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FOREWORD

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed by the Secretary of the Army to continue the Department of Defense (DOD) Prostate Cancer Research Program (PCRP). The deadlines, format, and other criteria specified for proposals in this PCRP Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC website (<http://mrmc-www.army.mil>). Specific information on the DOD PCRP can be obtained from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). A copy of this Announcement and associated forms (except for the Proposal Cover Booklet) can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>).

Questions concerning the preparation of proposals, formats, or required documentation can be addressed to the USAMRMC at:

Fax: (301) 619-7792
Phone: (301) 619-7079
E-mail: cdmrp_pa@ftdetrick-ccmail.army.mil
Mail: U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

Every effort will be made to answer questions within 10 working days of receipt. Inquiries should be restricted to format issues only; no questions relating to technical proposal content or reasonableness/allowability of costs will be answered. Applicants should submit any written questions regarding this program as early as possible.

Proposal Submission

To be considered for award, submit the following documentation to the address listed on the next page:

Proposal: 1 original (binder-clipped) and 30-collated photocopies (stapled or binder-clipped); please do not use rubber bands, or spiral or three-ring binders

Proposal Cover Booklet: 1 original and 3 photocopies

Abstract Pages: An additional 5 copies of both the technical and the public (non-technical) abstracts in a manila envelope along with a 3 ½” computer disk containing the abstract pages and clearly labeled with the name of the Principal Investigator (PI), institution, and word processing program. It is recommended that abstracts are formatted in WordPerfect, Word, or ASCII format. (Note: The abstracts are vital to the review of the proposal. Abstracts of all funded proposals will be reproduced in a PCRCP abstract book and posted on the USAMRMC website (<http://cdmrp.army.mil>.)

Send the proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRCP99-Announcement)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702

Please package only **ONE** complete proposal submission per box. If an acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with the submission. This postcard should state the proposal title and PI’s name.

Deadline

The submission deadline for individual award categories is provided below:

Post-doctoral Traineeships	February 3, 1999 at 4:00 p.m. Eastern Time
New Investigator Awards	March 10, 1999 at 4:00 p.m. Eastern Time
Idea Development Awards	March 10, 1999 at 4:00 p.m. Eastern Time
Minority Population Focused Collaborative Training Awards	March 10, 1999 at 4:00 p.m. Eastern Time
Prostate Cancer Center Initiation Awards	
Pre-proposal	March 10, 1999 at 4:00 p.m. Eastern Time
Full proposal	July 7, 1999 at 4:00 p.m. Eastern Time

Any proposal received after the exact time specified for receipt shall not be considered unless it is received before award is made, and it:

1. was sent by mail, and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. was sent by U.S. Postal Service Express Mail Next Day Delivery (Post Office to Addressee: ***Do not use Second Day Delivery***) and postmarked no later than 8:00 p.m. (local time at point of origination) the day before the proposal submission deadline, or

3. was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal submission deadline for delivery by 4:00 p.m. Eastern Time on the due date.

Investigators are advised that documentation of receipt by the delivery agent may be necessary if a problem should occur.

