

Program Announcement

I. GENERAL INFORMATION

This program announcement is being released prior to the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: *Breast Cancer Research Program (BCRP) Era of Hope Scholar Award.*

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

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

D. Agency Name: 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: Applicants 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

E-mail: cdmrp.pa@amedd.army.mil

Mail: Commander

US Army Medical Research and Materiel Command

ATTN: MCMR-ZB-C (BC06-EHSA)

1077 Patchel Street (Building 1077)

Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System 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 e-mail as follows:

Website: <https://cdmrp.org> (User's Guide located in upper right corner of the proposal submission website)

E-mail: help@cdmrp.org

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

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

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

H. Website to Access Application Package: Proposals must be submitted at <https://cdmrp.org>. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty in downloading documents should contact the CDMRP as indicated in [Subsection I.E.2](#).

I. Award/Regulatory Approval: The applicant 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 USAMRMC.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Era of Hope Scholar Award is one of the mechanisms of the Breast Cancer Research Program (BCRP), which was established in FY92 to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY05 totaled \$1.83 billion. During this time, 85 Era of Hope Scholar Award proposals were received and 15 were recommended for funding. The FY06 appropriation is \$127.5 million (M).

B. Program Objectives: The overall goal of the FY06 BCRP is to promote research focused on eradicating breast cancer. Therefore, 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. 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 scientific judgment and rationale.

The BCRP's objective within this context is to fund a balanced portfolio of scientifically 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 Era of Hope Scholar Award is to recognize individuals who have high potential for innovation in breast cancer research early in their careers. Candidates for this award should be exceptionally talented, early-career scientists who have demonstrated that they are the “best and brightest” in their field(s) through their extraordinary creativity, vision, and productivity. They also should exhibit strong potential for leadership in the breast cancer research community and be able to articulate a vision for the eradication of breast cancer. These individuals should challenge current dogma and demonstrate an ability to look beyond tradition and convention. Award recipients will be expected to challenge the status quo through creative, high-risk research that ultimately may lead to the eradication of breast cancer. This award will support these emerging innovators as they implement their visions and take on leadership roles in the breast cancer research community.

The Era of Hope Scholar Award proposal must focus on the candidate’s record of creative and original accomplishments, potential for leadership in the breast cancer research community, and vision for eradicating breast cancer. The proposal also must elaborate on the environment in which the candidate works and its potential to facilitate the candidate’s development as a leader and innovator. These aspects of the proposal will receive greater emphasis in the review process for this award mechanism than the proposed research project, although the proposed research project also will be considered.

Experience in breast cancer research is not required; however, the proposal must focus on breast cancer research and the applicant must commit at least 50% of his or her full-time professional effort during the award period to breast cancer research.

Applicants must be nominated to be considered for this award mechanism; self-nominations will be accepted.

Era of Hope Scholar Award recipients will be required to meet annually with each other, BCRP Innovator, Era of Hope Postdoctoral, and Multidisciplinary Postdoctoral Award recipients, the BCRP Integration Panel, and CDMRP staff for the purposes of open communication and mutual benefit.

III. AWARD INFORMATION

Funding for the Era of Hope Scholar Award may be requested for a maximum of \$2.5M for direct costs over the performance period. The performance period can be requested for up to 5 years. Indirect costs should be added, as appropriate. Proposals for projects requiring lower levels of funding also may be submitted. Possible uses for funds include project-related expenses such as 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.

The CDMRP expects to allot approximately \$20M of the \$127.5M FY06 BCRP appropriation to fund approximately five Era of Hope Scholar Awards, depending on the quality and number of proposals received.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent, non-mentored investigators within 6 years of their last mentored position as of the nomination deadline (April 11, 2006). Postdoctoral fellows, clinical fellows (including residents and interns), and other “mentored” researchers are not eligible for these awards.

Within these parameters, 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 [Subsection IV.B](#), “Institutions,” below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business 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/Minority Institutions (HBCU/MI).

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.¹ Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/spp> under “Minority Institutions.”

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.

