

# **Program Announcement**

**Defense Health Program**

**Department of Defense**

**Congressionally Directed Medical Research Programs**

## **Breast Cancer Research Program**

### **Clinical Translational Research Award**

**Funding Opportunity Number: W81XWH-12-BCRP-CTR**

**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), May 3, 2012
- **Invitation to Submit an Application:** June 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 15, 2012
- **Peer Review:** October 2012
- **Programmatic Review:** December 2012

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

Applications for the Breast Cancer Research Program (BCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The BCRP was established in fiscal year 1992 (FY92) to support innovative research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY11 totaled over \$2.6 billion. The FY12 appropriation is \$120 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of the vision to end breast cancer. Specifically, the BCRP seeks to accelerate high-impact research, encourage innovation and stimulate creativity, bring new investigators into the breast cancer field, and facilitate multidisciplinary collaborations.

### B. Award Information

The BCRP Clinical Translational Research (CTR) Award is intended to promote significant improvements over current approaches to breast cancer prevention and therapy, such as studies that will prevent primary or recurrent breast cancer and studies that may result in a new treatment to prevent breast cancer progression to metastasis. The CTR Award supports research projects that are likely to have a major impact on breast cancer by applying promising research findings to patients with, or populations at risk for, breast cancer.

Principal Investigators (PIs) and their collaborators may have originated projects in their laboratories that will form the basis for 1-2 years of advanced translational research leading to a prospective clinical trial to be conducted during this award period. Alternatively, PIs may leverage partnerships with industry. The ability to conduct the required translational research and early phase clinical trial during the award period must be demonstrated.

Applications must include preliminary data and a solid rationale to support the feasibility of advancing novel translational research to a prospective clinical trial. Due to the short period for the advanced translational research phase, PIs must have already demonstrated proof of concept and efficacy in an in vivo system at the time of application submission. Applications also must include a clear experimental plan and a properly powered statistical plan to perform the clinical trial. Investigators must demonstrate availability of and access to an appropriate patient population that will support meaningful clinical outcomes.

***PIs must provide a detailed plan for how they will meet the requirements for obtaining Investigational New Drug (IND) or Investigational Device Exemption (IDE) status (or other approvals required by the U.S. Food and Drug Administration [FDA]) early in the award period to further investigate preventive or therapeutic interventions developed through the CTR Award. Participating organizations must be willing to resolve potential intellectual and material property issues and remove barriers to achieving high levels of cooperation. If the application involves multiple organizations, an intellectual and material property plan agreed to by all participating organizations is required in the application's supporting documentation. Further, PIs must clearly outline a transition plan to move their findings or interventions into the breast cancer community.***

**Use of Human Subjects and Human Anatomical Substances:** All Department of Defense (DoD)-funded research involving new and ongoing research with human subjects and human anatomical substances 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) or IRB of record. Local IRB approval at the time of submission is NOT required. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives will require information in addition to that supplied to the local IRB. Allow a minimum of 2-3 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

**Partnering PI Option:** The CTR Award mechanism encourages applications that include meaningful and productive collaborations between investigators. The Partnering PI Option under the CTR Award mechanism is structured to accommodate two PIs who will each receive a separate award. One partner is identified as the Initiating PI and the other PI is identified as the Partnering PI. The Initiating and Partnering PI have different submission requirements; however, both PIs should contribute to the preparation of a single application. The collaborative partners may have expertise in similar or disparate scientific disciplines, but each partner is expected to bring different strengths to the application. New collaborations are encouraged, but not required. It is the responsibility of the collaborating investigators to describe how their combined expertise in the collaboration will better address the research question and explain why the work should be done together rather than through separate efforts.

The CTR Award will be supported in two stages. Stage I (Years 1-2) will enable the PI(s) to complete advanced translational studies, obtain IRB and HRPO approvals, and obtain the appropriate FDA approvals (if necessary). Stage II (Option Years 3-5) will involve the initiation and execution of the prospective clinical trial.

