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-12-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), June 19, 2012
- Invitation to Submit an Application: July 2012
- Confidential Letters of Recommendation Submission Deadline: 5:00 p.m. ET, September 12, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, September 12, 2012
- **Peer Review:** November 2012
- **Programmatic Review:** January 2013

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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 of exceptional scientific merit 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 FY11 totaled \$47 million (M). The FY12 appropriation is \$12.8M.

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 FY12 PRCRP fosters the next generation of cancer research by providing new and early career investigators opportunities to excel in groundbreaking cutting-edge research for the prevention, detection, and treatment of cancer.

B. FY12 PRCRP Topic Areas

The required FY12 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 brain tumors

All applications *must* address research into at least one of the FY12 PRCRP Topic Areas. The Government reserves the right to withdraw any pre-application or application if at least one of the FY12 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 FY12 PRCRP.

C. Award Information

The PRCRP Visionary Postdoctoral Fellowship Award mechanism was first offered in FY11. Since then, 81 Visionary Postdoctoral Fellowship Award applications have been received, and 13 have been recommended for funding.

To support the development of future generations of cancer researchers, this award offers an opportunity for a candidate postdoctoral fellow to collaborate with an early-career independent, not yet tenured investigator serving as mentor in at least one of the FY12 PRCRP Topic Areas toward investigations that are relevant to military beneficiaries.

The Visionary Postdoctoral Fellowship Award is intended to support exceptionally talented, recent medical or other doctoral graduates in their pursuit of cancer research during a postdoctoral fellowship with a focus on cutting-edge, innovative, high-risk/high-impact basic science or translational research that will have either short-term or long-term clinical impact. Translational research may include preclinical studies in animal models and/or human tissues that have a clear potential for translation into clinical applications. Correlative studies of existing clinical trials, and/or projects that develop clinical endpoints for clinical trials, may also be proposed. *Clinical trials are not permitted under this award mechanism*.

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

- **Principal Investigator (PI):** The PI must be recent medical or other doctoral graduates. The PI's record of accomplishment will be evaluated regarding his or her potential for contributing to the area of cancer research.
- **Mentorship:** The mentor must be an early-career independent, not yet tenured investigator. The mentor must have experience in a field that is responsive to at least one of the FY12 PRCRP Topic Areas as demonstrated by a record of funding and publications.
- **Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate promising cancer research into clinical applications.
- 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.
- **Relevance to Military Beneficiaries:** The proposed research should address cancer research that is relevant to service members, Veterans, and their families.

The Visionary Postdoctoral Fellowship Award presents a unique opportunity for collaboration between a postdoctoral candidate and an early-career investigator-mentor. Candidates for this award should exhibit a strong desire to pursue a career in cancer research in at least one of the FY12 PRCRP Topic Areas. *The postdoctoral fellow is to be considered the Principal*

Investigator of the application. The mentor must be an early-career independent, not yet tenured investigator (see <u>Section I.D., Eligibility Information</u>) with the appropriate expertise and experience in cancer research, as demonstrated by funding and publications. The selected mentor should demonstrate a clear commitment to the PI's training and be qualified to significantly contribute to the development of the PI toward pursuing a career in cancer research.

The PI must outline an individualized cancer-focused research and training plan 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 mentor.* The PRCRP seeks applications from the wide spectrum of basic, translational, and clinical multidisciplinary research.

Use of Human Subjects and Human Biological Substances: All Department of Defense (DoD)-funded research involving human subjects and human biological substances must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to local Institutional Review Boards. The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DoD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local review board. Allow a minimum of 6 months for regulatory review and approval processes for studies involving human subjects. Correlative clinical research studies are allowed under this mechanism. *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/.

The CDMRP intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

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 must, by the time of application submission deadline:
 - Hold a position at the level of Assistant or Associate Professor for less than 5 years without yet achieving tenure (or equivalent). Faculty appointments at any **combination** of institutions should be less than 5 years. Tenured Faculty or Full Professors (or equivalent) are not eligible to be a mentor for the PI, 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.
- 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 are \$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. In addition, for this award mechanism, direct costs:

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 CDMRP expects to allot approximately \$7.68M of the \$12.8M FY12 PRCRP appropriation to fund approximately 20 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 prohibited. The Government will 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-12-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 any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

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

FY12 PRCRP Integration Panel (IP) members should not be involved in any preapplication or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk (1-301-682-5507).

