

Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Cancer Research Program

Visionary Postdoctoral Fellowship Award

Funding Opportunity Number: W81XWH-11-PRCRP-VPFA

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), August 10, 2011
- **Invitation to Submit an Application:** October 3, 2011
- **Confidential Letters of Recommendation Submission Deadline:** 5:00 p.m. ET, November 22, 2011
- **Application Submission Deadline:** 11:59 p.m. ET, November 22, 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. The FY11 PRCRP fosters the next generation of cancer research by providing new investigators and their early career mentors opportunities to excel in groundbreaking cutting-edge research for the prevention, detection, and treatment of cancer.

B. FY11 PRCRP 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 into 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 or more 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 Areas.

C. Award Information

The PRCRP Visionary Postdoctoral Fellowship Award mechanism is being offered for the first time in FY11. To support the future generation of cancer research, this award offers opportunity for a candidate postdoctoral fellow to collaborate with an early career investigator mentor(s) in one or more of the FY11 PRCRP Topic Areas.

Important aspects of the Visionary Postdoctoral Fellowship Award are as follows:

1. Impact: The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising cancer research into clinical applications. Correlative clinical research studies are allowed under this mechanism; however, ***clinical trials are not permitted***. 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/.

2. Innovation: Research deemed innovative may examine a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may also be innovative in study concept, research methods or technology, or adaptations of existing methods or technologies. Research that represents an incremental advance on previously published work is not considered innovative.

3. Relevance to Military Beneficiaries: The proposed research should address cancer research that is relevant to military beneficiaries (service members and their families, veterans and their dependents).

The Visionary Postdoctoral Fellowship Award is intended to support exceptionally talented recent medical or other doctoral graduates in their pursuit of cutting-edge, innovative, high-

risk/high-impact cancer research during their postdoctoral fellowship. This funding opportunity includes a budget option for research supplies to support pioneering investigations and to allow for the necessary experience to be obtained for the establishment of an independent career at the forefront of cancer research. Candidates for this award should exhibit a strong desire to pursue a career in cancer research in one of the FY11 PRCRP Topic Areas. ***The postdoctoral fellow is considered the Principal Investigator (PI) of the application.***

The second unique aspect of this award mechanism aims to provide postdoctoral fellow support in the laboratory of outstanding ***early career*** investigators. The mentor(s) must be an early career independent, non-tenured investigator (see Section I.D., Eligibility Information) with the appropriate expertise and experience in cancer research as demonstrated by funding and publications. The selected mentor(s) should demonstrate a clear commitment to the PI's training and be qualified to significantly contribute to the development of the PI toward a career in cancer research.

The PI must outline an individualized cancer-focused research and training program that should include a research plan and may include cancer-relevant coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities to provide the PI with experience in key areas and foster the PI's development as a cancer researcher. An environment appropriate to the proposed training and research project must be clearly described.

All applications for the Visionary Postdoctoral Fellowship Award are to be written by the PIs, with appropriate direction from the mentors. The PRCRP seeks applications from the wide spectrum of basic, translational, and clinical multidisciplinary research.

In addition, applications are encouraged to be relevant to at least one or more of the Focus Areas within the ***required*** FY11 PRCRP Topic Areas in a manner relevant to military beneficiaries.

D. Eligibility Information

- ***The PI must, by the time of application submission deadline:***
 - Have successfully defended a doctoral thesis or possess an M.D. degree , and
 - Have 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 fellow, and
 - Have a total of less than 4 years of postdoctoral research experience (excluding clinical residency training).
- ***The Mentor(s) must, by the time of application submission deadline:***
 - Hold a position at the level of Assistant or Associate Professor for less than 7 years without yet achieving tenure (or equivalent). Faculty appointments including any **combination** of institutions should be less than 7 years. Tenured Faculty or Full Professors (or equivalent) are not eligible to be mentor(s) for the PI, and
 - Have not received more than \$750,000 in total direct costs as a PI of one or more federally funded non-mentored peer reviewed awards, and

- Have acquired sufficient skills and knowledge to function **independently** (a letter signed by appropriate senior organization official is required to verify independence), and
- Provide evidence of institutional support, such as start-up funds provided by the institution and/or use of a technician, space, facilities, and resources (a letter signed by appropriate senior organization official is required to verify institutional support).
- Cost sharing/matching is not an eligibility requirement.
- It is required that the PI and the mentor(s) be located at the same institution.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance is **\$240,000** 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.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- 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.

