

Program Announcement
for the
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs

Breast Cancer Research Program
Breakthrough Fellowship Award

**Funding Opportunity Number: W81XWH-16-BCRP-
BREAKTHROUGH_FELLOWSHIP**

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), April 21, 2016
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, May 10, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, May 5, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, May 10, 2016
- **Peer Review:** July 2016
- **Programmatic Review:** September 2016

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 2016 (FY16) 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 (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The BCRP was initiated in FY92 to support innovative, high-impact research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY15 totaled \$3.12 billion (B). The FY16 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. The Breast Cancer Landscape

The BCRP has prepared a brief overview, *The Breast Cancer Landscape*, that describes what is currently known about 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 Breast Cancer Landscape before preparing their applications.*** The *Landscape* may be found at http://cdmrp.army.mil/bcrp/pdfs/bc_landscape.pdf.

C. FY16 BCRP Overarching Challenges

Considering the current [breast cancer landscape](#) and the BCRP's vision to end breast cancer, each FY16 BCRP Breakthrough Fellowship 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 application.

- Prevent breast cancer (primary prevention)
- Identify determinants of breast cancer initiation, risk, or susceptibility
- Distinguish deadly from indolent breast 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 metastatic
- Determine why/how breast cancer cells lie dormant for years and then re-emerge (recurrence); determine how to prevent recurrence

- Revolutionize treatment regimens by replacing them with ones that are more effective and less toxic
- Eliminate the mortality associated with metastatic breast cancer

D. Award Information

The Breakthrough Fellowship Award mechanism is being offered for the first time in FY16. The Breakthrough Fellowship Award supports recent doctoral or medical graduates in pursuit of innovative, high-impact breast cancer research during their postdoctoral fellowship and allows them to obtain the necessary experience for an independent career at the forefront of breast cancer research. Those individuals should be exceptionally talented researchers who have demonstrated that they are the “best and brightest” of their peers. Applicants for this award must exhibit a strong desire to pursue a career in breast cancer research, with clear evidence for a researcher development plan that will lead to a successful independent career in breast cancer. Applicants must also demonstrate that the proposed research 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 Fellowship 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.

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

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

Researcher Development Plan: Applications must provide details on the suitability of the PI’s overall researcher development plan and research project for attaining the goals of this award mechanism. The project should be based on a sound scientific rationale and/or a thorough

review of the literature. Preliminary data are allowed, but not required. Applications must elaborate on the qualities of the research environment in which the candidate will work, provide details on the individualized breast cancer-focused researcher development plan, and describe how it will facilitate the PI's career development as an independent, innovative breast cancer researcher. A multidisciplinary research approach to breast cancer is highly encouraged, but not required; however, if there are multidisciplinary aspects, they should be clearly outlined in the application.

Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this funding opportunity.

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) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, 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.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, 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 4, Section K.

E. Eligibility Information

- As of the application submission deadline, all eligible PIs must have:
 - Successfully completed the requirements for a doctoral and/or medical degree, and
 - Been in the laboratory or clinical research setting in which the proposed research is to be performed for no more than 2 years as a postdoctoral researcher, and
 - A total of less than 4 years' experience in a postdoctoral fellowship or mentored clinical research training program (excludes any clinical residency or fellowship training)
- Only postdoctoral fellows are eligible for this award. Faculty members and all other non-postdoctoral positions are not eligible to apply.
- Senior postdoctoral fellows who do not meet the eligibility criteria of the Breakthrough Fellowship Award are encouraged to apply under the Breakthrough Award Funding Levels 1 and 2 Program Announcement/Funding Opportunity (W81XWH-16-BCRP-BREAKTHROUGH_FL12).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- Applications with intramural (DoD) investigators named as the PI may either be submitted as an "Intramural Submission" by the intramural organization or as an "Extramural Submission" through an extramural (non-DoD) organization (e.g., non-profit foundation). 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.***
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

F. Funding

- The maximum period of performance is **3** years.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$300,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government

exceeding **\$300,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The PI of the award is expected to have discretion over the management of the budget during the award period. ***The Breakthrough Fellowship Award is not intended to support general laboratory expenses for the mentor.***

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

- Salary/Stipend (**PI only**)
- Research supplies
- Equipment
- Research workshops
- Support for multidisciplinary collaborations, including travel
- Travel costs for -one investigator to travel to two scientific/technical meetings per year.

