Program Announcement

For the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Breakthrough Award Level 3

Funding Opportunity Number: W81XWH-15-BCRP-BREAKTHROUGH2_FL3

Catalog of Federal Domestic Assistance Number: 12.420

Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), September 18, 2015
- **Invitation to Submit an Application:** October 27, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, December 21, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, December 30, 2015
- **Peer Review:** February 2016
- **Programmatic Review:** April 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Fiscal Year 2015 (FY15) Breast Cancer Research Program (BCRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation appropriation. The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The BCRP was initiated in fiscal year 1992 (FY92) to support innovative, high-impact research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY14 totaled $3 billion. The FY15 appropriation is $120 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of ending breast cancer. Specifically, the BCRP seeks to accelerate high-impact research with clinical relevance, encourage innovation and stimulate creativity, and facilitate productive collaborations.

B. Breast Cancer Landscape

The BCRP has prepared a brief overview of the breast cancer landscape that describes what is currently known about incidence, death, recurrence, metastatic disease, risk factors, and treatments. This overview covers the most pertinent topics that are consistent with the BCRP's vision of ending breast cancer. ***Applicants are strongly urged to read and consider the landscape before preparing their applications.*** The landscape may be found at http://cdmrp.army.mil/bcrp/pdfs/bc_landscape.pdf.

C. FY15 BCRP Overarching Challenges

Considering the current breast cancer landscape and the BCRP's vision to end breast cancer, each FY15 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. One funding level, based on the scope of the research, is available under this Program Announcement. Two additional funding levels, Funding Levels 1 and 2, will be available under a different Program Announcement (**W81XWH-15-BCRP-BREAKTHROUGH2_FL12**) in August 2015. ***It is the responsibility of the Principal Investigator (PI) to select the funding level that is most appropriate for the research proposed. The funding level should be selected based on the scope of the research project, rather than the amount of the budget.***

The following is a general description, although not all-inclusive, of the scope of research projects that would be appropriate to propose under this Program Announcement:

- **Funding Level 3:** Advanced translational studies that have potential for near-term clinical investigation. Small-scale clinical trials may apply.

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. Their role should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, breast cancer. 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.

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

E. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit an application.
- Investigators who were invited to submit a Breakthrough Award Level 3 application under Funding Opportunity W81XWH-15-BCRP-BREAKTHROUGH_34 are not eligible to submit a pre-application for the same research project under the current Funding Opportunity.

- 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 Level 3 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, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

F. Funding

Applications submitted with a single PI or under the Partnering PI Option have the same funding limits:

- The maximum period of performance is **5** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **$2.5M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$2.5M** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- The applicant must submit a comprehensive budget, broken down by year, that 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 **5** years.
- **Partnering PI Option:** The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$2.5M**. The combined total direct costs of Initiating PI and the Partnering PI awards will not exceed **$2.5M** direct costs**.** If the Initiating PI's or Partnering PI's budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **$2.5M** or use an indirect rate exceeding each organization's negotiated rate. A separate award will be made to each PI's organization.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. ***For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions***.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings

Intramural (DoD), other Federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

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

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The CDMRP expects to allot approximately $11.25M of the $120M FY15 BCRP appropriation to fund approximately three Breakthrough Award Level 3 applications, depending on the quality and number of applications received. In addition to the FY15 appropriation, FY16 funds may be used to fund some of the recommended awards, if FY16 funds become available. As of the release date of this Program Announcement/Funding Opportunity, the FY16 Defense Appropriations Bill has not been passed, and there is no guarantee that any additional funds will be made available to support 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/). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP. ***Application viewing, modification, and verification in eBRAP is 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.***

Partnering PI Option: The Breakthrough Award Level 3 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. ***Each Partnering PI must follow the link in this email and register with eBRAP in order to associate his/her Grants.gov application package with that of the Initiating PI.*** Do not delay completing these steps. If this is not completed, the Partnering PI will not be able to view and modify his/her application submission in eBRAP.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-BCRP-BREAKTHROUGH2_FL3 in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

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 or 301-682-5507.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
    - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
    - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
    - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
    - Enter the name of each consumer advocate on the research team and indicate their role in the drop down list.
    - FY15 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 or 301-682-5507.
    - **Partnering PI Option:** The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.
- **Conflicts of Interest (COIs) – Tab 4**
    - To avoid COIs during the screening and review processes, list all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Pre-Application Files – Tab 5**

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

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

  1. 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. Briefly state how Funding Level 3 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 in which 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 Level 3 pre-applications being submitted as an Initiating PI, Partnering PI, or collaborator. Include the CDMRP log number; 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 6**
    - 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 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.
- 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. Full Application Submission Content

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

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

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 PI and Partnering PI) must be submitted by the Grants.gov deadline.***

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

Grants.gov application package components: For the Breakthrough Award Level 3, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

   - **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.
     - **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. 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.
- **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the research proposed, including power analysis as appropriate.
- **Research Team:** Describe how the combined backgrounds and breast cancer-related expertise of the research team will enable successful conduct of the project.

