Program Announcement
Fiscal Year 2006 (FY06)
Department of Defense (DOD)
Breast Cancer Research Program (BCRP)

Synergistic Idea Award

I. GENERAL INFORMATION

A. Program Name: Department of Defense (DOD) Breast Cancer Research Program (BCRP).

B. Funding Opportunity Number: W81XWH-06-BCRP –SIA2

C. Agency Name: USAMRMC, Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.

D. Agency Contact(s)

1. Questions Related to the Program Announcement, Proposal Format, or Required Documentation: Principal Investigators (PIs) and Authorized Organizational Representatives (AORs) 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 Pre-application Submissions: A help line for questions relating to the electronic submission of letters 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 of a 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.

E. 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

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

G. Timeline

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

- **Pre-application Submission Deadline: January 23, 2007**
- **Proposal Submission Deadline: February 13, 2007**
- **Peer Review: March 2007**
- **Programmatic Review: May 2007**

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Synergistic Idea Award is one of the mechanisms of the 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. The Synergistic Idea Award was first offered in FY06. The FY06 appropriation is $127.5 million (M) and ***the CDMRP expects to allot about $10M of this appropriation to fund approximately 13 to 15 Synergistic Idea 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. 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.

C. Award Description: The Synergistic Idea Award supports ***collaborations*** between two independent, faculty-level (or equivalent) investigators who address an ***innovative, high-risk, potentially high-reward breast cancer research question*** from synergistic and complementary perspectives.

The Synergistic Idea Award is designed to promote new ideas and new collaborations therefore proposals are not required to include preliminary data but a rationale for the work must be provided. Proposals should have a high probability of revealing new avenues of investigation, if successful. The Synergistic Idea Award requires the submission of a single proposal that addresses a critical issue in breast cancer research. The proposal may be structured as either two separate but complementary and highly synergistic objectives, or as a balanced, synergistic collaboration integrated into a single project. ***Proposals must clearly define the synergistic components*** that will enable or greatly accelerate the evaluation of a single innovative hypothesis. The BCRP seeks proposals from all areas of laboratory, preclinical, behavioral, and epidemiological research. Multi-institutional and/or multidisciplinary proposals

are encouraged but not required. Collaborators not from distinct disciplines must clearly explain why the proposed research is synergistic. Major disciplines include, but are not limited to: biological sciences (including both basic and clinical sciences); chemical sciences; social and behavioral sciences; engineering, physical, and mathematical sciences; and public health research.

1. Innovation: ***Innovation is the most significant feature of this award.*** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.
Examples of research that is ***not*** innovative and will not be considered for funding under this award mechanism include:

- Investigating the next logical step as an extension of previous work or incremental advancement of published data.
- Exploring a hypothesis in a different cell line or in a new population.
- Using a published series of in vitro assays to further characterize a model system.
- Incorporating known biomarkers into in vitro or clinical models of breast cancer.

2. Synergy: Synergy is another significant feature of this award. Research combinations that have the highest synergy will be those that significantly advance a project beyond what would be possible through separate channels. Contributions to the synergy of this mechanism are expected to be roughly balanced between the two investigators unless otherwise justified and it should be clear that both investigators have an equal level of intellectual input into the proposed project. ***This award mechanism is designed to support completely new ideas, not ideas that are extensions of existing collaborative efforts.*** New collaborations are strongly encouraged but not required. If the investigators have a history of collaboration, then they must clearly demonstrate how the proposed research is a new synergistic idea.

Examples of a collaboration that is ***not*** synergistic and will not be considered for funding under this award mechanism include:

- Tissue samples/cell lines/expression vectors supplied by one collaborator and molecular studies completed by the other collaborator.
- Laboratory investigations or statistical analyses provided as a service function or core support.

