Program Announcement

Department of Defense (DOD) Breast Cancer Research Program (BCRP)

Funding Opportunity Number: W81XWH-06-BCRP-CA

Concept Award

I. FUNDING OPPORTUNITY DESCRIPTION

A. Award Mechanism Description: This award is designed to fund the exploration of a highly innovative new concept. Presentation of preliminary data is not allowed. However, a rationale for the work must be provided. Proposals must describe how the new concept could create an entirely new avenue for investigation and how it is relevant to breast cancer.

Because these awards are designed for preliminary investigations, projects involving human subjects or human biological 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 Studies that do not qualify for exempt status will be administratively withdrawn and will not be funded. For studies using only commercially available unidentified specimens, a Claim of Exemption Form will be requested.

B. Eligibility: All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution. Additional information about individual and institutional eligibility may be found in Appendix 2.

C. Award Funding: Funding for the Concept Award may be requested for a maximum of $75,000 for direct costs over the period of performance. The period of performance can be requested for up to 1 year. Indirect costs should be added, as appropriate. Proposals for projects requiring lower levels of funding also may be submitted. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings.

> **Federal Agency Financial Requirement:** Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

D. Timeline: Please note that proposal submission is a two-step process, requiring both (1) pre-application submission and (2) proposal submission.

- **Pre-application Submission Deadline: January 23, 2007**
- **Proposal Submission Deadline: February 6, 2007**
- **Peer Review: March 2007**
- **Programmatic Review: May 2007**

II. BCRP OVERVIEW

A. Program History and Objectives: The Concept Award is one of the mechanisms of the Breast Cancer Research Program (BCRP). The BCRP was established in fiscal year 1992

(FY92) to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY05 totaled $1.83 billion. During this time, 7,568 Concept Award submissions were received and 817 were funded. The FY06 appropriation is $127.5 million (M) and ***the CDMRP expects to allot about $8M of this appropriation to fund approximately 75 to 80 Concept Awards, depending on the quality and number of proposals received.***

The overall goal of the FY06 BCRP is to promote research focused on eradicating breast cancer. The BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations and alliances. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

III. PRE-APPLICATION PROCESS (Step 1)

The pre-application for the Concept Award mechanism is a Letter of Intent (LOI). The LOI must be submitted electronically through the CDMRP eReceipt System at https://cdmrp.org. Completion of the pre-application process is REQUIRED before proceeding with submission of a Concept Award proposal.

1. Principal Investigators (PIs) submitting to the FY06 BCRP Concept Award mechanism are required to complete the pre-application process through the CDMRP eReceipt System, https://cdmrp.org .

a. Pre-application Submission Date and Time: Pre-application process must be completed on CDMRP eReceipt system by the ***5:00 p.m. Eastern time, January 23, 2007*** deadline. The LOI submission does **not** require **Authorized Organizational Representative (AOR)** approval.

b. Pre-application Components and Submission: This subsection provides a summary of the pre-application submission requirements.

1. **Proposal Information:** Applicants must submit the Proposal Information as described in https://cdmrp.org before uploading the LOI.
2. **Proposal Contacts:** Enter contact information for the Principal Investigator.
3. **Collaborators and Conflicts of Interest (COI):** To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project, including collaborators, consultants, and sub-awardees. Inclusion of BCRP Integration Panel members in any capacity in the proposal, budget, or any supporting document will result in administrative withdrawal of the proposal. A list of the FY06 BCRP Integration Panel members may be found at http://cdmrp.army.mil/bcrp/panel06

4. **Letter of Intent (LOI) Formatting Guidelines and Submission:** The LOI should be a PDF file, in accordance with the formatting guidelines, and uploaded under the "Required Files" tab of the CDMRP eReceipt system. The LOI should be submitted on the institution's letterhead and be signed by the applicant.

   LOI Content: Please state your intent is to submit a Concept Award proposal and provide the title of the proposal

Upon completion of the pre-application process, the applicant may proceed immediately to the grants.gov website to download their application package. Submission of BCRP proposals through grants.gov is a new procedure. Directions are included in Appendix 3.

