

Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

In an effort to identify individuals with a high potential for innovation in breast cancer research early in their careers, the Breast Cancer Research Program (BCRP) initiated the Era of Hope Scholar Award for the first time in fiscal year 2004 (FY04). Due to the success of this award mechanism in its initial presentation, the BCRP is currently offering a fast-track version to be awarded no later than September 30, 2005.

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 that supports a vision for the eradication of breast cancer. These individuals should challenge current dogma and demonstrate an 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 Award can be requested for a maximum of \$2.5 million (M) in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

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 candidate's emerging 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 research during the tenure of the award.

As noted above, this Program Announcement is for a fast-track version of the Era of Hope Scholar Award. Differences from the previous offering of this award mechanism include:

- There is no requirement for nominations or a pre-proposal;
- The Statement of Work and technical and public abstracts are required at the time of submission;
- Eligibility includes those 0-6 years from their last training position; and
- Three letters of reference are required with proposal submission and are a crucial component of the proposal. These letters must include 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, and
- Probability that this individual will establish a successful career at the forefront of breast cancer research.

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

B. Program Name: Department of Defense (DOD) FY04 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
 Mail: Commander
 US Army Medical Research and Materiel Command
 ATTN: MCMR-ZB-C (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> (User's Guide located in upper right corner of the proposal submission website)
 E-mail: help-proposals-cdmrp@cdmrp.org

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

G. Catalog of Federal Domestic Assistance (CFDA) Number(s): 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 needed to apply.

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

II. FUNDING OPPORTUNITY DESCRIPTION

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.

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately \$16M is available to fund FY04 BCRP Era of Hope Scholar Awards under this announcement.
- Depending on the number and quality of the applications, it is anticipated that three or four 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 6 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.

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

B. Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations. Agencies of local, state, and federal governments are eligible to the extent that

proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

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

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

V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

A. 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>.

B. 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.

C. Submission Date and Time: Deadline: February 10, 2005. 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 5:00 p.m. Eastern time.

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

VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tier review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of Program Announcement.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including regulatory documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances/Cadavers, 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

In an effort to identify individuals with a high potential for innovation in breast cancer research early in their careers, the Breast Cancer Research Program (BCRP) initiated the Era of Hope Scholar Award for the first time in fiscal year 2004 (FY04). Due to the success of this award mechanism in its initial presentation, the BCRP is currently offering a fast-track version to be awarded no later than September 30, 2005.

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 that supports a vision for the eradication of breast cancer. These individuals should challenge current dogma and demonstrate an 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 Award can be requested for a maximum of \$2.5 million (M) in direct costs for up to a 5-year performance period, plus indirect costs as appropriate.

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 candidate's emerging 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 research during the tenure of the award.

As noted above, this Program Announcement is for a fast-track version of the Era of Hope Scholar Award. Differences from the previous offering of this award mechanism include:

- There is no requirement for nominations or a pre-proposal;
- The Statement of Work (SOW) and technical and public abstracts are required at the time of submission;
- Eligibility includes those 0-6 years from their last training position; and
- Three letters of reference are required with proposal submission and are a crucial component of the proposal. These letters must include 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, and
- Probability that this individual will establish a successful career at the forefront of breast cancer research.

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

B. Program Name: Department of Defense (DOD) FY04 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
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-C (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> (User's Guide located in upper right corner of the proposal submission website)
E-mail: 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
Mail: Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-ZB-A
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 needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

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

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. The FY04 BCRP appropriation is \$150 (M). Of this, approximately \$16M will be available for Era of Hope Scholar Awards under this announcement.

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.

The BCRP is challenging 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. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing

technologies are highly sought. Although the BCRP encourages risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

C. Award Mechanism Description: 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.

The central features of this award will be the candidate’s record of creative and original accomplishments, potential for leadership in the breast cancer research community, the environment in which the candidate works and its potential to facilitate the candidate’s development as a leader and innovator, and the candidate’s vision for 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. 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.

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 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 to attend scientific/technical meetings. Travel funding of \$1,800 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 Staff for the purpose of open communication and mutual benefit. In addition, travel funding of \$1,800 should be requested to attend a 3½-day Breast Cancer Era of Hope meeting 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 \$16M to fund three or four Era of Hope Scholar Awards under this announcement.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent, non-mentored investigators within 6 years of their last training position. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below. 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, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI). Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under “Major Equipment” in Subsection V.G.2.d.

