

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Title of Award: Innovator Award (INNOV)

B. Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: DAMD17-BC03- 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 (DAMD17-BC03- INNOV)

1077 Patchel Street (Building 1077)

Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone numbers are provided on the web or may be requested by e-mail as follows:

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

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

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

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

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

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Innovator Award is to provide accomplished and creative individuals from public and private sectors with the funding and freedom to pursue their most innovative plans that could ultimately lead to the eradication of breast cancer.

Applicants must be nominated by executives and/or leaders in diverse fields including, but not limited to professional schools, advocacy groups, governmental agencies, the media, appropriate professional societies, and/or cancer detection and treatment centers. **No self-nominations will be accepted.**

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$25 million (M) is available for this award mechanism.
- Depending on the number and quality of the applications, it is anticipated that approximately five proposals will be funded.
- Funding for Innovator Awards can be requested for up to a maximum of \$5M for direct and indirect costs for up to a 5-year performance period.

IV. ELIGIBILITY INFORMATION

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

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

C. Cost Sharing: Not required.

D. Other Eligibility Criteria: Please see the Full Text of the 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

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

A. Nomination Process:

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

No self-nominations will be accepted. See the Full Text of the Program Announcement for details.

B. Nomination Preparation: All applications 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.

C. Nomination Submission Date and Time:

- **Nomination Deadline Date and Time:** April 16, 2003. Nomination letters must be received on the CDMRP eReceipt system at <https://cdmrp.org/proposals> by 5:00 p.m. (Eastern time).

D. Electronic Submission Requirements: Electronic submission is required. Proposals must be submitted electronically at <https://cdmrp.org/proposals>. Please see the Full Text of the Program Announcement for details.

VI. NOMINEE APPLICATION PREPARATION AND SUBMISSION INFORMATION

Nominations will be screened to determine which nominees fulfill the intent of the award mechanism. Following completion of the nomination screening process, invitations to prepare a full Innovator Award proposal will be sent to select nominees no later than May 2003. ***Do not submit a full Innovator Award proposal unless you receive a letter of invitation.***

The invited proposal deadline date is August 7, 2003. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the nominee's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

VII. PROPOSAL REVIEW INFORMATION

The CDMRP generally uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. However, the review process will be modified for applications to the Innovator Award. These submissions will be evaluated using a three-tiered process. Details of this review process can be found in the Full Text of the Program Announcement.

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 the Program Announcement.

B. Reporting Requirements: Annual reporting requirements apply.

IX. OTHER INFORMATION

Details pertaining to Disclosure of Proprietary Information outside the Government, Government Obligation, Information Service, Inquiry Panel Review, and Title to Inventions and Patents can be found in the Full Text of the Program Announcement.

Full Text of the Program Announcement

I. GENERAL INFORMATION

A. Title of Award: Innovator Award (INNOV)

B. Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Breast Cancer Research Program (BCRP).

C. Funding Opportunity Number: DAMD17-BC03- 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 (DAMD17-BC03- 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 numbers are provided on the web or may be requested by e-mail as follows:

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: q&a.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 Section E.1 above.

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 \$1.38 billion (B). The program history of the FY92-02 BCRP is shown in Table 1. The FY03 appropriation is \$150 million (M).

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

Program History	FY92-00	FY01	FY02 ¹
BCRP Congressional Appropriations	\$1.05B	\$175M	\$150M
Total Proposals Received	15,017	1,500	1,883
Total Proposals Funded	2,837	380	308
Innovator Award Proposals Received	N/A ²	75	43
Innovator Award Proposals Funded	N/A	5	1

¹Award negotiations will be finalized by September 2003.

²N/A= not applicable.

B. Program Objectives: The overall goal of the FY03 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.

The BCRP is challenging the scientific community to design innovative research that will open up new directions, address important but neglected areas, and bring new investigators to the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the BCRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

C. Award Mechanism Description: The intent of the Innovator Award is to identify accomplished and creative individuals from the public and private sectors who have demonstrated visionary leadership and innovation in their fields, and to provide these individuals with the funding and freedom to pursue their most innovative plans that could ultimately lead to the eradication of breast cancer.

The BCRP's goal is to recognize creative and innovative individuals rather than projects, and the central feature of the award is the innovative contribution that the recipient can make to the eradication of breast cancer.

This award is designed to help alleviate the constraints that may hamper the most creative individuals from pursuing their most innovative approaches, which could significantly contribute to the conquest of breast cancer. The primary criteria for making these awards will be the 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 the field of breast cancer is not required although the plan must center on breast cancer.

Innovator Award nominees should be distinguished in their field through their vision and creativity of approach. They 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.

Innovator Awards will provide recipients with the flexibility to explore new directions in breast cancer. For example, recipients may use the award to establish multidisciplinary collaborations, redirect their careers to innovative breast cancer research, and/or establish breast cancer-related efforts at new, intellectually stimulating environments. The preceding list is meant only to provide examples for use of the award and should not be considered comprehensive. The nominees are required to submit an essay addressing several areas including her/his area(s) of focus and how (s)he will use the award to pursue her/his most creative vision in breast cancer.