Reference Table of Proposal Categories and Submission Requirements

Proposal Category	Experience of PI	Key Category Elements	Dollars Available for Individual Awards	Proposal Submission Deadline	Instructions for Proposal Preparation
New Investigator	Independent investigators at the level of Assistant Professor or equivalent	<ul style="list-style-type: none"> • Reward innovative ideas and technology • Preliminary data not required 	\$225,000 inclusive of direct costs over a 3-year period of performance	March 10, 1999 4:00 p.m. ET	Section III
Idea Development	Independent investigators at the level of at least Assistant Professor or equivalent or above	<ul style="list-style-type: none"> • Reward innovative ideas and technology • Preliminary data required 	\$375,000 inclusive of direct costs over a 3-year period of performance	March 10, 1999 4:00 p.m. ET	Section IV
Post-doctoral Traineeships	Recent doctoral graduates with 3 years or less of post-doctoral experience	<ul style="list-style-type: none"> • Prepare new scientists for careers in prostate cancer • Preliminary data not required 	\$84,000 inclusive of direct and indirect costs over a 2-year period of performance	February 3, 1999 4:00 p.m. ET	Section V
Minority Population Focused Collaborative Training (MPFCT) Award	Status of at least Assistant Professor or equivalent with minimal or no other support; collaboration with an established investigator is required	<ul style="list-style-type: none"> • Develop a research concept that focuses on the disparity in prostate cancer incidence and mortality among different ethnic groups • Preliminary data not required 	\$75,000 inclusive of direct and indirect costs over a 1-year period of performance	March 10, 1999 4:00 p.m. ET	Section VI
Prostate Cancer Center Initiation Awards	Overall Principal Investigator should be an established investigator with a proven track record of leadership and scientific ability	<ul style="list-style-type: none"> • Engage experts from multiple disciplines to establish regional centers for the study and treatment of prostate cancer • Preliminary data required • Not less than two and no more than three research projects, and one single core 	\$2.5M inclusive of direct and indirect costs over at least a 3-year period of performance	<u>Pre-proposal:</u> March 10, 1999 4:00 p.m. ET <u>Full proposal:</u> July 7, 1999 4:00 p.m. ET	<u>Pre-proposal:</u> Section VII <u>Full proposal:</u> Instructions will be sent to invited investigators approximately April 21, 1999

Driving Directions to Fort Detrick

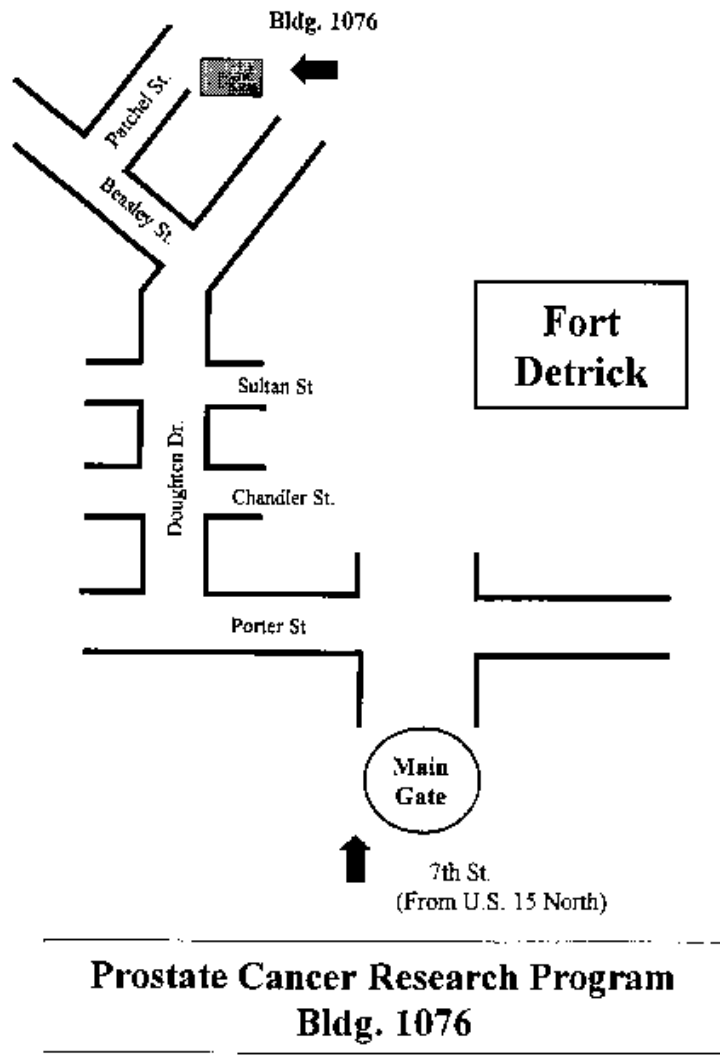
Directions from Washington, DC

Take interstate 495 to Interstate 270 North (exit #38) toward Rockville, Maryland. At Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to 7th Street exit. Turn right on 7th Street and go four blocks to Fort Detrick's Main Gate.

Directions from Baltimore, MD

Take interstate 695 around Baltimore to Interstate 70 West. In Frederick, take exit 53, Route 15 North. Follow 15 North to 7th Street exit. Turn right on 7th Street and go four blocks to Fort Detrick's Main Gate.

