Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Innovator Award

Funding Opportunity Number: W81XWH-14-BCRP-INNOV

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), May 14, 2014

- **Invitation to Submit an Application:** June 2014

- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, August 15, 2014

- **Application Submission Deadline:** 11:59 p.m. ET, August 15, 2014

- **End of Application Verification Period:** 5:00 p.m. ET, August 20, 2014

- **Peer Review:** October 2014

- **Programmatic Review, Stage 1:** December 2014

- **Invitation for Oral Presentation:** December 2014

- **Programmatic Review, Stage 2:** January 2015

__Change for Fiscal Year 2014__: 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.

TABLE OF CONTENTS

I.   FUNDING OPPORTUNITY DESCRIPTION

A.   Program Description

Applications to the Fiscal Year 2014 (FY14) Breast Cancer Research Program (BCRP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). 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 FY13 totaled $2.9 billion. The FY14 appropriation is $120.0 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.   FY14 BCRP Overarching Challenges

Considering the current breast cancer landscape and the BCRP's vision to end breast cancer, each FY14 Innovator 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 Innovator Award supports *visionary individuals* who have demonstrated creativity, innovative work, and leadership in any field including, but not limited to, breast cancer. The Innovator Award will provide these individuals with the funding and freedom to pursue their most novel, visionary, high-risk ideas that could ultimately lead to ending breast cancer.

Since the intent of the Innovator Award mechanism is to recognize creative and innovative individuals rather than projects, the central feature of the award is the innovative contribution that the Principal Investigator (PI) can make toward ending breast cancer. The PI should have a past record of creativity, promise for continued innovation in future work, and a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention. The PI is also expected to be established in his/her field and have demonstrated success at forming and leading effective partnerships and collaborations. To further the development of innovative individuals and spark the generation of novel ideas, applications are required to incorporate the mentoring of promising junior investigators.

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. 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.

Use of 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 6, for additional information.

The types of awards made under this Program Announcement/Funding Opportunity will be assistance agreements. Reference the General Application Instructions, Appendix 4, for additional information regarding award types.

The Congressionally Directed Medical Research Programs (CDMRP) intends that 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 4, Section L.

E.   Eligibility Information

- PIs must be at or above the level of Associate Professor (or equivalent).
- Previous recipients of the BCRP Innovator Award are ineligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, 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 maximum allowable direct costs for the entire period of performance are **$5M** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., 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.4. of the General Application Instructions*.

For this award mechanism, direct costs:

Must be requested for:

- Travel for attendance each year at a DoD-required meeting in Years 1 and 3. Costs associated with travel to the required meetings, up to $1,800 per meeting, should be included in each respective year 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 of up to $3,600 per year to attend scientific/technical meetings in addition to the required meeting described above

The CDMRP expects to allot approximately $15M of the $120M FY14 BCRP appropriation to fund approximately two Innovator 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 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/).

**New for FY14: *The CDMRP has replaced its eReceipt System with eBRAP.* Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at *https://ebrap.org/eBRAP/public/UserGuide.pdf*). Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***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.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see Section IV.A., Rejection).

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.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-14-BCRP-INNOV.

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. If any 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.

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**

    It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

    FY14 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.

- **Required Files – Tab 4**

    Notes: 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.

    Nomination Letter (two-page limit): The nominator should provide a letter on organizational letterhead describing the PI's unique qualifications and accomplishments that demonstrate how the PI is a true visionary in his/her field. The letter should address the nominee's creativity in past work, his/her potential for future creativity and innovation specifically in the field of breast cancer research, and his/her strong leadership qualities. Self-nominations will be accepted.

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. Letters of recommendation are only required for invited applications and are due by *5:00 p.m. ET on the application submission deadline*.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

○ PI Biographical Sketch (four-page limit).

- **Submit Pre-Application – Tab 5**

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, which is 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 equal criteria:

○ The PI's creativity in past work

○ The PI's potential for future innovation, especially in the field of breast cancer research

○ The PI's potential for leadership in breast cancer

○ The PI's accomplishments as a leader in his/her field

- **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 weakness) 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.