This award is designed to facilitate creative thinking and imaginative application of ideas to the field of breast cancer. Thus, it is expected that the nominee will commit a minimum of 50% of her/his full-time professional effort to breast cancer during the tenure of this award. Innovator Award recipients will meet annually with the Integration Panel (IP) and 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 for both direct and indirect costs for up to a 5-year performance period. Projects requiring lower levels of funding may also be submitted. Examples of possible uses for funds include project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies. The nature of our Program 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 IP and Program Staff. In addition, funding should also be requested for two, 3½-day meetings, one in 2005 and one in 2007, to disseminate the results of DOD-sponsored research.

All Innovator Award recipients are required to meet with the Postdoctoral Award recipients during the course of their award as designated by the BCRP. Details of the nature of this interaction will be provided at a later date.

Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$25M of the \$150M FY03 BCRP appropriation to fund approximately five 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 be nominated for the Innovator Award. However, if the application is recommended for funding, he/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 terminate the existing award and may negotiate a replacement grant with the new institution.

C. Cost Sharing: Cost sharing is not a requirement for this award.

D. Other Eligibility Criteria:

1. Duplicate Submissions: Submission of the same research project to the FY03 BCRP under different award mechanisms is not allowed. This includes duplicate submissions under different award mechanisms by different PIs. The government reserves the right to reject duplicative proposals.

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.¹ Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/funding/pdf/mibcrp012703.pdf> 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. 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.

Failure to comply with any of the five items listed below 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 submitted after the deadline.

¹Executive Orders 12876, 12900, and 13021

- 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 CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

V. NOMINATION SUBMISSION INFORMATION

Tier 1: Solicitation of Nomination Letter: Executives and leaders in diverse fields (i.e., professional schools; advocacy groups; governmental agencies; print, electronic or television media; appropriate professional societies; cancer detection and treatment centers, etc.) and the general public can nominate an individual who has distinguished themselves through their creativity of approach in their fields, and may impact some facet of breast cancer including, but not limited to its prevention, detection, and/or treatment. **No self-nominations will be accepted.**

In the letter of nomination, the nominator should provide a 1- to 2-page (maximum of 11,400 characters, including spaces) description of the qualifications of the candidate that stress the nominee's creativity in past work, the likelihood of continued innovation, and potential for creativity in the candidate's future work specifically related to advancing progress against breast cancer. In addition to the letter, the nominator must provide the names and contact information for three additional individuals who support the qualifications of the nominee for this award.

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

- **Nominator Identification:** The nominator for the Innovator Award must complete **all** the Nominator Information in the appropriate data field.
- **Nominee Identification:** The nominator for the Innovator Award must complete the contact information for the specified nominee. Additional nominations require generating a new submission.
- **Nomination Letter:** The nominator should use this data field to either type in or electronically cut and paste the nomination letter from a word processing application. In the letter of nomination, the nominator should provide a 1- to 2-page description (maximum of 11,400 characters, including spaces) of the qualifications of the candidate that stress the nominee's creativity in past work, the likelihood of continued innovation, and the potential for creativity in the candidate's future work specifically related to advancing progress against breast cancer.
- **Supporting Nominator Identification:** 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 additional nominators who support the qualifications of the nominee.

VI. INVITED NOMINEE 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 for the nominee. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The nominee is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields.
- **Statement of Work (SOW):** A SOW is not required for the Innovator Award application but the data field must be completed for the final submission process. Therefore, the applicant should type “N/A” into the SOW data field.
- **Proposal Abstracts:** The Technical Abstract and Public Abstract 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 appropriate fields.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the “File Upload” tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the “File Upload” tab. For Innovator Awards, complete the Cost Estimate Form.

The Contract Representative (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 "My Profile" tab.
- **Approval:** The Contract Representative must provide approval for all proposal components (Proposal Information, and Budget Information). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) **August 7, 2003**. Otherwise, the entire proposal will be considered a “LATE” submission and will not be forwarded for review.

B. Proposal Information: Nominees are required to submit the Proposal Information, Parts 1 and 2, (referred to in previous years as the Proposal Cover Booklet) 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 who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** A Letter of Intent is not necessary for invited proposal submission.

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 proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the “File Upload” 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, 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.
- 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 from the CDMRP website at <http://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 a draft of the Proposal Information is completed and saved).
- c. Nominee’s full name (first, middle initial, last).
- d. Submitting Institution.
- e. Award mechanism: Type in “Innovator Award.”
- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.

g. Conflicts of interest: To avoid real and apparent conflicts of interest during the peer review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subcontractors. 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 role(s) on the proposed project or perceived conflicts of interest.

3. Table of Contents/Checklist: Start section on a new page. Prepare a [Table of Contents/Checklist](#), with page numbers, using the form provided. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. If possible, provide headers throughout the proposal that include the nominee's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when a draft of the electronic Proposal Information is saved).

4. Application Essay: Start section on a new page; 5-page limit inclusive of any figures, tables, graphs, and photographs.

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 qualifies 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. 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).

6. Curriculum Vitae: No page limit. The nominee should submit their 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.

