

# Program Announcement

for the

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

## Breast Cancer Research Program

### Breakthrough Award Levels 3 and 4

**Funding Opportunity Number: W81XWH-14-BCRP-BREAKTHROUGH2\_FL34**

**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), October 22, 2014
- **Invitation to Submit an Application:** December 9, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, January 29, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, February 3, 2015
- **Peer Review:** March 2015
- **Programmatic Review, Stage 1:** May 2015
- **Invitation for Oral Presentation (Funding Level 4 Only):** May 2015
- **Programmatic Review, Stage 2 (Funding Level 4 Only):** June 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.***

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## 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 Acquisition 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](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 BCRP Breakthrough Award application must address at least one 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 pre-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 intent of the Breakthrough Award is to support promising research that has high potential to lead to or make breakthroughs in breast cancer. The critical components of this award mechanism are:

**Impact:** Research supported by the Breakthrough Award will have the potential for a major impact and accelerate progress toward ending breast cancer. The impact may be near-term or long-term, but must be significant and move beyond an incremental advancement. Applications must articulate the pathway to making a clinical impact for individuals with, or at risk for, breast cancer, even if clinical impact is not an immediate outcome.

**Research Scope:** Research proposed under this award mechanism may be small- to large-scale projects, at different stages of idea and research development. Two different funding levels, based on the scope of the research, are available under this Program Announcement. Funding Levels 1 and 2 are available under a different Program Announcement (**W81XWH-14-BCRP-BREAKTHROUGH2\_FL12**). *It is the responsibility of the Principal Investigator (PI) to select the funding level that is most appropriate for the research proposed.*

The following are general descriptions, although not all-inclusive, of the scope of research projects that would be appropriate to propose under each funding level:

- **Funding Level 3:** Advanced translational studies that have potential for near-term clinical investigation. Small-scale clinical trials may apply.
- **Funding Level 4:** Large-scale projects that will transform and revolutionize the clinical management and/or prevention of breast cancer. Near-term clinical impact is expected. PIs are expected to have experience in successfully leading large-scale projects.

**Note:** An *invited* oral presentation to the BCRP Integration Panel (IP) is a requirement for application review of Funding Level 4 projects, as described in Section II.C., Application Submission Content and Forms.

**Partnering PI Option:** The Breakthrough Award encourages applications that include meaningful and productive collaborations between investigators. The Partnering PI Option is structured to accommodate two PIs, called the Initiating PI and the Partnering PI, each of whom will each receive a separate award. The Initiating and Partnering PIs 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 (SOW), and other required components. The PIs may have expertise in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. New collaborations are encouraged, but not required. It is the responsibility of the PIs to describe how their combined expertise will better address the research question and explain why the work should be done together rather than through separate efforts. *To meet the intent of the Partnering PI Option, applicants are discouraged from submitting as a Partnering PI on multiple applications unless they are clearly addressing distinct research questions.*

**Personnel:** The PI(s) are expected to engage and assemble an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.

**Consumer Advocates:** Applications are required to include consumer advocate involvement. The research team must include two or more breast cancer consumer advocates who will be integral throughout the planning and implementation of the research project. Consumer advocates should be involved in the development of the research question, project design, oversight, recruitment, and evaluation, as well as other significant aspects of the proposed project. Interactions with other team members should be well integrated and ongoing, not limited to attending seminars and semi-annual meetings. As lay representatives, the consumer advocates must be individuals who have been diagnosed with breast cancer, and they should be active in a breast cancer advocacy organization. Their role in the project should be independent of their employment, and they cannot be employees of any of the organizations participating in the application. The consumer advocates should have a high level of knowledge of current breast cancer issues and the necessary background or training in breast cancer research to contribute to the project.

**Clinical trials are allowed.** A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. Additional information may be found at <https://ebrap.org/eBRAP/public/Program.htm> and in the General Application Instructions, Appendix 5.

**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 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**

- Independent investigators at all academic levels (or equivalent) are eligible to submit an application.
- Each individual may submit only one pre-application as a PI or Initiating PI.
- There are no limitations on the number of applications for which an investigator may be named as a Partnering PI. To meet the intent of the Partnering PI Option, applicants are discouraged from submitting as a Partnering PI on multiple applications unless they are clearly unique, meaningful collaborations addressing distinct research questions. PIs will be required to provide a brief description of all their applications submitted as an Initiating PI, Partnering PI, or collaborator, under this Breakthrough Award Levels 3 and 4 Program Announcement/Funding Opportunity.
- 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 requested funding level should be appropriate for the scope of research proposed.*

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

### **Funding Level 3:**

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$2.5M** plus indirect costs.