Shall not be requested for:

- Mentor or other salary
- General office supplies, including computers and software
- Clinical trial costs

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed 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 DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

The CDMRP expects to allot approximately \$6.7M of the \$120M FY16 BCRP appropriation to fund approximately 15 Breakthrough Fellowship Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission 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(s).

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.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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. For intramural DoD submissions of the full application through eReceipt, refer to the eReceipt website (<https://cdmrp.org>).

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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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.*** The Project Narrative and Budget cannot be changed in eBRAP. Revisions to the Project Narrative or Budget will require a changed/corrected application to be submitted to Grants.gov prior to the application deadline. Other application components may be changed until the end of the [application verification period](#).

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-16-BCRP-BREAKTHROUGH_FELLOWSHIP** in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

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):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
 - 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 SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “Add Organizations to this Pre-application.” The organization(s) must either be selected from the eBRAP drop-down 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.
- **Tab 3 – Collaborators and Key Personnel**
 - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
 - Include the name(s) of the mentor (and co-mentor, if applicable)

- Include the names of the individuals providing letters of recommendation.
- FY16 BCRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel 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.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- **Tab 4 – Conflicts of Interest (COIs)**
 - 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). Refer to Appendix 1, Section C of the General Application Instructions for further information regarding COIs.
- **Tab 5 – Pre-Application Files**
 - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
 - **List of Individuals Providing Confidential Letters of Recommendation:** Enter contact information for three individuals, who will provide letters of recommendation. The three individuals must include the mentor and, if applicable, co-mentor. Each individual will receive an email generated from eBRAP containing specific instructions on how to upload his/her letter.
- **Tab 6 – Submit Pre-Application**
 - This tab must be completed for the pre-application to be accepted and processed.

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of your organization’s Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

C. Full Application Submission Content

All contributors to and administrators of the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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 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/>). For the Breakthrough Fellowship Award, additional application components are also required and should be submitted as directed below.

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.*

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

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

1. SF424 (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 (six-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text

and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **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. Preliminary data are allowed, but not required, for Breakthrough Fellowship Award applications. If applicable, provide sufficient preliminary data to support the feasibility of work proposed. Regardless of whether preliminary data are available, 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.
- **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 scientific review and evaluation. Explain how this research strategy will meet the research goals and milestones. Describe the statistical plan including power analysis, as appropriate, for the research proposed. Address potential pitfalls and problem areas and present alternative methods and approaches. If the methodology is new or unusual, provide sufficient details for evaluation.
- **Career Goals:** The PI should describe his/her career goals in breast cancer research and/or patient care and articulate how the proposed researcher development plan and research project will contribute to these goals. The PI should specifically discuss his/her career and research plans after the completion of this award.
- **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 or 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 Patents Abstracts: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publically 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 that will demonstrate 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)
- Transcripts: Include a copy of the PI's transcripts from all graduate institutions attended. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations. Diplomas are not acceptable in lieu of academic transcripts. If an institution does not provide academic transcripts (i.e., a record of courses completed, grades and credit hours earned, and indication of completion of degree), complete and include the Academic Statement (available for download on the Full Announcement page in Grants.gov) in place of the transcript.
- Mentor Qualifications: Include a description of the qualifications of the mentor. Specifically address the following:
 - Experience in conducting innovative research
 - Experience in breast cancer to include publications and active funding
 - Record and success in mentoring pre-and/or postdoctoral trainees
- Co-Mentor Qualifications (if applicable): Include a description of the qualifications of the co-mentor. Specifically address the following:

- Experience in conducting innovative research
- Experience in breast cancer to include publications and active funding
- Record and success in mentoring pre- and/or postdoctoral trainees
- Letter of Formal Co-Mentorship Support (if applicable): Provide a signed letter from the chair of the department that acknowledges the formal designation and role of the co-mentor for the PI’s research and researcher development plan.
- 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. Therefore, it is important that you disclose/identify any Intellectual Property (software, data, patents, etc.) that will be used in performance of 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. A term of the award requires the recipient to grant to the Government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense. Refer to the Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315).
 - 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 4, Section K, for more information about the CDMRP expectations for making data and research resources publically available.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***Do not include proprietary or confidential information.*** 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 should include all of the following sections describing:

- Research Plan
 - Background: Present the ideas and reasoning behind the proposed work.

