Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Distinguished Investigator Award

Funding Opportunity Number: W81XWH-15-BCRP-DIA

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 24, 2015
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, July 28, 2015
- **Invitation to Submit an Application:** June 9, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, July 28, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, August 3, 2015
- **Peer Review:** September 2015
- **Programmatic Review, Stage 1:** November 2015
- **Invitation for Oral Presentation:** November 2015
- **Programmatic Review, Stage 2:** January 2016

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 1992 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.

C. FY15 BCRP Topic Areas

Considering the current [breast cancer landscape](#) and the BCRP's vision to end breast cancer, each FY15 Distinguished Investigator 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 BCRP Distinguished Investigator Award enables established visionary leaders from any field to pursue innovative ideas that could accelerate progress toward ending breast cancer. These individuals should be exceptionally talented researchers who have shown that they are leaders in their field(s) through extraordinary creativity, vision, and productivity. The Principal Investigator (PI) is expected to have a renowned reputation as a researcher who has made groundbreaking contributions to advancing his/her field. He/she should have demonstrated success at forming and leading effective partnerships and collaborations. Through his/her distinguished record of research and leadership, the PI should demonstrate the potential to make unique and significant advances in breast cancer.

The central feature of the Distinguished Investigator Award is that the PI must propose research that is a fundamental shift from his/her track record of research and addresses one or more BCRP overarching challenge(s). Proposals that are a continuation or incremental change from the PI's published line of research do not meet the intent of this award. High-risk/high-reward proposals with limited preliminary data are welcomed, but not required. All applications must include a well-formulated, testable hypothesis based on strong scientific rationale.

Experience in breast cancer research is not required; however, the application must focus on breast cancer. 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. If the PI does not have experience in breast cancer, inclusion of at least one collaborator with breast cancer expertise on the research team is required. The PI's research team must also 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

- PIs must be at or above the level of Assistant Professor (or equivalent) and be more than 6 years beyond their last mentored position.

- 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 **$3M**. Associated indirect costs can be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$3M** direct costs or uses 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.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **5** years.

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, up to $1,800, 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

- Clinical research costs

- Training

- Workshops

- Support for 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 $14.4M of the $120M FY15 BCRP appropriation to fund approximately three Distinguished Investigator 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 <u>strongly</u> 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-DIA 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/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission.

No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at 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 Integration Panel (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 or 301-682-5507.
- **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).
  - The PI must enter the name of each consumer advocate on the research team and indicate their role in the drop down list.

- **Pre-Application Files – Tab 5**

  Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Preproposal Narrative: Provide responses in the appropriate data fields for the following:

  1. Describe how your unique accomplishments demonstrate that you are an established and recognized leader in your field. (2,000 character limit)

  2. Describe and justify how your proposed work is a fundamental shift from your track record of research and how the work will impact breast cancer. (2,000 character limit)

  3. What BCRP overarching challenge(s) will the proposed research address? If "other," state the overarching challenge and provide justification within the context of the breast cancer landscape. (200 character limit)

  Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application *must be uploaded as individual documents* and are limited to:

  ○ PI Biographical Sketches (five-page limit per individual).

  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.

  If the PI is invited to submit an application, each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter. Three letters of recommendation are required only for invited applications and are due by **5:00 p.m. ET on the application submission deadline.**

- **Submit Pre-Application – Tab 6**

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

  Pre-applications will be reviewed by the BCRP IP, a group composed of scientists, clinicians, and consumer advocates. PIs whose qualifications meet the intent of the award mechanism will be invited to submit applications. To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the BCRP, pre-applications will be screened based on the following criteria:

  ○ The PI's unique qualifications demonstrate he/she is an established and recognized leader in his/her field.

  ○ The PI's proposed work is a fundamental shift from their track record of research and will impact breast cancer.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the title page of this Program Announcement/Funding Opportunity.

C.   Application Submission Content and Forms

Applications will not be accepted unless the PI has received notification of invitation.

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 Distinguished Investigator 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 Distinguished Investigator 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 state *why you, the PI, should be considered for this unique award and how your proposed research represents a fundamental shift from your track record of research.* The following items should be addressed specifically.

  - **Accomplishments:** Describe what you have accomplished that demonstrates your extraordinary creativity, vision, and productivity. Describe how these groundbreaking accomplishments had an impact beyond your own laboratory or research setting into the broader scientific, clinical, and/or patient community. Describe how your achievements reflect your capabilities as a distinguished investigator.

