Program Announcement

DEPARTMENT OF DEFENSE (DOD)

PEER REVIEWED CANCER RESEARCH PROGRAM (PRCRP)

COLLABORATIVE TRANSLATIONAL SCIENCE AWARD FOR MELANOMA AND OTHER SKIN CANCERS ONLY

Funding Opportunity Number: W81XWH-09-PRCRP-CTS

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Objectives

The Peer Reviewed Cancer Research Program (PRCRP) is new for fiscal year 2009 (FY09). Congress appropriated funds for research into cancers not addressed by the Breast Cancer Research Program (BCRP), the Prostate Cancer Research Program (PCRP), or the Ovarian Cancer Research Program (OCRP), which are executed and managed by the Office of the Congressionally Directed Medical Research Programs (CDMRP). The total FY09 appropriation for the PRCRP is $16 million (M).

The goal of the PRCRP is to improve quality of life by significantly decreasing the impact of cancer on service members, their families, and the American public. The PRCRP fosters groundbreaking research, team science, and partnerships for the development of better prevention against, earlier detection of, and more effective treatments for cancer. PRCRP funds appropriated by Congress are directed for research in the following areas:

- ***$4M for research of melanoma and other skin cancers as related to deployments of service members to areas of high exposure***;
- $2M for research of pediatric brain tumors within the field of childhood cancer;
- $8M for genetic cancer research and its relation to exposure to the various environments that are unique to a military lifestyle;
- $2M for non-invasive cancer ablation treatment research including selective targeting with nanoparticles.

B. Award Description

The key initiative of the Collaborative Translational Science Award is to encourage collaborations among clinicians and laboratory scientists that accelerate the movement of promising ideas in melanoma and other skin cancers into clinical applications. This award is intended to support both new and established scientists across a broad spectrum of disciplines in research projects that are likely to make a major impact on melanoma and other skin cancers for those service members (and their families) deployed in areas of high exposure. ***No other topic areas will be allowed***.

The FY09 PRCRP Collaborative Translational Science Award requests applications from these Focus Areas only:

Research into melanoma and other skin cancers related to deployments of service members to areas of high exposure by:

- Understanding molecular and immunological effects of UV at the level of the cell and at the level of the human host.
- The genetic epidemiology and increased susceptibility to melanoma and other skin cancers.

Applications to the FY09 PRCRP Collaborative Translational Science Award will be rated on their responsiveness to these Focus Areas. It is the responsibility of the applicant to clearly and explicitly articulate the project's military relevance.

The Collaborative Translational Research Award supports the development of translational research collaborations among **two or three** independent investigators (known as partners) to address one of the Focus Areas in melanoma and other skin cancers in a ***manner relevant to military service*** that would be less readily achievable through separate efforts. At least one partner must have experience either in melanoma/other skin cancer research or in melanoma/other skin cancer patient care. It should be clear that all partners have equal intellectual input into the design of the research project. ***A proposed project in which one of the partners merely supplies tissue samples or access to patients will <u>not</u> meet the intent of this mechanism***.

Observations that drive a research idea may be derived from a laboratory discovery, population-based studies, or a clinician's firsthand knowledge of patients and anecdotal data. The ultimate goal of translational research is to move an observation forward into the clinical application. The Collaborative Translational Science Award supports preclinical studies in animal models and human subjects and human anatomical substances, correlative studies that are associated with an existing clinical trial, and projects that develop clinical endpoints for clinical trials. Developing the research plan must involve a reciprocal flow of ideas and information within the research team (from bench to bedside, and from bedside to bench).

Important aspects of the Collaborative Translational Science Award are as follows:

1. **Collaboration:** The success of the project depends on the unique skills and contributions of each collaborator. Of the two to three partners, at least one partner must have experience either in melanoma/other skin cancer research or in melanoma/other skin cancer patient care.

2. **Translational:** The application should provide evidence for the reciprocal transfer of ideas between basic and clinical science and vice versa in developing and implementing the research plan.

3. **Military Relevance:** The proposed research should address melanoma and other skin cancers as related to deployments of service members to areas of high exposure.

4. **Impact:** The proposed research should have a significant impact on the concepts or methods that are likely to accelerate the movement of promising, militarily relevant ideas in melanoma and other skin cancers into clinical applications. Correlative clinical research studies are allowed under this mechanism. ***Clinical Trials are not permitted under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.***

5. **Innovation:** Research deemed innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. Research may 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.