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.*

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 at least one of the FY12 PRCRP Topic Areas. Briefly describe the training plan and future career goals. Clearly state the eligibility of the mentor. Describe the research goals and experience of the early-career mentor.
- **Research Idea:** State the ideas and reasoning on which the proposed work is based, and how the application addresses at least one of the FY12 PRCRP Topic Areas. 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.
- o **Impact:** Briefly state how the proposed research, if successful, will impact at least one of the relevant FY12 PRCRP Topic Areas as well as its relevance to military beneficiaries. Describe how the proposed research may have a significant impact on the concepts or methods that will accelerate the movement of the research into clinical applications.

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 Current/Pending Support (including mentor's, no page limit).

List of Individuals Providing Confidential Letters of Recommendation: If the PI receives a letter of invitation for application submission, he/she should identify individuals to submit confidential letters of recommendation. The PI must request a confidential letter of recommendation from the mentor 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 be entered to provide letters of recommendation; however, the total number of letters must not exceed three.

The mentor 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

This tab must be completed for the pre-application to be accepted and processed by CDMRP.

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 the PRCRP, pre-applications will be screened based on the following criteria:

o **Personnel:** Whether the PI is eligible and demonstrates potential for contributing to the field. Whether the mentor is eligible and has demonstrated a record of research in at least one of the FY12 PRCRP Topic Areas for the project. How the mentor will contribute to the training of the PI.

- **Research Idea:** How the rationale and specific aims support the project's objectives.
- o **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 at least one of the FY12 PRCRP Topic Areas and their relevance to military beneficiaries. How the proposed research will have a significant impact on the concepts or methods that will accelerate the movement of the research into clinical applications.

• Notification of Pre-Application Screening Results

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

The invitation date to submit an application is indicated on the <u>title page</u> of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received an invitation to submit an application.

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 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, 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.

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

Training Plan: Describe the training plan, which may include coursework, laboratory techniques, conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. Provide a timeline for the training plan and describe how it is integrated with and designed to support the proposed research. Explain how the training plan 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 at least one of the required FY12 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 will be recruited or human anatomical substances 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.
- o Impact: Provide a brief statement regarding the potential impact of this work on at least one of the FY12 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. There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award 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 a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
 - Letters of Organizational Support: Provide a letter (or letters, if applicable),
 signed by the Department Chair or appropriate organization official, 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.

Personnel

 Describe the eligibility of the PI and how the PI demonstrates potential for contributing to the field. Describe the eligibility of the mentor and whether the mentor has a demonstrable record of research in at least one of the FY12 PRCRP Topic Areas for the project.

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 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 at least one of the FY12 PRCRP Topic Areas and is relevant to military beneficiaries.
- Describe how the proposed research may have a significant impact on the concepts or methods that will accelerate the movement of the research into clinical applications.

• Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

- 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 plan support the PI in attaining these goals?
 - How does the research project support the PI in attaining these goals?
- o 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 at least one of the FY12 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. Describe how the proposed research addresses at least one of the FY12 PRCRP Topic Areas.
- Attachment 7: Innovation Statement (one-page limit): Upload as "Innovation.pdf." 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). Investigating the next logical step or an incremental advancement on published data is not considered innovative.
- 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 Eligibility Statement: 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 at least one of the FY12 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 biographical sketch.
 - Key Personnel Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."
 - Include the PI's and mentor'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, which must be uploaded by the mentor 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 plan 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 research 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: 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 <u>title page</u> of this Program Announcement/ Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will 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 Numbering 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 PRCRP 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, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria, of which the PI, mentor, and research project are most important:

• Principal Investigator

- o 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 at least one of the relevant FY12 PRCRP Topic Areas.
- To what extent the letters of recommendation from the mentor 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

- To what extent the training experience, as reflected by his/her previous 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 leader in cancer research in the future.
- o 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.

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.

• Training Plan and Environment

- How well the PI has outlined a detailed, individualized training plan that will effectively prepare the PI for a career at the forefront of cancer research.
- Whether the training plan 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).

Impact

- To what degree the expected results of the project will contribute to the goal of advancing research in at least one of the indicated FY12 PRCRP Topic 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

- o To what extent the project proposes challenges existing paradigms or offers new ideas, research 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 PRCRP, 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 FY12 PRCRP Topic 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 <u>title page</u> of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI 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 the same research project to different funding opportunities within the same program and fiscal year.
- 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, the PI 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:

- A FY12 PRCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY12 PRCRP IP members can be found at http://cdmrp.army.mil/prcrp/panels/panels12.shtml.
- 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 & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI and/or mentor do not meet the eligibility criteria as described in this Program Announcement/Funding Opportunity.
- The failure to address one of the required FY12 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 U.S. 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, 2013. 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 D, for general information regarding administrative and national policy requirements.

C. Reporting

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

D. Award Transfers

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

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through 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.	
	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 Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
Attachments Form	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.	
	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
Research & Related	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
Senior/Key Person Profile (Expanded)	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.	