Packages to be delivered to the Prostate Cancer Research Program should be taken to building 1076 as shown on the map below:



I. Overview of the Congressionally Directed Medical Research Programs

I-A. History of the Congressionally Directed Medical Research Programs

In the past decade, the work of consumer advocacy organizations has dramatically influenced the way scientific research is funded in this country resulting in Congressional appropriations targeted at research in specific diseases. Beginning in fiscal year 1992 (FY 92), the United States Congress directed the Department of Defense (DOD) to manage various extramural and intramural grant programs directed toward specific research initiatives. The United States Army Medical Research and Materiel Command (USAMRMC) constituted the office of the Congressionally Directed Medical Research Programs (CDMRP) to administer these funds in a responsible way. To date, between FY 92 and FY 98, \$916.6 million (M) has been targeted by Congress for research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense women's health, and osteoporosis. These six programs comprise the CDMRP programs.

For each appropriation, the CDMRP has developed and refined a flexible 6-year execution and management cycle which spans the development of an investment strategy through completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP programs. For each program, an expert Integration Panel of consumer advocates, scientists, and clinicians is convened periodically to deliberate issues and concerns unique to their program and to establish an appropriate investment strategy. Based upon this investment strategy, each program then employs a variety of award mechanisms to address the most urgent needs of a research community.

Overall, the CDMRP exists to support research that will impact upon the health of all Americans. The CDMRP strives to identify gaps in funding and provide award opportunities that will enhance program research objectives without duplicating existing funding opportunities. In meeting their goals, the CDMRP has developed unique mechanisms to facilitate funding of quality research that addresses individual program objectives.

I-B. Proposal Evaluation

The CDMRP uses a two-tiered review system for proposal evaluation, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on the program goals.

I-B.1. Scientific Peer Review

Scientific peer review is conducted by review panels organized by scientific discipline or specialty areas. The primary responsibility of the scientific peer review panel is to provide unbiased, expert advice on the scientific and technical merit of applications, based upon the review criteria developed for each award mechanism.

Each scientific review panel is composed of a chair, approximately 10-20 scientific reviewers, 2 consumer advocates, and a non-voting executive secretary. The chair and scientific reviewers are recognized leaders in their fields and are chosen on the basis of their scientific expertise. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their experience in scientific peer review. Consumer advocate reviewers are individuals who are affected by the disease, have been nominated by an advocacy organization, and have a demonstrated interest in and knowledge of the disease. The consumer advocates augment the scientific merit review by bringing the patient perspective to the assessment of science and to relevance of research.

Panel members rate each proposal based on the specific evaluation criteria developed for each award category. Two types of ratings are used. Each of the evaluation criteria, except for the budget, is rated on a scale of 1 (low merit) to 10 (high merit). The overall proposal is given a global score using a scale of 1 (high merit) to 5 (low merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global score.

A proposal may be disapproved at scientific peer review if it is so seriously flawed as to make its scientific merit review completion impractical, or if gravely hazardous or unethical procedures are involved.

The proposal summary statement is a product of scientific peer review. These statements include an evaluation of the project as assessed by the peer reviewers as they related to evaluation criteria, the investigators' abstract (verbatim), and an overall merit score. Summary statements not only assist investigators in assessing their research projects, but are forwarded to the next stage of the review process, programmatic review.

I-B.2. Programmatic Review

The second tier of the two-tiered review system is a programmatic review of the proposals considered eligible for funding. Programmatic review is accomplished by an integration panel (IP) composed of scientists and consumer advocates. The scientific members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. With their first-hand experience, the consumer advocates enhance the review process by

Overview of the Congressionally Directed Medical Research Programs

focusing attention upon critical patient issues and outcomes. The IP recommends an investment strategy for appropriated funds and conducts programmatic review to obtain a broad portfolio of grants across all disciplines.

Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members use the proposal abstracts, summary statements, and scientific peer review scores when reviewing proposals. The statement of work may also be reviewed. The full proposal is not forwarded for programmatic review.