### **Funding Level 4:**

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$10M** plus indirect costs.
- Research milestones to be accomplished by the end of each year in the period of performance must be clearly defined in the project SOW and will be finalized during award negotiations. The PI(s) will be required to present an update on progress toward accomplishing research milestones and goals of the project at an annual Milestone Meeting to be held in the National Capital Region. Annual Milestone Meetings will be held at the conclusion of Year 2 and every subsequent year in the period of performance and will be attended by members of the BCRP IP, USAMRMC staff, and the USAMRAA Grants Officer.

**For both funding levels:**

- The applicant must submit a comprehensive budget, broken down by year, which details the projected funding needed for the entire period of performance.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum period of performance.
- 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.
- **Partnering PI Option:** The combined total funding for the Initiating PI and Partnering PI may not exceed the maximum allowable direct costs for the selected funding level. No additional funds will be provided. A separate award will be made to each PI's organization.

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:

- (Funding Level 4 only) Travel for the PI(s) to attend three annual 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 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 in addition to the required meetings described above

Intramural (DoD), other federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be

named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

***The CDMRP expects to allot approximately \$20M of the \$120M FY14 appropriation to fund approximately 7 Breakthrough Award Levels 3 and 4 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 strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** 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](#)).

***Partnering PI Option:*** The Breakthrough Award mechanism is structured to accommodate two PIs. One PI 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 the 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, SOW, 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 of the pre-application submission separately by email. The Partnering PI must follow the link in this email and register with eBRAP 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 CDMRP.

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-BREAKTHROUGH2\_FL34.

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

All pre-application components must be submitted by the PI or Initiating 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](mailto:help@eBRAP.org) or 301-682-5507.

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

- **Application Information – Tab 1**

- **Application Contacts – Tab 2**

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

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

- **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.*

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

1. What BCRP overarching challenge(s) will the proposed research address? If “other”, state the overarching challenge and provide justification within the context of the [breast cancer landscape](#). (200-character limit)
2. How will the proposed research lead to a solution for the overarching challenge(s)? (2,000-character limit)
3. What are the major steps in the pathway to making a clinical impact on breast cancer and how will the proposed research fit into that pathway? How will the proposed research move beyond an incremental advancement? (2,000-character limit)
4. What funding level (direct costs) is requested for the proposed research? Select Funding Level 3 or 4. Briefly state how the funding level is appropriate for the scope of research proposed. (500-character limit)
5. What period of performance is requested? (1-5 years)
6. Will the proposed research include a clinical trial? If yes, briefly state the clinical intervention, subject population(s), and phase of the clinical trial. (500-character limit)

A clinical trial is defined as a prospective accrual of patients where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

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

- One page for additional information that the PI can use, at his/her discretion, to provide supporting data or rationale for the pre-application.
- If applicable, one page to provide a list of multiple Breakthrough Award pre-applications being submitted as an Initiating PI, Partnering PI, or collaborator. Include the CDMRP log number, Funding Level; role on the project; project title; specific aims; and a brief description of how each pre-application will address distinct research questions.

***Each individual may submit only one pre-application as a PI or Initiating PI. If an individual exceeds this submission limit, only the first pre-application that was received will be accepted; additional pre-applications will be administratively rejected.***

- **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**

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:

- Whether the pre-application addresses at least one overarching challenge that meets the program’s goals.
- To what degree the pre-application proposes research that will lead to a solution for the overarching challenge.
- To what degree the pre-application moves beyond an incremental advancement.
- To what degree the requested funding level is appropriate.

***NOTE: It is the responsibility of the PI to select the funding level that is most appropriate for the research proposed. PIs whose pre-applications request a funding level that is not deemed appropriate for the scope of research proposed will not be invited to submit an application.***

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

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

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

***Applications will not be accepted unless the PI or the Initiating 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 Breakthrough Award Levels 3 and 4, 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).**

**Partnering PI Option: The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and the Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned unique log numbers by eBRAP. Each Grants.gov application package must be submitted using the unique log number. Note: All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.**

<b>Application Components for Single PIs or for Initiating PIs under the Partnering PI Option:</b>
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**Grants.gov application package components:** For the Breakthrough Award Levels 3 and 4, 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 (page limit varies by funding level; see below):** 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.
    - **Page Limit:** Page limits for the project narrative are correlated with the application’s Funding Level:

- **Funding Level 3:** 15-page limit
- **Funding Level 4:**, 25-page limit
- o **Outline for Project Narrative:** Describe the project in detail using *one* of the two outlines below, depending on whether or not a clinical trial is proposed.

