequent

installments will be contingent upon the successful completion of specific milestones. Milestones from the approved SOW will be determined during the award negotiation process. *Failure to complete each milestone may result in forfeiture of the subsequent installment of the Breast Cancer Center of Excellence Award funding.*

2. Detailed Cost Estimate Form and Budget Justification Instructions: The budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. **Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.** The Detailed Cost Estimate form and Budget Justification for the proposal must be uploaded as a PDF file, separate from the proposal.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (<http://farsite.hill.af.mil>), Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

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 Budget 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 Budget 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 that the costs are treated consistently by the applicant organization for all sponsors. Documentation to support the fringe benefits should be included.
- 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 number to be used. If human cell lines are to be purchased, provide the source and a description.

e. Travel Costs: Travel costs may not exceed \$1,800 per year per investigator to attend scientific/technical meetings. An additional \$1,800 per investigator should be requested for annual meetings with the other Breast Cancer Center of Excellence Award recipients, the IP, and CDMRP Staff. In addition, travel funding of \$1,800 per investigator per meeting must be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research.

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 Direct Costs: 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 Budget 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 at <https://cdmrp.org/>.

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

H. 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/Cadavers; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

I. USAMRAA Required 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.

J. Submission Date and Time: 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 26, 2005 deadline.

The timeline for the Breast Cancer Center of Excellence Award is:

Pre-proposal Submission Deadline:	5:00 p.m. Eastern time April 5, 2005
Pre-proposal Screening:	Early May 2005
Full Proposal Invitations:	May 2005
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time July 26, 2005
Peer Review:	September 2005
Programmatic Review:	November 2005
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:	Anticipated between December 2005 and September 2006

K. 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/>.

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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- 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 26, 2005 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.

VIII. 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 on 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 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 maintain 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 the Proposal Relevance and Center of Excellence Synergy Statements will be available for programmatic review of Breast Cancer Center of Excellence Awards.* SOWs also will be reviewed and used to determine project milestones. 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 on 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 critical for the prevention, detection, diagnosis, and/or treatment of breast cancer? Is the unifying research question one that can be solved only 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 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? Are statistical support services included in the Center of Excellence's design if needed? Does each aim contribute to the solution of the overarching research question? Does the proposal describe the interdependence among participants in completing each aim of the study?
- **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 that integrates and optimizes the research and collaborations and results in a synergistic research effort proposed? Is a plan to maximize use of resources and avoid unnecessary duplication of effort provided? Does the Center of Excellence director (i.e., PI) have a clear strategy and plan to ensure cross-Center of Excellence participation and real-time communication of results, issues, problems, and progress? Does the proposal describe the use of state-of-the-art communication tools and a plan for data management and statistical support?

- **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 representation from all the areas of expertise needed to conduct the study successfully provided? Does the team 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 of the proposed Center of Excellence including program conception and design, discussions, research participant recruitment, program evaluation and dissemination of information to the public? Are consumer advocates active participants in each of the projects 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 for administering all the functions of the Center of Excellence (e.g., communications infrastructure, informatics, access to required databases) available? Have the institutions/organizations demonstrated their clear commitment to the Center of Excellence? Does the proposal describe an intellectual and material property management plan agreed to 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 maintain 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.

IX. 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 November 2005.

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 institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for the 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 (OMB 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/>.*

Any change in the institution, PI, and/or 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.

The government strongly discourages transferring any award that includes a Phase I, Phase II, or Phase III clinical trial. Should the PI move to another institution, the government reserves the right to approve the assignment of a new PI to the award.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist and/or representative 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 and project milestones will be determined during the negotiation process.

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiations, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver 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 <https://mrmc.detrick.army.mil/crprcqsohdfspplan.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 <https://mrmc.detrick.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 <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: (See Subsection VII.H for information pertaining to the submission of human subjects and/or human anatomical substances or cadavers documents.) For planning purposes, please be advised that in addition to local institutional review board (IRB) approval to conduct research involving human subjects and/or anatomical substances or cadavers, 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 Office of Research Protections (formerly Regulatory Compliance and Quality). 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. Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained prior to the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators 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.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at

[https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix\(13May04\).doc](https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc).

An informed consent form template can be located at

<https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc>.

6. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written approval from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

E. Reporting: All research awards will require the timely delivery of several reports during the research effort.

- **Research Progress Report Requirements:** 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. Each report must describe progress toward achieving the milestones listed on the USAMRMC-approved timeline. Continued funding under this award mechanism is contingent upon timely achievement of study milestones. *Failure to submit progress reports on or before the required date may result in a delay in or termination of award funding.*
- **Fiscal Report Requirements:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

X. 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 used. 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.

³Title 35, United States Code, Section 200 et seq.

XI. 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
DOD	Department of Defense
FY	Fiscal Year
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	Megabytes
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
PDF	Portable Document Format
PI	Principal Investigator
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