

# ***ERA OF HOPE SCHOLAR AWARD***

*A lifetime opportunity for early-career, gifted scientists to make extraordinary contributions in the fight against breast cancer*

For a few, genius shows itself early. In an effort to identify such individuals, the BCRP has initiated the Era of Hope Scholar Award for FY04. 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 extraordinary creativity, vision, and productivity, and who have shown a strong potential for leadership in the breast cancer research community as well as a vision for the eradication of breast cancer. These individuals should have the ability to look beyond tradition and convention. These awards will provide sufficient funding to allow these emerging innovators to implement their vision and assume leadership roles in the breast cancer research community. Award recipients will be expected to successfully challenge the status quo through creative, high-risk research that may ultimately lead to the eradication of breast cancer. Funding for the Era of Hope Scholar Awards can be requested for a maximum of \$2.5 million in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Since the intent of the Era of Hope Scholar Award is to recognize the talents and accomplishments of the individual, the primary features of this award are the nominee's record of creative and original accomplishments and potential for leadership in the field. Experience in breast cancer is not a requirement; however, the proposal must be focused on breast cancer and the applicant must commit a minimum of 50% time to breast cancer during the tenure of this award.

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**NOMINATIONS ARE DUE BY MARCH 24, 2004**

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*This document is a synopsis of details specific to the Breast Cancer Research Program (BCRP) Era of Hope Scholar Award. Detailed descriptions of each BCRP FY04 mechanism with specific evaluation criteria, submission requirements, and deadlines are available in the FY04 BCRP Program Announcements.*

BCRP

# Announcement of Federal Funding Opportunity

## Summary

### I. GENERAL INFORMATION

For a few, genius shows itself early. In an effort to identify such individuals, the BCRP has initiated the Era of Hope Scholar Award for FY04. 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 extraordinary creativity, vision, and productivity, and who have shown a strong potential for leadership in the breast cancer research community as well as a vision for the eradication of breast cancer. These individuals should have the ability to look beyond tradition and convention. These awards will provide sufficient funding to allow these emerging innovators to implement their vision and assume leadership roles in the breast cancer research community. Award recipients will be expected to successfully challenge the status quo through creative, high-risk research that may ultimately lead to the eradication of breast cancer. Funding for the Era of Hope Scholar Awards can be requested for a maximum of \$2.5 million in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Since the intent of the Era of Hope Scholar Award is to recognize the talents and accomplishments of the individual, the primary features of this award are the nominee's record of creative and original accomplishments and potential for leadership in the field. Experience in breast cancer is not a requirement; however, the proposal must be focused on breast cancer and the applicant must commit a minimum of 50% time to breast cancer during the tenure of this award.

**A. Title of Award:** Era of Hope Scholar Award (EHSA).

**B. Program Name:** Department of Defense Fiscal Year 2004 (FY04) Breast Cancer Research Program (BCRP).

**C. Funding Opportunity Number:** BC04-EHSA.

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

**E. Agency Contact(s):**

**1. Questions related to the Program, proposal format, or required documentation** may be addressed to the CDMRP at:

Phone: 301-619-7079  
Fax: 301-619-7792  
E-mail: [cdmrp.pa@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BC04-EHSA)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: <https://cdmrp.org/proposals> (the proposal submission website)  
E-mail: [help-proposals-cdmrp@cdmrp.org](mailto:help-proposals-cdmrp@cdmrp.org)

**F. Anticipated Instrument Type(s):** Grants/Cooperative Agreements.

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

**H. Website Address to Access Application Package:** Proposals must be submitted electronically at <https://cdmrp.org/proposals>. The website contains all the information, forms, documents, and links you will need to apply.

**I. Award/Regulatory Approval:** Please note, each award mechanism has specific requirements regarding human subjects and animal use. Please see the Full Text of Program Announcement for details pertaining to this award mechanism.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

## **II. FUNDING OPPORTUNITY DESCRIPTION**

For a few, genius shows itself early. In an effort to identify such individuals, the BCRP has initiated the Era of Hope Scholar Award for FY04. 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 extraordinary creativity, vision, and productivity, and who have shown a strong potential for leadership in the breast cancer research community as well as a vision for the eradication of breast cancer. These individuals should have the ability to look beyond tradition and convention. These awards will provide sufficient funding to allow these emerging innovators to implement their vision and assume leadership roles in the breast cancer research community. Award recipients will be expected to successfully challenge the status quo through creative, high-risk research that may ultimately lead to the eradication of breast cancer.