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, for the 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 for the PI
- Research supplies
- Tuition for coursework, seminars, and workshops (including textbooks and/or related materials)
- Publication costs
- Travel between collaborating organizations

- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

Must not be requested for:

- Mentor or other salary

The Office of the CDMRP expects to allot approximately \$13.7M of the \$16M FY11 PRCRP appropriation to fund approximately 35 Visionary Postdoctoral 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 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-VPFA.

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/>). 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 (COI) – Tab 3**
- **Required Files – Tab 4**

Preproposal Narrative (two-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 must be written by the PI while also showing evidence of appropriate direction from the mentor(s).*

The Preproposal Narrative should include the following:

- **Personnel:** Clearly state how the PI is eligible for this award. Describe the PI's potential for contributing to one or more of the FY11 PRCRP Topic Areas. Briefly describe the training program and future career goals. State the research goals and mentor experience of the early career mentor(s).
- **Research:**
 - **Idea:** State the ideas and reasoning on which the proposed work is based, and how the application addresses one or more of the FY11 PRCRP Topic Areas. Describe how the proposed research is responsive to one or more of the FY11 PRCRP Focus Areas.
 - **Aims:** Concisely state the project's objective and specific aims. *This award may not be used to conduct clinical trials.*
- **Innovation:** In brief, describe how the research examines a new paradigm, challenges existing paradigms, or looks at existing problems from new perspectives. Describe how the research represents more than an incremental advance on published data.
- **Impact:** Briefly state how the proposed research, if successful, will impact one or more of the relevant FY11 PRCRP Topic Areas as well as its relevance to military beneficiaries.

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

- References Cited (one-page limit): List relevant references 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). The inclusion of Internet URLs to references is encouraged.
- Key Personnel Biographical Sketches (four-page limit per individual)
- Key Personnel (including mentor's(s')) Current/Pending Support (no page limit).

List of Individuals Providing Confidential Letters of Recommendation: *If the PI receives a letter of invitation for application submission, the PI should identify individuals to submit confidential letters of recommendation.* The PI *must* request a confidential letter of recommendation from the mentor(s) named in the application by entering his/her name, position title, email address, and phone numbers into the appropriate data fields. Up to two additional individuals may also be entered to provide letters of recommendation; however, the total number of letters must not exceed three.

The mentor(s) and, if applicable, other individuals will receive an email generated from the CDMRP eReceipt System containing specific instructions on how to upload the letter(s). The PI should monitor via the CDMRP eReceipt System whether the letter(s) have been received; however, the PI will not be able to view the content of the letter(s). The confidential letter(s) of recommendation *must be submitted* through the *CDMRP eReceipt System* by 5:00 p.m. ET on the application deadline date.

The confidential letter(s) of recommendation must be submitted by the individuals named in the pre-application. If this is not possible, the PI must contact the CDMRP eReceipt Help Desk for assistance at help@cdmrp.org or 301-682-5507. Specific points to address in the letters of recommendation that are unique to the award mechanism are described under “Application Submission Content and Form” below.

- **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 the following criteria:

- **Personnel:** Whether the PI is eligible and demonstrates potential for contributing to the field. Whether the mentor(s) is eligible and has a demonstrated record of research in one or more of the FY11 PRCRP Topic Areas for the project. How the mentor(s) will contribute to the training of the PI.
- **Research Idea:** How the rationale and specific aims support the project’s objective.
- **Innovation:** How the research examines a new paradigm, challenges existing paradigms, or looks at existing problems from new perspectives. How well the research represents more than an incremental advance on published data.
- **Impact:** What impact these studies will have on one or more of the FY11 PRCRP Topic Areas and their relevance to military beneficiaries.

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

Grants.gov application package components: For the Visionary Postdoctoral 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. **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 (six-page limit):** Upload as “ProjectNarrative.pdf.”

The PI must describe the proposed research project. The inclusion of preliminary data relevant to cancer research and the proposed project is not required. Any preliminary data provided should be from the PI, mentor(s), or member(s) of the collaborating team. *The Project Narrative must be written by the PI while also showing evidence of appropriate direction from the mentor(s).*

PI’s Career Goals: The PI should describe his/her career goals and how the proposed training and research experience will promote his/her career development in cancer research. Describe how the PI’s goals are consistent with developing a career as a visionary leader at the forefront of cancer research. The PI should discuss his/her career/research plans after the completion of this award.