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

New for FY14: *Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.* The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing files (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a "Changed/Corrected Application" with the Previous Grants.gov Tracking ID *prior to the application submission deadline (which occurs earlier than the end of the application verification period).*

Grants.gov application package components: For the Innovator 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**

   - **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 will result in administrative withdrawal of the application.

     The Project Narrative should clearly state your *vision for ending breast cancer* and *why you, the PI, should be considered for this unique award.* The following items should be addressed specifically.

     ○ Current Status of Breast Cancer: Describe your views of the major problems/barriers in breast cancer that must be solved or overcome to accelerate progress to end breast cancer. Include in your description the major challenges in breast cancer beyond your specific research area.

     ○ 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.

     ○ Specific Ideas: 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 that you envision pursuing with the funding from this award. Explain why/how your ideas may challenge current assumptions and

have a significant impact toward ending breast cancer. Describe what you hope to accomplish during the award period. This should not be a description of research methodology.

- ○ Commitment: Describe the effort you will commit to this award and explain how you will devote at least 50% effort to breast cancer research during the award period. Explain specifically how you, as an innovator and leader, will mentor promising junior investigators.

- ○ Qualifications for This Award: Explain how you are qualified to receive this award. Give examples of breakthrough creative thinking and leadership skills that demonstrate your abilities as an innovator. Describe your success at forming and leading effective partnerships and collaborations. Describe how your achievements reflect your capabilities as an innovator.

- **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 may result in the removal of those items or 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, 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.

- ○ Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **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." Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

  The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Program Announcement and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Innovator Award mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

- **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. 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.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., 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."
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
- Key Personnel Biographical Sketches (four-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.4., for detailed information.

- Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

Additional Application Components:

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

In addition to the complete Grants.gov application package of forms and attachments, Innovator 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 "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 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 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.   Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***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.***

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 Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov 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 Commanding General, U.S. Army Medical Research and Materiel Command (USAMRMC), 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 non-disclosure 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 primary criteria, which are of equal importance:

   - **Principal Investigator**
     - How the PI has demonstrated a past record of creativity and abilities as an innovator.
     - How the PI's record of accomplishment demonstrates leadership in his/her field and outstanding qualifications as an independent and visionary scholar/ investigator.

   - **Research Ideas**
     - How the PI's proposed research ideas challenge current assumptions and reflect original and innovative thinking that is not hindered by convention.
     - How the PI communicates a clear vision of what he/she hopes to accomplish during the award period.
     - How the proposed ideas may have a significant impact toward ending breast cancer.
     - How the PI's research ideas could lead to a solution for an overarching challenge in breast cancer.

- **Research Team and Commitment**
  - How the expertise and combined efforts of the PI and research team will contribute to addressing the research ideas.
  - How consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
  - How the PI's committed effort is appropriate to this award.
  - How the PI will devote at least 50% effort to breast cancer research during the award period.
  - How the PI will mentor promising junior investigators.

In addition, the following secondary 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, 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 FY14 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 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:

- Nomination Letter is missing.
- Nominee 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.
- 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.

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.
- Following application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the application verification period; otherwise, the application will be reviewed as submitted.

C.   Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY14 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 FY14 BCRP IP members can be found at http://cdmrp.army.mil/bcrp/panels/panels14.

- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- 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, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B.   Administrative Requirements

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

C.   National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D.   Reporting

Refer to the General Application Instructions, Appendix 4, 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 4, Section M, 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 application package. If the 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	Action	Completed
SF-424 (R&R) Application for Federal Assistance	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Not required, leave Attachment 3 blank.	
	Lay Abstract: Not required, leave Attachment 4 blank.	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Research Team Statement: Upload as Attachment 6 with file name "Team.pdf."	
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	**Action**	**Completed**
Confidential Letters of Recommendations	Confirm upload to eBRAP.	
Oral Presentation	Confirm ability to give an oral presentation in the National Capital Region in January 2015 (if selected for Stage 2).	