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

### III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$34M is available for this award mechanism.
- It is anticipated that approximately 10 proposals will be funded.
- Funding for Era of Hope Scholar Awards can be requested for a maximum of \$2.5M in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

### IV. ELIGIBILITY INFORMATION

**A. Applicants:** Applicants must be independent, non-mentored investigators within 5 years of their last training position. Please note that postdoctoral fellows, clinical fellows (including residents and interns), and other “mentored” researchers are not eligible for these awards.

**B. Institutions:** Eligible institutions include for-profit, non-profit, public, and private organizations.

**C. Cost Sharing:** It is expected that institutions will cost share. Please see “Major Equipment” located in Subsection VI.F.2.c of the Full Text of Program Announcement for details.

**D. Other Eligibility Criteria:** Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

### V. NOMINATION SUBMISSION INFORMATION

**A. Nomination Preparation:** All nominations must be converted into an electronic PDF (Portable Document Format) file for electronic submission. Please see the Full Text of the Program Announcement for details.

**B. Nomination Submission Date and Time: March 24, 2004.** Nominations must be received on the CDMRP eReceipt system at <https://cdmrp.org/proposals> by 5:00 p.m. (Eastern time).

**C. Electronic Submission Requirements: Electronic submission is required.** No paper copy submissions will be accepted. Nominations must be submitted electronically at <http://cdmrp.org/proposals>. Please see the Full Text of Program Announcement for details.

### VI. FULL APPLICATION PREPARATION AND SUBMISSION INFORMATION

**A. Proposal Submission Invitation:** After completion of the nomination screening process, invitations to prepare a full Era of Hope Scholar Award proposal will be sent to selected applicants no later than May 2004. *Do not submit a full Era of Hope Scholar Award proposal unless you receive a letter of invitation.*

**B. Proposal Information:** Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at <https://cdmrp.org/proposals>.

**C. Proposal Preparation:** All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of Program Announcement for details.

**D. Submission Dates and Times:** Deadline Date: **July 27, 2004**. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institutional Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

## **VII. PROPOSAL REVIEW INFORMATION**

Due to the value and unique nature of the award, applications for the Era of Hope Scholar Award will be evaluated using a three-tier review process.

- **Tier 1:** Review of Era of Hope Scholar Award Nominations
- **Tier 2:** Peer Review of Invited Applications
- **Tier 3:** Programmatic Review of Invited Applications

**Self-nominations will be accepted.** See the Full Text of Program Announcement for details.

## **VIII. AWARD ADMINISTRATION INFORMATION**

**A. Award Notices and Administrative Requirements:** Details of award notification procedures, and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.

**B. Reporting Requirements:** Annual reporting requirements apply.

# Full Text of Program Announcement

## I. GENERAL INFORMATION

For a few, genius shows itself early. In an effort to identify such individuals, the BCRP has initiated the Era of Hope Scholar Award for FY04. 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 extraordinary creativity, vision, and productivity, and who have shown a strong potential for leadership in the breast cancer research community as well as a vision for the eradication of breast cancer. These individuals should have the ability to look beyond tradition and convention. These awards will provide sufficient funding to allow these emerging innovators to implement their vision and assume leadership roles in the breast cancer research community. Award recipients will be expected to successfully challenge the status quo through creative, high-risk research that may ultimately lead to the eradication of breast cancer. Funding for the Era of Hope Scholar Awards can be requested for a maximum of \$2.5 million in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

Applicants must be nominated to be considered for this award; however, self-nominations will be accepted. Nominations will be screened to determine which nominees meet the intent of the award and selected nominees will be invited to prepare a complete proposal. Since the intent of the Era of Hope Scholar Award is to recognize the talents and accomplishments of the individual, the primary features of this award are the nominee's record of creative and original accomplishments and potential for leadership in the field. Experience in breast cancer is not a requirement; however, the proposal must be focused on breast cancer and the applicant must commit a minimum of 50% time to breast cancer during the tenure of this award.

