CONCEPT AWARDS

A. CONCEPT AWARDS

To support the Congressionally Directed Medical Research Programs' (CDMRP's) mission to develop new and innovative means of expediting research, the Breast Cancer Research Program (BCRP) will be executing a fast-track proposal submission, review, and negotiation process for Concept Awards. 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; thus, no preliminary data are required. These awards are to encourage the exploration of untested, high-risk questions in breast cancer and are not intended to support the next step in an already established research project. The Concept Award should provide investigators that have potentially insightful ideas from disciplines and fields outside breast cancer with an entrée to the breast cancer research field. In addition, research proposals submitted by consumers are encouraged.

Studies outlined in Concept Award proposals should represent a new paradigm in the study of breast cancer, challenge existing paradigms, or look at an existing problem from a new, untested perspective. Proposals must describe how the new concept or theory will enhance existing knowledge of breast cancer, and should include little or no data. 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. Because these awards are designed for preliminary investigations, projects involving human subjects or specimens 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CFR 219.101(b)(4).[1] Studies that do not qualify for exempt status during review at any level will be administratively withdrawn and will not be funded.

Approximately $17M is available to support Concept Awards. Through this Program Announcement, the CDMRP is soliciting electronic submissions for short Concept Award proposals. Concept Awards can be requested for $75,000 for direct costs over a 1-year performance period, plus indirect costs as appropriate. The receipt deadline is March 10, 2003.

Funding of the same research project under different award mechanisms will not be allowed, and all such duplicate projects may be administratively withdrawn. This includes projects under different award mechanisms from different Principal Investigators (PIs). The government reserves the right to reject any proposal.

---

[1] Title 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). For additional information, refer to the document Research Involving Human Subjects and/or Anatomical Substances that will be available on the CDMRP web site at http://cdmrp.army.mil by April 2003.

B. SCIENTIFIC PEER REVIEW EVALUATION CRITERIA FOR CONCEPT AWARD PROPOSALS

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

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

- **Innovation and Novelty of Concept:** Does the proposal address an untested problem in breast cancer research, or look at an existing problem from a new and untested perspective?

- **Disease Relevance:** Does this study address a critical problem in 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, make an original and important contribution to the goal of eradicating breast cancer?

- **Plans for Testing the Concept:** Are the conceptual framework, design, methods, and analyses well integrated to the aims of the project?

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

C. PROGRAMMATIC REVIEW EVALUATION CRITERIA FOR CONCEPT AWARD PROPOSALS

Funding recommendations for this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Concept Award mechanism. The criteria used to make funding recommendations will include: (1) ratings and recommendations of the peer review panels; (2) programmatic relevance; (3) relative innovation; and (4) program portfolio balance with respect to research disciplines or specialty areas.

D. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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

The applicant is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of a number of data fields that must be completed prior to uploading the proposal.

- **Statement of Work (SOW):** The SOW is entered as a separate data field.

- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "File Upload" tab. The body of the Concept Award proposal is limited to **one page**, plus a list of five references, maximum, and because of the "blinded" nature of the two-tier review, should include the Log Number (i.e. BC02XXXX) but **NOT** include the name of the PI or the institution.

- **Budget Information:** The budget information is uploaded as a PDF file under the "File Upload" tab.

- **Proposal Abstract and PI Biographical Sketch:** Not required at the time of proposal submission.

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 must be uploaded as separate PDF files under the Contract Representative "My Profile" tab.

- **Approval:** The Contract Representative must provide approval of all proposal components (Proposal Information, SOW, Proposal, and Budget Information). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern Time) March 10, 2003. Otherwise, the entire proposal will be considered a "LATE" submission and will not be forwarded for review.

2. **Letter of Intent:** Not required for proposal submission.

3. **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 not be provided at either tier of review.

4. **Abstracts:** For the technical abstract and the public abstract please enter "Not applicable for the Concept Award." These entries are captured as separate data fields under the "SOW/Abstract" tab in the CDMRP eReceipt system and are required for final submission of your proposal.

5. Proposal

a. Format: The **Concept Award proposal plus the five references** must be converted into one 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 the 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
- **Acronyms:** Spell out all acronyms the first time they are used
- **Language:** English
- **Print Area:** 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm)

b. Title/Referral Page: Not applicable for proposal submission

c. Table of Contents: Not applicable for proposal submission

d. Main Body: Start section on a new page; one-page limit. No figures, tables, graphs, or photographs 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 preliminary data will not be accepted. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature.

Describe the proposed project using the outline provided below:

i. 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.

ii. Rationale/Purpose: State the rationale for the proposed research.

iii. Objectives: State concisely the project's specific aims and research strategy.

iv. Methods: Discuss the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

e. References: Start section on a new page; Cite relevant literature references (maximum five). 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).

f. Biographical Sketches: Not required at the time of proposal submission.

6. Budget Information: Budget Information includes the one-page Concept Award Cost Estimate Form. Budget Information is uploaded under the "File Upload" tab of the CDMRP eReceipt system.

a. Funding Restrictions: Funding for the Concept Award is $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.

b. 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.

7. Regulatory Compliance and Quality (RCQ) Requirements: Completed and signed copies of the Certificate of Environmental Compliance and the PI Safety Program Assurance Form must be uploaded under the "File Upload" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other RCQ documents (such as Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

8. USAMRAA Documents: A copy 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 applicant's Sponsored Programs Office. These documents must be uploaded as separate PDF files under the Contract Representative "My Profile" tab of the CDMRP eReceipt system.

9. Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's Sponsored Programs Office (or equivalent) by the submission deadline. If your approved proposal is submitted electronically after the deadline, it will not be considered for review.

The Timeline for the Concept Awards is:

Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern Time March 10, 2003**
Request for Additional Documents:	May 2003
Notification Letter:	June 2003
Award Start Date:	By September 30, 2003

---

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

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal; applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the applicant's Sponsored Programs Office must be included.
- Applicants 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.**
- Budget Information must be uploaded under the "File Upload" tab of the CDMRP eReceipt system.
- The RCQ 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.

E. AWARD ADMINISTRATION INFORMATION

1. Award Notices: After the two-tiered evaluation process is completed, every applicant will receive notification of the award status of his or her proposal. Applicants can expect to be notified of the agency's decision in June 2003.

2. 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).

No changes in the institution, the PI, and/or the SOW will be allowed for Concept Awards.

3. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to

negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed SOW and associated budgets may be required.

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

4. Regulatory Compliance and Quality Review (RCQ)

a. Overview: Concurrent with USAMRAA negotiations, RCQ will review the Certificate of Environmental Compliance, and PI Safety Program Assurance form submitted with the proposal, as well as RCQ documents related to research involving animal use and research exempt under 32 CFR 219.101 (b) (4) to ensure that Army regulations are met.

b. Certificate of Environmental Compliance: The Certificate of Environmental Compliance should be submitted with the proposal.

c. Safety Program Documents: The PI Safety Assurance Form should 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 web site at http://mrmc-www.army.mil/crprcqsohdfsplan.asp. If your institution is not listed on the aforementioned web site, 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.

d. 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.

e. Research Involving Human Subjects/Anatomical Substances: Projects involving human subjects or specimens **will not be supported** through this mechanism unless they are exempt under 32 CFR 219.101 (b) (4). 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 (IRB) approval of the project stating the level of risk and the USAMRMC RCQ Claim of Exemption form. It is important to note that the Department of Defense considers cell lines of human origin to be human anatomical substances. All exempt projects, including those using human cell lines are subject to RCQ 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.

5. Reporting: All research awards will require the timely delivery of a final report covering the entire project.

F. OTHER INFORMATION

1. 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.

2. 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 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.

3. 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.

4. 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.

5. 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.