

# **Program Announcement**

**for the**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Breast Cancer Research Program**

### **Era of Hope Scholar Award**

**Funding Opportunity Number: W81XWH-15-BCRP-EOHS**

**Catalog of Federal Domestic Assistance Number: 12.420**

#### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), April 8, 2015
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, April 22, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, April 22, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, April 27, 2015
- **Peer Review:** June 2015
- **Programmatic Review, Stage 1:** August 2015
- **Invitation for Oral Presentation:** August 2015
- **Programmatic Review, Stage 2:** November 2015

*The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications to the Fiscal Year 2015 (FY15) Breast Cancer Research Program (BCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The BCRP was initiated in fiscal year 1992 (FY92) to support innovative, high-impact research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY14 totaled \$3 billion. The FY15 appropriation is \$120 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of ending breast cancer. Specifically, the BCRP seeks to accelerate high-impact research with clinical relevance, encourage innovation and stimulate creativity, and facilitate productive collaborations.

### B. Breast Cancer Landscape

The BCRP has prepared a brief overview of the breast cancer landscape that describes what is currently known about incidence, death, recurrence, metastatic disease, risk factors, and treatments. This overview covers the most pertinent topics that are consistent with the BCRP's vision of ending breast cancer. ***Applicants are strongly urged to read and consider the landscape before preparing their applications.*** The landscape may be found at [http://cdmrp.army.mil/bcrp/pdfs/bc\\_landscape.pdf](http://cdmrp.army.mil/bcrp/pdfs/bc_landscape.pdf).

### C. FY15 BCRP Overarching Challenges

Considering the current [breast cancer landscape](#) and the BCRP's vision to end breast cancer, each FY15 Era of Hope Scholar Award application must address one or more of the following overarching challenges. Alternatively, with adequate justification, applications may identify and address another overarching challenge related to the breast cancer landscape. Justification must be provided in the application.

- Prevent breast cancer (primary prevention)
- Identify what makes the breast susceptible to cancer development
- Determine why some, but not all, women get breast cancer
- Distinguish aggressive breast cancer from indolent cancers
- Conquer the problems of overdiagnosis and overtreatment
- Identify what drives breast cancer growth; determine how to stop it
- Identify why some breast cancers become life-threatening metastasis

- Determine why/how breast cancer cells lay dormant for years and then re-emerge (recurrence); determine how to prevent recurrence
- Revolutionize treatment regimens by replacing interventions that have life-threatening toxicities with ones that are safe and effective
- Eliminate the mortality associated with metastatic breast cancer

#### **D. Award Information**

The Era of Hope Scholar Award supports individuals early in their careers who have demonstrated significant potential to effect meaningful change in breast cancer. These individuals should be exceptionally talented scientists who have shown that they are the “best and brightest” in their field(s) through extraordinary creativity, vision, leadership, innovation, and productivity. They should have demonstrated experience in forming effective partnerships and collaborations and should exhibit strong potential for future leadership in the breast cancer research community.

Since the intent of the Era of Hope Scholar Award is to recognize creative and innovative individuals rather than projects, the central feature of the award are the applicant’s demonstrated ability to go beyond conventional thinking in their field and the innovative contribution that the Principal Investigator (PI) can make toward ending breast cancer. The PI should articulate a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention.

***Experience in breast cancer research is not required;*** however, the application must focus on breast cancer, and the PI must maintain a 50% dedication of his/her full-time professional effort during the award period to breast cancer research. This professional effort in breast cancer research can be through a combination of this award and other current support. Individuals from other disciplines who will apply novel concepts to breast cancer are encouraged to submit.

The PI is expected to assemble a research team that will provide the necessary expertise and collaborative efforts toward accomplishing the research goals. The PI’s research team must include two or more breast cancer consumer advocates. As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer and are actively involved in a breast cancer advocacy organization. Their role should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. The consumer advocates should have a high level of knowledge of current breast cancer issues and the necessary background or training in breast cancer research to contribute to the project. Their role should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, breast cancer.

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is ***not*** required. The HRPO is mandated to comply with

specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

***The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.***

#### **E. Eligibility Information**

- The PI must be an independent investigator within 6 years of his/her last training position (e.g., postdoctoral fellowship; medical residency; clinical fellowship) as of the application submission deadline.
- Postdoctoral fellows, clinical fellows (including residents and interns), and other researchers currently in training positions are not eligible for this award.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

#### **F. Funding**

- The maximum period of performance is **5** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$2.5M**. Associated indirect costs can be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **\$2.5M** in direct costs or using an indirect rate exceeding the organization’s negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions.***

For this award mechanism, direct costs:

Must be requested for:

- Travel for attendance at a DoD-required meeting in Years 1 and 3. Costs associated with travel to the required meeting should be included in Years 1 and 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings

May be requested for (not all-inclusive):

- Salary
- Research Supplies
- Equipment
- Training
- Workshops
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required meetings described above

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from Federal agencies submit applications, they must submit through Grants.gov. Therefore, Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.A. of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to

the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

***The CDMRP expects to allot approximately \$12M of the \$120.0M FY15 appropriation to fund approximately three Era of Hope Scholar Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## **II. SUBMISSION INFORMATION**

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-BCRP-EOHS in Grants.gov (<http://www.grants.gov/>).