***The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities 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.***

### **C. Eligibility Information**

- PIs must be at or above the level of Assistant Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## D. Funding

Applications with a **single PI** or **Partnering PI Option** have the same funding levels.

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$12M** (for both Stage I and Stage II) plus indirect costs. ***The requested budget should be appropriate for the type of translational research and clinical trial proposed.***
- 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(s) may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The applicant(s) may request up to **\$2M** in direct costs for Years 1-2 (Stage I). Awards that require less than or more than 2 years to complete Stage I will be handled on a case-by-case basis at the discretion of the Grants Officer. Stage I will be funded using allocations from the FY12 BCRP Congressional appropriation.
- The applicant(s) may request direct costs for option Years 3-5 (Stage II) such that the combined total direct costs for Stages I and II do not exceed **\$12M**. Option years will be funded with future Congressional appropriations, if available. A total of three 1-year options will be allowed.
- Exercising the options for Stage II will be contingent on receipt of sufficient Congressional appropriations to the BCRP, submission and approval of written progress reports, and acceptable performance of the recipient. Milestones for the approved Statement of Work (SOW) will be finalized during award negotiation. Before moving from Stage I to Stage II, the PI(s) will be required to present an update on progress toward accomplishing the goals of the project at a Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be attended by members of the BCRP Integration Panel (IP), CDMRP staff, and the Grants Officer. Annual Milestone Meetings will also be held during Stage II. ***Failure to complete each milestone may result in forfeiture of the subsequent installment of CTR Award funding.***
- The applicant must submit a comprehensive budget, broken down by year, which details the projected funding needed for the entire period of performance, to include Stages I and II.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for the PI and key personnel to attend three Milestone Meetings in the National Capital Region. Costs associated with travel to these meetings should be included in Years 2, 3, and 4 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

- Travel for the PI and key personnel to attend two DoD BCRP Era of Hope meetings, which are held to disseminate the results of BCRP-sponsored research. Costs associated with travel to these meetings, up to \$1,800 per person for each meeting, should be included in Years 2 and 5 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Travel between collaborating organizations
- Travel costs of up to \$3,600 per year to attend scientific/technical meetings

*The CDMRP expects to allot approximately \$9M of the \$120M FY12 BCRP appropriation to fund approximately three Stage I Clinical Translational Research 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 multi-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/>).

**Partnering PI Option:** The Clinical Translational Research Award is structured to accommodate two PIs. One partner will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, both PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified separately by email. Please note that the Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI. If an application is invited, only the Initiating PI will receive notification of invitation via email from the CDMRP.

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

## 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-12-BCRP-CTR.

## 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/>). 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.

**Partnering PI Option:** *The Initiating PI is responsible for submission of all pre-application components.*

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](mailto:help@cdmrp.org) or 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 (COI) – Tab 3**

FY12 BCRP IP members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 1-301-682-5507.

**Partnering PI Option:** The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **Required Files – Tab 4**

**Pre-Application Narrative (five-page limit):** The Pre-Application Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Pre-Application Narrative should include the following:

- An explanation of how the results of this project have the potential to significantly improve the prevention and/or treatment of breast cancer.
- A description of how the proposed project applies novel, yet well-founded observational data, laboratory results, or other preclinical insights that justify the progression of the project into a clinical trial.
- An outline of the necessary translational studies to be conducted through this award in order to move the project into a clinical trial.

- A plan for the prospective clinical trial that will be conducted.
- Evidence for proof of concept and efficacy in an in vivo system.
- A discussion of the appropriateness of the patient population to be targeted for the clinical trial. Evidence supporting access to the patient population and ability to accrue sufficient study subjects for the clinical trial.
- A description of the expertise available for conducting the translational and clinical research.