Programmatic review balances the potential outcomes and risks of scientifically excellent proposals. The IP does not automatically recommend funding for all proposals highly scored by scientific peer review panels, nor does it re-review the scientific and technical merit. The criteria the IP uses to make funding recommendations are:

- ratings and recommendations of the peer review panels;
- programmatic relevance;
- scientific innovation;
- program portfolio balance with respect to research disciplines or specialty areas;
- other equitable factors such as adequate support for young investigators and gender, minority status, and geographic distribution; and
- research targeting special populations.

Scientifically excellent studies that directly address the unique focus and goals of the program are most likely to be recommended to the Commanding General (CG), USAMRMC, for funding.

II. Department of Defense Prostate Cancer Research Program

II-A. History of the Prostate Cancer Research Program

The DOD Prostate Cancer Research Program (PCRP) was established in FY 97 to promote innovative, multi-institutional, multidisciplinary, and regionally focused research directed toward eliminating prostate cancer. Congressional direction for FY 97 specified \$38M for peer-reviewed prostate cancer research. An additional \$38M was appropriated in FY 98 to continue the PCRP. FY 98 funds were combined with the FY 97 appropriation because of the enthusiasm from Congress and the scientific and advocacy communities to rapidly distribute funds to scientists.

The program history for the FY 97/98 PCRP is shown in Table II-1.

Table II-1: PCRP History

	New Investigator	Idea Development	Minority Population Focused Training Awards
Total Investment (\$61.35M), to date*	\$10.5M	\$50M	\$0.85M
Number of Applications Received (623)	162	444	17
Number of Applications Recommended for Funding (185), to date*	43	125	17
Percentage of Applications Recommended for Funding, to date*	26.5%	28.2%	100%

*Award negotiations have not been finalized.

II-B. Overview of the FY 99 PCRP

The USAMRMC, through this Program Announcement, is soliciting applications on prostate cancer research. The overall goal of this funding effort is to promote research directed toward conquering prostate cancer. Within this context, the objectives of the PCRP are to (1) prevent prostate cancer, (2) detect prostate cancer in its earliest stages of development, (3) cure prostate cancer, and (4) improve the quality of life for individuals and their families living with prostate cancer.

The USAMRMC is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the field of prostate cancer research. As in previous years, the central theme of the PCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the CDMRP wishes to encourage risk-taking

research, such projects must, nonetheless, demonstrate solid scientific judgment and rationale.

II-C. FY 99 Program Emphasis Areas

Recent advances in understanding prostate cancer present unique opportunities to benefit significantly from directed research efforts. Complementing current research initiatives by other funding agencies, the FY 99 PCRCP is offering to expand scientific inquiry in three research areas: (1) cancer biology, (2) prevention, and (3) therapy. The research focus for all proposals should address an issue relevant to prostate cancer biology, prevention, and/or therapy.

- ***Cancer Biology***
Cancer biology research seeks to better understand the causes of prostate cancer. The lack of knowledge of the biology of the prostate gland and the process of carcinogenesis is among the greatest barriers to progress in prostate cancer research. Increased research in prostate cancer biology is an essential prerequisite for the development of new treatments and preventive mechanisms of prostate cancer.
- ***Prevention***
Prevention research identifies both risk factors and effective prevention strategies for prostate cancer. Studies to identify which factors contribute to prostate cancer progression as well as studies to identify which interventions can prevent this progression are vital components of winning the war against prostate cancer.
- ***Therapy***
Cancer therapy studies focus on successful treatments of prostate cancer as well as methods of improving patients' quality of life. Although there is an intensive campaign to increase prostate cancer screening efforts, once the disease escapes the prostate gland, there are currently no curative therapies available. Development of new effective therapies is critical to conquering this disease and reducing its impact on the lives of survivors.

Additionally, support for training of prostate cancer researchers, encouragement of established scientists in the field, and attraction of new scientific expertise from other fields are essential in the fight against prostate cancer.

Proposals that address the above research areas are sought across all areas of laboratory, clinical, behavioral, and epidemiological research including all disciplines within the basic, clinical, psychosocial, behavioral, socio-cultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Proposals are encouraged from investigators working at Historically Black Colleges and Universities and Minority Institutions (HBCU/MIs). Additionally, proposals that address the needs of minority,

low-income, rural, and other underrepresented and/or medically underserved populations are encouraged from any eligible institutional source.

