Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Clinical Translational Research Award

Funding Opportunity Number: W81XWH-11-BCRP-CTR

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 20, 2011
- **Invitation to Submit an Application:** November 4, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, December 22, 2011
- **Scientific Peer Review:** February 2012
- **Programmatic Review:** April 2012

New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Breast Cancer Research Program (BCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The BCRP was established in fiscal year 1992 (FY92) to support innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY10 totaled over $2.5 billion. The FY11 appropriation is $150 million (M).

The BCRP challenges the scientific community to design innovative, high-impact research that will address critical issues and foster new directions toward the vision of eradicating breast cancer. The BCRP promotes unique partnerships and multidisciplinary collaborations that will accelerate advances in breast cancer research. In addition, the BCRP supports training the next generation of breast cancer investigators through mentored research. The BCRP seeks applications from all areas of basic, translational, clinical, behavioral, and epidemiological research. Applications focused on understudied areas, such as breast cancer prevention and health disparities, are encouraged.

B. Award Information

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

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

Applications must include preliminary data and a solid rationale to support the feasibility of novel translational research leading to a prospective clinical trial during the course of the award. Applications also must include a clear experimental plan and a properly powered statistical plan to perform the prospective clinical trial. Investigators must demonstrate availability of and access to an appropriate patient population that will support meaningful clinical outcomes.

PIs must provide a detailed plan for how they will meet the requirements for obtaining Investigational New Drug (IND) or Investigational Device Exemption (IDE) status (or other approvals required by the US Food and Drug Administration [FDA]) early in the award period to further investigate preventive or therapeutic interventions developed through the CTR Award. Participating organizations must be willing to resolve potential intellectual and material property issues and remove barriers to achieving high levels of cooperation. If the

application involves multiple organizations, an intellectual and material property plan agreed to by all participating organizations is required in the application's supporting documentation. Further, PIs must clearly outline a transition plan to move their findings or interventions into the breast cancer community.

Use of Human Subjects and Human Anatomical Substances: All Department of Defense (DOD)-funded research involving new and ongoing research with human subjects and human anatomical substances must be reviewed and approved by the US 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 directives governing all research involving human subjects that is supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. Allow a minimum of 4 months for regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

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

C. Eligibility Information

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

D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance is **$12M** (for both Phase I and Phase II) plus indirect costs**.**
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- 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 up to **$2M** in direct costs for Years 1-2 (Phase I). Awards that require less than or more than two years to complete Phase I will be handled on a case-by-case basis at the discretion of the Grants Officer. Phase I will be funded using allocations from the FY11 BCRP congressional appropriation.
- The applicant may request direct costs for option Years 3-5 (Phase II) such that the combined total direct costs for Phase I and II do not exceed **$12M**. Option years will be funded with future congressional appropriations, if available. A total of three one-year options will be allowed.
- Exercising the options for Phase II will be contingent on receipt of sufficient congressional appropriations to the BCRP, submission and approval of written progress reports, and acceptable performance of the recipient. Milestones for the approved Statement of Work will be finalized during award negotiation. Before moving from Phase I to Phase II, the PI and his/her team will be required to present an update on progress toward accomplishing the goals of the project at a 1-day Milestone Meeting to be held in the National Capital Region. The Milestone Meeting will be attended by members of the BCRP Integration Panel (IP), Congressionally Directed Medical Research Programs (CDMRP) staff, and the Grants Officer. Annual Milestone Meetings will also be held during Phase II. ***Failure to complete each milestone may result in forfeiture of the subsequent installment of CTR Award funding.***
- The applicant must submit a comprehensive budget, broken down by year, which details the projected funding needed for the entire period of performance, to include Phases I and II.

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

Must be requested for:

- Travel for the PI and key personnel to attend three 1-day Milestone Meetings in the National Capital Region. Costs associated with travel to these meetings should be included in Years 2, 3, and 4 of the budget.
- Travel for the PI and key personnel to attend two 3½-day DOD BCRP Era of Hope meetings, which are held to disseminate the results of BCRP-sponsored research. Costs associated with travel to these meetings, up to $1,800 per person for each meeting, should be included in Years 2 and 5 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs
- Travel between collaborating organizations

- Travel costs of up to $3,600 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately $6M of the $150M FY11 BCRP appropriation to fund Phase I of approximately 2 Clinical Translational Research Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (https://cdmrp.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

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

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (http://www.grants.gov/) basic search using the Funding Opportunity Number: W81XWH-11-BCRP- CTR.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted through the CDMRP eReceipt System (https://cdmrp.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

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

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest – Tab 3**
- **Required Files – Tab 4**

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

The Preproposal Narrative should include the following:

- Explain how the results of this project have the potential to significantly improve the prevention and/or treatment of breast cancer.
- Describe how the proposed project applies novel, yet well-founded observational data, laboratory results, or other preclinical insights that justify the progression of the project into a clinical trial.
- Outline the necessary translational studies to be conducted through this award in order to move the project into clinical trials.
- Outline a plan for the prospective clinical trial that will be conducted.
- Discuss the appropriateness of the patient population to be targeted for the clinical trial. Provide evidence supporting access to the patient population and ability to accrue sufficient study subjects for the clinical trial.
- Describe the expertise available for conducting the translational and clinical research.