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

- References Cited: (one-page limit)
- Key Personnel Biographical Sketches (four-page limit per individual): Include the Partnering PI, if applying under the Partnering PI Option.
- Access to Resources (two-page limit per letter or document)
  - Access to Materials: Provide signed letters from collaborating individuals or institutions documenting the availability of, access to, and quality control for all critical reagents. Include information regarding the resources available to aid in the development of sufficient quantities of the reagent under Good Manufacturing Practice (GMP), if applicable. If the reagent is to be provided from industrial sources, evidence of a cost-sharing plan also must be provided.
  - Access to Patients: Provide letters from collaborating individuals or institutions documenting the availability of and access to the patient population and evidence that the accrual rate can be achieved within the performance period of the award.

- **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.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DoD and the BCRP, pre-applications will be screened based on adherence to the intent of the award mechanism.

- **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.

Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## C. Application Submission Content and Form

*Applications will not be accepted unless the PI or Initiating PI has received a letter 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/>).

*Partnering PI Option: The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and Partnering PI. Initiating and Partnering PIs will each be assigned unique log numbers by the CDMRP eReceipt System. Each Grants.gov application package must be submitted using the unique log number.*

### **Application Components for Single PIs or for Initiating PIs under the Partnering PI Option:**

**Grants.gov application package components:** For the Clinical Translational Research 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 (25-page limit):** Upload as “ProjectNarrative.pdf.”

CTR Award applications must include promising preclinical data relevant to the proposed project. In addition, the PI is responsible for clearly articulating the ways in which the proposed research will have a significant impact on the prevention and/or treatment of breast cancer.

Describe the proposed research for Stages I and II using the following outline:

- **Background:** Provide a brief statement of the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of the translational and clinical work proposed. Importantly, describe the studies showing proof of concept and efficacy in an in vivo system. Explain why the proposed work should proceed to a prospective clinical trial for the prevention or treatment of breast cancer. Describe the pertinent experience of the investigators. Cite relevant literature.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims to be funded by this award.

- **Research Strategy:** Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches for the translational research. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe the advanced translational studies that will be performed through this award and *clearly link* the laboratory and other preclinical findings to the prospective clinical trial. If preliminary studies are not focused on breast cancer, explain how the preliminary work will support the proposed research and clinical trial in breast cancer. As appropriate, outline a plan for applying for and obtaining IND/IDE status (or other FDA approvals).
- **Clinical Trial:** Provide detailed plans for initiating and conducting the prospective clinical trial during the course of this award. Provide a properly powered statistical plan and information demonstrating that a sufficient number of participants will be accrued to the proposed clinical trial during the award period. The investigator(s) and his/her team must demonstrate appropriate expertise in conducting clinical trials, which may include the expertise of collaborating investigators and highly experienced support staff. (Do not submit a clinical trial protocol with the application.)
- **Strategic Plan:** Provide an overall strategic plan for completing the clinical trial during the award period.
- **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 component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection 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 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, 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.
  - Availability of, access to, and quality control for all critical reagents.
  - Availability of and access to the appropriate patient population(s).
- GMP (if applicable; two-page limit): Provide information regarding the resources available to aid in the development of sufficient quantities of the reagent under GMP. If the reagent is to be provided from industrial sources, evidence of a cost-sharing plan must also be provided.
- 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.”

Use the outline below.

- 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: Briefly describe how the proposed project, if successful, will have an impact on 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.”
  - Clearly describe, in a manner readily understood by lay persons, the rationale, objective, and aims of the application.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability 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?
  - What is the likely impact of this study on ending breast cancer?

- **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.

Establish milestones in the SOW for the following:

- Completion of toxicity and pharmacokinetic studies, as applicable.
- Strategic meeting with the FDA prior to applying for IND/IDE or other required approval (if necessary).
- Achievement of the necessary regulatory approvals (e.g., IRB, FDA, HRPO).
- Patient accrual goals relevant to the clinical trial.

*For the Partnering PI Option: Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.*

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Describe how the proposed work, if successful, will result in significant improvements over current approaches to breast cancer prevention and therapy. Describe how the research has the potential to make an important contribution toward accelerating the end of breast cancer.

- **Attachment 7: Translatability Statement (one-page limit):** Upload as “Translatability.pdf.”

Describe how the project is expected to translate promising research findings into a clinical trial for novel prevention strategies or treatments for breast cancer.