**A. Title of Award:** Era of Hope Scholar Award (EHSA).

**B. Program Name:** Department of Defense (DOD) Fiscal Year 2004 (FY04) Breast Cancer Research Program (BCRP).

**C. Funding Opportunity Number:** BC04-EHSA

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

**E. Agency Contact(s):**

**1. Questions related to the Program, 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@det.amedd.army.mil](mailto:cdmrp.pa@det.amedd.army.mil)

Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (BC04- EHSA)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission or the process of electronic submission. The help line phone number is 301-682-5507 and is also provided on the web. Other help desk contact information is:

Website: <https://cdmrp.org/proposals> (the proposal submission website)  
E-mail: [help-proposals-cdmrp@cdmrp.org](mailto:help-proposals-cdmrp@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@det.amedd.army.mil](mailto:qa.baa@det.amedd.army.mil)  
Mail: Director  
US Army Medical Research Acquisition Activity  
ATTN: MCMR-AAA  
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 electronically at <https://cdmrp.org/proposals>. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.1 above.

**I. Award/Regulatory Approval:** Please note that each award mechanism has specific requirements regarding human subjects and animal use. Once an award is made, the applicant may not use, employ, or subcontract for the use of any human anatomical substances, or laboratory animals without express written permission from the applicable USAMRMC Regulatory Compliance and Quality (RCQ) office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution's Sponsored Programs Office (or equivalent).

## II. FUNDING OPPORTUNITY DESCRIPTION

**A. Program History:** The Era of Hope Scholar Award is part of the DOD BCRP, which was established in FY92 to promote innovative research directed toward the eradication of breast cancer. Appropriations for the BCRP since FY92 total \$1.53 billion (B). The program history of the FY92-03 BCRP is shown in Table 1. The FY04 BCRP appropriation is \$150 million (M). The Era of Hope Scholar Award is a new award mechanism for FY04.

**Table 1: History of the DOD’s Peer Reviewed BCRP**

<b>Program History</b>	<b>FY92-02</b>	<b>FY03<sup>1</sup></b>
Congressional Appropriations for the BCRP	\$1.38B	\$150M
Total Proposals Received	19,840	1,543
Total Proposals Funded	3,671	240

<sup>1</sup>Award negotiations will be finalized by September 2004.

**B. Program Objectives:** The overall goal of the FY04 BCRP is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research related to all aspects of breast cancer. Proposals are sought across 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; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

**C. Award Mechanism Description:** For a few, genius shows itself early. In an effort to identify such individuals, the BCRP has initiated the Era of Hope Scholar Award for FY04. 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 extraordinary creativity, vision, and productivity, and who have shown a strong potential for leadership in the breast cancer research community as well as a vision for the eradication of breast cancer. These individuals should have the ability to look beyond tradition and convention. These awards will provide sufficient funding to allow these emerging innovators to implement their vision and assume leadership roles in the breast cancer research community. Award recipients will be expected to successfully challenge the status quo through creative, high-risk research that may ultimately lead to the eradication of breast cancer.

Because of the unique nature of this award, the review process will be less focused on the proposed project, though that will be a consideration. Instead, the central features of this award will be the nominee’s record of creative and original accomplishments, potential for leadership in the breast cancer research community, the environment in which the nominee works and its potential to facilitate the nominee’s development as a leader and innovator, and the nominee’s vision for the eradication of breast cancer. ***Experience in breast cancer research is not required***; however, the application must be focused on breast cancer research and the applicant must commit a minimum of 50% of his or her full-time professional effort to breast cancer research during the tenure of this award.

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

Era of Hope Scholar Award recipients will be required to meet annually with other Era of Hope Scholars, recipients of the BCRP Innovator Award and the Multidisciplinary Postdoctoral Award, the BCRP

Integration Panel (IP), and CDMRP Program Staff for the purpose of open communication and mutual benefit.