Outline for projects <u>with</u> a clinical trial (Note: The Project Narrative is not the formal clinical trial protocol. If recommended for funding, the clinical trial protocol will be requested.):

- **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.

Attachment 2: Supporting Documentation. Start each document on a new page. **Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only***

those components described below; inclusion of items not requested will result in the removal of those items and may result in administrative withdrawal of the application.

- References Cited: List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patent Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may 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 support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration (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 each consumer 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. Provide a list of all background intellectual property to be used in the project or

provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.

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

- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  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."** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  - 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 does not have near-term clinical applicability, describe the interim outcomes.

- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf."** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Breakthrough Award Level 3 mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.
  - ○ 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 Level 3 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; 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."**
  - Provide information on potential methods and strategies to move the project's findings to the next phase of development, 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.

- **Attachment 11: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as "MFBudget.pdf."**

  If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP "Funding Opportunities & Forms" web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."
    - Include biographical sketches for team members, including consumer advocates.
    - 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.5., for detailed information.

    - Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
    - **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 the Partnering PI, even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and the Partnering PI's applications will not exceed **$2.5M**. The combined total direct costs of Initiating PI and the Partnering PI awards will not exceed **$2.5M**. If the Initiating PI's or Partnering PI's budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **$2.5M** or use an indirect rate exceeding each organization's negotiated rate.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

Application Components for the Partnering PI if applying under the Partnering PI Option:

Each 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 Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package 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.3., 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.5., for detailed information.

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

   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 the Partnering PI, even if they are located within the same organization. The anticipated combined direct costs budgeted for the entire period of performance for the Initiating PI's and Partnering PI's applications will not exceed **$2.5M.** If the Initiating PI's or Partnering PI's budget contains a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the Government will not exceed **$2.5M** or use an indirect rate exceeding each organization's negotiated rate.

4. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

5. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application"***

with the previous Grants.gov Tracking ID prior to the application submission deadline. The Project Narrative and Budget Form cannot be changed after the application submission deadline.

E. Submission Dates and Times

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

F. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and BCRP, and to the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Process

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

   For applications <u>without</u> 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, and analyses are developed.
     - Whether an appropriate statistical plan is provided, including power analysis.
     - 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.
   - **Transition Plan**
     - How the application demonstrates feasible methods and strategies to move the project's findings to the next phase of development, clinical trials, and/or delivery to the commercial market after successful completion of the award.
     - Whether the application has an adequate and reasonable 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 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.

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 <u>with</u> 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 an adequate and reasonable 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.

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 and select the application(s) that, individually or collectively, will best achieve the program objectives, 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 FY15 BCRP, as evidenced by the following:**
      - Adherence to the intent of the award mechanism
      - Program portfolio composition
      - Programmatic relevance
      - Relative impact

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.
- A pre-application proposing the same research project invited for application submission under Funding Opportunity W81XWH-15-BCRP-BREAKTHROUGH_34 will be administratively rejected.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Partnering PI Option: Both associated (Initiating and Partnering PI) applications are not submitted by the deadline.
- Consumer advocates are not included in the application.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

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

- A FY15 BCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. **A list of the FY15 BCRP IP members can be found at http://cdmrp.army.mil/bcrp/panels/panels15.**
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The 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, 2016. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

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

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

Quarterly technical progress reports may be required.

In addition to written progress reports, in-person presentations may be requested.

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The institution transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf.".		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."		
	7	Partnership Statement: Upload as Attachment 7 with file name "Partnership.pdf," if applicable.		
	8	Submissions Statement: Upload as Attachment 8 with file name "Submissions.pdf," if applicable.		
	9	Advocate Statement: Upload as Attachment 9 with file name "Advocate.pdf."		
	10	Transition Plan: Upload as Attachment 10 with file name "Transition.pdf."		
	11	Collaborating DoD Military Facility Budget Form: Upload as Attachment 11 with file name "MFBudget.pdf", if applicable.		
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget		Complete 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.		