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

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

- **Submit Pre-application – Tab 5**
- **Other Documents Tab**

  No additional documents are required**.**

Pre-Application Screening

- **Pre-Application Screening Criteria**

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

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

  Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the title page of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received a letter of invitation.

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

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

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

2. **Attachments Form**

   - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf."

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

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

     - **Background:** Provide a brief statement of the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of the translational and clinical work proposed. Explain why the proposed work should proceed to a clinical trial for the prevention or treatment of breast cancer. Describe the pertinent experience of the investigators. Cite relevant literature.
     - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
     - **Specific Aims:** Concisely explain the project's specific aims to be funded by this application.
     - **Research Strategy:** Describe the experimental design and methodology, including reagents, assay validation, statistical analysis, potential pitfalls, and alternative approaches for the translational research. Provide a well-developed, well-integrated research strategy that supports the translational feasibility and

promise of the approach. If the methodology is new or unusual, provide sufficient details for evaluation. Describe the translational studies that will be performed through this award and ***clearly link*** the laboratory and other preclinical findings to the prospective clinical trial. If preliminary studies are not focused on breast cancer, explain how the preliminary work will support the proposed research on breast cancer. As appropriate, outline a plan for applying for and obtaining IND/IDE status (or other FDA approvals).

- **Clinical Trial:** Provide detailed plans for initiating and conducting the prospective human clinical trial during the course of this award. Provide a properly powered statistical plan and information demonstrating that a sufficient number of participants will be accrued to the proposed clinical trial during the award period. The investigator and his/her team must demonstrate appropriate expertise in conducting clinical trials, which may include the expertise of collaborating investigators and highly experienced support staff. (Do not submit a clinical trial protocol with the application.)
- **Strategic Plan:** Provide an overall strategic plan for completing the clinical trial during the award period.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***Each component has no page limit unless otherwise noted.***
  - 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 US Army Medical Research and Materiel Command (USAMRMC). Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.
  - Letters of Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
  - Letters of Collaboration (if applicable; two-page limit per letter): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work, including, but not limited to:

- Availability of, access to, and quality control for all critical reagents. If applicable, include information regarding the resources available to aid in the development of sufficient quantities of the reagent under Good Manufacturing Practice (GMP). If the reagent is to be provided from industrial sources, evidence of a cost-sharing plan must also be provided.
- Availability of and access to the appropriate patient population(s).

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

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  Use the outline below.

  - Background: Present the ideas and reasoning behind the proposed work.
  - Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - Specific Aims: State the specific aims of the study.
  - Study Design: Briefly describe the study design, including appropriate controls.
  - Impact: Briefly describe how the proposed project will have an impact on the eradication of breast cancer.

- **Attachment 4: Public Abstract (one-page limit):** Upload as "PublicAbs.pdf."
  - Clearly describe, in a manner readily understood by lay persons, the rationale, objective, and aims of the application.
    - Do not duplicate the technical abstract.
  - Describe the ultimate applicability of the research.
    - What types of patients will it help, and how will it help them?
    - What are the potential clinical applications, benefits, and risks?
    - What is the projected time it may take to achieve a patient-related outcome?
  - What is the likely impact of this study on the eradication of breast cancer?

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

  Establish milestones in the SOW for the following:

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

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

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

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

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

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

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

3. **Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
   - PI Biographical Sketch (four-page limit): Upload as "Biosketch_LastName.pdf."
   - PI Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (four-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf."

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

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

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

D. Submission Dates and Times

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

E. Other Submission Requirements

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

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, and the specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

B. Application Review Criteria

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

    - **Impact**
        - How the project, if successful, will result in significant improvements over current approaches to breast cancer prevention and therapy.
        - Whether the aims of the application, if achieved, are likely to have a ***significant clinical impact***.

- How the research, if successful, has the potential to make an important contribution toward accelerating the eradication of breast cancer.

- **Translational/Clinical Strategy**
  - How the project will translate promising, well-founded research findings into a clinical trial for novel preventions or treatments for breast cancer.
  - Whether the PI demonstrates the ability to accrue a sufficient number of subjects.
  - Whether the research design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.
  - How well the strategic plan to complete the clinical trial during the award period is developed.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, preliminary data, and logical reasoning.
  - How the hypotheses, objectives, aims, experimental design, methods, and analyses are developed.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether there is documented availability of, access to, and quality control for all critical reagents.
  - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP.
- **Statistical Plan**
  - Whether an appropriate statistical plan is provided, including power analysis.
  - Whether the clinical trial is designed with enough statistical power to lead to meaningful results.
- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed work.
  - How the levels of effort are appropriate for successful conduct of the proposed work.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- Whether there is evidence of a cost-sharing plan, if critical reagents are to be provided from industrial sources.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influenced the review.

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

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

C. Recipient Qualification

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

D. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds the page limit
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

B. Modification

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

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY11 BCRP IP member is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 BCRP IP members may be found at http://cdmrp.army.mil/bcrp/panels/panels11.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The PI does not meet the eligibility criteria.
- Application does not include a planned clinical trial.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

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

C. Reporting

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

D. Award Transfers

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

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

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

Phone: 1-800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Translatability Statement (Translate.pdf) as Attachment 7.	
	Upload Transition Plan (Transition.pdf) as Attachment 8.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	