Program Announcement

Breast Cancer Research Program

Innovator Award

I. GENERAL INFORMATION

A. Title of Award: ***Breast Cancer Research Program (BCRP) Innovator Award.***

B. Program Name: Department of Defense (DOD) BCRP.

C. Funding Opportunity Number: W81XWH-06-BCRP-INNOV.

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

E. Agency Contact(s)

1. Questions related to the program 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 electronic nomination: A help line for questions relating to the electronic nomination 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 of the invited full proposal 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.

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
Email: qa.baa@amedd.army.mil

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

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Innovator Award is one of the mechanisms of the Breast Cancer Research Program (BCRP), which 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 $1.68 billion. During this time, 144 Innovator Award submissions were received and 12 were funded. The FY06 appropriation is $127.5 million (M) and ***the CDMRP expects to allot about $22M of this appropriation to fund approximately three Innovator Awards, depending on the quality and number of proposals received.***

B. Program Objectives: The overall goal of the FY06 BCRP is to promote research focused on eradicating breast cancer. Therefore, the BCRP challenges the 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. Underinvestigated avenues of research and novel applications of existing technologies are strongly encouraged. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

The BCRP's objective within this context is to fund a balanced portfolio of meritorious research related to all aspects of breast cancer. The BCRP seeks proposals from 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; ethics; and economics. Proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are strongly encouraged.

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

Innovator Award Nominees may be from diverse organizations including, but not limited to, professional schools, advocacy groups, government agencies, the private sector, the media, and/or professional societies. Since the intent of the Innovator Award mechanism is to recognize creative and innovative *individuals* rather than projects, the central feature of the award is the innovative contribution that the recipient can make to the eradication of breast cancer. As such, a Nominee selected to submit a full proposal is required to submit an essay addressing several areas including his or her area(s) of focus and how he or she will use the award to pursue his or her most creative vision in breast cancer research. The primary criteria for making these awards will be the Nominee's past record of creativity, the promise for continued innovation in future work, and an indication of how this award will create and further innovate strategies to solve the breast cancer problem. ***Experience in breast cancer research is allowed, but not required***; however, the proposal must center on breast cancer and it is expected that the Nominee will

commit a minimum of 50% of his or her full-time professional effort to breast cancer research during the tenure of this award.

Individuals must be nominated to be considered for this award mechanism; self-nominations will be accepted. Full proposals will be rejected if the Nominee has not received an invitation to submit a full proposal.

D. Award Funding: Funding for the Innovator Award may be requested for a maximum of $5M for direct costs over the performance period. The performance period requested can be up to 5 years. Indirect costs should be added, as appropriate. Proposals for projects requiring lower levels of funding may also be submitted. No more than $5M in total costs (direct and indirect) will be granted in any single year during the lifetime of the award. Funds can cover salaries, travel, support for multidisciplinary collaborations, workshops, training, tuition, equipment, and supplies. The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants.

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.

III. ELIGIBILITY INFORMATION

A. Nominee: 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.

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.)

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies.

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.

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI). This provision is based on guidance from Executive Orders.[1] Proposals are assigned HBCU/MI status when the

[1]Executive Orders 12876, 12900, and 13021

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.

IV. NOMINATION SUBMISSION INFORMATION

Nominations must be submitted electronically through the CDMRP eReceipt System at https://cdmrp.org.

Individuals must be nominated to be considered for the Innovator Award; self-nominations will be accepted. Nominations will be screened by the BCRP Integration Panel to identify those individuals who best fulfill the intent of the award mechanism. Invitations to submit a full Innovator Award proposal will be sent to those individuals selected by the Integration Panel no later than January 2007. ***Do not submit a full Innovator Award proposal unless you receive a letter of invitation.***

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

1. Nominator Responsibility: The nominator is responsible for entering the following information into the CDMRP eReceipt System at https://cdmrp.org:

- Nominee Identification
- Nomination
- List of individuals to provide confidential letters of recommendation should a full proposal be requested

2. Authorized Organizational Representative: The Innovator Award nomination does not require Authorized Organizational Representative approval before submission.

B. Nomination Process: Nominations must be initiated by clicking on the award nomination link on the home page of the CDMRP eReceipt System at https://cdmrp.org. Once the nomination has been verified and submitted, there will be no opportunity for modification. A confirmation of submission will be sent by email to the nominator after the Submit Nomination button is selected.