3. Impact: This award mechanism supports high-risk, potentially high-reward research. Therefore, the evaluation of the impact of the proposed research will be based on the probability of significantly advancing the understanding, prevention, detection, diagnosis, and/or treatment of breast cancer, if the project is successful. ***The investigators must clearly and explicitly articulate the potential impact the project may have on the field of breast cancer research and/or patient care.***

D. Award Funding: Funding can be requested for up to $250,000 per year for direct costs. The period of performance may be requested for up to 2 years. The maximum funding for a 2-year period of performance is $500,000 in direct costs. Indirect costs should be added as appropriate. The two collaborating investigators are expected to be equal partners in the proposal; therefore, funding should be divided accordingly unless otherwise warranted and clearly justified.

Funds can cover salary, research supplies, clinical costs, equipment, and travel to scientific/technical meetings. The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants.

The Congressionally Directed Medical Research Programs (CDMRP) requires attendance at the biennially scheduled 3½-day DOD Era of Hope meeting, which is held to disseminate the results of DOD-sponsored research. It is anticipated that the next Era of Hope meeting will be held in June 2008.

Federal Agency Financial Requirements: 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 (attach as a PDF to Block 11 of the SF 424 (R&R) Application for Federal Assistance Form discussed in Section VI.A. below.)

III. ELIGIBILITY INFORMATION

A. Investigators: This award mechanism requires the collaboration of two independent, faculty-level (or equivalent) investigators; multi-institutional and/or multidisciplinary proposals are encouraged but not required.

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 in Section III-B 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. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities and Minority Institutions (HBCU/MI). Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the

FY06 BCRP Synergistic Idea Award 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."

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.

IV. PRE-APPLICATION SUBMISSIONS AND GUIDELINES

The pre-application for the Synergistic Idea 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 Synergistic Idea Award proposal.

A. Letters of Intent Submission Deadline: LOIs *must be submitted electronically* through the CDMRP eReceipt system at https://cdmrp.org by ***5 p.m. Eastern time, January 23, 2007.***

B. LOI Review: The LOI will be administratively reviewed and will not be used during peer and programmatic reviews.

C. LOI Components and Submission: This subsection provides a summary of LOI submission requirements.

1. Proposal Information: PIs must submit the Proposal Information as described in the CDMRP eReceipt system at https://cdmrp.org before uploading the LOI.

2. Proposal Contacts: While both collaborating investigators are named PIs on the proposal, one must be designated the Contact PI. Enter contact information for the Contact PI.

3. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposed research project including PIs, collaborators, consultants, and subawardees. 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.htm.

4. LOI Narrative: The LOI narrative has a ***one-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The LOI should be a brief description of the research to be conducted.

5. 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.

6. **Contact PI's Responsibility:** The Contact PI is responsible for uploading the LOI narrative (one-page limit) as a PDF file under the "Required Files" tab of the CDMRP eReceipt system.

7. **Authorized Organizational Representative Approval:** The LOI does not require approval by the AOR before submission.

The electronic PDF file uploaded in the CDMRP eReceipt system is the official LOI submission file. After conversion of word processing documents to PDF files and before electronic submission, PIs should review their files to ensure that the LOI complies with the formatting guidelines.

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

Upon completion of the pre-application process, the PIs 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 2.

V. PROPOSAL COMPONENTS SUMMARY (Step 2)

Proposals must be submitted electronically by the Authorized Organizational Representative through Grants.gov (www.grants.gov) by February 13, 2007. No paper copies will be accepted.

This subsection is a summary of the proposal submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this document. Proposals will be evaluated according to the peer and programmatic review criteria in Section VIII. Following the submission deadline for the required pre-application materials, the Contact 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.

Synergistic Idea Award Proposal Components		
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
Attachments Form (Research & Related Other Project Information (R&R OPI) Form)	Technical and Public Abstracts and Statement of Work	Attachment 1
	Project Narrative	Attachment 2
	Supporting Documentation	Attachment 3
	Innovation Statement	Attachment 4
	Synergy Statement	Attachment 5
	Impact Statement	Attachment 6
	Federal Agency Financial Requirement (if applicable)	Attachment 7
Research & Related Senior/Key Person Profile (Expanded) Form	PI Current/Pending Support	Attach to PI Current & Pending Support field
	PI's Curriculum Vitae	Attach to PI Biographical Sketch field
	Key Personnel's Biographical Sketches	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
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s)		Enter the appropriate information in data fields

During award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, and regulatory documents related to human use and animal use will be requested from the PIs. At that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the AOR.