For the FY 99 PCRCP, an estimated \$40M will be available to fund peer-reviewed research. The programmatic strategy for FY 99 is to fund proposals in three categories: (1) Research Awards, (2) Training/Recruitment Awards, and (3) Prostate Cancer Center Initiation Awards.

Prospective responders familiar with USAMRMC programs from previous years are urged to review this Program Announcement carefully, as revisions to award category definitions have been made.

II-C.1. Research Awards

Approximately \$18M will be allocated for Research Awards, which consist of New Investigator Awards (Section III) and Idea Development Awards (Section IV). The intent of both New Investigator and Idea Development Awards is to stimulate and reward creative research ideas that may be viewed as speculative but have the potential for high payoff. The CDMRP is particularly interested in preparing new scientists for careers in prostate cancer research and presenting an opportunity to move established investigators into the prostate cancer field. While New Investigator Awards are targeted to investigators in the early phases of their careers, Idea Development Awards are aimed at giving established prostate cancer investigators and those investigators who want to move into prostate cancer research the necessary support and time to undertake underinvestigated areas of research.

II-C.2. Training/Recruitment Awards

Approximately \$4M will be allocated for Training/Recruitment Awards, which consist of Post-doctoral Traineeship Awards (Section V) and Minority Population Focused Collaborative Training (MPFCT) Awards (Section VI). The intent of Post-doctoral Traineeship Awards is to prepare new scientists for careers in prostate cancer research. The goal of the MPFCT Awards is to increase research efforts focused on the disparity in prostate cancer incidence and mortality among different ethnic groups by fostering collaborative research and training in this area.

II-C.3. Prostate Cancer Center Initiation Awards

Approximately \$18M will be allocated for Prostate Cancer Center Initiation Awards. The intent of these awards is to invigorate the research community, bring new investigators into the field of prostate cancer, and make great strides toward eradicating prostate cancer by engaging experts from multiple disciplines to establish regional centers for the study and treatment of prostate cancer. A proven track record of scientific research, strong leadership in the field of prostate cancer, and an institutional commitment of resources and space are required for successful competition in this category.

III. New Investigator Awards

III-A. New Investigator Awards

The intent of New Investigator Awards is to promote and reward innovative ideas and technology to conquer prostate cancer from investigators in the early phases of their careers. The research focus of New Investigator proposals should address an issue relevant to prostate cancer biology, prevention, and/or therapy. A New Investigator is defined as an independent investigator (**Assistant Professor or equivalent**) in the early phase of his/her career. In accordance with the challenge to be innovative, **proposals lacking pilot data will be accepted if they demonstrate solid scientific judgment**. New Investigator proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative. The proposed studies may be untested, but with a high probability of revealing new avenues of investigation. Although this research is inherently risky in nature and does not require preliminary or pilot data, these proposals nonetheless should be based on a sound scientific rationale that is established through a critical review and analysis of the literature and/or logical reasoning. Table III-1 delineates the differences between traditional research and New Investigator proposals.

Table III-1: Differences between Traditional Research Proposals and New Investigator Research Proposals

Type of Proposal	Preliminary or Pilot Data	Research Approach
Traditional Research Proposal	Required	Expansion of well-established avenues of research
New Investigator Proposal	Not required (can be included if available)	Novel, challenging existing paradigms, high risk

Funding for New Investigator Awards can be requested for up to \$225,000 for direct costs over a 3-year period of performance plus indirect costs as appropriate. Funds can be requested for salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. A level of institutional support and commitment should be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. No more than one trip to a scientific meeting per award per year is funded. Please provide complete justification for expenses in any category.

Applicants may submit only one individual proposal in only one of the following categories: the New Investigator (Section III), Idea Development (Section IV), Post-doctoral Traineeship (Section V), or Minority Population Focused Collaborative Training Awards (Section VI). However, a similar or identical proposal may be incorporated into a Prostate Cancer Center Initiation submission (Section VII). Investigators should be cautioned that if both projects are recommended for funding, the individual proposal will not be funded but will be negotiated as part of the Prostate Cancer Center Initiation Award. Additionally, investigators submitting a Research Award proposal as part of a Prostate Cancer Center Initiation submission should understand that the intents of these two awards are different and will be evaluated by separate evaluation criteria.