If the nominee chooses to include biographical information on key collaborators as part of the Innovator Award application, the Public Health Service Biographical Sketch form should be used; a three-page limit is placed on the Biographical Sketches of collaborators. Curriculum vitae of collaborators should not be included. The PHS Biographical Sketch form can be downloaded from the CDMRP website at <http://cdmnp.org/programAnnouncements.cfm>. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

7. Existing/Pending Support: Start section on a new page; no page limit. List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending projects involving the nominee and key personnel. If no support exists, state “none.” Proposals submitted under this program announcement should not duplicate other funded projects

8. Facilities/Equipment Description: No page limit. Describe the facilities available.

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

10. Publications and/or Patent Abstracts: 5-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.

11. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not for additional data, figures, or other similar information.** 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.

All administrative documentation must be incorporated into your electronic PDF 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 proposal prior to submission.

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 candidate’s nomination for an 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.

F. Budget Information: Budget Information includes the [Cost Estimate Form \(including Budget Justifications\)](#). Budget Information is uploaded under the “File Upload” tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for the Innovator Award can be requested for a maximum of \$5M for a period of up to 5 years, inclusive of direct and indirect costs. 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. 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 the IP and Program Staff. In addition, funding should also be requested for two, 3½-day meetings, one in 2005 and one in 2007, to disseminate the results of DOD-sponsored research.

2. Cost Estimate Form: 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 US.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.
- 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. A copy of the Rate Agreement or other 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.
- 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.
- 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:** Funds should be requested for annual meetings of recipients of the Innovator Award with the IP and Program Staff. In addition, funding should also be requested for two, 3½-day meetings, one in 2005 and one in 2007, to disseminate the results of DOD-sponsored research. A justification of 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. Subcontract 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 sub-grantee, if known, and an explanation of why and how the subcontractor or sub-grantee was selected or will be selected.

- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition.
- 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. All amounts should be in US 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. USAMRAA Documents: If available, a copy of the institution’s negotiated Rate Agreement, the [Certifications and Assurances for Assistance Agreements](#), and the [Representations for Assistance Agreements](#) can be uploaded by the Contract Representative from the Sponsored Programs Office. These documents must be uploaded as separate PDF files under the Contract Representative “My Profile” tab of the CDMRP eReceipt system.

H. 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 submitted and approved electronically after the deadline, it will not be considered for review.

The timeline for Innovator Award is:

Nomination Deadline:	5:00 p.m. Eastern time April 16, 2003.
Nomination Screening:	April 2003.
Invitations to Nominees:	May 2003
Nominee Submission/Approval Deadline:	5:00 p.m. Eastern time August 7, 2003.
Second Tier Review:	September 2003.
Third Tier Review:	November 2003.
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 2003 and September 2004.

I. 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. Nominees 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.
- Nominees are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- **If final approval is not accomplished by the submission deadline, the proposal will be considered a “LATE” submission and will not be considered for review.**
- Any supporting documentation that the nominee 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, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Cost Estimate Form (including Budget Justifications). Budget Information must be uploaded under the “File Upload” tab of the CDMRP eReceipt system.
- The Regulatory Compliance and Quality documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed PI Safety Program Assurance Form. These must be uploaded under the “File Upload” tab of the CDMRP eReceipt system.

VII. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

The CDMRP generally uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. However, the review process will be modified for the applications for the Innovator Award and will be evaluated using a three-tiered process.

B. Review Criteria

- 1. First Tier Review:** The Innovator Award letters of nomination will be submitted to a Review Panel of representatives from academia, government, industry, media, corporate, and breast cancer consumer organizations. Their primary responsibility will be to select nominations to move to the next level. Selection will be based on the nominator, the nominee, and the nominee’s described past, present, and future creativity.
- 2. Second Tier Review:** The selected Innovator Award nominees’ application, letters of supporting nomination, and initial nomination letter will be evaluated in the second tier peer review 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?

- **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. Third Tier Review: The third tier of review for the Innovator Award is programmatic review. The ratings and evaluations of the second tier peer review panel are primary factors in programmatic review. The IP also considers other criteria to establish 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 with respect to research disciplines or specialty areas.
- Adherence to the award mechanism and programmatic review criteria.

The complete Innovator Award application package sent to the second tier review will be forwarded for the third tier review.

Applications 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-tiered 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 2003.

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).

Any change in the institution 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 new

institution will be designated as the recipient institution for the remaining award amount. 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 the 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 Statement of Work and associated budgets may be required.

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

D. Regulatory Compliance and Quality Review

- 1. Overview:** Concurrent with the USAMRAA negotiations, Regulatory Compliance and Quality will review the Certificate of Environmental Compliance, and PI Safety Program Assurance form submitted with the proposal, as well as Regulatory Compliance and Quality 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](#) will be requested at a later date.
- 3. Safety Program Documents:** The [Principal Investigator Safety Assurance Form](#) and a Facility Safety Plan are 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> and for the Certificate of Environmental Compliance at <http://cdmrp.org/programAnnouncements.cfm>.
- 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 approval to conduct research involving human subjects and/or anatomical substances, a second tier of 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 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. 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.

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 US 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.

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