VI. PROPOSAL INSTRUCTIONS

Each FY06 BCRP submission must include the completed package of forms identified in www.grants.gov for the FY06 BCRP Synergistic Idea Award. The package includes:

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

All attachments that require signatures must be filled out, printed, signed, and scanned prior to being uploaded. All attachments should be PDF files, in accordance with the formatting guidelines.

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

The **Applicant Identifier** box should be filled in with the submitting Institution's Control Number.
Block 4 - Federal Identifier box should be used to identify the CDMRP 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.

B. Attachments Form, Research & Related Other Project Information (R&R OPI) Form: The following information must be included as attachments to this form:

Attachment 1: Technical and Public Abstracts and the Statement of Work: The technical and public abstracts (one page each) and the Statement of Work (two pages) should be submitted in a single PDF file, in accordance with the formatting guidelines. 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: 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 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. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review.

- 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 ultimate applicability of the research.
    - What types of patients will it help and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a consumer-related outcome?
- If the research is too basic for clinical applicability, describe the interim outcomes.
    - What types of contributions will this study make to advance research?
    - How will the research enhance this or other studies being conducted?

3. Statement of Work: 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 performance period for the proposed effort;
    - Allow 4 to 6 months for regulatory review and approval processes for human use studies;
    - 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.

Attachment 2: Project Narrative – The Project Narrative is the main body of the proposal. Six-page limit. The 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. The attachment should be a PDF file, in accordance with the formatting guidelines.

Describe in detail how the proposed research is innovative and synergistic, and the potential impact it will have on breast cancer if successful. Presentation of preliminary data is not required. However, PIs must demonstrate the rationale through a critical review and analysis of the literature for the proposal to be competitive.

Describe the proposed project using the following outline:

1. Background: Present the ideas and reasoning behind the proposed work. Cite relevant literature.

2. Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.

3. Specific Aims: Concisely explain the projects' specific aims.

4. Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

5. Innovation: Describe concisely how the proposed research uses innovation to advance the prevention, detection, diagnosis, and/or treatment of breast cancer. Demonstrate how the proposed research represents more than an extension or incremental advance to previous work.

6. Synergy: Describe briefly the synergy between the collaborating principal investigators and how it will facilitate or greatly accelerate a significant achievement in breast cancer research that would not be achievable through the efforts of a single laboratory.

7. Impact: The rationale should clearly reflect that the research is focused on results that will have a significant potential impact on the concepts or methods that drive the field and make an original and important contribution to the goal of advancing research on the prevention, detection, diagnosis, and/or treatment of breast cancer.

Attachment 3: Supporting Documentation: Submit only material specifically requested in this program announcement. ***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. 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.

These attachments should be a single PDF file, in accordance with the formatting guidelines.

1. Abbreviations: Start section on a new page; one-page limit. Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.

2. References: Start section on a new page; no page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

3. Letters of Support: Provide letters of support from any collaborating individuals or institutions.

4. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five publications are included in the submission, the extra items will not be peer reviewed.

Attachment 4: Innovation Statement – one-page limit. The attachment should be a PDF file, in accordance with the formatting guidelines.

Describe in detail how the proposal is innovative. The following list of ways in which proposals may be innovative, although not all-inclusive, is intended to help investigators frame the innovative features of their proposals:

- Study concept – Investigation of a novel idea and/or research question.
- Research method or technology – Use of novel research methods or new technologies including technology development to address a research question.
- Clinical interventions – Use of a novel method or technology for preventing, detecting, diagnosing, or treating breast cancer.
- Adaptations of existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

Attachment 5: Synergy Statement – one-page limit: The attachment should be a PDF file, in accordance with the formatting guidelines.