### III. AWARD INFORMATION

Funding for the Era of Hope Scholar Award can be requested for up to a maximum of \$2.5M in direct costs for up to a 5-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. Examples of possible uses for funds include project-related expenses such as salaries, travel, support of 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 amount allotted for travel is \$1,800 per year per investigator to attend scientific/technical meetings. Travel funding of \$1,800 per individual should also be requested for annual meetings of recipients of the Era of Hope Scholar Award with the recipients of the Innovator Award and the Multidisciplinary Postdoctoral Award, the IP, and CDMRP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per individual per meeting should also be requested to attend two 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$34M of the \$150M FY04 BCRP appropriation to fund approximately 10 Era of Hope Scholar Awards.

### IV. ELIGIBILITY INFORMATION

**A. Applicants:** Applicants must be independent, non-mentored investigators within 5 years of their last training position. All individuals who meet this criterion, regardless of ethnicity, nationality, or citizenship status, may be nominated as long as they are employed by, or affiliated with, an eligible institution as defined below. Please note that postdoctoral fellows, clinical fellows (including residents and interns), and other “mentored” researchers are not eligible for these awards.

**B. Institutions:** Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

If an Era of Hope Scholar Award recipient moves to a new institution during the tenure of the award, the U.S. Army reserves the right to transfer the existing award.

**C. Cost Sharing:** It is expected that institutions will cost share. Please see full details under “Major Equipment” located in Subsection VI.F.2.c.

#### **D. Other Eligibility Criteria:**

**1. Duplicate Submissions:** Submission of the same research project to the FY04 BCRP under different award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

**2. HBCU/MI:** A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders.<sup>1</sup> Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of Education list is posted on the CDMRP website under Minority Institutions at <http://cdmrp.army.mil/funding/pdf/mibcrp120803.pdf>.

**3. 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. Nonadherence 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 or a lower global priority score.

*The following will result in administrative rejection of the entire proposal prior to peer review:*

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.
- Required administrative documentation is not included.

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

Unless specifically requested by the Government, any material submitted after the submission deadline will not be forwarded for peer review.

## V. NOMINATION SUBMISSION INFORMATION

**A. Nomination Preparation:** In the nomination, 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 suggest that this individual is among the best and brightest in his or her field including 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 that this individual will establish a successful career at the forefront of breast cancer research.

In addition to the letter, the nominator must provide the names and contact information for three individuals who support the qualifications of the nominee for this award and who will provide letters of support should a full proposal be requested.

The nominator also is responsible for completing the following data field information through the CDMRP eReceipt system at <https://cdmrp.org/proposals>.

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<sup>1</sup>Executive Orders 12876, 12900, and 13021

- **Applicant Identification:** The nominator for the Era of Hope Scholar Award must complete **all** the Nomination Information in the appropriate data field.
- **Nomination:** The nominator should use this data field to either type in or electronically “cut and paste” the nomination from a word processing application.
- **Letters of Support:** The nominator must either type in or electronically “cut and paste” from a word processing application into the designated data field a list of names, position titles, addresses, and phone numbers of three individuals who support the qualifications of the applicant for this award.

**B. Nomination Submission Date and Time: March 24, 2004.** Nominations must be submitted to the CDMRP eReceipt system at <https://cdmrp.org/proposals> by 5:00 p.m. (Eastern time).

**C. Electronic Submission Requirements: Electronic submission is required.** No paper copy submissions will be accepted. Nominations must be submitted electronically at <https://cdmrp.org/proposals>. Please see the Full Text of Program Announcement for details.

## VI. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

*Do not submit a full Era of Hope Scholar Award proposal unless you receive a letter of invitation.*

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

The Principal Investigator (PI) is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields.
- **Statement of Work (SOW) and Proposal Abstracts:** The SOW and abstracts are not required for Era of Hope Scholar Award applications, but the data field must be completed (by typing “N/A” into the fields) for the final submission process.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the “Required Files” tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the “Required Files” tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the “Required Files” tab.

The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) from the applicant’s institution is responsible for the following:

- **US Army Medical Research Acquisition Activity (USAMRAA) Documents:** The institute’s currently negotiated “Rate Agreement,” “Certifications and Assurances for Assistance Agreements,” and the “Representations for Assistance Agreements” are to be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab.

- **Approval:** The Contract Representative or institutional official responsible for sponsored program administration must provide approval of all proposal components (Proposal Information, Proposal, Budget Information, and Regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) **July 27, 2004**. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time **July 27, 2004** deadline.