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. Duplicate Submissions: Submission of the same research project to the FY06 BCRP to different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

¹Executive Orders 12876, 12900, and 13021

V. NOMINATION SUBMISSION INFORMATION

*Individuals must be nominated to be considered for the Era of Hope Scholar Award; self-nominations will be accepted. Nominations will be screened by the Integration Panel to identify those individuals who best fulfill the intent of the award mechanism. Invitations to prepare a full Era of Hope Scholar Award proposal will be sent to those individuals selected by the Integration Panel no later than May 2006. **Do not submit a full Era of Hope Scholar 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. Nominations will be screened according to the criteria described in [Subsection V.D.](#)

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

Item	Format	Action
Applicant Identification	Typed	Enter appropriate information in the data field.
Nomination	Typed or Cut and Paste	Enter appropriate information in the data field.
List of Individuals Providing Letters of Recommendation	Typed or Cut and Paste	Enter the names, position titles, addresses, phone numbers, and e-mail addresses of three individuals.

2. Contract Representative Responsibility: The Era of Hope Scholar Award nomination does not require Contract Representative approval before submission.

B. Nomination Format: On the home page of the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>, nominations must be initiated by clicking on the award nomination link. Nominators can type the nomination into the data field or “cut and paste” it from a word processing application. Once the nomination has been verified and submitted, there will be no opportunity for modification. A confirmation of submission will be sent by e-mail to the nominator after the Submit Nomination button is selected.

C. Applicant Identification: The nominator must complete *all* the Nomination Information in the appropriate data field.

D. Nomination: The nominator should type the nomination or “cut and paste” it from a word processing application 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:

- History of creative and original accomplishments,
- Likelihood of continued innovation and productivity,
- Potential for leadership in the breast cancer research community, and
- Probability of establishing a successful career at the forefront of breast cancer research.

E. List of Individuals Providing Letters of Recommendation: The nominator must provide the names, position titles, addresses, phone numbers, and e-mail addresses of three individuals who support the qualifications of the applicant for this award and are willing to provide letters of recommendation should a full proposal be requested by typing or “cutting and pasting” from a word processing application into the designated data field.

F. Submission Date and Time: Nominations must be received on the CDMRP eReceipt Online Proposal Submission System by the deadline. Nominations that are incomplete will *not* be considered for review. The CDMRP eReceipt Online Proposal Submission System will not accept data entry after the *5:00 p.m. Eastern time, April 11, 2006* deadline.

VI. INVITED PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. Proposal Components Summary: *Do not submit an Era of Hope Scholar Award proposal unless you receive an invitation.* This subsection is a summary of 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 VII](#).

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	None. Not required.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative at the applicant’s institution.

Item	Tab	Format	Action
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/SOW	Typed or Cut and Paste	None. Not required.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
List of Individuals Providing Letters of Recommendation	Required Files	Typed or Cut and Paste	Enter the names, position titles, e-mail addresses, and phone numbers of individuals providing letters of recommendation.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative's Responsibility: The Contract Representative at the applicant's institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative's Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA ^a -Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.

Item	Tab	Format	Action
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, July 25, 2006.

^aUS Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of 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 the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **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, applicants 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 significant 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 allowed.
- **Language:** English.

Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

C. 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:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Applicant does not meet eligibility criteria as described in [Subsection IV.A.](#)
- Required Supporting Documentation is missing including:
 - Statement of Eligibility
 - Letters of recommendation
 - Letter(s) of support
- Era of Hope Scholar Award Cost Estimate and Budget Justification is missing.
- Proposal is incomplete after the deadline.

For any other sections of a 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 submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

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

E. Proposal Information: Applicants are required to submit the Proposal Information as described in <https://cdmrp.org> before uploading the proposal, supporting documentation and the budget information.

- A *Title/Referral Page* for the proposal will be generated from the information uploaded in eReceipt and appended to the proposal electronically by the CDMRP eReceipt system.

F. Proposal Contacts: The Proposal Contacts *must* include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant’s institution. The Proposal Contacts must be approved by the Contract Representative at the applicant’s institution.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators, consultants, and subawardees. In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.

