Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Postdoctoral Fellowship Award

Funding Opportunity Number: W81XWH-13-BCRP-POSTDOC Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 18, 2013
- Confidential Letters of Recommendation Submission Deadline: 5:00 p.m. ET, July 2, 2013
- Application Submission Deadline: 11:59 p.m. ET, July 2, 2013
- **Peer Review:** August 2013
- **Programmatic Review:** October 2013

This Program Announcement 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. Fu | nding Opportunity Description | . 3 |
|---------|---|-----|
| A. | Program Description | 3 |
| B. | FY13 BCRP Overarching Challenges | 3 |
| C. | Award Information | 4 |
| D. | Eligibility Information | 4 |
| E. | Funding | 5 |
| II. Su | bmission Information | . 6 |
| A. | Where to Obtain the Application Package | 6 |
| B. | Pre-Application Submission Content and Form | 6 |
| C. | Application Submission Content and Form | 7 |
| D. | Submission Dates and Times | |
| E. | Other Submission Requirements | 13 |
| III. Ap | plication Review Information | 13 |
| A. | Application Review and Selection Process | 13 |
| B. | Application Review Criteria | 14 |
| C. | Recipient Qualification | 16 |
| D. | Application Review Dates | 16 |
| E. | Notification of Application Review Results | 16 |
| IV. Ad | Iministrative Actions | 16 |
| A. | Rejection | |
| В. | Modification | 16 |
| C. | Withdrawal | 16 |
| D. | Withhold | 17 |
| V. Av | vard Administration Information | 17 |
| A. | Award Notice | |
| В. | Administrative and National Policy Requirements | |
| C. | Reporting | 17 |
| D. | Award Transfers | 17 |
| VI. Ag | ency Contacts | |
| A. | CDMRP Help Desk. | |
| В. | Grants.gov Contact Center | |
| VII. Ap | plication Submission Checklist | 19 |

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2013 (FY13) 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 FY12 totaled \$2.8 billion. The FY13 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, facilitate multidisciplinary collaborations, and support future breast cancer leaders.

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_landscape13.pdf.

B. FY13 BCRP Overarching Challenges

Considering the current <u>breast cancer landscape</u> and the BCRP's vision to end breast cancer, the FY13 BCRP encourages Postdoctoral Fellowship Award applications that address one of the following overarching challenges:

- Eliminate the mortality associated with metastatic breast cancer
- Prevent breast cancer (primary prevention)
- Distinguish aggressive breast cancer from indolent cancers; overcome the problems of overdiagnosis and overtreatment
- Revolutionize treatment regimens by replacing drugs that have life-threatening toxicities with safe, effective interventions
- Identify what drives breast cancer growth and metastasis; identify why some breast cancers become life-threatening metastases
- Identify what makes the breast susceptible to cancer development
- Determine why some, but not all, women get breast cancer
- Determine why/how breast cancer cells lay dormant for years and then re-emerge (recurrence); determine how to eliminate dormant cells early

C. Award Information

The Postdoctoral Fellowship Award supports exceptionally talented recent doctoral or medical graduates in pursuit of innovative, high-impact breast cancer research during their postdoctoral training and allows them to obtain the necessary experience for an independent career at the forefront of breast cancer research. Those individuals should be exceptionally talented scientists who have demonstrated that they are the "best and brightest" of their peers. Applicants for this award must exhibit a strong desire to pursue a career in breast cancer research.

Under this award mechanism, the postdoctoral fellow is considered the Principal Investigator (PI) and, as such, should write the project narrative, training plan, and other application components with appropriate guidance from the mentor. While the PI is not required to have previous experience in breast cancer research, the proposed project and training must focus on breast cancer. Applications must emphasize the PI's high potential for success in becoming an independent breast cancer researcher based on his/her qualifications, achievements (including first-author publications), and letters of recommendation.

The mentor (or co-mentor, if applicable) must possess the appropriate expertise and experience in breast cancer, to include publications and active peer reviewed breast cancer funding, and clearly demonstrate a commitment to guiding the PI's research and training. If the mentor is not an experienced breast cancer researcher, then formal co-mentorship by an established breast cancer researcher is required. The application must include information about the mentor's experience in conducting innovative research and how he/she intends to support the PI's endeavors in breast cancer. Mentorship by an investigator without an established record of mentoring pre- and postdoctoral trainees may be offset by the overall strength of the training plan.