1. Nominee Identification: The nominator must complete ***all*** the Nomination Information in the appropriate data fields.

2. Nomination: The nominator should type the nomination into this data field. The nominator should provide a one- to two-page (maximum of 11,400 characters, including

spaces) description of the Nominee's unique qualifications and accomplishments that demonstrates how this Nominee is among the best and brightest in his or her field.

The nomination should address the Nominee's:

- Unique qualifications that stress creativity in past work,
- Likelihood of continued innovation, and
- Potential for creativity in future work, specifically related to progress against breast cancer.

If the Nominee is invited to submit a full proposal, the nomination content will be provided to the PI.

3. List of Individuals to Provide Confidential Letters of Recommendation: In the designated field, the nominator must provide the names, position titles, addresses, phone numbers, and email addresses of three individuals who support the qualifications of the nominee for this award and are willing to provide confidential letters of recommendation should a full proposal be requested.

C. Submission Date and Time: Nominations must be received on the CDMRP eReceipt System by ***5:00 p.m. Eastern time, November 7, 2006*** deadline. Nominations that are incomplete will ***not*** be considered for review.

D. Nomination Review: The Innovator Award nominations are reviewed by the BCRP 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. Candidates whose qualifications meet the intent of this award mechanism will be invited by the Integration Panel to submit Innovator Award full proposals.

Selection will be based on the Nominee's unique qualifications that stress creativity in past work, likelihood of continued innovation, and potential for creativity in future work, specifically related to progress against breast cancer.

V. INVITED FULL PROPOSAL COMPONENTS SUMMARY

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

A. Full Proposal Components Summary: ***Do not submit an Innovator Award proposal unless you have received a full proposal invitation. Full proposals will be rejected if you have not received a full proposal invitation.***

This subsection is a summary of the full 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 VIII.

Form	Attachment	Action
SF 424 (R&R) Application for Federal Assistance Form		Enter the appropriate information in data fields
Research & Related Other Project Information Form	Project Summary/Abstract	Attach to Block 6
	Project Narrative (5-page maximum)	Attach to Block 7
	References Cited and Acronyms and Symbol Definitions	Attach to Block 8
	Facilities & Other Resources	Attach to Block 9
	Description of existing equipment	Attach to Block 10
	Letters of Institutional Support	Attach to Block 11
	Letters of Collaborations (if applicable)	Attach to Block 11
Research & Related Senior/Key Person Profile (Expanded) Form	PI's Curriculum Vitae	Attach to PI Biographical Sketch field
	PI Current/Pending Support	Attach to PI Current & Pending Support field
	Key Personnel's Biographical Sketches (4-page limit each)	Attach to Biographical Sketch field for each senior/key person
	Key Personnel's Current/Pending Support	Attach to Current & Pending Support field for each senior/key person
Research & Related Budget Form	Budget Justification	Attach to Section K for each budget period
R&R Subaward Budget Attachment(s) (if applicable)		Enter the appropriate information in data fields
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
Confidential Letters of Recommendation*		Not submitted by PI; letters to be uploaded by signatory

*These letters will be requested by the CDMRP eReceipt system from the three individuals named by the nominator as willing to support the qualifications of the PI. Each individual submitting a confidential letter of recommendation will receive specific instructions on how to upload the letter. The PI will only be able to view the names of the individuals invited to submit letters of recommendation and whether the letters have been received; the PI will not be able to view these letters. All letters must be submitted prior to the full proposal submission deadline.

During award negotiations, the Statement of Work, Certificate of Environmental Compliance, and Principal Investigator Safety Program Assurance will be requested from the PI, and the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the Authorized Organizational Representative.

VI. INVITED FULL PROPOSAL INSTRUCTIONS

Each submission must include the completed package of forms identified in www.grants.gov. The package includes:

- SF 424 (R&R) Application for Federal Assistance Form,
- Research & Related Other Project Information Form,
- Research & Related Senior/Key Person Profile (Expanded) Form,
- Research & Related Budget Form,
- R&R Subaward Budget Attachment(s) Form, if applicable, and
- Research & Related Project/Performance Site Location(s) Form.

NOTE: All attachments that require signatures must be filled out, printed, signed, and scanned prior to being uploaded. Each attachment should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.

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 unique CDMRP Proposal Log Number, provided in the full proposal invitation letter. The **Block 4 - Federal Identifier** box should be used to identify the Funding Opportunity number, which is: W81XWH-06-BCRP-INNOV.

