

Program Announcement

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

Synergistic Idea Development Award

Funding Opportunity Number: W81XWH-08-PCRP-SIDA

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I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (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

2. 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. Eastern time.

Phone: 301-682-5507

Website: <https://cdmrp.org>

Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to submitting applications through the [Grants.gov](http://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the “send me change notification emails” link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication

of scientific and engineering effort and the expenditure thereby represented. All other sources should also be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (i.e., pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History and Objectives

The PCRCP was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRCP from FY97 through FY07 totaled \$810 million (M). The FY08 appropriation is \$80M.

The overall goal of the FY08 PCRCP is to find and fund innovative, high-impact research relevant to the prevention, detection, diagnosis, and/or treatment of human prostate cancer. Specifically, the PCRCP seeks to:

- Support innovative research by individual investigators in multiple disciplines;
- Sponsor multidisciplinary team science to bring together diverse expertise and approaches that will accelerate the conquest of prostate cancer;

- Fund translational research to promote the bench-to-bedside-to-bench transition between basic and clinical science;
- Foster the next generation of prostate cancer investigators through mentored research and training; and
- Promote research into prostate cancer health disparities, including, but not limited to, race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs.

B. Award Description

The PCRP Synergistic Idea Development Award mechanism was introduced in FY07. Since then, a total of 73 proposals have been received and 8 (representing 18 individual awards) have been recommended for funding.

The Synergistic Idea Development Award supports innovative, high-risk/high-gain approaches to prostate cancer research involving two or three independent, faculty-level (or equivalent) PIs. These investigators should use synergistic and complementary perspectives to address a central problem or question in prostate cancer research. This award is designed to encourage and support both new and pre-existing partnerships. The overall goal of this award is to accelerate advances in prostate cancer research to support the PCRP vision of conquering prostate cancer.

The Synergistic Idea Development Award requires that investigators jointly design a single project. However, each partner will be recognized as a PI, submit a separate proposal, and receive an individual award. The proposal must be supported by the unique expertise of each PI, and must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts. Multidisciplinary projects are encouraged, and multi-institutional projects are allowed. Each proposed study must include clearly stated plans for interactions among all PIs and institutions involved. The plans must include ongoing communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional proposals must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

The PCRP seeks proposals from all areas of basic, preclinical, behavioral, and epidemiological research. ***NEW FOR FY08: Clinical trials are not acceptable under this mechanism. PIs wishing to apply for funding for a clinical trial should utilize the Clinical Trial Award mechanism.***

Important aspects of the Synergistic Idea Development Award are as follows:

1. Synergy: Synergy is a significant feature of this mechanism. These awards should accelerate research progress through ongoing communication and problem solving that approach the research problem from a variety of perspectives. The combined efforts of the PIs should result in a level of productivity that is greater than that achievable by each PI working independently. It should be clear that all PIs have an equal level of intellectual input into the proposed project. Contributions to the project are expected to be balanced between all PIs unless otherwise justified. The PIs' past history of collaborative study with each other or with other investigators will also be evaluated.

2. Innovation: Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. It is the responsibility of each PI to clearly and explicitly articulate how the proposed research is innovative. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this mechanism.

3. Impact: Research that has high impact will, if successful, significantly advance current methods and concepts for the prevention, detection, diagnosis, or treatment of human prostate cancer. It is the responsibility of the PI to clearly and explicitly articulate the potential impact the proposed research will have on human prostate cancer.

4. Preliminary Data: *NEW FOR FY08: Inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required.* Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, these proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

5. PI Experience: This award mechanism is designed to accommodate multiple PIs. Therefore, each PI must demonstrate that he or she possesses the research experience and resources to function as a PI in a synergistic project among equals, as well as an appropriate level of authority and responsibility to direct the project supported by the grant.

C. Eligibility

The Synergistic Idea Development Award requires the input of two or three independent investigators at or above the level of an Assistant Professor (or equivalent).

Refer to the Application Instructions, Appendix 1, for general eligibility information.

D. Funding

Funding for a Synergistic Idea Development Award can be requested for up to \$750,000 for direct costs for up to a 3-year performance period plus indirect costs as appropriate. The PIs are expected to be equal partners in the research, so direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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

- Salary
- Research supplies
- Equipment
- Clinical costs
- Travel to scientific/technical meetings
- Travel between collaborating institutions

In addition, funding must be requested for each PI to travel to the next PCRIP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting (tentatively scheduled for 2010).

The CDMRP expects to allot \$5.6M of the \$80M FY08 PCRIP appropriation to fund approximately five Synergistic Idea Development Award proposals (representing 10-15 individual awards), depending on the quality and number of proposals 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

Changes in Initiating or Partnering PIs will not be allowed for the Synergistic Idea Development Award except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

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

III. TIMELINE FOR SUBMISSION AND REVIEW

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

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time, May 22, 2008
- **Proposal Submission Deadline:** 11:59 p.m. Eastern time, June 12, 2008
- **Peer Review:** September 2008
- **Programmatic Review:** November 2008

Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009.

IV. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/) and (2) a proposal submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

The Synergistic Idea Development Award mechanism is structured to accommodate two or three PIs. Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute equally to the preparation of the proposal. The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI(s). After the Initiating PI finalizes the pre-application, the Partnering PI(s) will then be contacted via email by the CDMRP eReceipt system and provided the information necessary to begin proposal submission through Grants.gov. Please note that the Partnering PI(s) must follow the link in this email and register with CDMRP eReceipt in order to associate his or her grant application package with that of the Initiating PI.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

A. Step 1 – Pre-Application Components and Submission

The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by **5:00 p.m. Eastern time on the pre-application deadline**.