Mentor’s(s’) Expertise: Describe the mentor’s(s’) background and experience in cancer research, and explain how the mentor(s) will assist the PI in developing his/her career. Demonstrate that the mentor(s) has the potential to be a leader in cancer research in the future.

Training Program: Describe the training program, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Provide a timeline for the training program and describe how it is integrated with and designed to support the proposed research. Explain how the training program is supported by the training environment; this should include a description of ongoing cancer research at the organization. Include information on training or collaborations with other investigators.

Research Project: Indicate how the proposed research is innovative, and note the potential impact it will have on one or more of the required FY11 PRCRP Topic Areas.

- **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
- **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 supported by this application.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, appropriately powered statistical plan in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials.*
- **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.*
- **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): 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.
- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Transcripts: Include a copy of the PI's transcripts from both undergraduate and graduate institutions. All foreign-language transcripts must be accompanied by a certified English translation. The Government reserves the right to request official transcripts during award negotiations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

Technical abstracts should be written using the outline below. The technical abstract is used by all reviewers; however, programmatic reviewers do not have access to the full application and rely on the technical abstract for appropriate description of the project's key aspects.

- Training Plan
 - The PI should describe his/her career goals and how the proposed training supports him/her in attaining these goals.
 - The PI should describe how the proposed research project will train him/her to make valuable contributions to the study and/or treatment of cancer.
 - The PI should describe how the proposed training in an early career investigator will promote his/her career development in cancer research.
- Research Plan
 - 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.
- Innovation: In brief, state how the research examines a new paradigm, challenges existing paradigms, or looks at existing problems from new perspectives. Describe how the research represents more than an incremental advance on published data.

- Impact: Summarize how the proposed research will have an impact on one or more of the FY11 PRCRP Topic Areas and is relevant to military beneficiaries.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.”
Public abstracts should be written using the outline below. Do not duplicate the technical abstract. The public abstract is used by lay peer reviewers along with other components of the application package.
 - Describe the scientific objective and rationale for the proposed project in a manner that will be *readily understood by readers without a background in science or medicine*.
 - Describe the PI’s career goals in cancer research.
 - How does the training program support the PI in attaining these goals?
 - How does the research plan support the PI in attaining these goals?
 - 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 are the likely contributions of this study to advancing the field of cancer research?
 - Summarize how the proposed research will have an impact on one or more of the FY11 PRCRP Topic Areas and is relevant to military beneficiaries.
- **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: Impact Statement (one-page limit):** Upload as “Impact.pdf.” State explicitly how the proposed research project will have an impact on cancer research and/or patient care, including its contribution to the goal of eliminating death and suffering from cancer. Describe how the proposed research addresses one of the FY11 PRCRP Topic Areas.
- **Attachment 7: Innovation Statement (one-page limit):** Upload as “Innovation.pdf.” Summarize how the proposed research is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative. Describe how the proposed research is innovative in one or more ways (e.g., concept or question, research methods or technologies, adaptations of existing methods or technologies).
- **Attachment 8: PI’s Eligibility Statement (one-page limit):** Upload as “PIEligibility.pdf.” Use the Eligibility Statement template (available for download on the Full announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.

- **Attachment 9: Mentor’s(s’) Eligibility Statement(s) (one-page limit for each mentor):** Upload as “MentorEl.pdf.” Use the Eligibility Statement template (available for download on the Full announcement page in Grants.gov) signed by the Department Chair, Dean, or equivalent official to verify that the eligibility requirements will be met.
 - **Attachment 10: 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 in a militarily relevant manner. Describe how the study design will replicate field conditions, if appropriate. If active duty military, military families, or U.S. veteran population(s) will be used in the proposed research project, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of using the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., Armed Forces, their family members, and/or the U.S. veteran population).
- 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.”
 - *Include the PI’s and the mentor’s(s’) biographical sketch.*
 - Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - *Include the PI’s and mentor’s(s’) current/pending support.*
- 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.

Additional Application Components: In addition to the completed Grants.gov application package of forms and attachments, Visionary Postdoctoral Fellowship Award applications also require the submission of a confidential letter of recommendation from the mentor(s), which must be uploaded by the mentor(s) to the CDMRP eReceipt System. *Additional letters of*

recommendation may also be submitted by up to two other individuals (the maximum total number of letters is three). All letters of recommendation should be provided on letterhead, signed, and uploaded as PDF files.