2. Research & Related Other Project Information Form: The following information must be included as attachments to this form:

Blocks 1 - 5: This section is self-explanatory in addressing the use of human subjects, the use of animals, proprietary information, and environmental impact of the research.

Block 6: Project Summary/Abstract. Technical and public abstracts (not to exceed one page per abstract) should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.

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.

- **Technical Abstract:** Use the outline below when preparing the technical abstract.
  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: 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.

- Impact: Provide a brief statement explaining the impact of the proposed work to the eradication of breast cancer.

- **Public Abstract:** Describe the scientific objective and rationale for the proposal in a manner readily understood by a non-scientifically trained audience.

Block 7: Project Narrative (limit 5 pages) – The Project Narrative is the main body of the invited full proposal. The content of the project narrative should state clearly ***why you, the PI, should be selected for this unique award*** and should address the following questions specifically from your perspective:

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

The five-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. There is no form for this information. The attachment should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.

Block 8 – Bibliography & References Cited. No page limit.

- **References Cited:** 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). The inclusion of Internet URLs to references is encouraged.

- **Acronyms and Symbol Definitions:** Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols**.**

In Block 8, upload the two sections (References Cited and Acronyms and Symbol Definitions) as a single PDF file in accordance with the formatting guidelines specified for full proposal preparation.

Block 9 – Facilities & Other Resources. No page limit. Describe the facilities available for performance of the proposed research project and any additional facilities or equipment proposed for acquisition at no cost to the USAMRMC. Indicate if a Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information. The attachment should be in PDF, in accordance with the formatting guidelines outlined for full proposal preparation.

Block 10 – Equipment: Include a description of existing equipment to be used for the proposed research project. There is no form for this information. The attachment should be in PDF, in accordance with the formatting guidelines outlined for full proposal preparation.

Block 11 – Other Attachments. Submit the attachments listed below. There is no form for this information. These attachments should be in PDF, in accordance with the formatting guidelines outlined for full proposal preparation.

- **Attachment 1: Letters of Institutional Support:** Provide signed letter(s) of institutional support that reflect the extent to which the PI will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals pertinent to this award.
- **Attachment 2: Letters from Collaborators:** Provide a signed letter from each collaborating individual or institution (if applicable).

Submit only material that is specifically requested in this program announcement. Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal. ***This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.***

3. Research & Related Senior/Key Person Profile (Expanded) Form: Include the requested information for each senior/key person proposed on the project. The attachments should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation.

a. PI's Curriculum Vitae: No page limit. The PI should submit his or her complete curriculum vitae including employment, experience, honors, and a list of achievements that includes publications and patents. Indicate up to three publications you consider most significant to the proposed work.

b. Senior/Key Person Biographical Sketch: Four-page limit per individual. Suggested format is provided in Attachment 1.

c. Current/Pending Support: Proposals submitted under this program announcement should not duplicate other funded research projects. For all current and pending research projects involving the PI and senior/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." The attachments should be in PDF, in accordance with the formatting guidelines specified for full proposal preparation. These data will be required to be updated during award negotiations.

4. Research & Related Budget Form: An estimate of the total research project cost, with a breakdown by category and year, must accompany each full 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 an Innovator Award may be requested for a maximum of $5M for direct costs over the performance period. The performance period may be requested for up to 5 years. Indirect costs should be added as appropriate. No more than $5M in total costs (direct and indirect) will be granted in any single year during the lifetime of the award. 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.

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: 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.

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).

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 Research & Related Budget Form, list the percentage of each appointment to be spent on this project.

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 per year.** 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.
- **Travel costs to attend CDMRP-required meetings.** All PIs are required to attend one meeting with the CDMRP per year of the proposed project. 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 October 2007. In years when the Era of Hope meeting is not held, the PI is required to attend a CDMRP research forum meeting. Travel funds for these meetings should not exceed $1,800 per 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 – 10) – Research-Related Subject Costs: Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

Section F (8 – 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 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** (www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html) submitted with the full 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 specified for full proposal preparation. 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.

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

If the resultant award is a contract that exceeds $500,000 and the offeror is a large business or an educational institution (other than HBCU/MI), the contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

6. 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.

VII. PROPOSAL FORMAT AND COMPLIANCE GUIDELINES

A. Proposal Format: 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, highresolution, 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.