Applications must provide details on the suitability of the PI's overall training plan and research project for attaining the goals of this award mechanism. Applications must elaborate on the qualities of the training environment in which the candidate will work, provide details on the individualized, breast cancer-focused training plan, and describe how this training will facilitate the PI's career development as an independent, innovative breast cancer researcher. A multidisciplinary research approach to breast cancer is highly encouraged but not required; however, if there are multidisciplinary aspects to the training, they should be clearly outlined in the application. The application must articulate the potential impact that the proposed work will have on breast cancer. The research should be based on a sound scientific rationale and/or a thorough review of the literature. Preliminary data are not required.

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 K.

D. Eligibility Information

- As of the application submission deadline, all eligible PIs must have:
 - o Successfully completed the requirements for a doctoral or medical degree, and

- Been in the laboratory or clinical research setting in which the proposed research is to be performed for no more than 2 years as a postdoctoral researcher, and
- A total of less than 4 years of postdoctoral research experience (excluding clinical residency or clinical fellowship training).
- Only postdoctoral fellows are eligible for this award. Faculty members, instructors, and all other non-postdoctoral positions are not eligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- 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.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance are \$300,000 plus indirect costs.
- Up to \$100,000 per year can be requested in direct 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.
- The PI of the award is expected to have discretion over the management of the budget during the award period. *The Postdoctoral Fellowship Award is not intended to support general laboratory expenses for the mentor*.

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 and are so noted in Section II.C.4. of the General Application Instructions.

In addition, for this award mechanism, direct costs:

Must be requested for:

• Travel for the PI to attend one Department of Defense (DoD) BCRP Era of Hope meeting, if the meeting falls within the period of performance of the award. The Era of Hope meeting is held to disseminate the results of BCRP-sponsored research. Costs associated with travel to this meeting, up to \$1,800, should be included in Year 2 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/stipend (PI only)
- Health insurance
- Research supplies
- Equipment
- Training
- Tuition
- Workshops
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings in addition to the required Era of Hope meeting described above

Shall not be requested for:

Mentor or other salary

The CDMRP expects to allot approximately \$9M of the \$120M FY13 BCRP appropriation to fund approximately 20 Postdoctoral Fellowship 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 CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

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-13-BCRP-POSTDOC.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (https://cdmrp.org/).

PIs and organizations identified in the application should be the same as those identified in the pre-application. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System 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
- Collaborators and Conflicts of Interest Tab 3
 - Include the name(s) of the mentor (and co-mentor, if applicable)
 - o Include the names of the individuals providing letters of recommendation. FY13

BCRP Integration Panel (IP) members

(http://cdmrp.army.mil/bcrp/panels/panels13) should not be involved in any preapplication 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@cdmrp.org or 1-301-682-5507.

Required Files – Tab 4

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

Note: At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.

• 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. The three individuals must include the mentor and, if applicable, co-mentor. Each individual will receive an email generated from the CDMRP eReceipt System containing specific instructions on how to upload his/her letter.

• Submit Pre-Application – Tab 5

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

Other Documents Tab

No additional documents are required.

C. Application Submission Content and Form

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 Postdoctoral Fellowship Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Postdoctoral Fellowship 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.

Describe the proposed project using the following outline:

- PI's Career Goals: The PI should describe his/her career goals and how the proposed training and research experience will promote his/her career development in breast cancer research or patient care. The PI should discuss his/her career and research plans after the completion of this award.
- Research Project: Describe the proposed research project, including background, hypothesis/rationale/purpose, and objectives. Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical substances will be used, include a statistical plan, as well as a detailed plan for the recruitment of subjects or the acquisition of samples. The PI should discuss the relevance of this research to his/her career goals and the potential impact it might have on breast cancer. Preliminary data are not required.
- 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 if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present 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 they must be included. Extra items will not be reviewed.
- Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
- Letters of Collaboration (if applicable) (two-page limit per letter): 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.
- Transcripts: Include a copy of the PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts.
 - If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.
- Mentor Qualifications (one-page limit): Include a description of the qualifications of the mentor. Specifically address the following:
 - Experience in conducting innovative research
 - Experience in breast cancer to include publications and active funding
 - Record and success in mentoring pre- and/or postdoctoral trainees
- Co-Mentor Qualifications (if applicable, one-page limit): Include a description of the qualifications of the co-mentor. Specifically address the following:
 - Experience in conducting innovative research
 - Experience in breast cancer to include publications and active funding
 - Record and success in mentoring pre- and/or postdoctoral trainees
- Letter of Formal Co-Mentorship Support (if applicable): Provide a signed letter from the Chair of the department that acknowledges the formal designation and role of the co-mentor for the PI's training plan.

- Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."
 - o Training Plan
 - Describe the PI's career goals and how the proposed training will support him/her in attaining these goals.
 - Describe how the proposed research project will train the PI to make valuable contributions to breast cancer.
 - Describe the unique aspects of the training plan and environment.
 - o Research Plan
 - Background: Present the ideas and reasoning behind the proposed work.
 - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
 - Specific Aims: State the specific aims of the study.
 - Study Design: Briefly describe the study design, including appropriate controls.
 - Impact: Describe how the proposed project will have an impact and accelerate progress toward ending breast cancer.

The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."
 - Describe the scientific objective and rationale for the proposed project in a manner readily understandable by non-scientists.
 - Do not duplicate the technical abstract.
 - Describe the PI's career goals in breast cancer.
 - How will the training plan support the PI in attaining these goals?
 - How will the research plan support the PI in attaining these goals?
 - Describe the ultimate applicability and impact of the research.
 - What types of patients will it help and how will it help them?
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected time it may take to achieve a patient-related outcome?
 - If the research is too basic for clinical applicability, describe the interim outcomes.
 - What are the likely contributions of this study to advancing the field of research?

- Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

 Include both the training plan and research plan in the SOW.
- Attachment 6: Impact Statement (one-page limit): Upload as "Impact.pdf." State explicitly how the proposed work addresses a critical problem in breast cancer. Describe the pathway to making an impact on breast cancer and explain how the PI's specific research goals, if achieved, would fit into that pathway.
- Attachment 7: Detailed Training Plan (two-page limit): Upload as "Training.pdf."
 - Clearly describe the *breast cancer-focused* training plan that is *individualized* for the PI and will be utilized to prepare him/her for an independent career at the forefront of breast cancer research. The description should include details such as a timeline, coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Inclusion of a chart, graph, or table is suggested.
 - Highlight the unique features of the PI's training plan as it pertains specifically to breast cancer research training.
 - Indicate specifically how the individualized training plan will advance the PI's development as a breast cancer researcher.
 - Briefly describe how the training plan is supported by the research environment, including a description of ongoing breast cancer research at the institution.
 Include information on training or collaborations with other investigators.
- Attachment 8: Eligibility Statement: Upload as "Eligibility.pdf."
 - Use the Eligibility Statement form (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official verifying that the eligibility requirements will be met by the application submission deadline.
- 3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.
 - PI Biographical Sketch (four-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."
 - o Include mentor's and co-mentor's (if applicable) biographical sketch.
 - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Include mentor's and co-mentor's (if applicable) previous/current/pending support.
- **4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., 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., for detailed information.
- **6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

Additional Application Components: In addition to the completed Grants.gov application package, Postdoctoral Fellowship Award applications also require the following components:

- 1. Three Confidential Letters of Recommendation (two pages per letter recommended): Confidential letters of recommendation must be submitted by the three individuals designated during the pre-application process. The individuals submitting letters must include the mentor and co-mentor, if applicable. All letters must be submitted electronically through the CDMRP eReceipt System by 5:00 p.m. ET on the application deadline. The PI should monitor whether the letters have been received in the eReceipt System; however, the PI is not 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@cdmrp.org or 1-301-682-5507.
 - Confidential letter(s) of recommendation from the mentor(s): A letter must come from the PI's mentor, describing his/her commitment to the PI's training, career development, and mentorship. If the PI has a co-mentor, then that individual must also submit a letter of recommendation. Each mentor's or co-mentor's letter of recommendation should describe:
 - The PI's potential to become a successful and independent breast cancer researcher;
 - The degree to which the PI participated in the idea development and application preparation;
 - The mentor's or co-mentor's commitment to the training, career development, and mentorship of the PI, including details of his/her proposed interactions with the PI during the PI's training and how he/she intends to support the PI's research endeavors; and
 - The relevance of the proposed research project to training the PI in breast cancer.
 - Additional confidential letter(s) of recommendation: The remaining letter(s) should highlight the PI's potential for success in pursuing a career in breast cancer research. Specifically, each letter should include the writer's perspective on:
 - The PI's qualifications, characteristics, and achievements;