H. Proposal Abstracts: Abstracts are not required at the time of proposal submission. The data fields must be completed by typing “N/A” into both the technical abstract and the public abstract data fields.

I. Impact Statement: An Impact Statement is not required for this award mechanism, but “N/A” must be typed into the Impact Statement data field.

J. Statement of Work: An SOW is not required at the time of proposal submission. The data field must be completed by typing “N/A” into the SOW data field.

K. Proposal Main Body: Start section on a new page; five-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal.

The proposal main body is uploaded as a PDF file under the “Required Files” tab of the CDMRP eReceipt System.

The content should clearly state your *vision for the eradication of breast cancer* and *why you should be considered for this unique award* and should address the following questions specifically:

- What is your vision for the eradication of breast cancer? Include your current research goals (without listing specific projects) and how these will change should you receive this award. Explain how these plans/goals are innovative.
- What have you accomplished that demonstrates your extraordinary creativity, vision, and productivity? Have these accomplishments had an impact beyond your own laboratory or research setting into the broader scientific, clinical, and/or patient community?
- What experience do you have that suggests a strong potential for leadership in the breast cancer research community?
- How would you bring your creative energy and experience together to make an impact on breast cancer?
- Describe the environment in which you work. How will this environment facilitate your development as an innovator and leader in breast cancer research? Does your environment need to change? If so, what would you do to make this happen?

- What are your long-term career goals, and how would these be affected by receiving this award?
- What barriers, aside from funding, exist that could inhibit your research and career goals, and what strategies will you employ to overcome these barriers? How would this award aid you in overcoming these barriers?
- What inspired you to pursue innovative, high-risk research despite the potential danger of losing support to those pursuing more traditional research?

L. 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.

Supporting Documentation must be uploaded as a single PDF file under the “Required Files” tab of the CDMRP eReceipt system. All documents or letters that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The first item in the Supporting Documentation file is the [Checklist/Table of Contents page](#). The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

- 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. Curriculum Vitae and Biographical Sketches**
 - a. Applicant’s Curriculum Vitae: No page limit.** The applicant should submit his or her complete curriculum vitae including employment, experience, honors, and a list of achievements that includes publications and patents. Both mentored and non-mentored positions should be listed under employment, with the names of mentors noted as appropriate. The publication list must not contain abstracts and should distinguish peer reviewed from non-peer reviewed publications. The candidate should indicate up to three publications he or she considers most significant to the proposed work.
 - b. Biographical Sketches: Four-page limit per individual.** Include biographical sketches for all key personnel including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower proposal scores. The [Biographical Sketch form](#)

should be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

4. Existing/Pending Support: Start section on a new page; no page limit. List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel on a separate page. If no support exists, enter “None.” Proposals submitted under this program announcement should not duplicate other funded research projects.

5. Facilities/Equipment Description: No page limit. Describe the facilities available for performing the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate whether Government-owned facilities or equipment are proposed for use.

6. Statement of Eligibility: Include the [Statement of Eligibility form](#) signed by the Department Chair, Dean, or equivalent official verifying that as of April 11, 2006 the applicant is an independent investigator within 6 years of his or her last mentored position with access to appropriate research facilities to indicate that the candidate is eligible for this award mechanism.

7. Letters of Recommendation: The applicant must request three letters of recommendation through the “Required Files” tab of the CDMRP eReceipt system. An e-mail generated from eReceipt will notify the individuals selected to provide confidential letters of recommendation. This e-mail also will provide instructions for the selected individual to upload the letter of recommendation. The applicant will be able to monitor only whether the letters have been received; the applicant will not be able to view these letters. All letters must be submitted prior to the proposal submission deadline.

The letters of recommendation should be submitted by the three individuals named by the nominator in the original nomination. If this is not possible, the applicant must justify the change in the body of the proposal.

Each letter of recommendation should describe the applicant’s unique qualifications and those accomplishments that suggest that he or she is among the best and brightest in his or her field. Specifically, each letter should offer the writer’s perspective on the applicant’s:

- History of creative and original accomplishments,
- Likelihood of continued innovation and productivity,
- Potential for leadership in the breast cancer research community,
- Likelihood of establishing a successful career at the forefront of breast cancer research, and
- Ability to manage this award.