- Overarching Challenge(s): State which 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.
- Researcher Development Plan
 - Describe the PI’s career goals and how the proposed research experience will support him/her in attaining these goals.
 - Describe how the proposed research project will enable development of the PI as a researcher making valuable contributions to breast cancer research and/or patient care.
 - Describe the unique aspects of the researcher development plan and the research environment.
- Impact
 - Describe how the proposed project will have an impact on breast cancer research and/or patient care, and accelerate progress toward ending breast cancer.
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***Do not include proprietary or confidential information.*** 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 lay abstract should:

- Not duplicate the technical abstract.
- Describe the scientific objective and rationale for the proposed project in a manner readily understandable by non-scientists.
- Describe the PI’s career goals in breast cancer.
 - How will the researcher development plan support the PI in attaining these goals?
 - How will the research plan support the PI in attaining these goals?
- Describe the ultimate applicability and impact of the research.
 - What overarching challenge(s) does the 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?
 - If the research is too basic for clinical applicability, describe the interim outcomes.
 - What are the likely contributions of this study to advancing the field of breast cancer research?
- **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 Fellowship Award mechanism, use the SOW format example titled “SOW (Statement of Work) for Basic Research (Training Section optional).” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

The SOW should indicate a feasible plan and timeline to conduct the research and researcher development plan and should provide clearly defined milestones.

- **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. Explain how the PI’s specific research goals, if achieved, would fit into that pathway.
- **Attachment 7: Researcher Development Plan (two-page limit): Upload as “Development.pdf.”**
 - Clearly describe the *breast cancer-focused* researcher development plan that is *individualized* for the PI and will be utilized to prepare him/her for an independent career at the forefront of highly impactful research aimed at ending breast cancer. The description should include a timeline and details on the PI’s intellectual development as a breast cancer researcher, such as laboratory techniques, workshops, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Inclusion of a chart, graph, or table is suggested.
 - Highlight the unique features of the PI’s researcher development plan as it pertains specifically to breast cancer.
 - Indicate specifically how the individualized plan will advance the PI’s development as a breast cancer researcher.
 - Briefly describe how the plan is supported by the research environment, including a description of ongoing breast cancer research at the institution.

Include information on interactions or collaborations with other breast cancer investigators.

- **Attachment 8: Eligibility Statement: Upload as “Eligibility.pdf.”**

Use the Eligibility Statement form (available for download on the Full Announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official verifying that the eligibility requirements will be met by the application submission deadline.

- **Attachment 9: 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 (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Application Instructions, Section II.C.4., for detailed information.

- **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. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
 - Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **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 mentor’s (and co-mentor’s, if applicable) biographical sketch(es).
- **Key Personnel Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
 - Include mentor’s (and co-mentor’s, if applicable) previous/current/pending support.

4. Research & Related Budget: Refer to the General Application Instructions, Section II.C.4., 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.
- 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.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 9, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

<p>Additional Application Components:</p>
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In addition to the complete Grants.gov application package, Breakthrough Fellowship Award applications also require the following components:

- 1. Three Confidential Letters of Recommendations (two pages per letter recommended)**

The PI should monitor whether the letters have been received in eBRAP by viewing the status in the “Pre-Application Files” tab of the pre-application; however, the PI will not be able to view these letters.

Letters of recommendation must include one from the mentor and, if applicable, one from the co-mentor.

- **Confidential letter(s) of recommendation from the mentor(s):** A letter must come from the PI’s mentor describing his/her commitment to the PI’s career development and mentorship. If the PI has a co-mentor, then that individual must also submit a letter of recommendation. These letters of recommendation should describe:
 - The PI’s potential to become a successful and independent breast cancer researcher;
 - The degree to which the PI participated in the development of the research idea and preparation of the application;
 - The mentor or co-mentor’s commitment to the career development, and mentorship of the PI, including details of his/her proposed interactions with the PI and how he/she intends to support the PI’s research endeavors; and

- The relevance of the proposed research project to the PI’s development as a breast cancer researcher.
- **Additional confidential letter(s) of recommendation:** The remaining letter(s) should highlight the PI’s potential for success in pursuing a career in breast cancer research. Specifically, each letter should include the writer’s perspective on:
 - The PI’s qualifications, characteristics, and achievements;
 - The PI’s potential for productivity and desire for establishing a successful career at the forefront breast cancer research;
 - The relevance of the proposed research project to the PI’s development as an breast cancer researcher; and
 - The suitability of the mentor (and co-mentor, if applicable) and individualized researcher development plan for providing the PI with a solid foundation in breast cancer research.