Discuss in detail the advantages of addressing this problem through the combined expertise of two investigators and how this contributes to the synergy of the proposal. Describe the elements of interdependence in the proposed work. Discuss how this collaboration will

create an entity that is greater than the sum of all individual components. Describe each investigator's history of synergistic and collaborative study.

Attachment 6: Impact Statement – one-page limit: The attachment should be a PDF file, in accordance with the formatting guidelines.

State explicitly how the proposed work will have an impact on breast cancer research or patient care. Describe how the combination of innovation, synergy, and the expected results of the proposal will contribute to the goals of eradicating breast cancer and advancing research in the field. Clearly and simply state how the research will potentially significantly advance methods, concepts, prevention, diagnosis, or treatment of breast cancer or quality of life for patients. The Impact Statement will be available at both peer and programmatic reviews.

Attachment 7: Federal Agency Financial Plan – no page limit: 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.

C. 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 a PDF file, in accordance with the formatting guidelines.

1. PIs' Curriculum Vitae: No page limit. Each 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 considered most significant to the proposed work.

2. Senior/Key Person Biographical Sketch: Four-page limit per individual. The suggested format is provided in Appendix 1.

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

D. 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.

1. Funding for a Synergistic Idea Award: Funding can be requested for up to $250,000 per year for direct costs. The performance period may be requested for up to 2 years. The maximum funding for a 2-year performance period is $500,000 in direct costs. Indirect costs should be added as appropriate.

For the Synergistic Idea Award, the two collaborating investigators are expected to be equal partners in the research effort; therefore, funding should be divided accordingly unless otherwise warranted and clearly justified. The nature of the BCRP does not allow for renewal of grants or supplementation of existing grants.

2. 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.

3. Cost Regulations and Principles: Costs proposed must conform to the following regulations and principles:

a. Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (http://farsite.hill.af.mil) Contract Cost Principles and Procedures.

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

c. 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.

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

e. Cost of Preparing Proposals: The cost of preparing proposals in response to this FY06 BCRP Synergistic Idea Award 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 each PI and the amount of time that they 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 scientific research. Normally the title will vest in the recipient if vesting will facilitate scientific 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 per PI.** Costs should not exceed $1,800 per PI.
- **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 to CDMRP-Related Meeting**. 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 per PI.

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) 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: 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–F.10 – Other Direct Costs: 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 proposal.

Section K – Budget Justification: The Budget Justification must be included as an attachment at Research & Related Budget – Section K for each research period. The attachment should be a PDF file, 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 PDF file that addresses each of the cost elements proposed.

E. Research & Related Project/Performance Site Location(s): 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 for 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.

F. R&R Subaward Budget Attachment(s) Form, if applicable: 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 R&R Subaward Budget Attachment(s) Form must be PureEdge documents (instructions on installing PureEdge Viewer, a free software program, can be found on Grants.gov).

The Budget Justification for each subaward must be included as an attachment at Research & Related Budget – Section K of 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).

If the resultant award is a contract that exceeds $500,000 and the offer or 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.

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 PDF files.
- **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. Links to publications referenced in the proposal are 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:

- Collaborating investigators do not meet eligibility criteria.
- Innovation Statement is missing.
- Synergy Statement is missing.
- All attached files are not in the specified format.
- Project narrative exceeds page limit.
- Project narrative is missing.
- Required supporting documentation is missing including:
    - Letter(s) of collaboration (in cases involving collaborations between two or more institutions).
    - Complete Curriculum Vitae for each PI
- Budget justification is missing.
- Project Narrative is incomplete after the deadline.

- Inclusion of BCRP Integration Panel (IP) members in any capacity in the proposal, budget, and any supporting document. A list of the FY06 BCRP IP members may be found at http://cdmrp.army.mil/bcrp/panel06.htm.
- Federal Agency Financial Plan is not included (if applicable).

