

Program Announcement

**Defense Health Program
Department of Defense Congressionally Directed Medical Research Programs**

Peer Reviewed Cancer Research Program

Discovery Award

Funding Opportunity Number: W81XWH-11-PRCRP-DA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), October 13, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, October 27, 2011
- **Scientific Peer Review:** January 2012
- **Programmatic Review:** March 2012

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

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Peer Reviewed Cancer Research Program (PRCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The PRCRP was established in 2009 to provide support for cancer research not addressed by the breast cancer, prostate cancer, lung cancer, and ovarian cancer research programs executed and managed by the Office of the Congressionally Directed Medical Research Programs (CDMRP). Appropriations for the PRCRP from FY09 through FY10 totaled \$31 million (M). The FY11 appropriation is \$16M. The goal of the PRCRP is to improve quality of life by decreasing the impact of cancer on service members, their families, and the American public.

B. FY11 PRCRP Congressionally Directed Topic Areas

The required FY11 PRCRP Topic Areas as directed by Congress are:

- Blood cancers
- Colorectal cancer
- Genetic cancer research
- Kidney cancer
- *Listeria* vaccine for cancer
- Melanoma and other skin cancers
- Mesothelioma
- Pancreatic cancer
- Pediatric cancers
- Radiation protection utilizing nanotechnology

All applications *must* address research in one or more of the FY11 PRCRP Topic Areas. The Government reserves the right to withdraw any pre-application or application if at least one of the FY11 PRCRP Topic Areas is not addressed. Research applications in the areas of breast, prostate, lung (excluding mesothelioma) or ovarian cancer will *not* be accepted by the FY11 PRCRP.

New for FY11: The PRCRP encourages submission of applications for the following FY11 Focus Areas:

- Analysis of molecular signaling pathways relevant to the progression of cancers
- Biomarkers of resistance and/or sensitivity to standard chemotherapies and approved target agents
- Identification of populations at higher risk of developing cancers due to exposure(s) to militarily relevant environmental or chemical carcinogens based on genetic polymorphisms

- Immunological and inflammatory responses as well as the microenvironment in the development of cancers
- Studies of precursor lesions and molecular interventions that reverse the progression of cancer

One or more of the FY11 PRCRP Focus Areas is encouraged to be studied within the **required** FY11 PRCRP Topic Area(s).

C. Award Information

The PRCRP Discovery Award mechanism is being offered for the first time in FY11. The intent of the PRCRP Discovery Award is **to support innovative, untested, high-risk/potentially high-reward concepts, theories, paradigms, and/or methods**. Studies supported by this award are expected to develop robust preliminary data that will lay the groundwork for future avenues of scientific investigation. The proposed research project should include a well-formulated, testable hypothesis based on strong scientific rationale and study design.

The Discovery Award is not intended to support a logical progression of an already established research project. **The proposed research project should be novel and innovative**. Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this award mechanism.

Inclusion of preliminary data is strongly discouraged. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for future research projects to understand the mechanisms of initiation, or progression of and/or improving patient care for a disease or condition. **This award is not intended to support ongoing work**; therefore, inclusion of preliminary data other than serendipitous findings or in very small numbers is not consistent with the exploratory nature of this award. The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism.

Use of human subjects and human anatomical substances is limited. Because this award mechanism is designed to support preliminary investigations, research projects involving human subjects and/or human anatomical substances will not be supported unless they are exempt under Title 32, Code of Federal Regulations (CFR), Part 219, Section 101(b) (32 CFR 219.101[b]) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). Exemption or expedited status is first determined by the local Institutional Review Board (IRB) of record. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt or expedited status. Studies that do not qualify for exempt or expedited status will be administratively withdrawn and will not be funded. **Clinical trials are not allowed under this funding opportunity.** Refer to the General Application Instructions, Appendix 5, for additional information about studies involving human subjects, human subjects' data, or human anatomical substances. Definitions of human subject use may be accessed at [https://cdmrp.org/Program Announcements and Forms/](https://cdmrp.org/Program%20Announcements%20and%20Forms/).

D. Eligibility Information

- All investigators are eligible to submit applications. Postdoctoral fellows and early career independent investigators are encouraged to apply.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **2 years**.
- The maximum allowable direct costs for the entire period of performance is **\$200,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2 years**.

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 costs, up to \$1,800 per year, for the Principal Investigator (PI) to attend one Department of Defense (DOD) research-related meeting to be determined at the discretion of the Government. Costs associated with this travel should be included in year one of the budget.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately \$6.4M of the \$16M FY11 PRCRP appropriation to fund approximately 20 Discovery 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-PRCRP-DA.