IV. PROPOSAL INSTRUCTIONS (Step 2)

A. Proposal Forms Summary:

Each submission must include the completed package of forms identified in http://www.grants.gov/ for the BCRP Concept Award program announcement (Funding Opportunity Number: W81XWH-06-BCRP-CA). Following the submission deadline for the required pre-application materials, the PI will receive email instructions on how to download his or her pre-application file from the CDMRP eReceipt system. This file should be attached to form SF424 in Block 20-Pre-application as a part of the proposal submission through grants.gov.

Proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov www.grants.gov. No paper copies will be accepted.

Form	Attachment	Action
SF 424 (R&R) Application for Federal Assistance Form	Pre-application file	Enter the appropriate information in data fields and attach Pre-application file to Block 20
Attachment Form, (Research and Related Other Project Information [R&R OPI] Form)	Project Narrative (1-page maximum)	Attachment 1
	References Cited and Acronyms and Symbol Definitions	Attachment 2
Research &Related Budget Form	Budget Justification	Attach to Section K for one budget period
Research &Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) (if applicable)		Enter the appropriate information in data fields

B. Proposal Components and Submission Summary: This subsection is a summary of the proposal submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement. Proposals will be evaluated according to the peer and programmatic review criteria in Section V.

Proposals recommended for funding will require the submission of additional documents (see Appendix 5)

1. SF 424 (R&R), Application for Federal Assistance Form. The form is self-explanatory, with the following exceptions:

The **Applicant Identifier** box should be filled in with the institution proposal control number. **Block 4 - Federal Identifier** box should be used for the unique CDMRP Proposal Log Number. **Block 20 – Pre-application** file associated with this proposal should be attached here. This pre-application form can be downloaded from the CDMRP eReceipt system.

2. Attachment Form, Research and Related Other Project Information [R&R OPI] Form. The following information must be included as attachments to this form:

> **Attachment 1: Project Narrative (limit 1 page) – The Project Narrative is the main body of the proposal.** Describe the proposed project using the outline provided below. There is no form for this information.

The investigator must clearly explain how the proposed research is innovative and relevant to breast cancer research. ***Preliminary data is not allowed.*** However, applicants must demonstrate logical reasoning and a sound scientific rationale for the proposal to be competitive.

Reviewers will be blinded to the identity of the applicant and the applicant's institution. References to the PI or the institution in the proposal body are prohibited and will result in administrative withdrawal of the proposal. In addition the use of "I," "our," "this institution," or similar phrases that make it possible to identify the applicant and/or institution through the references listed will result in administrative withdrawal of the proposal.

Describe the proposed project using the following outline:

- **Innovation:** Innovation should be the primary feature of the proposed study.
- **Hypothesis/Rationale/Purpose:** State the rationale for the proposed research. Do not include preliminary data.
- **Objectives**: State concisely the specific aims and research strategy of the study. Do not request funding as part of a larger study.
- **Methods:** Describe the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

- **Significance/Relevance**: Provide a brief statement in nontechnical terms regarding the importance of this work to breast cancer.
- **References: Cite relevant literature references using Attachment 2.**

The one-page limit for the project narrative is inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

Attachment 2: Bibliography & References Cited. Two page limit. Upload these two sections as a single PDF file.

- **References Cited:** ***A maximum of five references*** are to be included in this section. List up to five 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). The inclusion of Internet URLs for publications referenced is encouraged.
- **Acronyms and Symbol Definitions:** Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.

The attachments should be PDF files, in accordance with the formatting guidelines.

3. Research & Related Budget Form: An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. All costs must be entered in U.S. dollars. Recipients performing outside of the U.S. should include the cost in local currency, the rate used for converting to U.S. dollars, and justification/basis for the conversion rate used.

Funding for the Concept Award may be requested for a maximum of $75,000 for direct costs over the period of performance. The period of performance can be requested for up to 1 year. Indirect costs should be added, as appropriate. Proposals for projects requiring lower levels of funding also may be submitted. Direct costs can include (but are not limited to) any project-related expenses such as salaries, travel, support for multidisciplinary collaborations, seminars, conferences, workshops, training, tuition, equipment, and supplies.

Maximum Obligation: The USAMRMC support of this project shall not exceed the amount specified in the assistance agreement or as amended. The USAMRMC does not amend grants to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

Costs proposed in the **SF 424 (R&R)** must conform to the regulations and principles in Appendix 4.