***Outline for projects without a clinical trial:***

- **Overarching Challenge:** State explicitly which overarching challenge(s) the proposed research will address.
- **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. The PI must demonstrate logical reasoning and provide a sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system.
- **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, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how this research strategy will meet the research goals and milestones. Describe the statistical plan, as appropriate, for the research proposed. Address potential pitfalls and problem areas and present alternative methods and approaches. If proposing translational research, provide a well-developed, well-integrated, and detailed research plan that supports the translational feasibility and promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation.
- **Research Team:** Describe how the combined backgrounds and breast cancer-related expertise of the research team will enable successful conduct of the project. For Funding Level 4 applications, describe how the PI(s) has/have experience in successfully leading large, focused efforts.

***Outline for projects with a clinical trial as allowed under Funding Level 3 or 4 (Note: The Project Narrative is not the formal clinical trial protocol.):***

- **Overarching Challenge:** State explicitly which overarching challenge(s) the proposed research will address.
- **Background:** Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial. Importantly, describe the studies showing proof of concept and efficacy in in vivo system(s) that led to the current proposed work. Provide a summary of relevant clinical trials and

distinguish how the proposed study differs from other relevant or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). The background section should clearly support the choice of study variables and should explain the basis for the study questions and/or study hypotheses. This section should establish the relevance of the study and explain the applicability of the proposed findings.

If the proposed clinical trial was initiated using other funding prior to this application, explain the history and background of the clinical trial and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.

- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Strategy (include only if laboratory research studies are proposed as a component of the application):** Describe the laboratory research studies that will be performed through this award and how they are *clearly linked* to the clinical trial. Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches. Provide a well-developed, well-integrated research strategy that supports the feasibility of the approach. If the methodology is new or unusual, provide sufficient details for evaluation.
- **Clinical Trial:** Provide detailed plans for initiating and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other Food and Drug Administration [FDA] approvals). Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
  - Identify the intervention to be tested and describe the projected outcomes.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
  - Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random). Provide information on the availability of and access to the appropriate patient population(s), as well as the ability to accrue sufficient subjects for the clinical trial.

- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
  - **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
  - **Clinical Team:** Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate expertise in conducting clinical trials. For Funding Level 4 applications, describe how the PI(s) has/have experience in successfully leading large, focused efforts.
- **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 available for the project.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization confirming that the PI has the support or resources necessary for the proposed work, including but not limited to:
  - Availability of, access to, and quality control for all critical reagents.
  - Availability of and access to the appropriate patient population(s).
- Advocate Letter of Commitment: Provide a letter signed by the advocate confirming her/his commitment to participate in the proposed project.
- Good Manufacturing Practice (GMP) (if applicable): 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 Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”

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.

Use the outline below.

- Background: Present the ideas and reasoning behind the proposed work.
- Overarching Challenge(s): State which of the overarching challenge(s) will be addressed.
- 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 and accelerate progress toward ending breast cancer.

- **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.
    - Which overarching challenge(s) does this research address?
    - 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?
  - If the research is too basic for clinical applicability, describe the interim outcomes.
- **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 Breakthrough Award Levels 3 and 4 mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.

- The SOW should indicate a feasible plan and timeline to conduct the research. The SOW must include specific research milestones to be accomplished by the end of each year in the period of performance.
- **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.”
  - State which overarching challenge(s) the proposed research will address and explain how the proposed research will lead to a solution for the overarching challenge(s). Describe the major steps in the pathway to making a clinical impact for individuals with, or at risk for, breast cancer, and explain how the proposed research will fit into that pathway. Explain how the proposed research will move beyond an incremental advancement. Articulate how the project, if successful, could lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- **Attachment 7: Partnership Statement (one-page limit):** Upload as “Partnership.pdf.” (*Attachment 7 is only applicable and required for applications submitted under the Partnering PI Option.*)