  - **Leadership:** Describe your qualifications as an established leader in your field, including examples of national and international recognition. Describe your success at forming and leading effective partnerships and collaborations.

  - **Commitment:** If you are not a breast cancer researcher, describe how you will commit your research efforts to breast cancer during the award period.

  - **Vision of the Future of Breast Cancer:** Explain your vision of the future of breast cancer. Describe what you foresee as the critical approaches that will most likely produce breakthrough thinking and discoveries to ultimately solve or overcome the major problems/barriers and accelerate progress to end breast cancer. Explain what has motivated you to make the proposed shift in your research and how it addressed your vision.

  - **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. Summarize key examples of specific innovative ideas and hypotheses that you envision pursuing with the funding from this award. Provide the rationale for your ideas and explain why/how your ideas may challenge current assumptions and have a significant impact toward ending breast cancer. Without describing specific research methodology, list the key research goals you propose to pursue.

  - **Research Environment:** Describe the environment in which you work. How will this environment facilitate your development as a distinguished investigator and leader in breast cancer research? If you do not have experience in breast cancer, describe the research environment of the collaborator(s) on your team with breast cancer expertise.

- **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 (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must 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 available for the project, and also include the extent to which the PI will be relieved of academic, clinical, or administrative responsibilities and allowed protected time for breast cancer research. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.

  ○ Letters of Collaboration: 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."**

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

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."**

  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 Distinguished Investigator Award 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.

- **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 addressing the research ideas. If you do not have experience in breast cancer, identify at least one collaborator on your team with breast cancer expertise and describe how he/she will contribute to your transition into breast cancer. Describe how the consumer advocates' knowledge of current breast cancer issues and how their backgrounds 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: Fundamental Shift Statement (two-page limit): Upload as "Shift.pdf."**

  Describe in detail how your proposed work is a fundamental shift from your track record of research, and how the work will impact the overarching challenge(s) you

selected/identified. Describe how the proposed work will accelerate progress toward ending breast cancer.

Attachment 8: 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, Distinguished Investigator Award applications 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 "Required 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 or 1-301-682-5507.

   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
   - Visionary and leadership qualities
   - Success at forming and leading partnerships and collaborations
   - Likelihood of innovation and productivity in breast cancer research

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 January 2016.

   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 motivates your proposed fundamental shift in research and how will it address barriers that you consider to be the most urgent to overcome in order to end breast cancer?
   - How will your vision for breast cancer challenge current dogma and look beyond tradition and convention?
   - 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 highestscoring 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.

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 accomplishments demonstrate leadership in his/her field.
  - How the PI's accomplishments demonstrate his/her creativity and productivity.
  - How the PI's groundbreaking 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 within one's respective field and/or presentations at international scientific meetings.
  - Whether the PI has received awards or other forms of acknowledgment for his/her achievements.

- **Research Ideas**
  - How the PI's proposed research ideas are a fundamental shift from his/her track record of research.
  - How the PI's proposed research ideas are innovative and challenge current paradigms.
  - Whether the PI's research ideas could lead to a solution for an overarching challenge in breast cancer.
  - How the PI's research ideas have significant potential to accelerate progress toward ending breast cancer.
  - How the PI communicates a clear plan of what he/she hopes to accomplish during the award period.

- **Research Team and Environment**
  - How the combined expertise and efforts of the PI and research team will contribute to addressing the research ideas.
  - For PIs with no or limited breast cancer experience:
    - How the PI has integrated a collaborator(s) with breast cancer expertise onto the research team.
  - How consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
  - How the PI's committed effort to breast cancer is appropriate to this award.
  - Whether the environment will facilitate the proposed efforts in breast cancer research.
  - 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 in breast cancer research.

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 for impact in 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 pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Biographical Sketch is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- 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.
- Collaborator with breast cancer expertise is not included in the application, if applicable.

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 pre-application or 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.

- 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

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

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

Grants.gov Application Components	Upload Order	Action	Completed
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	Fundamental Shift Statement: Upload as Attachment 7 with file name "Shift.pdf."	
	8	Collaborating DoD Military Facility Budget Form(s): Upload Attachment 8 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.	
Additional Application Components	**Upload Order**	**Action**	**Completed**
Confidential Letters of Recommendation		Confirm upload to eBRAP.	
Oral Presentation		Confirm ability to give an oral presentation in the National Capital Region in January 2016 (if selected for Stage 2).	