**B. Proposal Information:** Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal Information as described in <https://cdmrp.org/proposals>. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institute.

- **Letter of Intent:** A Letter of Intent is not necessary for invited Era of Hope Scholar Award submissions.

**C. SOW –** A SOW is not required for Era of Hope Scholar Awards, but the data field must be completed for the final submission process. Therefore, the applicant should type “N/A” into the SOW data field.

**D. Proposal Abstracts –** Abstracts are not required at this stage of the Era of Hope Scholar Award application process, but the data fields must be completed for the final submission. Therefore, the applicant should type “N/A” into both abstract data fields.

**E. Proposal:**

**1. Format:** All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single PDF file for electronic submission. Proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines:

- **Type Font:** 12 point, 10 pitch.
- **Type Density:** No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- **Spacing:** Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- **Margins:** Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- **Color, 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 items must not exceed 15 seconds in length and a size of 10 megabytes (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.

- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).

**2. Title/Referral Page: No page limit.** Complete the Title/Referral Page, which can be downloaded at <https://cdmrp.org/programAnnouncements.cfm>. Complete each section as described:

- a. Proposal title (up to 160 characters).
- b. Proposal log number (this will be automatically provided when the Proposal Information is completed and saved).
- c. PI's full name (first, middle initial, last).
- d. Submitting institution.
- e. Award mechanism: Type in "Era of Hope Scholar Award."
- f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
- g. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

**3. Table of Contents/Checklist: Start section on a new page; one-page limit.** Prepare a [Table of Contents/Checklist](#), with page numbers. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Please note that headers should not be included, as the proposal log number will be placed on each page of the proposal after receipt.

**4. Main Body Application Essay: 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 content of the essay should clearly state *why you should be considered for this unique award*, and should specifically address the following questions:

- What have you accomplished that demonstrates extraordinary creativity, vision, and productivity? Have these accomplishments had an impact beyond your own laboratory – in 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 impact 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?

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

**5. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used.

**6. 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).

**7. Curriculum Vitae and Biographical Sketches:**

- **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, including publications and patents. The publication list should exclude abstracts and should distinguish which publications are peer reviewed. On the curriculum vitae, the candidate should indicate up to three publications he or she considers most significant to the proposed work.
- **Key Collaborator’s Biographical Sketches: Three-page limit per individual.** If the applicant chooses to include biographical information on key collaborators as part of the Era of Hope Scholar Award application, curriculum vitae should not be used. Instead, the [Biographical Sketch](#) form may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.

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

**9. Facilities/Equipment Description: No page limit.** Describe the facilities available for performance of 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 if Government-owned facilities or equipment are proposed for use.

**10. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit.** Include an appropriately titled page listing the documents you have included in this section.

**11. 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 such items are included in the submission, the extra items will not be peer reviewed.

**12. Administrative Documentation: No page limit.** Submit only material specifically requested or required in this program announcement. **This section is not for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other relevant information needed to judge the proposal.** Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

The first item in this section must be a list of all the items included in the Administrative Documentation section. Provide the following in the Administrative Documentation section of the proposal.

- A [Statement of Eligibility form](#) signed by the Department Chair, Dean, or equivalent official, verifying that the applicant is an independent investigator within 5 years of his or her last training experience with access to appropriate research facilities and therefore is an eligible applicant for this award type. This form must be signed and then scanned into the PDF file of your proposal prior to its submission to the CDMRP.
- Letter(s) of institutional support (if applicable) for the applicant to the Era of Hope Scholar Award, as reflected by the extent to which the applicant will be relieved of academic or administrative responsibilities and allowed to pursue his or her research goals.
- Three letters of support addressing the applicant's accomplishments, creativity, potential for leadership, and other qualifications for this award.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted proposal.

**F. Budget Information:** Budget Information includes the [Cost Estimate form and Budget Justification](#). Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

**1. Funding Restrictions:** Funding for the Era of Hope Scholar Award can be requested for a maximum of \$2.5M in direct costs for a period of up to 5 years, plus indirect costs 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. Funds should be requested for annual meetings of recipients of the Era of Hope Scholar Award with the recipients of the Innovator Award and the Multidisciplinary Postdoctoral Award, the IP, and CDRMP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per meeting should also be requested to attend two, 3½-day Breast Cancer Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined).

