

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

In an effort to spark new ideas and fertilize the development of new, innovative, potentially high-risk avenues of investigation, the Breast Cancer Research Program (BCRP) is once again offering the Concept Award. These awards provide investigators with the opportunity to pursue serendipitous observations and/or explore new, untested ideas relevant to breast cancer. It is anticipated that research completed through a Concept Award may provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research. As such, preliminary data are not consistent with this award mechanism.

Because these awards are designed for preliminary investigations, projects involving human subjects or human anatomical substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4)¹. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

Funding for Concept Awards may be requested for up to \$75,000 in direct costs over a 1-year performance period, plus indirect costs as appropriate. Of note, both peer and programmatic review of these proposals will be blinded; the Principal Investigator and institution names will not be provided during the review process.

A. Title of Award: Concept Award (CA).

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

C. Funding Opportunity Number: BC04-CA.

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:

¹Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-C (BC04-CA)
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> (User's Guide located in upper right corner of the proposal submission website)
E-mail: help-proposals-cdmrp@cdmrp.org

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

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

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

I. Award/Regulatory Approval: For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4).² Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

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

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Concept Award is to fund the exploration of an initial concept or theory that could give rise to a testable hypothesis. Presentation of preliminary data is not consistent with the intent of this award mechanism. These awards are to encourage the exploration of untested, innovative, high-risk questions in breast cancer and are not intended to support the next step in an already established research project.

²Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately \$10 million is available to fund FY04 BCRP Concept Awards.
- Depending on the number and quality of the applications, it is anticipated that approximately 80 proposals will be funded.
- Funding for Concept Awards can be requested for a maximum of \$75,000 for direct costs over a 1-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 as defined below.

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

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

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

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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

B. Proposal Preparation: 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.

C. Submission Date and Time: Deadline: February 1, 2005. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution’s Sponsored Programs Office (or equivalent) by 5:00 p.m. Eastern time.

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

VI. PROPOSAL REVIEW INFORMATION

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

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including regulatory documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances/Cadavers, 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

In an effort to spark new ideas and fertilize the development of new, innovative, potentially high-risk avenues of investigation, the Breast Cancer Research Program (BCRP) is once again offering the Concept Award. These awards provide investigators with the opportunity to pursue serendipitous observations and/or explore new, untested ideas relevant to breast cancer. It is anticipated that research completed through a Concept Award may provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research. As such, preliminary data are not consistent with this award mechanism.

Because these awards are designed for preliminary investigations, projects involving human subjects or human anatomical substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4)³. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

Funding for Concept Awards may be requested for up to \$75,000 in direct costs over a 1-year performance period, plus indirect costs as appropriate. Of note, both peer and programmatic review of these proposals will be blinded; the Principal Investigator (PI) and institution names will not be provided during the review process.

A. Title of Award: Concept Award (CA).

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

C. Funding Opportunity Number: BC04-CA.

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.

³Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-C (BC04-CA)
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> (User's Guide located in upper right corner of the proposal submission website)
E-mail: help-proposals-cdmrp@cdmrp.org

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

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

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

H. Website to Access Application Package: Proposals must be submitted electronically at <https://cdmrp.org/proposals>. This website will contain all the information, forms, documents, and links needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. For Concept Awards, projects involving

human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4)⁴. Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

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

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Concept Awards are 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. The FY04 appropriation is \$150 million (M). Of this, approximately \$10M will be available for Concept Awards.

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.

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

C. Award Mechanism Description: The intent of the Concept Award is to fund the exploration of an initial concept or theory that could give rise to a testable hypothesis. Presentation of preliminary data is not consistent with the intent of this award mechanism. These awards provide investigators with the opportunity to pursue serendipitous observations; it is anticipated that research completed through a Concept Award may provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for future research. Proposals must describe how the new concept or theory will enhance existing knowledge of breast cancer or create an entirely new avenue for investigation.

⁴Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

Because these awards are designed for preliminary investigations, projects involving human subjects or human anatomical substances will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

III. AWARD INFORMATION

Funding for Concept Awards can be requested for a maximum of \$75,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings. The amount allotted for this travel is \$1,800 per year.

The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants. Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$10M to fund approximately 80 Concept Awards.

IV. ELIGIBILITY INFORMATION

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

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI). Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

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

D. Other Eligibility Criteria

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

2. HBCU/MI: A goal of the DOD is to allocate funds for the CDMRP’s peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.⁵ Proposals submitted to the DOD are assigned HBCU/MI status if the

⁵Executive Orders 12876, 12900, and 13021

submitting institution is so designated by the Department of Education on the date the program announcement is released. The Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/spp> under Minority Institutions.

3. Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. 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 rating.

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

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inch on any side.
- PI and/or institution names are included in proposal body.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Concept Award Cost Estimate is missing.
- Proposal is incomplete after the deadline.

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

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

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- **Proposal Contacts:** Contact information for the PI and the Contract Representative are required to complete the proposal submission process.

- **Statement of Work (SOW) and Proposal Abstracts:** The SOW is entered as a separate data field. The technical and public abstracts are not required for Concept Award submissions, but the appropriate data fields must be completed for final submission of the proposal. Please complete these fields by entering “Not Applicable for Concept Awards” in the appropriate data field(s).
- **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:

- **The Contract Representative’s Contact Information Profile: This must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA)-Required Documents:** The institution’s currently negotiated “Rate Agreement,” “Certifications and Assurances for Assistance Agreements,” and the “Representations for Assistance Agreements” are to be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab.
- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, SOW, Proposal, Budget Information, and regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time February 1, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described in <https://cdmrp.org/proposals>. The Proposal Information may be “Verified & Saved” for editing purposes until “Submit Final” for approval by their Sponsored Programs Office’s (or equivalent’s) representative.

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

C. Proposal Contacts: The Proposal Contacts **must** include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

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

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

As appropriate, the SOW should:

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

E. Proposal Abstracts: Abstracts are not required for the Concept Awards, but the data fields must be completed for the final submission. Therefore, the applicant should type “N/A” into both abstract data fields.

F. Proposal

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

Please Note New Format Requirements

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

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

Failure to adhere to the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.

- Color, Resolution, and Multimedia Objects: Not allowed for Concept Award submissions.
- Language: English.

2. Title/Referral Page: Not applicable for Concept Award submissions.

3. Table of Contents/Checklist: Not applicable for Concept Award submissions.

4. Main Body: Start section on a new page; one-page limit. The body of the proposal should consist only of text. No figures, tables, graphs, photographs, diagrams, chemical structures, pictures, cartoons, schematics, pictorials, or pathways will be accepted.

It is the investigator's responsibility to clearly articulate how the proposed research is innovative and relevant to breast cancer research. Presentation of data from preliminary studies is not consistent with the intent of this award mechanism. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale.

Due to the blinded nature of the review process (see Subsection VI.A), references to the PI or institution are prohibited and will be cause for administrative withdrawal of the proposal.

Describe the proposed project using the outline provided below:

- a. Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- b. Rationale/Purpose:** State the rationale for the proposed research.
- c. Objectives:** State concisely the project's specific aims and research strategy.
- d. Methods:** Discuss the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.
- e. Relevance:** Provide a brief statement in non-technical terms regarding the relevance of this work to breast cancer.

5. References: Start section on a new page. Cite relevant literature references (maximum five). List 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. Biographical Sketches: Not required at the time of proposal submission.

G. Budget Information: Budget Information includes the one-page [Concept Award Cost Estimate form](#). Budget Information is uploaded under the “Required Files” tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for the Concept Award is a maximum of \$75,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for this travel is \$1,800 per year.

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

Costs proposed must conform to the following regulations and principles:

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

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

a. Personnel

- i. Name:** Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries

are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.

ii. Role on Project: Identify the role of each individual listed on the project.

iii. Type of Appointment (Months): List the number of months reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

iv. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project.

v. Percentage of Effort on Project: The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

vi. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization for all sponsors. Documentation to support the fringe benefits should be provided.

viii. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

b. Consultant Costs: Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.

c. Major Equipment: It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases in which specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed \$5,000.

d. Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate

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

e. Travel Costs: Travel costs to scientific/technical meetings may not exceed \$1,800 per year.

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

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

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

h. 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 with a statement identifying whether the proposed rates are provisional or fixed.

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

Do not submit other regulatory documents (for example, documents supporting research exempt under 32 CFR 219.101(b)(4) or Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

I. USAMRAA-Required Documents: The most current version of the institution’s negotiated “Rate Agreement,” the “[Certifications and Assurances for Assistance Agreements](#)”, and the “[Representations for Assistance Agreements](#)” must be uploaded by the Contract Representative from the Sponsored Programs Office (or equivalent). These documents must be uploaded as

separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system prior to negotiations.

J. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by the deadline. If the 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 February 1, 2005 deadline.

The timeline for the Concept Award is:

| | |
|---|---|
| Online Proposal Information: | Prior to proposal submission |
| Proposal Submission/Approval Deadline: | 5:00 p.m. Eastern time February 1, 2005 |
| Peer Review: | March 2005 |
| Programmatic Review: | May 2005 |
| Request for Additional Documents: | As early as 2 weeks after the completion of programmatic review |
| Notification Letter: | Approximately 4 weeks after programmatic review |
| Award Start Date: | Anticipated between July and September 2005 |

K. Electronic Submission Requirements: Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at <https://cdmrp.org/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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time February 1, 2005 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.

- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Concept Award Cost Estimate form. Budget Information must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview:

1. Process: This will be a blinded review process; the PI and institution names will not be provided during the review process.

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

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

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

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (Subsection VI.B). This criteria rating ensures that each component is considered in peer review. The overall proposal is then given a global priority rating. Reviewers are asked to use the criteria ratings as a guide in determining the global priority rating. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

3. Programmatic Review: The second tier is programmatic review. Programmatic review is accomplished by the Integration Panel (IP), which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to maintain a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the ratings from the peer reviewers and the one-page Concept Award proposal.

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

B. Review Criteria:

1. Peer Review: Scientific peer review will focus on the intent of the Concept Award mechanism to encourage the exploration of untested, innovative questions in breast cancer. Only the proposal body and the references will be forwarded for review.

Concept Award proposals will be evaluated according to the criteria listed below:

- **Innovation and Novelty of Concept:** Is the proposed concept innovative? Is the concept in the initial stage of development? Is the concept untested? If successful, will this concept give rise to a testable hypothesis? If successful, does this proposal hold the potential to make a significant impact? Are logical reasoning and a sound scientific rationale the basis for this proposal?
- **Disease Relevance:** Does this study address a problem applicable to breast cancer research? What will be the effect of this study on the concepts or methods that drive this field? To what extent will the project, if successful, lead to an original and important contribution to the prevention, detection, diagnosis, or treatment of breast cancer?

Proposals will be evaluated, prioritized according to rating, and sent forward for programmatic review.

2. Programmatic Review: The one-page Concept Award proposal will be forwarded to programmatic review. The ratings of peer reviewers are primary factors in programmatic review. The IP also considers other criteria to maintain the BCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings of the peer reviewers;
- Programmatic relevance;
- Relative innovation;
- Program portfolio balance; and

- Adherence to the award mechanism.

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

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal. Peer review summary statements will not be provided to the applicants. Applicants can expect to be notified of the agency's decision in May 2005.

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

No changes in the institution will be allowed for Concept Awards.

C. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the 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. In addition, both technical and public abstracts will be requested at this time.

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

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that Army regulations are met.

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

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

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at <https://mrmc.detrick.army.mil/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 <https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc>.

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

4. Research Involving Animal Use: Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: Projects involving human subjects or specimens **will not be supported** through this mechanism unless they are exempt under 32 CFR 219.101(b)(4).⁶ For exempt projects, documents supporting the exempt status of a project will be requested at a later date. These documents shall include local Institutional Review Board approval of the project stating the level of risk and the USAMRMC Office of Research Protections (ORP) (formerly Regulatory Compliance and Quality) Claim of Exemption form. All exempt projects, including those using human cell lines, are subject to ORP review and approval.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at [https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix\(13May04\).doc](https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc).

6. Award/Regulatory Approval: Please note that each award mechanism has specific requirements regarding human subjects and animal use. For Concept Awards, projects involving human subjects or specimens will not be supported unless they are exempt under

⁶Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

32 CFR 219.101(b)(4). Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded.

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

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

- **Research Progress Report Requirements:** All Concept Awards will require the timely delivery of an annual report. Annual reports must present a detailed summary of scientific issues and accomplishments for the previous year.
- **Fiscal Report Requirements:** Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

VIII. OTHER INFORMATION

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

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

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

D. Inquiry Review Panel: Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, the

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.⁷), 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.

IX. ACRONYM LIST

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| AVI | Audio Video Interleave |
| BCRP | Breast Cancer Research Program |
| CA | Concept Award |
| CCR | Central Contractor Registration |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFDA | Catalog of Federal Domestic Assistance |
| DOD | Department of Defense |
| FAR | Federal Acquisition Regulations |
| FY | Fiscal Year |
| HBCU/MI | Historically Black Colleges and Universities/Minority Institutions |
| HSRRB | Human Subjects Research Review Board |
| IP | Integration Panel |
| M | Million |
| MPEG | Moving Picture Experts Group |
| OMB | Office of Management and Budget |
| ORP | Office of Research Protections (formerly Regulatory Compliance and Quality) |
| PDF | Portable Document Format |
| PI | Principal Investigator |
| SOW | Statement of Work |
| USAMRAA | US Army Medical Research Acquisition Activity |
| USAMRMC | US Army Medical Research and Materiel Command |
| USC | United States Code |
| WAV | Wave |

⁷Title 35, United States Code, Section 200 et seq.