- The PI's potential for productivity and desire for establishing a successful career at the forefront breast cancer research;
- The relevance of the proposed research project to training the PI in breast cancer; and
- The suitability of the mentor and individualized training plan for providing the PI with a solid foundation in breast cancer research.

D. Submission Dates and Times

All submission dates and times are indicated on the <u>title page</u> of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. 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 applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a 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, based on technical merit, the relevance to the mission of the DHP and BCRP and the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review 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 Criteria

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 achievements demonstrate that he/she is among the "best and brightest" of his/her peers (as reflected by outstanding academic performance, publications, awards, honors, funding, patents and other outstanding achievements) and indicate a potential for a successful career in breast cancer research.
- Whether the PI has a strong publication record, including first-author publications.
- How the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career at the forefront of breast cancer research; prior breast cancer research experience is not required of the PI.
- How the letters of recommendation support the PI's high potential for success and dedication to a career in breast cancer research.

• Mentor (and Co-Mentor, if applicable)

- How the mentor is appropriately trained and well-suited to guide this research project, including the mentor's active funding, publications, and strong background in breast cancer research.
- How the mentor's background, qualifications, research program, committed resources, and available time support his/her ability to supervise the PI's training and research project.
- How the mentor's training achievements, as reflected by his/her previous trainees' career achievements and areas of interest, indicate the potential for successful training of the PI in breast cancer research.
- Whether the mentor's letter of recommendation indicates a high level of commitment to training the PI.
- Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.

• Training Plan

- How detailed and individualized is the training plan.
- How the training plan is breast cancer-focused.
- How the training will provide valuable experience to prepare the PI for an independent career at the forefront of breast cancer research.

Impact

- How the proposed research addresses a critical problem in breast cancer.
- How the proposed research goals, if achieved, will contribute to a pathway toward making an impact on breast cancer; impact may be near- or long-term.

Research Strategy and Feasibility

- How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PI acknowledges potential problems and addresses alternative approaches.

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

Environment

- How the scientific environment is appropriate for the proposed training and research.
- How the training and research requirements are adequately supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- How the application provides evidence of a strong institutional commitment to research training in breast cancer.

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 influenced the review.
- **2. Programmatic Review:** To make funding recommendations, the following criteria are used by the programmatic reviewers:
 - a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and FY13 BCRP, as evidenced by the following:

- Programmatic relevance
- Relative impact
- Program portfolio composition
- Adherence to the intent of the award mechanism

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 <u>title page</u> of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the application:

• A FY13 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 document. A list of the FY13 BCRP IP members can be found at http://cdmrp.army.mil/bcrp/panels/panels13.

- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- 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, 2014. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

D. Award Transfers

Changes in PI, mentor or institution 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.

Refer to the General Application Instructions, Appendix 4, Section F, 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 the CDMRP eReceipt System 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@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the 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 Form | Complete form as instructed. | |
| Attachments Form | Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1. Upload Supporting Documentation (Support.pdf) as Attachment 2. Upload Technical Abstract (TechAbs.pdf) as Attachment 3. Upload Lay Abstract (LayAbs.pdf) as Attachment 4. Upload Statement of Work (SOW.pdf) as Attachment 5. Upload Impact Statement (Impact.pdf) as Attachment 6. Upload Detailed Training Plan (Training.pdf) as Attachment 7. | |
| Research & Related Senior/Key Person Profile (Expanded) | Upload Eligibility Statement (Eligibility.pdf) as Attachment 8. 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 (Support_LastName.pdf) for each senior/key person to the appropriate field. | |
| Research & Related Budget | Complete form 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 Recommendation | Confirm upload of all three letters to the CDMRP eReceipt System. | |