**2. Cost Estimate Form and Justifications Instructions:** Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided

for expenses in all categories. Complete the [Cost Estimate form](#). The Cost Estimate form for your proposal must be uploaded as a PDF file, separate from the proposal. Budgets will be reviewed during award negotiations.

The following section provides instructions for preparing the Cost Estimate form. All amounts entered should be in U.S. dollars.

**a. Personnel:** Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project. Only ONE person may be identified as the PI of the proposal.

**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 organization. Documentation to support the fringe benefits should be provided.

**c. Consultant Costs:** Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants in the Justification section of the Cost Estimate form.

**d. Major Equipment:** It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed \$5,000.

**e. Materials, Supplies, and Consumables:** A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories with amounts less than \$1,000 do not need to be itemized. 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.

**f. Travel Costs:** Travel costs may not exceed \$1,800 per year per investigator to attend scientific/technical meetings. Funds should be requested for annual meetings of recipients of the Innovator Award with the recipients of the Era of Hope Scholar Award, BCRP Multidisciplinary Postdoctoral Awards, the IP, and CDMRP Program Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 per meeting should also be requested to attend two 3½-day Era of Hope meetings to disseminate the results of DOD-sponsored research (dates to be determined). A justification of all travel costs must be provided on the [Cost Estimate form](#).

**g. Research-Related Subject Costs:** Itemize 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.

**h. Other Expenses:** 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.

**i. Subaward Costs:** A description of services or materials that are to be awarded by subcontract or sub-grant is required. For awards totaling \$10,000 or more, provide the following specific information:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- 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;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.

**j. 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.

**k. Cost Estimate Form:** Enter the totals under each budget category for all additional years of support requested and itemize these totals in the Justification section of the Cost Estimate form. Note with an asterisk (\*) and explain any significant increases or decreases from the initial year budget in the Justification section of the Cost Estimate form. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should agree with the amount previously entered online in the Proposal Information <https://cdmrp.org/proposals>.

**G. 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 (Research Involving Human Subjects and/or Anatomical Substances; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

**H. USAMRAA Documents:** The most current version of the institution’s negotiated “Rate Agreement,” the “[Certifications and Assurances for Assistance Agreements](#),” and the “[Representations for Assistance Agreements](#)” must be uploaded by the Contract Representative from the Sponsored Programs Office (or equivalent). These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system prior to negotiations.

**I. Submission Dates and Times:** Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution’s Sponsored Programs Office (or equivalent) by the deadline. If your proposal is either incomplete or not approved electronically before the deadline, it 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 27, 2004 deadline.

**The timeline for the Era of Hope Scholar Award is:**

<b>Nomination Submission Deadline:</b>	<b>5:00 p.m. Eastern time March 24, 2004</b>
Nomination Screening:	April 2004
Full Proposal Invitations:	May 2004
<b>Proposal Submission/Approval Deadline:</b>	<b>5:00 p.m. Eastern time July 27, 2004</b>
Peer Review:	September 2004
Programmatic Review:	November 2004.
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
<b>Award Start Date:</b>	<b>Between December 2004 and September 2005</b>

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

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the 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 27, 2004 deadline.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Cost Estimate form and the Justification section. Budget Information must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.
- The Regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

## VII. PROPOSAL REVIEW INFORMATION

### A. Proposal Review and Selection Overview:

Era of Hope Scholar Award applications will be evaluated using a three-tier review process. The first tier is the screening of nominations. The second tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The third tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit as well as overall program goals.

**1. Nomination Review:** The Era of Hope Scholar Award nominations will be reviewed by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. Their primary responsibility will be to select the candidates to be invited to submit Era of Hope Scholar Award proposals.

**2. Peer Review:** The second tier is peer review of the invited proposals. Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals, based upon the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their 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 by bringing the patient perspective to the assessment of science and to the relevance of 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:** The third tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions 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. IP members primarily use the peer review summary statements; full proposals to the Era of Hope Scholar Award will also be forwarded to programmatic review.