C. Eligibility

Independent investigators are eligible to submit applications. Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

D. Funding

Each collaborative partner will be a Principal Investigator (PI), and a separate award will be made to each partner's institution. The PIs are expected to be equal partners in the research, and the direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

- The maximum period of performance is 5 years.
- The maximum combined allowable funding for each collaborative partnership for the entire period of performance, regardless of whether there are two or three PIs, is $1,125,000 including direct and indirect costs. The maximum allowable funding is to be divided between the PIs of each collaborative partnership.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 5-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with the institution's negotiated rate agreement.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs (***Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.)***
- Travel to scientific/technical meetings
- Travel between collaborating institutions

The Office of the Congressionally Directed Medical Research Program expects to allot $3.4M of the $16M FY09 appropriation to fund approximately 3 Collaborative Translational Science Award applications, depending on the quality and number received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

E. Award Administration

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission. ***Pre-application submission is a required first step***.

Pre-application Submission Deadline:	**August 5, 2009, 5:00 p.m. Eastern Time (ET)**
Invitation to Submit an Application:	**October 19, 2009**
Application Submission Deadline:	**December 9, 2009, 11:59 p.m. ET**
Scientific Peer Review:	**January 2010**
Programmatic Review:	**March 2010**

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) an application submission through Grants.gov (http://www.grants.gov/). ***Applications will not be accepted unless a PI has been invited. Do not submit an application unless a letter of invitation has been received.***

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

The Collaborative Translational Science Award is structured to accommodate two to three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) will be identified as the Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute to the preparation of the proposal. ***The Initiating PI must complete the pre-application process and submit contact information for each Partnering PI.***

Failure by the Initiating PI or any Partnering PI to submit his or her required application components will result in administrative rejection of all applications associated with the proposed research project.

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

A. Step 1 - Pre-Application Components, Submission, and Screening

1. Pre-application Components for the Initiating PI

Pre-application submission is a required first step. The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the CDMRP eReceipt system by ***5:00 p.m. ET on the pre-application deadline***. Refer to the Application Instructions and General Information for detailed information.

- **Proposal Information:** The Initiating PI must enter the Application Information before continuing the pre-application.
- **Proposal Contacts:** The Initiating PI must enter his/her contact information.
- **Partners and Conflicts of Interest (COI):** The Initiating PI must enter the contact information for the collaborating PI(s) in the "Partnering PIs" section. In addition, any other persons who should be excluded from review of the application should be named.
- **Preproposal Narrative:** The Preproposal Narrative has a ***three-page limit*** inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the pre-application. The Preproposal Narrative should address the following:
    - **Research Idea:** State the ideas and reasoning on which proposed research is based and how the application addresses one of the focus areas of melanoma and other skin cancers as related to deployments of service members to areas of high exposure. Show how the perspective of each team member contributes to the development of the idea.
    - **Research Aims:** Concisely state the project's objective and specific aim. ***Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.***
    - **Collaboration:** Describe how the project depends on the unique skills of each partner. Provide the time commitment for each partner as well. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information.
    - **Translational:** Describe the reciprocal transfer of ideas between basic and clinical science in developing, implementing, and moving the proposed research into clinical applications in melanoma or other skin cancers.
    - **Impact:** Briefly state how the proposed research will have an impact on accelerating the movement of a promising, ***military relevant*** idea in melanoma or other skin cancers into clinical applications. ***Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6.***

- **Innovation:** Describe how the research represents more than an incremental advance on published data.

- **Pre-Application Supporting Documentation:**
  - **References Cited:** List up to five relevant references.
  - **Biographical Sketches:** Include biographical sketches for all partners and other key collaborators.

Pre-Application Screening

Pre-applications will be screened by the PRCRP Integration Panel, composed of scientists, clinicians, and consumer advocates. The pre-application screening criteria are as follows:

- **Research Idea:** How the application addresses the intent of the award and the Focus Area(s).
- **Collaboration:** How the partners' backgrounds and expertise are appropriate to accomplish the proposed research that could not be accomplished by either a single investigator or through separate efforts. Appropriateness of the proposed disciplines and the levels of effort.
- **Translational:** How the project will translate promising, well-founded research findings into clinical applications in melanoma and other skin cancers.
- **Impact**: What impact these studies will have on the concepts or methods that drive the field for ***militarily relevant*** studies.
- **Innovation**: How the proposed research represents more than an incremental advance on published data.

B. Step 2 - Application Components and Submission

Principal Investigators will receive notification of invitation to submit an application for the Collaborative Translational Science Award. Application submissions will not be accepted unless the PI has been invited. Do not submit an application unless the Initiating and Partnering PIs receive a letter of invitation. If invited to submit an application, the Partnering PIs will be contacted via email by the CDMRP eReceipt system and provided the information necessary to begin application submission through Grants.gov. Please note that the Partnering PIs must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov). No paper copies will be accepted.