Section A & B – Senior/Key Person: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-

of-living increases that will occur during the period of performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K).

Section C – Equipment Description: It is DOD policy that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 2 years and an acquisition cost of $5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification (Section K) to include:

(1) Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.

(2) Historical Cost: Identify vendor, date of purchase and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.

(3) Estimate: Include rationale for estimate and reasons for not soliciting current quotes.

(4) Special test equipment to be fabricated by the contractor for specific research purposes and its cost.

(5) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.

(6) Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.

(7) Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of research. Normally, the title will vest in the recipient if vesting will facilitate research performed by the institution or organization for the Government.

(8) Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

Section D – Travel: Costs for travel include:

- **Travel costs to attend one scientific/technical meeting.** Costs should not exceed $1,800.
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $1,800 limitation on travel to meetings. Justification for these

travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity and the MRMC Deputy Chief of Staff for Operations, Overseas Force Protection Office.

- **Travel costs to attend CDMRP-required meetings.** The CDMRP requires attendance at the 3½-day DOD Era of Hope meeting, which is held every 2 to 3 years to disseminate the results of DOD-sponsored research. The next Era of Hope meeting is anticipated to be held in June 2008. Travel funds for these meetings should not exceed $1,800 per meeting. If the award has expired before the meeting is held, funding will be made available for PIs to participate in the meeting.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F – Other Direct Costs

Section F.1 – Materials and Supplies (Consumables): The justification (to be included in Section K) for supporting materials and supplies (consumable) costs should include a general description of expendable equipment and supplies. 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.

Section F.2 – Publication Costs: This section is self-explanatory.

Section F.3 – Consultant Services: Regardless of whether funds are requested, the justification (to be included in Section K) should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

Section F.4 – ADP/Computer Services: This section is self-explanatory.

Section F.5 – Subaward/Consortium/Contractual Costs: Enter the total funds requested for (1) all subaward/consortium organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

Section F.6 – Equipment or Facility Rental/User Fees: This section is self-explanatory.

Section F.7 – Alterations and Renovations: Not allowable.

Section F.8 – F.10 – Research-Related Subject Costs: Not allowable.

Section F.8 – F.10 – Other Direct Cost: Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified in Section K.

Section G – Direct Costs: This section is self-explanatory.

Section 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, along with a statement identifying whether the proposed rates are provisional or fixed. If negotiated forecast rates do not exist, provide sufficient detail in the budget justification (Section K) regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions. Commercial firms can also visit http://www.dcaa.mil/for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established.

As a minimum, justification for indirect costs should identify:

a. All individual cost elements included in the forecast rate(s);
b. The basis used to prorate indirect expenses to cost pools, if any;
c. How the rate(s) was calculated; and
d. The distribution basis of the developed rate(s).

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

Section J – Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a profit/fee is negotiated, a contract will be awarded. Any fixed fee applied to the research project must be listed and any claimed Facilities Capital Cost of Money supported by **DD Form 1861** (http://www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html) submitted with the proposal.

Section K – Budget Justification: The Budget Justification must be included as an attachment at Section K for each research period. The attachment should be in PDF, in accordance with the formatting guidelines. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. Attach one file that addresses each of the cost elements proposed.

4. Research & Related Project/Performance Site Location(s) Form: Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address of each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form.

5. R&R Subaward Budget Attachment(s) Form: On this form, attach all subaward budget file(s) for this application.

Complete the subawardee budget(s) using the Research & Related Subaward Budget in accordance with the instructions. Please note that the files to be attached to the Research & Related Subaward Budget Attachment(s) Form must be PureEdge documents (instructions on installing PureEdge Viewer, a free software program, can be found in Grants.gov).

The Budget Justification for each subaward must be included as an attachment at Section K of the Research & Related Budget Form for each subaward budget. A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. The following information must be provided on subawards totaling $10,000 or more:

a. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);

b. 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;

c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;

d. The proposed acquisition price; and

e. The PI's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

C. Formatting Guidelines: The proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Proposals may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, PIs 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. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Providing URLs for publications referenced in the proposal is encouraged.

- **Language:** English.
- **Headers and Footers:** Should not be used.
- **Page Numbering:** Should not be used.