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 or 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.*** 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 submission rejection.

F. Other Submission Requirements

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

All extramural 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 consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD (HA), based on technical merit, the relevance to the mission of the DHP and BCRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. *The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2](#).* 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 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:

- **Impact**
 - How the proposed research could lead to a solution for an overarching challenge in breast cancer.
 - How the proposed research goals, if achieved, will contribute to a pathway toward making an impact on breast cancer; impact may be near- or long-term.
 - 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 the literature, logical reasoning, and preliminary data, if applicable. Preliminary data are allowed, but not required.
 - How well the hypotheses, 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 milestones.
- **Principal Investigator**
 - How the PI's achievements demonstrate that he/she is among the "best and brightest" of his/her peers (as reflected by outstanding academic performance, publications, awards, honors, funding, and other outstanding achievements) and indicate a potential for a successful career in breast cancer research.
 - Whether the PI has a strong publication record, including first-author publications.
 - How the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career at the forefront of breast cancer research; prior breast cancer research experience is not required of the PI.
 - How well the letters of recommendation support the PI's high potential for success and dedication to a career in breast cancer research.
 - Whether the PI's proposed level of effort, if not 100%, is appropriate for successful development as a breast cancer researcher and completion of the proposed work.
- **Mentor (and Co-Mentor, if applicable)**
 - How the mentor is appropriately trained and well-suited to guide this research project, including the mentor's active funding, publications, and strong background in breast cancer research.
 - How the mentor's background, qualifications, research program, committed resources, and available time support his/her ability to supervise the PI's research project and development as a researcher.
 - How the mentor's training achievements, as reflected by his/her previous trainees' career achievements and areas of interest, indicate the potential to successfully mentor the PI in breast cancer research.
 - How the PI has strong potential to manage the technical and administrative aspects of the award and successfully accomplish the proposed research.
 - Whether the mentor's letter of recommendation indicates a high level of commitment to the PI's development as a breast cancer researcher.

- Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.
- **Researcher Development Plan**
 - How detailed and individualized is the plan.
 - How the plan is breast cancer-focused.
 - How the plan will provide valuable experience to prepare the PI for an independent career at the forefront of highly impactful breast cancer research and/or patient care.
- **Environment**
 - How the scientific environment is appropriate for the proposed researcher development plan and research project.
 - How the researcher development plan and research requirements are adequately supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
 - How the application provides evidence of a strong institutional commitment to researcher development in breast cancer.

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

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influence 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 criteria are used by programmatic reviewers:
 - a. Ratings and evaluations of the peer reviewers
 - b. Relevance to the mission of the DHP and FY16 BCRP, as evidenced by the following:
 - Adherence to the intent of the award mechanism
 - Program portfolio composition
 - 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 applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

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

B. Modification

- Pages exceeding the 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 application:

- An FY16 BCRP Programmatic Panel 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 FY16 BCRP Programmatic Panel members can be found at <http://cdmrp.army.mil/bcrp/panels/panels16>.*
- 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).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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.
- An application submitted by a PI who does not meet the eligibility criteria.
- The application proposes a clinical trial.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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, 2017. 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 H, for general information on reporting requirements.

E. Award Transfers

Changes in PI are not allowed.

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

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Breast Cancer Research Program Breakthrough Fellowship Award and the Program Announcement/Funding Opportunity version code [20160210b]. The numeric sequence of the Program Announcement/Funding Opportunity version code will match the General Application Instructions version code, 20160210.

B. 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

C. 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; International 1-606-545-5035

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	Completed
SF424 (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	Researcher Development Plan: Upload as Attachment 7 with file name "Development.pdf."	
	8	Eligibility Statement: Upload as Attachment 8 with file name "Eligibility.pdf"	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 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 as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	
Additional Application Components	Upload Order	Action	Completed
Three Confidential Letters of Recommendation		Confirm upload to eBRAP.	