The PIs and Organizations identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. The Initiating and Partnering PIs will each be assigned unique and separate log numbers by the CDMRP eReceipt system. Each PI must submit his or her Grants.gov application package using only his or her unique log number. If there is a change in PI or Organization after the submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507. In addition to the specific instructions below, refer to the Application Instructions for detailed information. ***The Initiating PI is responsible for submission of all pre-application components.***

1. Proposal Information

- The Initiating PI must enter the Proposal Information before continuing the pre-application.

2. Proposal Contacts

- The Initiating PI must enter his or her contact information.

3. Collaborators and Conflicts of Interest

- The Initiating PI must enter the contact information for the Partnering PI(s) in the Partnering PI(s) section to indicate his or her role in the project.

4. Letter of Intent Narrative

B. Step 2 – Proposal Components and Submission

Proposal submission will not be accepted unless the pre-application process is completed by the pre-application deadline. Proposals must be submitted electronically by the Authorized Organizational Representative through Grants.gov (www.grants.gov). No paper copies will be accepted. The PIs and Organizations identified in the proposal 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 the submission of the pre-application, the PI must contact the eReceipt help desk at help@cdmrp.org or 301-682-5507. In addition to the specific instructions below, refer to the Application Instructions for detailed information.

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

1. Proposal Components and Submission for the Initiating PI

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in [http://www.grants.gov/](http://www.grants.gov) for the US Army Medical Research Acquisition Activity (USAMRAA) program announcement. In addition to the specific instructions below, please refer to the Application Instructions for detailed requirements of each component.

The Initiating PI package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 1: Project Narrative (15-page limit)

Describe the proposed research in detail using the following outline. ***The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required.***

Background: Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this proposal. Describe each PI's history of synergistic and collaborative study with one another or with other investigators.

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 proposal 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. Include specific examples of synergistic elements incorporated into the research design. 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.*

Project Coordination and Communication: Describe plans for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and institutions participating in the project.

- Attachment 2: Supporting Documentation
 - References Cited
 - Acronyms and Symbol Definitions
 - Facilities & Other Resources
 - Description of Existing Equipment
 - Publications and/or Patent Abstracts (five-document limit)
 - Letters of Institutional Support
 - Letters of Collaboration (if applicable)
 - Intellectual and Material Property Plan (if applicable)

- Attachment 3: Technical and Public Abstracts

- Attachment 4: SOW

- Attachment 5: Impact Statement

State explicitly how the proposed work will, if successful, have an impact on human prostate cancer and how the expected results of the proposal will contribute to the goals of conquering prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.

- Attachment 6: Innovation Statement

Summarize how the proposal is innovative. The following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- Study concept – Investigation of a novel idea and/or research question.

- Research method or technology – Use of novel research methods or new technologies, including technology development, to address a research question.
- Existing methods or technologies – Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.

Investigating the next logical step as an incremental advancement on published data is not considered innovative.

- Attachment 7: Synergy Statement

Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the proposal. Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.

- Attachment 8: Federal Agency Financial Plan (if applicable)

3. Research & Related Senior/Key Person Profile (Expanded)

- PI Biographical Sketch
- PI Current/Pending Support
- Key Personnel Biographical Sketches
- Key Personnel Current/Pending Support

4. Research & Related Budget Form

- Budget Justification

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

6. R&R Subaward Budget Attachment(s) Form (if applicable)

2. Proposal Components and Submission 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 proposal submission deadline in order to associate their grant application package with that of the Initiating PI.

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

The Partnering PI package includes:

1. SF-424 (R&R) Application for Federal Assistance Form

2. Attachments Form

- Attachment 4: SOW
- Attachment 8: Federal Agency Financial Plan (if applicable)

3. Research & Related Budget Form

- Budget Justification

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

5. R&R Subaward Budget Attachment(s) Form (if applicable)

V. INFORMATION FOR PROPOSAL REVIEW

A. Proposal Review and Selection Overview

All proposals are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of proposals 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 and overall goals of the program. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and program review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that proposal 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 correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal 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 proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the peer review and

program review processes may also result in suspension or debarment of their employing institutions from Federal awards.

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

B. Review Criteria

1. Peer Review: All proposals will be evaluated according to the following criteria. Of these, Synergy, Innovation, and Impact are equally the most important, with the remaining criteria listed in decreasing order of importance.

- **Synergy**
 - How the proposed partnership between independent PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
 - How well the proposal outlines the balanced contributions of each PI to the overall synergy of the project.
 - How the proposed project is centered on a unified theme that addresses a single research question rather than an additive set of unrelated subprojects.
 - How well the proposal addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and institutions.
- **Innovation**
 - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
 - How the proposed research represents more than an incremental advance upon published data.
- **Impact**
 - How the project, if successful, will make an original and significant contribution to the goals of conquering human prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.
 - How the potential gain justifies the perceived risk.
- **Research Strategy and Feasibility**
 - How the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.

- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed.
- How well the PIs acknowledge potential problems and address alternative approaches.
- **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 prostate 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.
- **Environment**
 - How the scientific environment is appropriate for the proposed research.
 - How 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**
 - How the budgets are appropriate for the proposed research.
 - Whether the resources are divided appropriately among all PIs.

2. Programmatic Review: Criteria used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio include:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative synergy, innovation, and impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

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, USAMRMC.

VI. COMPLIANCE GUIDELINES

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in preapplication or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

The following will result in administrative rejection of the entire proposal:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Any budget and/or budget justification is missing.
- FY08 IP members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at <http://cdmrp.army.mil/research>

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to include plagiarized information will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.