D. Other Eligibility Criteria

1. Duplicate Submissions: Submission of the same research project to the 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 on guidance from Executive Orders.¹ 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 the program announcement is released. The Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/spp> under Minority Institutions.

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.

¹Executive Orders 12876, 12900, and 13021

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

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inch on any side.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Applicant does not meet eligibility criteria (see Subsection IV.A).
- Required administrative documentation is missing (see Subsection V.F.11).
- Era of Hope Scholar Award Cost Estimate is missing.
- Proposal is incomplete after the deadline.

For any other sections of a proposal with a defined page limit, any pages exceeding 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. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- **Proposal Contacts:** Contact information for the PI and the Contract Representative are required to complete the proposal submission process.
- **SOW and Proposal Abstracts:** The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **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:

- **The Contract Representative’s Contact Information Profile: This must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA)-Required Documents:** The institution’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 (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, SOW, Abstracts, Proposal, Budget Information, and regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time February 10, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time 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 may be “Verified & Saved” for editing purposes until “Submit Final” for approval by their Sponsored Programs Office’s (or equivalent’s) representative.

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

C. Proposal Contacts: The Proposal Contacts **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 institution. The Proposal Contacts must be “Finalized” for approval by the applicant’s Sponsored Programs Office’s (or equivalent) representative.

D. SOW – 11,400-character limit, including spaces (approximately two pages): The SOW is captured as a data field under the “SOW/Abstract” tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW or “cut and paste” it from a word processing application into the data field. Sample SOWs can be found at <https://cdmrp.org/samples.cfm>. The SOW will be utilized only during award negotiations.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Identify the timeline and milestones for the work over the period of the proposed effort;
- Indicate the number of research subjects (animal or human) and/or anatomical samples projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

E. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts will be utilized only during award negotiations.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the “SOW/Abstracts” tab of the CDMRP eReceipt system. Applicants can either type in their abstracts or “cut and paste” them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at <https://cdmrp.army.mil>. Thus, proprietary or confidential information should not be included in the abstract.

1. Technical Abstract: Sample technical abstracts can be found at <https://cdmrp.org/samples.cfm>. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, hypothesis or objective and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the Program’s goals.

Use the outline below for preparing the structured technical abstract.

- **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work.
- **Hypothesis or objective:** State the hypothesis or objective. Provide evidence or rationale that supports the hypothesis or objective.
- **Specific Aims:** State concisely the specific aims of the study.
- **Study Design:** Briefly describe the study design.
- **Relevance:** Provide a brief statement explaining the relevance of the proposed work to the Program’s goals. For example, describe how the study will cure, prevent, or improve the detection or treatment of the disease.

2. Public Abstract: Sample public abstracts can be found at <https://cdmrp.org/samples.cfm>. The public abstract is intended to communicate the purpose of, and rationale for, the study to

non-scientific audiences. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. **The public abstract should not be a duplicate of the technical abstract**, but should describe the goals and objectives of the research project and its relevance to the Program.

In addition to describing the project, the public abstract must answer the following questions:

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

F. 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.

Please Note New Format Requirements

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

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inch in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

Failure to adhere to the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to peer review.

- 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, but applicants should keep in mind that 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.
- Language: English.

2. Title/Referral Page: No page limit. Complete the Title/Referral Page, which can be downloaded at https://cdmrp.org/programAnnouncements.cfm?prg=BCRP&prg_fy=2004. Please note that all forms are available on the “Summary Tab” of eReceipt. 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 that may have a conflict of interest in the 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 electronically captured on each page of the proposal after receipt.

4. 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 content 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 or research setting – 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? Does your environment need to change? If so, what would you do to make this happen?
- 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?
- Aside from funding, 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 research despite the potential danger of losing support to those pursuing more traditional 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. 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:

- A [Statement of Eligibility form](#) signed by the Department Chair, Dean, or equivalent official, verifying that the applicant is an independent investigator within 6 years of his or her last training position 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 the 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:** Each letter should include a description of the applicant’s unique qualifications and accomplishments that suggest that this individual is among the best and brightest in his or her field. Specifically, each letter should include 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, and
- Probability that this individual will establish a successful career at the forefront of breast cancer research.
- Letters of support from any collaborating individuals or institutions.