8. Letters of Support

a. Letter(s) of Institutional Support: Provide signed letter(s) of institutional support that reflect the extent to which the applicant will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals.

b. Letters from Collaborators: Provide a signed letter from each collaborating individual or institution (if applicable).

9. 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. A maximum of five publication reprints and/or patent abstracts is allowed; extra items will not be peer reviewed.

M. Budget Information: Applicants must complete the [Era of Hope Scholar Cost Estimate form and the Budget Justification form](#), and upload them as a single PDF file under the “Required Files” tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal’s budget justification should include only DOD-funded tasks.

1. Funding Restrictions: Funding for an Era of Hope Scholar Award may be requested for a maximum of \$2.5M 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. 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.

Travel funds should be requested for annual meetings of Era of Hope Scholar Award recipients with Innovator, Era of Hope Postdoctoral, and Multidisciplinary Postdoctoral Award recipients, the Integration Panel, and CDMRP staff for the purposes of open communication and mutual benefit. In addition, travel funding of \$1,800 should be requested to attend two 3½-day DOD BCRP Era of Hope meetings, which are held biennially to disseminate the results of DOD-sponsored research. It is anticipated that the next Era of Hope meeting will be held in October 2007.

2. Era of Hope Scholar Award Cost Estimate Form and Justification Section

Instructions: Budget is an important consideration in both peer review and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. *Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.* All costs must be entered in U.S. dollars.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property, equipment, and/or supplies (e.g., drugs, devices,

reagents) directly benefiting and specifically identifiable to the research project. *It is expected that institutions will share the cost of equipment purchased for this research proposal. Please see full details under “Major Equipment” in [Subsection VI.M.2.e](#).*

Costs proposed must conform to the following regulations and principles:

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

Follow the instructions below when providing the information requested in the Era of Hope Scholar Award Cost Estimate form.

a. Personnel: Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. *The applicant must be identified as the Principal Investigator of the proposal.*

Clinical studies must have a clinical coordinator who has sufficient time dedicated to the project to carry out the record keeping, coordination, and/or other administrative duties the project entails.

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

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

d. Consultant Costs: Provide the names and organizational affiliations of all consultants whether or not funds are requested.

e. Major Equipment: It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare

cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

- i.** If the purchase of equipment for this research project is requested, it is expected that the applicant's institution will share 50% of the cost.
 - ii.** Permanent equipment is any article of nonexpendable tangible property having a useful life of 2 years or longer and an acquisition cost of \$5,000 or more per unit.
 - iii.** The basis for the cost of each item of permanent equipment included in the budget must be disclosed.
 - iv.** 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.
- f. Materials, Supplies, and Consumables:** A general description and estimated total cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals will be purchased, state the species, strain (if applicable), and the number of animals to be used. If human cell lines are to be purchased, state the source and the description.

g. Travel Costs: Costs for travel to scientific/technical meetings may not exceed \$1,800 per year. Travel funds should be requested for annual meetings of Era of Hope Scholar Award recipients with Innovator, Era of Hope Postdoctoral, and Multidisciplinary Postdoctoral Award recipients, the Integration Panel, and CDRMP staff for the purposes of open communication and mutual benefit. In addition, travel funding of \$1,800 should be requested to attend two 3½-day DOD BCRP Era of Hope meetings, which are held biennially to disseminate the results of DOD-sponsored research. It is anticipated that the next Era of Hope meeting will be held in October 2007.

Travel costs associated with the execution of the proposed work should be entered in this section. 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 US Army Medical Research Acquisition Activity (USAMRAA).

h. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses associated specifically with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs not related to a subject's participation in the research study.

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

j. Subaward Costs: A description of services or materials to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more:

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

k. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed with a statement identifying whether the proposed rates are provisional or fixed.

l. Total Costs for the Entire Proposed Period of Support: Enter the totals in each budget category for all additional years of support requested and itemize these totals in the Justification section of the Era of Hope Scholar Award Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Direct costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the "Required Files" tab at <https://cdmrp.org>.