Confidential Letters of Recommendation (two-page limit per letter recommended):

The confidential letters should include the following:

- ***A confidential letter of recommendation from the mentor***, describing his/her commitment to the PI's training, career development, and mentorship in cancer research. The mentor's letter should address the following:
 - The PI's potential to become a successful and independent investigator at the forefront of cancer research;
 - The individualized training program and how it will facilitate the PI's development as a successful cancer researcher;
 - The degree to which the PI participated in the project development and application preparation, and the degree to which the PI will participate in the execution of the application if funded;
 - The commitment of the mentor to the training, career development, and mentorship of the PI, including details of the proposed interactions of the mentor with the PI during the PI's training;
 - The training environment, including ongoing cancer research in the mentor's laboratory (or laboratories) and in the organization as a whole, resources available, and how this environment will promote the development of the PI as a cancer researcher;
 - The mentor's record in training postdoctoral fellows.
- ***One or two additional confidential letters of recommendation (optional)***. Each additional letter should describe the PI's unique qualifications and accomplishments that highlight his/her potential for success in pursuing a career in cancer research. Specifically, each letter should offer 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 in cancer research;
 - The relevance of the proposed research project to training the PI in cancer research; and
 - The suitability of the mentor and training environment for providing the PI with a solid foundation in cancer research.

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/prcrp/panels/panels11.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:

- **Principal Investigator**

- To what extent the PI's achievements (as reflected by exceptional academic performance, awards, honors, and/or previous publications and funding) indicate a potential for a successful career as a cancer researcher.
- To what extent the PI's stated career goals demonstrate a strong personal commitment to pursuing an independent career as a visionary leader in cancer research, and potentially contributing to one or more of the relevant FY11 PRCRP Topic Areas.
- To what extent the letters of recommendation from the mentor(s) and others, if applicable, support the PI's high potential for a productive career as a cancer researcher.
- Whether the proposed PI's level of effort is appropriate for successful training and completion of the proposed work.

- **Mentor(s)**

- To what extent the training experience, as reflected by his/her previous PIs' career achievements and areas of interest, indicate the potential of the mentor to successfully train the PI in cancer research.
- Whether the background, funding, and publication record demonstrate the potential of the mentor to be a visionary leader in cancer research in the future.
- To what extent the mentor's own training and experience in cancer research, and his/her research program(s) and committed resources support his/her ability to supervise the PI's training and research project.
- Whether the mentor's letter indicates a high level of commitment to training the PI.
- Whether the quality of the application suggests that the mentor provided appropriate guidance in its preparation.

- **Training Program and Environment**

- How well the PI has outlined a detailed, individualized training program that will effectively prepare the PI for a career at the forefront of cancer research.
- Whether the training program and research project are appropriately integrated.
- To what extent the scientific environment is appropriate for the proposed training activities, including professional interaction with established cancer researchers.
- To what extent the training and research requirements are adequately supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).

- **Research Project**
 - How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, cancer-relevant preliminary data (if included), and/or logical reasoning.
 - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
 - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Impact**
 - To what degree the expected results of the project will contribute to the goal of advancing research in one or more of the indicated FY11 PRCRP Topic Areas and Focus Areas.
 - How the research will decrease the pain and suffering from cancer in either the short or long term.
 - How the research is relevant to military beneficiaries.
- **Innovation**
 - How the project proposes new paradigms or challenges existing paradigms.
 - To what extent the proposed research is innovative in one or more ways (e.g., concept or question, research methods or technologies, adaptations of existing methods or technologies).
 - How well the proposed research represents more than an incremental advance to published data.

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 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 composition with consideration of 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 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 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 pre-application or 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 PI and/or mentor(s) do not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The failure to address one of the required FY11 PRCRP Topic Areas.
- The pre-application or application proposes breast, prostate, lung (excluding mesothelioma) or ovarian cancer research.
- The proposed research is a 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 changes.

Changes in PI or mentor are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case 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 Innovation Statement (Innovation.pdf) as Attachment 7.	
	Upload PI's Eligibility Statement (PIEligibility.pdf) as Attachment 8.	
	Upload Mentor's Eligibility Statement (MentorEl.pdf) as Attachment 9.	
	Upload Relevance to Military Beneficiaries Statement (MilBen.pdf) as Attachment 10.	
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 (if applicable).	
Additional Application Components	Action	Completed
Confidential Letters of Recommendation	Confirm upload to CDMRP eReceipt System.	