### B. Review Criteria:

**1. Nomination Review:** The Era of Hope Scholar Award nominations will be reviewed by the IP. Their primary responsibility will be to select candidates that meet the intent of this award mechanism to be invited to submit Era of Hope Scholar Award proposals. Selection will be based 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, and the probability that this individual will establish a successful career at the forefront of breast cancer research.

**2. Peer Review:** Era of Hope Scholar Award proposals will be evaluated according to the following criteria:

- **Accomplishments:** Does the candidate’s record of accomplishments support his or her future abilities as an independent and visionary scholar/investigator? Do the letters of support suggest that the candidate is one of the “best and brightest” in his or her field?
- **Potential for Leadership:** Does the application provide sufficient evidence to suggest that the candidate will become a leader in the field of breast cancer research? Do the letters of recommendation support the candidate as a future leader in his or her field?
- **Innovation:** 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? 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?
- **Relevance and Impact:** Do the applicant’s goals address an important problem(s) in breast cancer? Are these goals demonstrably creative and do they 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 have a significant impact on breast cancer? Does the applicant indicate that he or she will commit 50% effort to breast cancer research during the tenure of this award?
- **Environment:** Does the candidate provide a clear description of their current working environment? Is there evidence that this environment will facilitate the candidate’s growth as an emerging innovator and leader? Is there appropriate documentation of institutional support reflecting the extent to which the applicant will be relieved of academic or administrative responsibilities, and allowed to pursue his or her goals?
- **Budget:** Is the budget appropriate for the proposed project?

**3. Programmatic Review:** The ratings and evaluations of scientific second tier peer review panel are primary factors in programmatic review. The complete Era of Hope Scholar Award application package will be forwarded for both peer and programmatic review. The IP also considers other criteria to structure the BCRP’s broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation;
- 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 are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

## VIII. AWARD ADMINISTRATION INFORMATION

**A. Award Notices:** After the three-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in December 2004.

**B. Administrative Requirements:** All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support. To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110 and DOD Grant and Agreement Regulations). Any organization requesting receipt of an award from 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>.

**Any change in the institution will require that the PI resubmit contact information.** If an Era of Hope Scholar Award recipient moves to a new institution during the tenure of the award, the U.S. Army reserves the right to transfer the existing award to the new institution. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

**C. Award Negotiation:** Award negotiation consists of discussions, reviews, and justifications of critical issues involving USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the associated budgets may be required.

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

### **D. Regulatory Review:**

**1. Overview:** Concurrent with the USAMRAA negotiations, the office of Surety, Safety and Environmental will review the Certificate of Environmental Compliance, and Principal Investigator Safety Program Assurance form submitted with the proposal. The USAMRMC RCQ office will review documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army 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 your 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 also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at <http://mrmc-www.army.mil/crprcsohdfsplan.asp>. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate

completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at <http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc>.

If multiple research sites/institutions are funded in your proposal, then 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:** Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at <http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc>.

**5. Research Involving Human Subjects/Anatomical Substances:** Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be requested at a later date. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances, a second tier of IRB review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC RCQ office. 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. For example:

- Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants 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.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at <http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf>. An informed consent form template can be located at [http://mrmc-www.army.mil/docs/rcq/consentform\\_template.pdf](http://mrmc-www.army.mil/docs/rcq/consentform_template.pdf).

**6. Award/Regulatory Approval:** Please note that each award mechanism has specific requirements regarding human subjects and animal use.

Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances, or use of laboratory animals without express written approval from the applicable USAMRMC RCQ office. USAMRMC RCQ will forward these express written approvals directly to the applicant with a copy furnished to the institution’s Sponsored Programs Office (or equivalent).

**E. Reporting:** All research awards will require the timely delivery of several reports during the research effort. 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.

## IX. OTHER INFORMATION

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

**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. To the extent practical, all other sources should also be consulted for the same purpose.

**D. Inquiry Review Panel:** Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

**E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq.<sup>2</sup>), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. 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.

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<sup>2</sup>Title 35, United States Code, Section 200 et seq.

## **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
DOD	Department of Defense
EHSA	Era of Hope Scholar Award
FY	Fiscal Year
HBCU	Historically Black Colleges and Universities
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MB	Megabyte
PDF	Portable Document Format
PI	Principal Investigator
RCQ	Regulatory Compliance and Quality
SOW	Statement of Work
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Wave