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

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

VIII. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: Proposals are evaluated using a two-tier review process. The first tier is a scientific peer review of proposals against established criteria for determining scientific 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. 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.

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 programmatic review primarily on the peer review summary statements and the proposal abstracts. The Integration Panel also may review SOWs, innovation, synergy, and impact statements. Full proposals are not forwarded to programmatic review.

B. Review Criteria: Innovation is the single-most important review criterion; synergy is the second most important criterion. Innovation and synergy together will account for half of the numerical global score.

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

- **Innovation**
  - How the project proposes new paradigms or challenges existing paradigms.
  - How the overall research question is innovative.
  - How the proposed research represents more than an extension or an incremental advance upon published data.
  - How the potential gain warrants any perceived risk.
- **Synergy**
  - How the proposed collaboration between independent investigators is likely to facilitate or greatly accelerate a significant achievement in breast cancer research and could not be otherwise accomplished through the efforts of a single laboratory.
  - Whether the proposal provides a clear and balanced plan outlining the contributions of each investigator to the overall synergy of the project.
  - Whether the proposal describes a project centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
- **Impact**
  - How the project addresses a critical problem in breast cancer research or patient care.
  - How the project may potentially make an original and important contribution to the goal of advancing research on the prevention, detection, diagnosis, and/or treatment of breast cancer.
- **Research Strategy**
  - How the scientific rationale supports the project, and its feasibility as demonstrated by both a critical review and analysis of the literature and logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
  - How well the PIs acknowledge potential problems and addresses alternative approaches.
- **Personnel**
  - Whether both investigators meet the eligibility requirements.

- Whether the investigators have collaborated in the past. If they have collaborated in the past, whether the idea proposed is a new one and not an extension of an existing collaborative effort.
- How the research team's background and expertise are appropriate to accomplish the proposed work.
- Appropriateness of the levels of effort for successful conduct of the proposed work.

- **Environment**
  - The appropriateness of the scientific environment for the proposed research.
  - How adequately the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - The quality and extent of institutional support.
- **Budget**
  - How the budget is appropriate for the proposed research.
  - How appropriately the resources are divided between the collaborating principal investigators.

2. Programmatic Review: Criteria used by the Integration Panel to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers (scientific and consumer),
- Programmatic relevance,
- Relative innovation, synergy, and potential impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically 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

BIOGRAPHICAL SKETCH TEMPLATE

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.

APPENDIX 2

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 on 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 (PIs) 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 US Army Medical Research and Materiel Command requires proposals submitted in response to the FY06 BCRP Synergistic Idea Award Program Announcement to be submitted through Grants.gov APPLY. This requires that Organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual PIs/Project Directors DO NOT register; however, the Authorized Organization Representative (AOR) 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/PIs/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 PI 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 3

AWARD ADMINISTRATION INFORMATION

A. Award Notices: The Contact Principal Investigator (PI) 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. The Contact PIs can expect to receive this notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. The Contact PI 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 FY06 BCRP Synergistic Idea Award 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 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. ***Transferring an award that includes a Phase I, Phase II, or Phase III clinical trial will not be permitted.***

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 Contact PI'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 PI 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: PIs 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. PIs 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: PIs 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: PIs 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.), 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.

APPENDIX 4

REGULATORY REQUIREMENTS AND REVIEWS

The Principal Investigator (PI) 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 PI'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 PI'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. PIs 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.

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 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 a DOD-supported experiment 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 PIs 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 5

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. 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 scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. 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 Animal Care International, and the Office of Laboratory Animal Welfare.

APPENDIX 6

ACRONYM LIST

ACURO	Animal Care and Use Research 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
COI	Conflicts of Interest
CR	Contract Representative
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
IP	Integration Panel
IRB	Institutional Review Board
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 OPI	Research & Related Other Project Information
SIA	Synergistic Idea Award
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs
WAV	Waveform Audio