All administrative documentation must be incorporated into the electronic PDF version of the 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.

12. 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.

G. Budget Information: Budget Information includes the Era of Hope Scholar Award [Cost Estimate form and Budget Justification form](#). 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.

The amount allotted for travel to scientific/technical meetings is \$1,800 per year. In addition, 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 Staff for the purpose of open communication and mutual benefit. Funds should also be requested to attend a 3½-day Breast Cancer Era of Hope meeting to disseminate the results of DOD-sponsored research. (Dates to be determined.)

2. Era of Hope Scholar Award Cost Estimate Form and Justification 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. **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.** Complete the Era of Hope Scholar Award [Cost Estimate form](#). The Era of Hope Scholar Award Cost Estimate form for the proposal must be uploaded as a PDF file, separate from the proposal.

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).

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

- 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.
- 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.
- Consultant Costs:** Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants in the Justification section of the Era of Hope Scholar Award Cost Estimate form.
- 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. 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.
- 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 should be requested to attend a 3½-day Era of Hope meeting to disseminate the results of DOD-sponsored research. (Dates to be determined.)

A justification of all travel costs must be provided on the Era of Hope Scholar Award 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. Total Costs for the Entire Proposed Period of Support: Enter the totals under 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 in the Justification section of the Era of Hope Scholar Award 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>.

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

H. 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/Cadavers; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

I. USAMRAA-Required 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.

J. Submission Date and Time: 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 the 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 February 10, 2005 deadline.

The timeline for the Era of Hope Scholar Award is:

Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time February 10, 2005
Peer Review:	March 2005
Programmatic Review:	May 2005
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after programmatic review
Award Start Date:	Anticipated between July and September 2005

K. 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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).
- 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 February 10, 2005 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 Era of Hope Scholar Award Cost Estimate form and the Budget Justification form. 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.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second 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.

2. Peer Review: 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. For Era of Hope Scholar Award proposals, each summary statement includes an evaluation of the application as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

3. Programmatic Review: The second 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. For Era of Hope Scholar Awards, the five-page main body and all required administrative documentation will also be forwarded to programmatic review.

B. Review Criteria

1. Peer Review: 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, reviewers will attempt to identify 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 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 application 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?**
 - Did the applicant’s work challenge the status quo and/or result in a significant change in scientific and/or clinical dogma?
 - Have any products, patents, or licenses resulted from the applicant’s work?
 - Did the applicant’s previous work result 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 have a significant impact on 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?
 - 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?
 - Does the applicant indicate that he or she will commit 50% effort to breast cancer research during the tenure of this award?

2. Programmatic Review: The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. For Era of Hope Scholar Awards, the five-page main body and all required administrative documentation will be forwarded to both peer and programmatic review. The IP also considers other criteria to maintain 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.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: After the two-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 May 2005.

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, nonprofit research institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for an 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 (OMB 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 the USAMRAA. A Contract Specialist and/or representative from the 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 budget 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 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 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 <https://mrmc.detrick.army.mil/crpreqsohdfsplan.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 <https://mrmc.detrick.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

<https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc>.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: (See Subsection V.H for information pertaining to the submission of documents related to the use of human subjects, human anatomical substances, and/or cadavers.) In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances or cadavers, 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 Office of Research Protections (ORP) (formerly Regulatory Compliance and Quality). 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.** Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 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 prior to 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.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at

[https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix\(13May04\).doc](https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc).

An informed consent form template can be located at

<https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc>.

6. Award/Regulatory Approval: Once an award is made, 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. The applicable USAMRMC regulatory office will forward applied-for written approvals directly to the applicant.

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

1. Research Progress Report Requirements: 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.

2. Fiscal Report Requirements: 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.

VIII. 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 used. 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, 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.²), 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.

IX. 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
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
ORP	Office of Research Protections (formerly Regulatory Compliance and Quality)
PDF	Portable Document Format
PI	Principal Investigator
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

²Title 35, United States Code, Section 200 et seq.