3. Budget Justification (second page of the Era of Hope Scholar Award Cost Estimate form): Each item in the budget must be clearly justified in the Budget Justification section of the Era of Hope Scholar Award Cost Estimate form.

4. 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.

Start the plan on a new page at the end of the Budget Information section. The Federal Agency Financial Plan must be uploaded as part of the budget information before the submission deadline of ***5:00 p.m. Eastern time, July 25, 2006.***

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

Do not submit other regulatory documents (see [Subsection VIII.D.5](#), Research Involving Human Subjects and/or Biological Substances/Cadavers; and [Subsection VIII.D.4](#), Research Involving Animals) with the proposal. The applicant should provide these documents to the USAMRMC only upon request.

O. USAMRAA-Required Documents: The Contract Representative at the applicant’s institution must upload the current version of the institution’s negotiated Rate Agreement, the [Certifications and Assurances for Assistance Agreements](#), and the [Representations for Assistance Agreements](#). These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system by the proposal submission deadline.

P. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline will not be considered for review. The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, July 25, 2006 deadline.

The timeline for the Era of Hope Scholar Award is:

<i>Nomination Submission Deadline:</i>	<i>5:00 p.m. Eastern time, April 11, 2006</i>
Nomination Screening (First Tier):	Early May 2006
Full Proposal Invitations:	May 2006
<i>Proposal Submission/Approval Deadline:</i>	<i>5:00 p.m. Eastern time, July 25, 2006</i>
Peer Review (Second Tier):	September 2006
Programmatic Review (Third Tier):	November 2006
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after the completion of programmatic review
Award Start Date:	Anticipated between December 2006 and September 2007

Q. Electronic Submission Requirements: Electronic submission is required. Only proposals submitted as PDF files through the CDMRP eReceipt system at <https://cdmrp.org> will be accepted.

Several steps are critical to successful proposal submission:

- The Proposal Information must be “Finalized for CR Approval” before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.

- Proposal Contacts must be “Finalized for CR Approval” before the proposal is submitted. The e-mail address of a Contract Representative at the applicant’s institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant’s institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will *not* accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time, July 25, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Era of Hope Scholar Award Cost Estimate form with its Justification section must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

VII. NOMINATION AND PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview: Era of Hope Scholar Award proposals are evaluated using a three-tier review process. The first tier is the review of nominations. The second tier is a scientific peer review of proposals against established criteria for determining scientific merit. The third 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. Nomination Review: The Era of Hope Scholar Award nominations are reviewed 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. The primary responsibility of the Integration Panel during nomination review is to select the individuals to be invited to submit Era of Hope Scholar Award proposals.

2. Peer Review: Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the

scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Scientific reviewers are selected for their subject matter expertise and experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review process by bringing the patient perspective to the assessment of science and the relevance of the research.

The peer review summary statement is a product of scientific 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.

3. 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 Era of Hope Scholar Award proposal and supporting documentation also are available to the Integration Panel.*

B. Review Criteria

1. Nomination Review: Candidates whose qualifications meet the intent of this award mechanism will be invited by the Integration Panel to submit Era of Hope Scholar Award proposals. Selection will be based on each applicant's history of creative and original accomplishments, likelihood of continued innovation and productivity, potential for leadership in the breast cancer research community, and probability of establishing a successful career at the forefront of breast cancer research.

2. Peer Review: The proposal and all required supporting documentation are used during peer review. Because of the unique nature of this award, the proposed project, although important, is not the primary focus of the review process. Instead, peer reviewers will attempt to identify those characteristics and accomplishments that set the candidate apart from his or her peers.

The following criteria will be used:

- **What has the applicant accomplished that demonstrates a history of innovation, productivity, and the potential for leadership in the breast cancer research community?**
 - Does the candidate's record of accomplishments support his or her future abilities as an independent and visionary scholar/investigator?