Each application submission must include the completed Grants.gov application package of forms and attachments identified in www.grants.gov for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title, research objectives, or focus area(s).

The CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs. The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting their application to Grants.gov, each Partnering PI must associate him- or herself with the Initiating PI's application by accepting the link sent by the CDMRP eReceipt system. ***Each PI also must submit an identical copy of a jointly created Statement of Work (SOW).***

Failure by the Initiating PI or any Partnering PI to submit his or her required application components will result in administrative rejection of all applications associated with the proposed research project.

APPLICATION SUBMISSION COMPONENTS FOR THE INITIATING PI

1. **SF-424 (R&R) Application for Federal Assistance Form**
2. **Attachments Form**
    - **Attachment 1: Project Narrative (10-page limit).** The Project Narrative is the main body of the application and should demonstrate that a translational research collaboration either exists or will be developed to address one of the Focus Areas in melanoma and other skin cancers as related to deployments of service members to areas of high exposure.

      Describe the proposed research project in detail using the outline below. ***The presentation of preliminary data is not required.*** However, PIs must demonstrate logical reasoning and sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive.

        - **Background:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations. Describe previous experience most pertinent to this application.
        - **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
        - **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that the DOD award would fund.
        - **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, 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. ***Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical***

Trial, refer to the Application Instructions and General Information, Appendix 6.

- **Collaboration:** Describe how the project depends on the unique skills of each partner. Provide the time commitment for each partner as well. Describe how the proposed collaboration involves a substantial contribution by each partner and the reciprocal flow of ideas and information. Demonstrate how the translational collaboration will maximize the use of existing resources and minimize unnecessary duplication. Describe the communication plan and provide evidence of institutional support for resolving potential intellectual and material property issues, and removing institutional barriers to achieving high levels of cooperation.

- **Attachment 2: Supporting Documentation**
  - References Cited
  - Acronyms & Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publication URLs and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support
  - Letters of Collaboration (if applicable)
- **Attachment 3: Technical Abstract**
- **Attachment 4: Public Abstract**
- **Attachment 5: Statement of Work (SOW, three-page limit)**
- **Attachment 6: Detailed Budget and Justification**
- **Attachment 7: Impact Statement (one-page limit)**

  Explain how the proposed research will have an impact on one or more of the requested Focus Areas in the field of melanoma or other skin cancers as related to deployments of service members to areas of high exposure.
- **Attachment 8: Innovation Statement (one-page limit)**

  Summarize how the proposed research is innovative. Investigating the next logical step or an incremental advancement on published data is not considered innovative.
- **Attachment 9: Translatability Statement**

  Describe the translational research that will be performed through this award, and articulate why it could not be achieved through separate efforts. State explicitly how the proposed research will translate promising, well-founded research findings into clinical applications in melanoma or other skin cancers as related to deployments of service members to areas of high exposure.
- **Attachment 10: Military Relevance Statement (one-page limit)**

Demonstrate how the proposed study is responsive to the health care needs of the Armed Forces and their family members. 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). Describe how the study design will replicate field conditions, if appropriate. Explain how the proposed research study is aligned with the military research gap(s) appropriate for the topic area.

- **Attachment 11: Approval for Access to Military Populations (if applicable; one-page limit)**

  A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving: active duty military, military families, or veterans; military-controlled study materials; databases; and/or restricted facilities (e.g., biological or chemical containment facilities). ***Correlative clinical research studies <u>are allowed</u> under this mechanism. Clinical Trials are <u>not permitted</u> under this mechanism. For the definition of a Clinical Trial, refer to the Application Instructions and General Information, Appendix 6. The Approval for Access to Military Populations letter of support will not be forwarded for peer or programmatic review and will be used for administrative purposes only.***

- **Attachment 12: Federal Agency Financial Plan (if applicable): No page limit, named "FedFin.pdf"**

  Proposals from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

  (1) The Recipient can show that such funds will not originate from the USAMRMC award, or

  (2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or

  (3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

  Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility after the normal expiration of the Appropriation from which the

award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

- **Attachments 13-15: Subaward Detailed Budget and Justification (if applicable)**

3. **Research & Related Senior/Key Person Profile (Expanded Form)**
   - PI Biographical Sketch (four-page limit)
   - PI Current/Pending Support
   - Key Personnel Biographical Sketches (four-page limit each)
     - All Partnering PIs must submit
   - Key Personnel Current/Pending Support
4. **Research & Related Project/Performance Site Location(s) Form**

APPLICATION COMPONENTS FOR THE PARTNERING PI(S)

The Partnering PI(s) must follow the link in the email from CDMRP eReceipt and complete the registration process prior to the application submission deadline in order to associate their grant application package with that of the Initiating PI.