D. 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. ***Failure to adhere 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.***

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- Pre-application process is not completed by January 23, 2007.
- Preliminary data is included in the proposal.
- All attached files are not in specified format.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget justification is missing.
- Applicant and/or institution names are included in the proposal body.
- Use of "I," "Our," "this institution," or similar phrases that make it possible to identify the applicant and/or institution through the references listed.
- Inclusion of BCRP Integration Panel members in any capacity in the proposal, budget, or any supporting document. A list of the FY06 BCRP Integration Panel members may be found at http://cdmrp.army.mil/bcrp/panel06

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

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

V. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: Concept Award proposals are evaluated using a two-tier review process. The first tier is peer review of proposals against established criteria for determining scientific/technical merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit and overall goals of the program.

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

1. Peer Review: The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the merit and relevance of proposals based on the review criteria published for each award mechanism. Peer review panels consist of both technical and consumer reviewers. Scientific/technical reviewers are selected for their subject matter expertise and experience. 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 process by bringing the patient perspective to the assessment and the relevance of the research. The summary statement is a product of peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement. The peer review summary statement is forwarded to the Integration Panel for use during programmatic review; applicants will not receive a copy of the peer review summary statement.

2. Programmatic Review: Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. A function of programmatic review is to structure a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. *Integration Panel members base their decisions on the one-page Concept Award proposal and the peer review evaluations.*

B. Review Criteria

1. Peer Review: Concept Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- **Innovation (Innovation is the most important review criteria):**
  - How the proposed concept is innovative.
  - Whether the concept is untested (no preliminary data allowed).
- **Relevance:**
  - How the study is relevant to breast cancer.
- **Research Strategy:**
  - Whether the research strategy is appropriate to answer the question.

2. Programmatic Review: The Integration Panel also uses the one-page Concept Award proposal body during programmatic review. Other criteria used by the Integration Panel to make funding recommendations that maintain the BCRP's broad portfolio include:

- Relative innovation,
- Ratings and evaluations of the scientific and consumer reviewers,
- Programmatic relevance,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Technically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be selected by the Integration Panel and recommended for funding to the Commanding General, USAMRMC.

VI. APPENDICES

APPENDIX 1

CONTACT INFORMATION

Funding Opportunity Number: W81XWH-06-BCRP-CA.

A. 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.

B. Agency Contact(s)

1. Questions related to the program announcement, proposal format, or required documentation: Principal Investigators (PIs) and Authorized Organizational Representatives 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
Email: cdmrp.pa@amedd.army.mil

2. Questions related to the Letter of Intent Submission: A help line for questions relating to the electronic submission of the Letter of Intent is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by email as follows:

Website: https://cdmrp.org
Email: help@cdmrp.org

3. Questions related to electronic submission through the Grants.gov portal: Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov. The Contact Center hours of operation are Monday through Friday, 7 a.m. to 9 p.m. Eastern Time.

C. 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
Email: qa.baa@amedd.army.mil

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

APPENDIX 2

ELIGIBILITY INFORMATION

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov/. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] 25.110.)

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

Eligible Institutions: The USAMRMC makes awards to institutions. Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies.

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI): A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.[1] Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions." The USAMRMC is especially interested in receiving applications from HBCU/MI.

Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

[1]Executive Orders 12876, 12900, and 13021

APPENDIX 3

GRANTS.GOV INSTRUCTIONS

A. PUBLIC LAW 106-107

The Federal Financial Assistance Management Improvement Act of 1999, also known as Public Law 106-107 (P.L. 106-107), was enacted in November 1999. The purposes of the Act are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

B. GRANTS.GOV

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between Principal Investigators and the Federal agencies that manage grant funds. The grant community, including state, local and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

In compliance with P.L. 106-107, the USAMRMC requires proposals submitted in response to this program announcement to be submitted through Grants.gov. This requires that Organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual Principal Investigators/Project Directors DO NOT register; however, the Authorized Organizational Representative is required to register. The registration process can take several weeks, so please register as soon as possible.

The following actions are required as part of the registration process. If you do business with the Federal government on a continuing basis, it is likely you have already completed some of the actions, e.g., obtaining a DUNS number or registration in CCR. Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp

DUNS Number

An organization will need a Data Universal Number System (DUNS) Number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (D&B). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 1-866-705-5711 or online via web registration. Organizations located outside of the United States can request and register for a DUNS number online via web registration.