- Does the proposal provide sufficient evidence to suggest that the candidate will become a leader in the field of breast cancer research?
- Do the letters of support suggest that the candidate is one of the “best and brightest” in his or her field?
- Do the letters of recommendation support the candidate as a future leader in his or her field?
- **Have these accomplishments changed the knowledge base and/or had an impact in the broader scientific, clinical, and/or patient community?**
 - Has the applicant’s work challenged the status quo and/or resulted in a significant change in scientific and/or clinical dogma?
 - Have any products, patents, or licenses resulted from the applicant’s work?
 - Has the applicant’s work resulted in publications in high-impact journals and/or presentations at international scientific meetings?
 - Has the applicant received awards or other forms of acknowledgment for his or her achievements?
- **What is the applicant’s vision of the future related to breast cancer?**
 - Does the applicant’s vision for the eradication of breast cancer suggest innovative, creative thinking that is not hindered by convention?
 - Does the candidate communicate a clear vision of what he or she hopes to accomplish during the tenure of the award?
 - Are the concepts and ideas original and innovative?
- **What will be the impact of the proposed innovation? Will it be a groundbreaking effort?**
 - Do the applicant’s goals address an important problem(s) in breast cancer?
 - Do the candidate’s research goals reflect innovative thinking and does he or she present a clear and compelling argument for how this award will be used to pursue creative (potentially groundbreaking) work in breast cancer?
 - Do the applicant’s goals have the potential to significantly impact breast cancer?
 - Do the letters of support suggest that the candidate could direct his or her creative energy to significantly impact breast cancer?
- **Will the applicant develop a robust team that will be able to accomplish the goal(s)?**
 - Does the candidate provide a clear description of his or her current working environment?
 - Does evidence indicate that this environment will facilitate the candidate’s growth as an emerging innovator and leader?

- Does appropriate documentation of institutional support reflect the extent to which the applicant will be relieved of academic or administrative responsibilities and allowed to pursue his or her goals?
- Does the candidate have the necessary experience and/or ability to manage this award?
- Does the applicant indicate that he or she will commit 50% effort during the award period to breast cancer research?

3. Programmatic Review: 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 (scientific and consumer),
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance,
- Adherence to the intent of the award mechanism, and
- Era of Hope Scholar Award proposal and supporting documentation.

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.

VIII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant 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 CDMRP eReceipt system. Applicants can expect to receive this notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. An applicant 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 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>.

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.

A change in Principal Investigator is not allowed for the BCRP Era of Hope Scholar Award. 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 USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the applicant's institution. Additional documentation including abstracts, an SOW, 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. Regulatory Review

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

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

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

A Facility Safety Plan is required; it will be requested at a later date. A Facility Safety Plan from the applicant'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/crprcsohdfspan.asp>. If the applicant'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.

4. Research Involving Animal Use: Specific documents relating to the use of animals in the proposed research will be requested by the 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 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. Applicants 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>.

Questions related to animal use may be directed to ACURO as follows:

Phone: 301-619-6694
Fax: 301-619-4165
E-mail: acuro@amedd.army.mil
Mail: MCMR-ZB-PA
504 Scott Street
Fort Detrick, MD 21702-5012

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

5. Research Involving Human Subjects/Biological Substances/Cadavers: 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 IRB review and approval also is required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Office of Research Protections. The HSRRB 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.

a. Requirements: Specific requirements for research involving human subjects, human biological substances, and/or cadavers can be found at <https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix.pdf>.

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-2²; 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.

²Title 42 United States Code, Sections 289g through 289-2

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 applicants are required to register clinical trials individually on <http://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 register. Address questions on registration to the www.clinicaltrials.gov administrator.

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

E. 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 USAMRMC 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 scientific publications and patent applications resulting from CDMRP 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 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: Applicants 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.

IX. OTHER INFORMATION

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

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

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

D. Inquiry Review Panel: Applicants 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.

E. 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.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

X. ACRONYM LIST

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
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
HSRRB	Human Subjects Research Review Board
IRB	Institutional Review Board
M	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
SOW	Statement of Work
TIFF	Tagged Image File Format
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform Audio