## **B. Pre-Application Submission and Content Form**

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY15 BCRP IP members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
  - The PI must enter the name of each consumer advocate on the research team and indicate their role in the drop down list.
- **Conflicts of Interest (COIs) – Tab 4**
  - To avoid COIs during the screening and review processes, list all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).
- **Pre-Application Files – Tab 5**
  - Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
  - List of Individuals Providing Confidential Letters of Recommendation:** Enter into the appropriate data fields the names, position titles, email addresses, and phone



numbers for three individuals, who will provide letters of recommendation. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.

- **Submit Pre-Application – Tab 6**

- This tab must be completed for the pre-application to be accepted and processed.

## **C. Application Submission Content and Forms**

***The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>). For the Era of Hope Scholar Award, additional application components are also required and should be submitted as directed below.

***Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.*** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID ***prior to the application submission deadline.***

**Grants.gov application package components:** For the Era of Hope Scholar Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

- 1. SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 2. Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (six-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer

an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

The Project Narrative should clearly convey ***why you, the PI, should be considered for this unique award.*** Since the intent of the Era of Hope Scholar Award is to recognize creative and innovative individuals rather than projects, the central feature of the award is the innovative and meaningful contribution that the PI can make toward ending breast cancer.

The following items should be addressed specifically:

- **Vision:** Clearly state your vision of the future of breast cancer. Describe your views of the major problems or barriers in breast cancer that must be solved to accelerate progress toward ending breast cancer. Describe what you foresee as the critical approaches that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems or barriers.
- **Accomplishments:** Describe what you have accomplished that demonstrates your extraordinary creativity, vision, and productivity. Describe how these accomplishments had an impact beyond your own laboratory or research setting into the broader scientific, clinical, and/or patient community.
- **Leadership:** Describe the experience you have that suggests a strong potential for leadership in the breast cancer community. Describe your plans for leadership within the breast cancer community as a BCRP Era of Hope Scholar.
- **Research Goals:** State explicitly which BCRP overarching challenge(s) your research will address. If addressing another overarching challenge related to the breast cancer landscape, provide justification. Without describing specific research methodology, list the key research goals you propose to pursue. Describe what you hope to accomplish during the award period. Explain why/how your goals are innovative and distinct within your field and within the broader field of breast cancer research.
- **Research Barriers:** Aside from funding, what barriers exist that could inhibit your research goals and what strategies will you employ to overcome these barriers?
- **Commitment:** Explain how you will devote at least 50% effort to breast cancer research during the award period.
- **Research Environment:** Describe the environment in which you work. How will this environment facilitate your development as an innovator and leader in breast cancer research?
- **Attachment 2: Supporting Documentation.** Start each document on a new page. **Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will be removed or may result in administrative withdrawal of the application.***

- References Cited: List the references cited (including URLs if available) in the Project Narrative 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).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources, and also include the extent to which the PI will be relieved of academic, clinical, or administrative responsibilities and allowed at least 50% protected time for breast cancer research.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Advocate Letter of Commitment: Provide a letter signed by each advocate confirming her/his commitment to participate in the proposed project.
- Intellectual Property:
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research

community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Not required at this time. Leave Attachment 3 space blank.

- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Not required at this time. Leave Attachment 4 space blank.

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Era of Hope Scholar mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

*Note: The SOW is used for administrative purposes only and will not be forwarded for peer or programmatic review.*

- **Attachment 6: Research Team Statement (one-page limit): Upload as “Team.pdf”.** Describe how you and your research team’s combined backgrounds and breast cancer-related expertise will contribute to accomplishing the research goals. Describe how the consumer advocates’ knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the proposed research. Explain how the consumer advocates will be integrated into the planning, design, implementation, and evaluation of the research.
- **Attachment 7: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. *Note: Some of the items in this attachment may be made available for programmatic review.*
  - PI Biographical Sketch (no page limit): Upload as “Biosketch\_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
  - PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Include biographical sketches for team members, including consumer advocates.
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
  - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

#### **Additional Application Components:**

1. **Three Confidential Letters of Recommendations (two-page limit per letter recommended):**

In addition to the complete Grants.gov application package of forms and attachments, Era of Hope Scholar Award applications also require the submission of *three confidential letters of recommendation* from the three individuals named during the pre-application process. The three letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files to eBRAP by 5:00 p.m. ET on the application deadline. The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI should contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

Each letter should describe the PI’s unique qualifications and accomplishments that highlight his/her potential for success in pursuing highly innovative research avenues.