B. Pre-Application Submission Content and Form

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

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 (COI) – Tab 3**
- **Required Files – Tab 4**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY11 PRCRP Topic Area(s) under which the application will be submitted. 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.

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

No additional documents are required.

C. Application Submission Content and Form

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 Discovery 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 (three-page limit):** Upload as “ProjectNarrative.pdf.”

Describe the proposed project in detail using the outline below.

- **Hypothesis:** State concisely the new concept, theory, paradigm, and/or method that addresses an important problem relevant to at least one of the FY11 PRCRP Topic Areas.
- **Rationale:** State concisely the rationale for the proposed research. Inclusion of preliminary data is strongly discouraged.
- **Objectives:** State the specific aims and research strategy of the study.
- **Methods:** Describe the experimental design and methodology in sufficient detail for evaluation.
- **Innovation:** State concisely how the proposed research is novel and innovative.
- **Impact:** Provide a brief statement regarding the potential impact of this work on one or more of the FY11 PRCRP Topic Areas. *It is the responsibility of the applicant to clearly and explicitly articulate the project’s impact on military beneficiaries.* Describe how the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical cancer research, or on the quality of life of individuals with cancer.
- **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 (five-citation limit):** 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.
 - **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
State the FY11 PRCRP Topic Area(s) addressed by the proposed research project. Clearly describe the proposed research including the idea to be studied and the objectives, the innovative aspect of the research, and the expected results and how they will be used as a foundation for future research projects.
 - **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
State the FY11 PRCRP Topic Area(s) addressed by the proposed research project. Include an overview of the proposed research project that can be readily understood by lay persons. Clearly describe the idea to be studied, the innovative aspect of the research, and the expected results and how they will be used as a foundation for future research projects. Do not duplicate the technical abstract.
 - **Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
 - **Attachment 6: Relevance to Military Beneficiaries Statement (one-page limit):** Upload as “MilBen.pdf.” Describe the impact either short-term or long-term of the proposed research on the health and welfare of service members, their families, and other military beneficiaries. Describe how the proposed project is responsive to one or more of the FY11 PRCRP Topic Areas with respect to its significance to military beneficiaries.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
- PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
 - 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.”
- 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, US Army Medical Research and Materiel Command (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.shtml>.

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 of equal importance:

- **Scientific Merit**
 - How the proposed research project addresses an important scientific question relevant to at least one of the FY11 PRCRP Topic Areas.
 - Whether the research demonstrates the potential to generate robust preliminary data that can be used as a foundation for future research projects.
 - How the proposed study is responsive to the health care needs of military service members, veterans, and/or beneficiaries.
 - How the rationale, experimental design, and methodology are appropriate to test the hypothesis.
- **Innovation**
 - To what extent the research proposes new paradigms or challenges existing paradigms.
 - To what extent the proposed research is innovative in one or more of the following ways: concept or question, research methods or technologies, adaptations of methods or technologies or other ways.
 - How the proposed research represents more than an incremental advance.
- **Impact**
 - How well the study addresses a critical problem in cancer research or care.
 - How the project will lead to an original and important contribution to the goal of advancing basic, translational, or clinical research or the quality of life of individuals.
 - To what extent the proposed research will provide original and important contributions to the goal of advancing research with relevance to military beneficiaries in one or more of the FY11 PRCRP Topic Areas and Focus Areas.
 - What impact this study will have on the concepts or methods that drive the field.

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

- **Personnel**
 - How the research team's background and expertise are appropriate to accomplish the proposed research.
 - To what degree the levels of effort are appropriate for successful conduct of the proposed research.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- **Application Presentation**

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

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

- Adherence to the intent of the award mechanism
- Programmatic relevance
- Program portfolio balance with consideration to the relevance to military beneficiaries
- Ratings and evaluations of the peer reviewers
- Relative impact and innovation
- Responsiveness to FY11 PRCRP Topic Areas and Focus Areas

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 applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- LOI is not submitted.

- The proposed research includes a clinical trial.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, 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 PRCRP Integration Panel (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 PRCRP IP members may be found at <http://cdmrp.army.mil/prcrp/panels/panels11.shtml>.
- 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 proposed research project is not in one of the FY11 PRCRP Topic Areas.
- The proposed research is in the topic areas of breast, prostate, lung (excluding mesothelioma) or ovarian cancer.
- Studies not exempt under 32 CFR 219.101(b) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).

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.

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 US 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 Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 6.	
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.	