- Describe the expertise of the Initiating and Partnering PIs. Describe the contribution and the time commitment of each PI toward the proposed research project. Describe how the combined effort will better address the research question and explain why the work should be done together rather than through separate efforts.
  - **Attachment 8: Submissions Statement (one-page limit):** Upload as “Submissions.pdf.” (*Attachment 8 is only applicable and required for individuals who are submitting multiple Breakthrough Award applications. Attachment 8 will be available for programmatic review only.*)
    - Provide the following information for each Breakthrough Award application being submitted as an Initiating PI, Partnering PI, or collaborator:
      - CDMRP Log Number; Funding Level; role on the project; project title; and specific aims.
      - Brief description of how the application addresses a research question that is distinct from the other application(s).
  - **Attachment 9: Advocate Statement (one-page limit):** Upload as “Advocate.pdf.”
    - The Advocate Statement should be written by the PI. Describe the integral roles that consumer advocates will play in the planning, design, implementation, and evaluation of the research. Describe how the consumer advocates’ knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project. Explain how the consumer advocates’ experience and expertise will be integrated into the research project and management of the collaboration.
  - **Attachment 10: Transition Plan (one-page limit):** Upload as “Transition.pdf.” (*Attachment 10 is only applicable and required for applications with a clinical trial.*)
    - 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 commercial market after successful completion of the award (e.g., specific potential industry partners; specific funding opportunities to apply for). In addition, provide a plan to distribute the findings or intervention to the breast cancer community.
- 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 (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.”
    - Include biographical sketches for team members, including consumer advocates.
    - Include the Partnering PI, if applying under the Partnering PI Option.
  - Key Personnel Previous/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.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- For the Partnering PI Option:** Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI, even if they are located within the same organization. The combined total direct costs for the Initiating and Partnering PIs’ budgets cannot exceed the maximum allowable direct costs for the Funding Level applied for.
- 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.

<b>Application Components for the Partnering PI if applying under the Partnering PI Option:</b>
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*The Partnering PI MUST follow the link in the email from eBRAP 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 (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C.2., 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.”

**For the Partnering PI Option:** Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts 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 the maximum allowable direct costs of the Funding Level applied for.

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

**5. 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 for Funding Level 4 Applications:** In addition to the completed Grants.gov application package of forms, Breakthrough Award applications submitted under Funding Level 4 also require the following component:

**Oral Presentation:** PIs applying for Funding Level 4 whose applications are selected for final consideration in Stage 2 of Programmatic Review will be required to give an oral presentation (see Section III.B.2., Programmatic Review) that will be held in the National Capital Region area in June 2015. *If applying under the Partnering PI Option, both the Initiating and Partnering PI will attend and give the oral presentation.*

Each presentation will include a 10-minute talk by the PI(s), 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 invited must prepare a presentation consisting of no more than three slides that specifically address these questions:

- Without addressing your specific project, what conceptual or intellectual barriers do you consider the most urgent to overcome in the overarching challenge(s) you selected/identified?
- Without addressing the specific technical/scientific aspects of your project, how do you envision transitioning the breakthrough results from your proposed research into a near-term clinical impact for individuals with, or at risk of breast cancer?
- Without addressing the specific technical/scientific aspects of your project, what leadership skills will you use in your research team’s effort and beyond to transform and revolutionize the clinical management and/or prevention of breast cancer?

#### **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 DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, 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 highest-

scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

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 scored criteria, which are of equal importance:

*For applications without a clinical trial:*

- **Impact**
  - How the proposed research could lead to a solution for an overarching challenge in breast cancer.
  - How the proposed research, if successful, will contribute to a pathway toward making a clinical impact for individuals with, or at risk for, breast cancer.
  - How the proposed research moves beyond an incremental advancement.
  - How the project, if successful, could lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.
  - How well the hypothesis, objectives, specific aims, experimental design, methods, statistical plan, and analyses are developed.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - How the SOW indicates a feasible plan and timeline to conduct the research and provides clearly defined research milestones at the end of each year of the award period.

- **Personnel**

- How the PI(s) has/have assembled an appropriate and robust research team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
- How the levels of effort are appropriate for successful conduct of the proposed work.
- How consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
- How the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project.
- **Partnering PI Option:** How the partners' combined expertise will better address the research question.
- **Funding Level 4 Applications:** To what degree the PI(s) is/are experienced in successfully leading large, focused efforts and therefore well-positioned to lead the research team in accomplishing the aims of the proposed project.