B. 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:

- All attached files are not in PDF.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Required supporting documentation is missing including:
  - Letter(s) of institutional support
  - Confidential letters of recommendation
- Budget justification is missing.
- Project Narrative is incomplete after the deadline.
- Inclusion of BCRP Integration Panel members in any capacity in the nomination process, or in the invited full 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.

VIII. FULL PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: Innovator 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.

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.

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 an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

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. ***The Innovator Award full proposal and supporting documentation are available to the Integration Panel.***

B. Review Criteria

1. Peer Review: The proposal and all required supporting documentation are used during peer review. Because of the unique nature of this award, the review process is focused less on the proposed project, although that is a consideration. Instead, reviewers attempt to identify those characteristics and accomplishments that set the PI apart from his or her peers. The reviewers will evaluate:

- **Principal Investigator**
  - How the application reflects creativity and innovative thinking and supports the likelihood that the PI could have a significant impact on breast cancer.
  - How the PI's record of accomplishment demonstrates outstanding ability as an independent and visionary scholar/investigator.
  - Whether the PI indicates that he or she will commit at least 50% effort to breast cancer during the tenure of this award.
- **Relevance and Impact**
  - How the PI's vision for the tenure of the award addresses an important problem(s) in breast cancer.
  - How the work has potential to significantly impact breast cancer.
- **Vision and Ideas**
  - Whether the PI communicates a clear vision of what he or she hopes to accomplish during the tenure of the award.
  - How the PI's ideas reflect original and innovative thinking.
  - Whether PI presents a clear and compelling argument for how this award will be used to pursue creative (potentially groundbreaking) work in breast cancer.
- **Budget**
  - Whether the budget is appropriate for the proposed project.

2. Programmatic Review: The Integration Panel will use the peer review summary statement, Innovator Award proposal, and supporting documentation. Criteria used by the Integration Panel to make funding recommendations that maintain the BCRP's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative innovation and impact,
- 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.

IX. APPENDICES

APPENDIX 1

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 2

AWARD ADMINISTRATION INFORMATION

A. 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 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.

B. 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 (OMB Circular A-110 and 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.

A change in Principal Investigator is not allowed for the Innovator Award mechanism. A change in institutional affiliation will require the investigator to resubmit the entire proposal packet through his or her new institution to include any regulatory documentation that may require protocols, etc. to be approved for the new institution. The investigator's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting, regulatory review, and a subsequent delay in resuming work on the project.

C. 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.

D. 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.

E. 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.

F. 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.

G. 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.

H. 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.

I. 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.

[2] Title 35, United States Code, Sections 200 et seq.

APPENDIX 3

REGULATORY REQUIREMENTS AND REVIEWS

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).

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 to be submitted upon request. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use also to be submitted upon request to ensure that Department of Defense (DOD) regulations are met.

1. 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.

2. 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.

3. 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 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.

4. Research Involving Human Subjects/Biological Substances/Cadavers: Documents related to the use of human subjects or substances or cadavers will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the proposal). In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or human biological substances or cadavers, a second tier of human subjects regulatory review and approval is also required by the DOD. This second review is conducted by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. Allow 4 to 6 months for regulatory review and approval processes for human use studies.

a. Requirements: Specific requirements for research involving human subjects, human biological substances, and/or cadavers can be found at https://mrmc.amedd.army.mil/rodorptoolkit.asp.

Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming that this instruction has been completed will be required during the regulatory review process.

It is expected that there will be timely resolutions of human subjects protocols submitted to the investigator's local IRB.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.detrick.army.mil/rodorphrpo.asp.

b. Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

c. Intent to Benefit: Investigators must consider the requirements of Title 10 United States Code Section 980 (10 USC 980) applicable to DOD-sponsored research before writing a research protocol. Title 10 United States Code Section 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

d. 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.

e. Clinical Trial Registry: All Principal Investigators are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: CDMRP-CDMRP Log Number-A, B, C, etc. ***Clinical trials must be registered prior to enrollment of the first patient.*** All trials that meet the definition on the NIH database (see http://prsinfo.clinicaltrials.gov/, click on "Data Element Definitions," see section 6, "Study Phase" and "Study Type") including all Phase I-IV clinical trials and trials that do not fit into one or more phases, but that are clearly interventional or observational (e.g., some epidemiological or behavioral studies) are required to register.

APPENDIX 4

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 5

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
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

X. ATTACHMENT

BIOGRAPHICAL SKETCH

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order, the titles, all authors and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY.
DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.