Central Contractor Registry (CCR)

An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates Principal Investigator information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer.

You can register by calling the CCR Assistance Center at 1-888-227-2423 or register online at http://www.ccr.gov/. If you have the necessary information, online registration will take about 30 minutes to complete, depending upon the size and complexity of your organization.

Authorized Organizational Representative (AOR)

Before submitting a proposal, an organization representative needs to register to submit on behalf of the organization at grants.gov - https://apply.grants.gov/OrcRegister . An organization's E-Business point of contact (POC), identified during CCR Registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals without permission. **Note: In some organizations, a person may serve as both an E-Business POC and an AOR.**

An AOR must first register with the Grants.gov credential provider at https://apply.grants.gov/OrcRegister and then with Grants.gov. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

APPENDIX 4

PROPOSED COSTS 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: OMB Circular A-21, Cost Principles for Educational Institutions.

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.

State, Local and Tribal Governments: OMB Circular A-87, Cost Principles for State, Local and Indian Tribal Governments.

Cost of Preparing Proposals: The cost of preparing proposals in response to this program announcement is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18 and OMB Circulars A-21 and A-122.

APPENDIX 5

AWARD ADMINISTRATION INFORMATION

During award negotiations, the following items will be requested from the PI:

- Statement of Work,
- Public Abstract,
- Technical Abstract,
- PI's Biographical Sketch,
- Current/Pending Support,
- Key Personnel's Biographical Sketches,
- Certificate of Environmental Compliance, and
- Principal Investigator Safety Program Assurance

Also during award negotiations, the following items will be requested from the Authorized Organizational Representative:

- Negotiated Indirect Rate Agreement
- Certifications and Assurances for Assistance Agreements, and
- Representations for Assistance Agreements

Concurrent with the US Army Medical Research Acquisition Activity (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 during negotiations. 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 Department of Defense (DOD) regulations are met.

A. Statement of Work – 11,400-character limit including spaces (approximately two pages): The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include DOD-funded tasks only. Sample SOWs can be found at https://cdmrp.org/samples.cfm.

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 performance for the proposed effort;

    - Allow 2 to 4 months for regulatory review and approval processes for animal studies;
- For animal and human studies (including tissue, anatomical, or biological substances), indicate the sample size projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

B. Proposal Abstracts – 5,700-character limit including spaces (approximately one page), for each abstract: Each abstract must include the applicant's name and the title of the proposal. A structured technical abstract and a public (nontechnical) abstract are required. ***Spell out all Greek letters, other non-English letters, and symbols.*** Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included in either the technical or the public abstract.

1. Technical Abstract: Sample technical abstracts can be found at https://cdmrp.org/samples.cfm. The structured technical abstract must provide a clear and concise overview of the proposed work. Use the outline below when preparing the structured technical abstract.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis/Rationale: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Innovation/Relevance: Provide a brief statement explaining the innovation and relevance of the proposed work to the program goals. Describe how the proposed project will have a potential impact on breast cancer research or patient care.

2. Public Abstract: Sample public abstracts can be found at https://cdmrp.org/samples.cfm. The public abstract is intended to communicate the purpose and rationale of the study to a non-scientifically trained audience.

- Describe the innovative aspects of the proposed work.
    - Clearly explain why the objective, methods, research design, and/or implementation of the proposal is innovative.
- Describe the scientific objective and rationale for the proposal in a manner readily understood by non-scientists.
    - Do not duplicate the technical abstract.
- Describe the relevance of the research to breast cancer
    - What types of contributions might this study make to advance breast cancer research or patient care?

C. PI's Biographical Sketch: Four-page limit per individual. The suggested format will be provided at award negotiations.

D. Current/Pending Support: Proposals submitted under this program announcement should not duplicate other funded research projects. For all existing and pending research projects involving the PI and key personnel, include the title, time commitments, supporting agency, the name and address of the Procuring Contracting/Grants Officer, period of performance, and level of funding, *a brief description of the project's goals, and a list of the specific aims*. Provide justification for the requested support and interest where the projects overlap or parallel. If no current support exists, enter "None." These data will be required to be updated during award negotiations.