Specifically, each letter should offer the writer's perspective on the PI's:

- Creative and original accomplishments
- Likelihood of continued innovation and productivity
- Potential for leadership in the breast cancer community
- Likelihood of establishing a successful career at the forefront of breast cancer research
- Ability to manage the technical and administrative aspects of this award

**2. Oral Presentation:** PIs whose applications are selected for Programmatic Review, Stage 2, will be required to give an oral presentation (see [Section III.B.2., Programmatic Review](#)) that will be held in the National Capital Region in November 2015.

Each presentation will include a 10-minute talk by the PI, followed by a 20- to 30-minute question and answer session with IP members. The following questions will be the topics for discussion during the PI's talk and the question and answer session. PIs who are selected must prepare a presentation consisting of no more than four slides that specifically address these questions:

- What conceptual or intellectual barriers do you consider the most urgent to overcome in order to end breast cancer?
- How does your vision for breast cancer research challenge current dogma within the broader field of breast cancer research?
- Without addressing any specifics of the project, how do you envision your research contributing to the next leap forward toward ending breast cancer?
- How will you use your leadership skills to form partnerships and collaborations that will make an impact on breast cancer within your research efforts, as well as beyond?

**D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

## **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in application rejection.

## **F. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

## **III. APPLICATION REVIEW INFORMATION**

### **A. Application Review and Selection Process**

All applicants are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and BCRP, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## **B. Application Review Process**

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Principal Investigator**

- How the PI's record of accomplishments supports his/her future abilities as an independent and visionary scholar/investigator.
- How the application provides sufficient evidence to suggest that the PI will become a leader in the field of breast cancer research, including a plan for leadership.
- How the PI's accomplishments demonstrate his/her creativity and productivity.
- How the PI's accomplishments have had an impact on the broader scientific, clinical, and/or patient community.
- Whether any products, patents, or licenses have resulted from the PI's work.
- Whether the PI's work has resulted in publications in high-impact journals and/or presentations at international scientific meetings.
- Whether the PI has received awards or other forms of acknowledgment for his/her achievements.

- **Research Goals**

- How the PI's research goals suggest innovative, creative thinking that is not hindered by convention.
- How the proposed research goals are distinct within the PI's field and within the broader field of breast cancer research.
- How the PI communicates a clear plan of what he/she hopes to accomplish during the award period.
- How the PI identifies barriers that could inhibit his/her research goals and proposes appropriate strategies to overcome these barriers.
- Whether the PI's research goals could lead to a solution for an overarching challenge in breast cancer.

- **Research Team and Environment**

- How the expertise and combined efforts of the PI and research team will contribute to accomplish the research goals.
- How consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
- Whether the environment will facilitate the PI's growth as an emerging innovator and leader.
- Whether appropriate documentation of institutional support reflects the extent to which the PI will be relieved of academic or administrative responsibilities and allowed to pursue his/her goals.



- How the PI will devote at least 50% effort to breast cancer research during the award period.
- Whether the PI has the necessary technical and administrative experience and/or ability to manage this award.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- a. **Ratings and evaluations of the peer reviewers**
- b. **Relevance to the mission of the DHP and FY15 BCRP, as evidenced by the following:**

**Stage 1:** During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:

- Programmatic relevance
- Relative innovation
- Adherence to the intent of the award mechanism

**Stage 2:** During the second stage of programmatic review, the following criteria will be used:

- Understanding of barriers in breast cancer
- Articulation of a realistic vision with a high potential to impact breast cancer
- Leadership capabilities to form partnerships and collaborations that will impact breast cancer

## C. **Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

## **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- Consumer advocates are not included in the application.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

### **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- A FY15 BCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY15 BCRP IP members can be found at <http://cdmrp.army.mil/bcrp/panels/panels15.shtml>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The PI does not meet the eligibility criteria.

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

#### **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

#### **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.

## **D. Reporting**

Refer to the General Application Instructions, Appendix 3, Section J, for general information on reporting requirements.

## **E. Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The institution transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 3, Section N, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Grants.gov Application Components</b>	<b>Upload Order</b>	<b>Action</b>	<b>Completed</b>
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Not required, leave Attachment 3 blank.	
	4	Lay Abstract: Not required, leave Attachment 4 blank.	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Research Team Statement: Upload as Attachment 6 with file name "Team.pdf."	
	7	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 7 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	
<b>Additional Application Components</b>	<b>Upload Order</b>	<b>Action</b>	<b>Completed</b>
Confidential Letters of Recommendation		Confirm upload to eBRAP.	
Oral Presentation		Confirm ability to give an oral presentation in the National Capital Region in November 2015 (if selected for Stage 2).	