- **Attachment 8: Transition Plan (one-page limit):** Upload as “Transition.pdf.”

Provide information on potential methods and strategies to move the clinical trial findings to the next phase of clinical trials and/or delivery to the civilian market after successful completion of the award (e.g., specific potential industry partners; specific funding opportunities to be applied for). In addition, provide a plan to distribute the findings or interventions to the breast cancer community.

### 3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI 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 the Partnering PI, if applying under the Partnering PI Option.
- Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
  - Include the Partnering PI, if applying under the Partnering PI Option.

- 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.”

*Include a detailed budget and justification that covers the projected funding needed for each year of the entire period of performance, to include Stages I and II.*

*For the Partnering PI Option: Initiating and Partnering PIs must each submit a budget and justification as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for the Partnering PI, even if they are at the same organization.*

- 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.

#### **Application Components the Partnering PI, if applying under the Partnering PI Option:**

*The Partnering PI must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate his/her grant application package with that of the Initiating PI.*

The application submission process for Partnering PI uses an abbreviated application package of forms and attachments from Grants.gov that includes:

- 1. SF 424 (R&R) Application for Federal Assistance Form**

- 2. Attachments Form**

- **Attachment 5: Statement of Work (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI should be noted for each task.*

- 3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

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

*Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the effort as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are at the same organization. The combined total direct costs for the Initiating and Partnering PIs’ budgets cannot exceed \$12M.*

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

#### **D. 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 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. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) 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 compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DoD 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. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs 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 panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations 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:

- **Impact**
  - How the project, if successful, will result in significant improvements over current approaches to breast cancer prevention and therapy.
  - Whether the aims of the application, if achieved, are likely to have a *significant clinical impact*.
  - How the research, if successful, has the potential to make an important contribution toward accelerating the end of breast cancer.
- **Translational and Clinical Strategy**
  - How the project will translate promising, well-founded research findings into a clinical trial for a novel prevention or treatment for breast cancer.
  - Whether the PI demonstrates the ability to accrue a sufficient number of subjects.
  - Whether the research design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.
  - How well the strategic plan to complete the clinical trial during the award period is developed.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning.
  - How the hypotheses, objectives, aims, experimental design, methods, and analyses are developed.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether there is documented availability of, access to, and quality control for all critical reagents.
  - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP.
  - Whether preliminary studies show proof of concept in an in vivo system.
- **Statistical Plan**
  - Whether an appropriate statistical plan is provided, including power analysis.
  - Whether the clinical trial is designed with enough statistical power to lead to meaningful results.

- **Personnel**

- How the research team's background and expertise are appropriate to accomplish the proposed work.
- How the levels of effort are appropriate for successful conduct of the proposed work.

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 influenced the review.

**2. Programmatic Review:** To determine the application's relevance to the mission of the DoD and BCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers
- Programmatic relevance
- Relative impact
- Program portfolio composition
- Adherence to the intent of the award mechanism

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

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

## IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

### A. Rejection

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

- Pre-Application Narrative is missing.

The following will result in administrative rejection of the application:

- 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.
- Submission of an application for which a letter of invitation was not received.
- **Partnering PI Option:** Both associated (Initiating and Partnering PI) applications are not submitted by the deadline.

### 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 pre-application or application:

- A FY12 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 FY12 BCRP IP members can be found at <http://cdmrp.army.mil/bcrp/panels/panels12>.
- 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.
- Any of the PIs do not meet the eligibility criteria.
- Application does not include a planned clinical trial.

#### **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 U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/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, 2013. 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 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: 1-301-682-5507

Email: [help@cdmrp.org](mailto: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: 1-800-518-4726

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

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. 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

<b>Grants.gov Application Components</b>	<b>Action</b>	<b>Initiating PI Completed</b>	<b>Partnering PI Completed</b>
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 Translatability Statement (Translatability.pdf) as Attachment 7.		
	Upload Transition Plan (Transition.pdf) as Attachment 8.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI 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 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.		