E. Key Personnel's Biographical Sketches: Four-page limit per individual. The suggested format will be provided at award negotiations.

F. Certificate of Environmental Compliance: The Certificate of Environmental Compliance will be requested at award negotiations. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

G. Safety Program Documents: The Principal Investigator Safety Program Assurance form will be requested at award negotiations.

A Facility Safety Plan is required; it will be requested at award negotiations. A Facility Safety Plan from the Principal Investigator's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. If the Principal Investigator's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

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

H. Award Notices: Each Principal Investigator will receive notification of the award status of his or her proposal. A copy of the peer review summary statement *will not* be posted to the Congressionally Directed Medical Research Programs (CDMRP) eReceipt system. Principal Investigators can expect to receive this notification approximately four weeks after programmatic review.

I. Administrative Requirements: Awards are made to organizations, not individuals. The Principal Investigator must 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. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (DOD Grant and Agreement Regulations) to be eligible for an award. Any organization requesting receipt of an award through this program 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.

For Concept Awards, no changes in the PI will be allowed once the proposal has been submitted. No changes in the institution will be allowed after the award is made.

J. Award Negotiation: Award negotiation consists of discussions, reviews, and justifications of critical issues involving the US Army Medical Research Acquisition Activity (USAMRAA). A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the Principal Investigator's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

The award start date will be determined during the negotiation process.

K. Disclosure of Proprietary Information outside the Government: By submitting a proposal, the Principal Investigator understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The US Army Medical Research and Materiel Command (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 are not subject to public release.

L. Government Obligation: Principal Investigators 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. Principal Investigators 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.

M. Information Service: Principal Investigators 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. All other sources also should be consulted to the extent practical for the same purpose.

N. Inquiry Review Panel: Principal Investigators may 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.

O. Title to Inventions and Patents: In accordance with the Bayh-Dole Act (35 USC 200 et seq.), 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.

P. 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.

APPENDIX 6

ANIMAL AND HUMAN USE REQUIREMENTS

The Principal Investigator may not use, employ, or subcontract for the use of any human subjects, human biological substances, cadavers, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the US Army Medical Research and Materiel Command (USAMRMC).

1. Research Involving Animal Use: Specific documents relating to the use of animals in the proposed research will be requested by the Congressionally Directed Medical Research Programs (CDMRP) if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. Principal Investigators must complete and submit the animal use appendix titled "Research Involving Animals," which can be found on the ACURO website https://mrmc-www.army.mil/rodorpaurd.asp). Allow 2 to 4 months for regulatory review and approval processes for animal studies.

Specific requirements for research involving animals can be found at https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

2. Research Involving Human Subjects/Biological Substances/Cadavers:
Because these awards are designed for preliminary investigations, projects involving human subjects or human biological 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. For studies using only commercially available unidentified specimens, a Claim of Exemption Form will be requested.

3. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells:
Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g-2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

APPENDIX 7

REPORTING REQUIREMENTS

The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full US Army Medical Research and Materiel Command reporting requirements can be found at https://mrmc-www.army.mil, under "Links and Resources.") ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

1. Research Progress Reports: Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of 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. Copies of all publications and patent applications resulting from Congressionally Directed Medical Research Programs funding should be included in the progress report.

2. Fiscal Reports: 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.

3. Non-Exempt Human Studies Reports: For non-exempt human subjects research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB but at least annually) and approval for continuation must be submitted directly to Office of Research Protections – Human Research Protection Office.

4. Animal Use Reports: Principal Investigators are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

APPENDIX 8

ACRONYM LIST

ACURO	Animal Care and Use Office
AOR	Authorized Organizational Representative
AVI	Audio Video Interleave
BCRP	Breast Cancer Research Program
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
CFR	Code of Federal Regulations
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Number System
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
hES	Human Embryonic Stem
HRPO	Human Research Protection Office
IRB	Institutional Review Board
JPEG	Joint Photographers Expert Group
M	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
NIH	National Institutes of Health
OMB	Office of Management and Budget
PDF	Portable Document Format
PI	Principal Investigator
P.L.	Public Law
POC	Point of Contact
R&R	Research & Related
TIFF	Tagged Image File Format
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio