

INNOVATOR AWARD

A lifetime opportunity to change the course of science and medical discovery and make an extraordinary impact on breast cancer

The Innovator Award seeks to identify and fund uniquely gifted individuals who have a history of visionary scholarship, leadership, and creativity. This prestigious award will provide the recipient with unprecedented freedom to pursue a novel course of action that could ultimately lead to a critical discovery or major advancement in the battle to eradicate breast cancer. Acknowledging that critical insights often come from those with an outside perspective, the BCRP is looking for creative thought-leaders from all fields, not just the sciences traditionally involved in breast cancer research. Funding for Innovator Awards can be requested for a maximum of \$5 million in direct costs for up to a 5-year performance period.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Proposals will be evaluated by peer and programmatic reviews, with a major emphasis on the candidate's record of outstanding accomplishment, creativity, and ability to make a revolutionary contribution in the fight against breast cancer.

NOMINATIONS ARE DUE BY MARCH 24, 2004

This document is a synopsis of details specific to the Breast Cancer Research Program (BCRP) Innovator 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 Innovator Award seeks to identify and fund uniquely gifted individuals who have a history of visionary scholarship, leadership, and creativity. This prestigious award will provide the recipient with unprecedented freedom to pursue a novel course of action that could ultimately lead to a critical discovery or major advancement in the battle to eradicate breast cancer. Acknowledging that critical insights often come from those with an outside perspective, the BCRP is looking for creative thought-leaders from all fields, not just the sciences traditionally involved in breast cancer research. Funding for Innovator Awards can be requested for a maximum of \$5 million in direct costs for up to a 5-year performance period.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Proposals will be evaluated by peer and programmatic reviews, with a major emphasis on the candidate's record of outstanding accomplishment, creativity, and ability to make a revolutionary contribution in the fight against breast cancer.

A. Title of Award: Innovator Award (INNOV).

B. Program Name: Department of Defense Fiscal Year 2004 Breast Cancer Research Program.

C. Funding Opportunity Number: BC04- INNOV.

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- INNOV)

1077 Patchel Street (Building 1077)

Fort Detrick, MD 21702-5024

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

Website: <https://cdmrp.org/proposals> (the proposal submission website)

E-mail: help-proposals-cdmrp@cdmrp.org

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

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

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

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

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

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Innovator Award is to identify and fund visionary individuals who have a history of creative, innovative work and leadership in any field including (but not limited to) breast cancer. The Innovator Award will provide these individuals with the funding and freedom to pursue their most novel, visionary, high-risk ideas that could ultimately lead to the eradication of breast cancer.

Applicants must be nominated to be considered for this award mechanism. However, self-nominations will be accepted.

This award is not intended to acknowledge lifetime achievements in breast cancer.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$30M is available for this award mechanism.
- It is anticipated that approximately four proposals will be funded.
- Funding for Innovator Awards can be requested for a maximum of \$5M in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

IV. ELIGIBILITY INFORMATION

- A. Applicants:** All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.
- B. Institutions:** Eligible institutions include for-profit, non-profit, public, and private organizations.
- C. Cost Sharing:** It is expected that institutions will cost share. Please see “Major Equipment” located in Subsection VI.F.2.c of the Full Text of Program Announcement for details.
- D. Other Eligibility Criteria:** Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

V. NOMINATION AND SUBMISSION INFORMATION

- A. Nomination Preparation:** All nominations must be converted into an electronic PDF (Portable Document Format) file for electronic submission. Please see the Full Text of the Program Announcement for details.
- B. Nomination Submission Date and Time: March 24, 2004.** Nominations must be received on the CDMRP eReceipt system at <https://cdmrp.org/proposals> by 5:00 p.m. (Eastern time).
- C. Electronic Submission Requirements: Electronic submission is required.** No paper copy submissions will be accepted. Nominations must be submitted electronically at <https://cdmrp.org/proposals>. Please see the Full Text of Program Announcement for details.

VI. FULL APPLICATION PREPARATION AND SUBMISSION INFORMATION

- A. Proposal Submission Invitation:** After completion of the nomination screening process, invitations to prepare a full Innovator Award proposal will be sent to selected applicants no later than May 2004. ***Do not submit a full Innovator Award proposal unless you receive a letter of invitation.***
- B. 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>.
- C. Proposal Preparation:** All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of Program Announcement for details.
- D. Submission Date and Time:** Deadline Date: **July 27, 2004.** Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institutional Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

VII. PROPOSAL REVIEW INFORMATION

Due to the value and unique nature of the award, applications for the Innovator Award will be evaluated using a three-tier review process.

- **Tier 1:** Review of Nominations
- **Tier 2:** Peer Review of Invited Applications
- **Tier 3:** Programmatic Review of Invited Applications

Self-nominations will be accepted. See the Full Text of the Program Announcement for details. Innovator Award will be evaluated using a three-tier process. See Section VI of the Full Text of Program Announcement for details.

VIII. 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 Innovator Award seeks to identify and fund uniquely gifted individuals who have a history of visionary scholarship, leadership, and creativity. This prestigious award will provide the recipient with unprecedented freedom to pursue a novel course of action that could ultimately lead to a critical discovery or major advancement in the battle to eradicate breast cancer. Acknowledging that critical insights often come from those with an outside perspective, the BCRP is looking for creative thought-leaders from all fields, not just the sciences traditionally involved in breast cancer research. Funding for Innovator Awards can be requested for a maximum of \$5 million in direct costs for up to a 5-year performance period.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Proposals will be evaluated by peer and programmatic reviews, with a major emphasis on the candidate's record of outstanding accomplishment, creativity, and ability to make a revolutionary contribution in the fight against breast cancer.

A. Title of Award: Innovator Award (INNOV).

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

C. Funding Opportunity Number: BC04- INNOV.

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

E. Agency Contact(s):

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

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BC04- INNOV)
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.

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

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Innovator 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 BCRP appropriation is \$150M.

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

Program History	FY92-02	FY03¹
Congressional Appropriations for the BCRP	\$1.38B	\$150M
Total Proposals Received	19,840	1,543
Total Proposals Funded	3,671	240
Innovator Award Proposals Received	119	14
Innovator Award Proposals Funded	6	2

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, the objective of the BCRP 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; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

C. Award Mechanism Description: The intent of the Innovator Award is to identify and fund visionary individuals who have a history of creative, innovative work and leadership *in any field* including (but not limited to) breast cancer. The Innovator Award will provide these individuals with the funding and freedom to pursue their most novel, visionary, high-risk ideas that could ultimately lead to the eradication of breast cancer.

Applicants must be nominated to be considered for this award mechanism. However, self-nominations will be accepted. Innovator Award nominees may be from diverse fields including, but not limited to professional schools, advocacy groups, governmental agencies, the private sector, the media, and/or appropriate professional societies.

Since the intent of the Innovator Award mechanism is to recognize creative and innovative *individuals* rather than projects, the central feature of the award is the innovative contribution that the recipient can make to the eradication of breast cancer. As such, applicants selected to submit a full proposal are required to submit an essay addressing several areas including his or her area(s) of focus and how he or she will use the award to pursue his or her most creative vision in breast cancer research (see Subsection VI.E.4). The primary criteria for making these awards will be the applicant's past record of creativity, the promise for continued innovation in future work, and an indication of how this award will create and further innovate strategies to solve the breast cancer problem. ***Experience in breast cancer research is allowed, but not required;*** however, the proposal must center on breast cancer and it is expected that the applicant will commit a minimum of 50% of his or her full-time professional effort to breast cancer research during the tenure of this award.

Innovator Award recipients will meet annually with other Innovator Award recipients, the recipients of the Era of Hope Scholars Award, BCRP Multidisciplinary Postdocs, the BCRP Integration Panel (IP), and BCRP Program Staff for the purpose of open communication and mutual benefit.

III. AWARD INFORMATION

Funding for the Innovator Award can be requested for up to a maximum of \$5M in direct costs for up to a 5-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. Examples of possible uses for funds include project-related expenses such as salaries, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies. The amount allotted for travel is \$1,800 per year per investigator to attend scientific/technical meetings. The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants. Funds should be requested for annual meetings of recipients of the Innovator Award with the recipients of the Era of Hope Scholar Award and the Multidisciplinary Postdoctoral Award, the IP, and CDMRP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per meeting should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$30M of the \$150M FY04 BCRP appropriation to fund approximately four Innovator Awards.

IV. ELIGIBILITY INFORMATION

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

Individuals not affiliated with an institution may apply for the Innovator Award. However, if the application is recommended for funding, he or she will be required to submit documentation for a determination of responsibility to be made by the USAMRMC. Such documentation may include, but is not limited to, information on time management, project management, and financial accountability.

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).

If an Innovator Award recipient should move to a new institution during the tenure of the award, the US Army reserves the right to transfer the existing award to the new institution.

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

D. Other Eligibility Criteria:

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

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP’s peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.¹

¹Executive Orders 12876, 12900, and 13021

Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website under Minority Institutions at <http://cdmrp.army.mil/funding/pdf/mibcrp120803.pdf>.

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

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

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

V. NOMINATION SUBMISSION INFORMATION

A. Nomination Preparation: The nominator should provide a one- to two-page (maximum of 11,400 characters, including spaces) description of the nominee's qualifications that stress creativity in past work, the likelihood of continued innovation, and potential for creativity in the nominee's future work specifically related to advancing progress against breast cancer. In addition to the nomination, the nominator must provide the names and contact information for three individuals who support the qualifications of the nominee for this award and will submit letters of support should a full proposal be requested.

The nominator is responsible for completing the following data field information through the CDMRP eReceipt system at <https://cdmrp.org/proposals>.

- **Nominee Identification:** The nominator for the Innovator Award must complete **all** the Nomination Information in the appropriate data field.
- **Nomination:** The applicant should use this data field to either type in or electronically cut and paste their nomination from a word processing application.
- **Letters of Support:** The nominator must either type in or electronically cut and paste from a word processing application into the designated data field a list of names, position titles, addresses, and phone numbers of three individuals who support their qualifications of the nominee for this award and who will submit letters of support should a full proposal be requested.

B. Nomination Submission Date and Time: March 24, 2004. Nominations must be received on the CDMRP eReceipt system at <https://cdmrp.org/proposals> by 5:00 p.m. (Eastern time).

C. 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. FULL PROPOSAL PREPARATION AND SUBMISSION INFORMATION

Do not submit a full Innovator Award proposal unless you receive a letter of invitation.

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

The Principal Investigator (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.
- **Statement of Work (SOW) and Proposal Abstracts:** An SOW and Abstracts are not required for the Innovator Award application, but the data fields must be completed for the final submission process. Therefore, the applicant should type “N/A” into the SOW and Proposal Abstracts data fields.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the “Required Files” tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the “Required Files” tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the “Required Files” tab.

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

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute’s currently negotiated “Rate Agreement,” “Certifications and Assurances for Assistance Agreements,” and the “Representations for Assistance Agreements” are to be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal Information, Proposal, Budget Information, and Regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) **July 27, 2004**. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time **July 27, 2004** deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as

described in <https://cdmrp.org/proposals>. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** A Letter of Intent is not required for invited Innovator Award submissions.

C. SOW – A SOW is not required for Innovator Awards, but the data field must be completed for the final submission process. Therefore, the applicant should type “N/A” into the SOW data field.

D. Proposal Abstracts – Abstracts are not required at this stage of the Innovator Award application process, but the data fields must be completed for the final submission. Therefore, the applicant should type “N/A” 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>. 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 "Innovator."
- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

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

4. Main Body Application Essay: Start section on a new page; five-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 content of the essay should address the following points:

- **Current Status of Breast Cancer Research:** Describe your views of the major problems/barriers in breast cancer that must be solved to accelerate progress and hasten the eradication of breast cancer.
- **Your Vision of the Future:** What do you see as the critical approaches, discipline combinations, etc., that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems/barriers in breast cancer that you have defined?
- **Your Specific Ideas:** Summarize some of the key examples of specific innovative ideas that you envision pursuing under the auspices of this award. Explain why/how your ideas may challenge current assumptions and ultimately produce significant progress toward the eradication of breast cancer. *This should not be a summary of research methodology.*
- **Preparation for This Award:** Explain why/how your past training and experience qualify you to receive this award. Give some examples of breakthrough creative thinking in your past work that demonstrates your abilities as an innovator. How do you think your past achievements reflect your capabilities as an innovator?

5. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used.

6. 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).

7. Curriculum Vitae and Biographical Sketches:

- **Applicant's Curriculum Vitae: No page limit.** The applicant should submit his or her complete curriculum vitae including employment, experience, honors, and a list of achievements, including publications and patents. The publication list should exclude abstracts and should distinguish which publications are peer reviewed. On the curriculum vitae, the candidate should indicate up to three publications he or she considers most significant to the proposed work.
- **Key Collaborator Biographical Sketches:** If the applicant chooses to include biographical information on key collaborators as part of the Innovator Award application, curriculum vitae should not be used. Instead, 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.

8. 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.

9. 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.

10. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit. Include an appropriately titled page listing the documents you have included in this section.

11. 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.

12. 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. Provide the following in the Administrative Documentation section of the proposal.

- Letter(s) of institutional support (if applicable) for the applicant to the Innovator Award, as reflected by the extent to which the applicant will be relieved of academic or administrative responsibilities.
- Three letters of support addressing the past and current creativity and innovation of the applicant.

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 [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 Innovator Award can be requested for a maximum of \$5M in direct costs for up to 5 years, plus indirect costs as appropriate. Direct costs can include (but are not limited to) any project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies. Travel costs may not exceed \$1,800 per year per investigator to attend scientific/technical meetings. Funds for the support of “to be named” trainees may be requested. Funds should be requested for annual meetings of recipients of the Innovator Award with recipients of the Era of Hope Scholar Award and the Multidisciplinary Postdoctoral Award, the IP, and CDMRP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per meeting should also be requested to attend two 3½-day Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

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

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

- a. Personnel:** 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. Only ONE person may be identified as the PI of the proposal.
- b. 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. Documentation to support the fringe benefits should be provided.
- c. Consultant Costs:** Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants in the Justification section of the Cost Estimate form.
- d. 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.

e. 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 with amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

f. Travel Costs: Travel costs may not exceed \$1,800 per year per investigator to attend scientific/technical meetings. Funds should be requested for annual meetings of recipients of the Innovator Award with the recipients of the Era of Hope Scholar Award and Multidisciplinary Postdoctoral Award, the IP, and CDMRP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per meeting should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined). A justification of all travel costs must be provided on the [Cost Estimate form](#).

g. 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.

h. 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.

i. Subaward Costs: A description of services or materials that are to be awarded by subcontract or sub-grant 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.

j. 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.

k. 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 Cost Estimate form.

Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget in the Justification section of the Cost Estimate form. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should agree with the amount previously entered online in the Proposal Information <https://cdmrp.org/proposals>.

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

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

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

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

The timeline for the Innovator Award is:

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

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

Several steps are critical to successful proposal submission.

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

- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time July 27, 2004 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Cost Estimate form and the Budget Justification form. Budget Information must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The Regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

VII. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview:

Innovator Award submissions will be evaluated using a three-tier review process. The first tier is the screening of nominations. The second tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The third 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.

1. Nomination Review: The Innovator Award nominations will be reviewed 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. Their primary responsibility will be to select candidates to be invited to submit Innovator Award proposals.

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

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

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 third tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review summary statements; full Innovator Award proposals will also be forwarded to programmatic review.

B. Review Criteria:

1. Nomination Review: The Innovator Award nominations will be reviewed by the IP. Their primary responsibility will be to select candidates with great potential to be invited to submit proposals. Selection will be based on the applicant's described past, present, and future creativity.

2. Peer Review: Innovator Award proposals will be evaluated according to the following criteria:

- **Candidate:** Does the application reflect creativity and innovative thinking and support the likelihood that the candidate could have a significant impact on breast cancer? Does the candidate's record of accomplishment demonstrate outstanding ability as an independent and visionary scholar/investigator? Does the applicant indicate that he or she will commit 50% effort to breast cancer during the tenure of this award?
- **Relevance and Impact:** Does the applicant's vision for the tenure of the award address an important problem(s) in breast cancer? Is the work demonstrably creative and does it have the potential to significantly impact breast cancer?
- **Vision and Ideas:** Does the candidate communicate a clear vision of what he or she hopes to accomplish during the tenure of the award? Are the concepts and ideas original and innovative? Do the candidate's ideas reflect innovative thinking and does he or she present a clear and compelling argument for how this award will be used to pursue creative (potentially groundbreaking) work in breast cancer?
- **Budget:** Is the budget appropriate for the proposed project?

3. Programmatic Review: The ratings and evaluations of scientific peer review panel are primary factors in programmatic review. The complete Innovator Award application package sent to peer review will also be forwarded to the IP for programmatic review. The IP also considers other criteria to structure the BCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

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

Scientifically sound proposals that best fulfill the above criteria and most effectively address the

unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

VIII. AWARD ADMINISTRATION INFORMATION

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

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

Any change in the institution and/or the SOW will require that the PI resubmit contact information. If an Innovator Award recipient should move to a new institution during the tenure of the award, the US Army reserves the right to transfer the existing award to the new institution. 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/crprcqsohdfsplan.asp>. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at <http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc>.

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

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

5. Research Involving Human Subjects/Anatomical Substances: Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be requested at a later date. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC RCQ office. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. For example:

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

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

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

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

E. Reporting: All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist of an annual report (for each year of research except the final year)

that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project.

IX. OTHER INFORMATION

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

B. Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

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

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

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

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

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

X. ACRONYM LIST

AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
DOD	Department of Defense
FY	Fiscal Year
HBCU	Historically Black Colleges and Universities
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
INNOV	Innovator Award
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MB	Megabyte
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