The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his/her Grants.gov application package using only his/her unique log number. Each PI must also submit an identical copy of a joint Statement of Work (SOW).

The application submission process for the Partnering PI(s) uses an abbreviated application package of forms and attachments from Grants.gov.

The Partnering PI(s) package includes:

1. **SF-424 (R&R) Application for Federal Assistance Form**
2. **Attachments Form**
   - **Attachment 5: Statement of Work (SOW):** The Initiating and Partnering PI(s) must create a joint SOW.

- **Attachment 6: Detailed Budget and Justification**
- **Attachment 12: Federal Financial Plan (if applicable). No page limit, named "FedFin.pdf."** Proposals from Federal agencies must provide a plan delineating how all funds will be obligated by September 30, 2010, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

  (1) The Recipient can show that such funds will not originate from the USAMRMC award, or

  (2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or

  (3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

  Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment (MTF) facility after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

  Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

- **Attachments 13-15: Subaward Detailed Budget and Justification (if applicable)**

3. Research & Related Project/Performance Site Location(s) Form

IV. INFORMATION FOR APPLICATION REVIEW

A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at http://cdmrp.army.mil/fundingprocess.htm.

The peer review and program review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions 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).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

B. Review Criteria

1. Peer Review: All applications will be evaluated according to the following criteria, which are listed in order of decreasing importance:

- **Impact**
  - If successful, how the collaboration and the aims of the study project will eventually move from a clinical observation, a laboratory discovery, or population-based study into clinical applications.
  - How the proposed research will have an impact on the concepts or methods that drive the field of melanoma or other skin cancer research as related to deployments of service members to areas of high exposure.
  - How the proposed research will make original and important contributions towards the goal of advancing melanoma or other skin cancer research or patient care for those service members deployed to areas of high exposure.

- **Innovation**
  - How the project proposes new paradigms or challenges existing paradigms.
  - 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).
  - How the proposed research represents more than an incremental advance to published data.
- **Research Strategy and Feasibility (no preliminary data required)**
  - How the scientific rationale supports the research project and its feasibility, as demonstrated by a critical review and analysis of the literature.
  - How well the hypotheses or objectives, experimental design, methods, and analyses are developed, and how well these support completion of the aims.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
- **Collaboration**
  - How the proposal addresses the Focus Areas in a way that could not be accomplished by a single investigator.
  - Evidence that all partners contribute substantially to the development and implementation of the research plan, and to the reciprocal flow of ideas.
  - How the multiple disciplines within the collaboration support the proposed project.
  - How the partners' background, expertise, and levels of effort support the proposed project.
- **Translational Potential**
  - How the project will translate promising, well-founded laboratory or clinical research findings into clinical applications for ***military populations*** at risk for or patients with melanoma or other skin cancers.
- **Personnel**
  - The degree to which each PI possesses the research experience to function as a PI in a synergistic project.
  - How the research team's background and skin cancer-related expertise are appropriate with respect to its ability to perform the proposed work.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

- **Environment**
  - How the scientific environment is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
  - How the quality and extent of institutional support are appropriate.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of the award mechanism.
- **Application Presentation**
  - How the writing and components of the application influenced the review.

2. Programmatic Review: The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

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

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding.

V. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from 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.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

The following will result in administrative rejection of all applications associated with the proposed research project:

- Initiating or Partnering PI(s) application is missing.
- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Initiating or Partnering PI(s) budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

B. Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- ***NEW for FY09:*** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section 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 peer reviewed without the missing documents.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) 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 FY09 IP members may be found at http://cdmrp.army.mil/09prcrppanel.htm.
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to

provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

VI. CONTACT INFORMATION

A. Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079
Fax: 301-619-7792
Email: cdmrp.pa@amedd.army.mil

B. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET.

Phone: 301-682-5507
Website: https://cdmrp.org
Email: help@cdmrp.org

C. Grants.gov contacts: Questions related to application submission through the Grants.gov (http://www.grants.gov/) portal should be directed to the Grants.gov help desk, which is available Monday through Friday from 7:00 a.m. to 9:00 p.m. ET. Deadlines for application submission are 11:59 p.m. ET on the deadline date. Please note the CDMRP help desk is unable to answer questions regarding Grants.gov submissions.

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