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 research.
- How the research requirements are supported by the availability of and access to facilities and resources (including collaborative arrangements).
- How the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.

- **Budget**

- Whether the budget is appropriate for the proposed research and funding level 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.

*For applications with a clinical trial:*

- **Impact**

- How the proposed research could lead to a solution for an overarching challenge in breast cancer.
- How the proposed research, if successful, will contribute to a pathway toward making a clinical impact for individuals with, or at risk for, breast cancer.

- How the proposed research moves beyond an incremental advancement.
- How the project, if successful, could lead to or make a breakthrough and accelerate progress toward ending breast cancer.
- **Clinical Strategy**
  - How the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
  - How the clinical trial is designed with appropriate study variables, controls, and endpoints.
  - How the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
  - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.
  - Whether potential challenges and alternative strategies are appropriately identified.
- **Research Strategy and Feasibility (applicable only to applications that include laboratory research studies)**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of published literature, logical reasoning, and preliminary data.
  - How the hypothesis, objectives, specific 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, if applicable.
  - How the proposed laboratory research studies are *clearly linked* to the clinical trial.
- **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.

- **Transition Plan**
  - How the application demonstrates feasible methods and strategies to move the clinical trial findings to the next phase of clinical trials and/or delivery to the commercial market after successful completion of the award.
  - Whether the application has a plan to distribute the findings or intervention to the breast cancer community.
- **Personnel**
  - How the PI(s) has/have assembled an appropriate and robust research/clinical team with the combined backgrounds and breast cancer-related expertise to enable successful conduct of the project.
  - How the levels of effort are appropriate for successful conduct of the proposed work.
  - How consumer advocates are integrated into the planning, design, implementation, and evaluation of the research.
  - How the consumer advocates' knowledge of current breast cancer issues and how their background or training in breast cancer research will contribute to the project.
  - **Partnering PI Option:** How the partners' combined expertise will better address the research question.
  - **Funding Level 4 Applications:** To what degree the PI(s) is/are experienced in successfully leading large, focused efforts and therefore well-positioned to lead the research/clinical team in accomplishing the aims of the proposed project.

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

- **Environment**
  - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment from each participating institution.
  - If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.
- **Budget**
  - Whether the budget is appropriate for the proposed research and funding level 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 equally considered 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 recommended for funding (Funding Level 3) or selected for Stage 2 (Funding Level 4) using the following equally considered criteria:

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

**Stage 2:** (Funding Level 4): During the second stage of programmatic review, the following criteria will be used:

- Understanding of barriers to overcome in the overarching challenge selected/identified.
- Articulation of a vision for transitioning the results of the project into a near-term clinical impact for individuals with, or at risk for, breast cancer.
- Capability to lead efforts to transform and revolutionize the clinical management and/or prevention of 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:

- Multiple pre-applications are received from the same investigator as a PI or Initiating PI. Only the first pre-application will be accepted; additional pre-applications will be administratively rejected.

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- 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.
- Partnering PI Option: Both associated (Initiating and Partnering PI) applications are not submitted by the deadline.

### **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.
- More than one pre-application is submitted by the same investigator as a PI or Initiating PI.
- Consumer advocates are not included in the application.
- The invited application does not propose the same research project described in the pre-application.

#### **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.

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

## **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 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.

Quarterly technical progress reports will be required for awards that include a clinical trial.

In addition to written progress reports, oral presentations may be requested.

## **E. Award Transfers**

Changes in PI are not allowed under Funding Level 4 awards, 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](mailto:help@eBRAP.org)

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

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

Phone: 800-518-4726

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

*Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the 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

<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	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: Upload as Attachment 3 with file name "TechAbs.pdf."		
	Lay Abstracts: Upload as Attachment 4 with file name "LayAbs.pdf."		
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	Partnership Statement: Upload as Attachment 7 with file name "Partnership.pdf," if applicable.		
	Submissions Statement: Upload as Attachment 8 with file name "Submissions.pdf," if applicable.		
	Advocate Statement: Upload as Attachment 9 with file name "Advocate.pdf."		
	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf," if applicable.		
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget	Complete 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.		
<b>Additional Application Component</b>	<b>Action</b>	<b>Initiating PI Completed</b>	<b>Partnering PI Completed</b>
Oral Presentation ( <i>Funding Level 4 only</i> )	Confirm ability to give an oral presentation in the National Capital Region in June 2015 (if selected for Stage 2).		