III-B. Scientific Peer Review Evaluation Criteria for New Investigator Awards

New Investigator proposals will be evaluated according to the following criteria:

- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms; develop new methodologies or technologies; or address underexplored or unexplored areas?
- **Scientific Relevance and Impact:** What will be the effect of these studies on the concepts or methods that drive this field? To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does this study address a critical problem in prostate cancer research? Does the proposal make a convincing case for the relevance of the research to prostate cancer?
- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? (Preliminary data are not required but may be included.)
- **Principal Investigator:** Is the PI functioning at the Assistant Professor or equivalent level and appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the prostate cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?

New Investigator Awards

- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

III-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). Please fax, e-mail, or mail the “Letter of Intent” form to:

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrick-ccmail.army.mil
Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

III-D. Proposal Preparation

The following proposal preparation information is specific for the New Investigator Award category. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 7 pages and that the deadline for submission is March 10, 1999 at 4:00 p.m. Eastern Time.

1. Who May Apply – See Appendix B, part 1
2. Proposal Acceptance Criteria – See Appendix B, part 2
3. Proposal Cover Booklet – See Appendix B, part 3
4. Peer Review Referral Page – See Appendix B, part 4
5. Proposal Title Page – See Appendix B, part 5
6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.

(New Investigator Award)

Table of Contents

	Page Number
Proposal Cover Booklet (12 pages)	
Peer Review Referral Page (no page limit).....	i
Proposal Title Page (1 page limit).....	1
Table of Contents (1 page limit)	2
Technical Abstract (1 page limit)	3
Public Abstract (1 page limit)	4
Statement of Work (2 page limit)	5
Proposal Relevance and Impact Statement (1 page limit)	7
Proposal Body (7 page limit)	___
References (no page limit)	___
Biographical Sketches (3 page limit per PI and participating investigators)	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit)	___
Support Documentation (no page limit)	___
Detailed Cost Estimate (no page limit).....	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (2 document limit).....	___

New Investigator Awards

7. Proposal Abstracts – See Appendix B, part 7

8. Statement of Work – See Appendix B, part 8

9. Proposal Relevance and Impact Statement – See Appendix B, part 9

In addition to the instructions found in Appendix B, part 9, New Investigator applicants should state explicitly how the proposed work is innovative and relevant to prostate cancer research. Articulate how the combination of innovation and relevance in the proposal will impact and further the programmatic goals. Describe how the project will make a contribution to the goal of conquering prostate cancer and/or advancing research in the field.

10. Proposal Body – See Appendix B, part 10

The body of New Investigator proposals is limited to 7 pages. Figures, tables, and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2). Presentation of preliminary or pilot data is not required for New Investigators but can be included if available.

For New Investigator Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Describe the proposed project using the **general** outline provided below:

- a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- b. **Hypothesis/Purpose:** State the hypothesis to be tested and the expected results.
- c. **Objectives:** State concisely the specific aims of the study.
- d. **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the synthesis. All figures, tables, and diagrams must be included within the proposal body.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

New Investigator Awards

13. Existing/Pending Support – See Appendix B, part 13
14. Facilities/Equipment Description – See Appendix B, part 14
15. Support Documentation – See Appendix B, part 15
In addition to the instructions found in Appendix B, part 15, New Investigator Awards require a form signed by the Department Chair, Program Director, or Dean indicating that the PI is an Assistant Professor or equivalent and, therefore, an eligible applicant for this award type. The form on the following page should be used.
16. Detailed Cost Estimate – See Appendix B, part 16
17. Instruments – See Appendix B, part 17
18. Publications and Patent Abstracts – See Appendix B, part 18
19. Proposal Submission Address – See Appendix B, part 19
20. Proposal Submission Deadlines – See Appendix B, part 20
Please note that the deadline for submission for New Investigator awards is March 10, 1999 at 4:00 p.m. Eastern Time.
21. Notification – See Appendix B, part 21
22. Set-Aside for Historically Black Colleges and Universities and Minority Institutions – See Appendix B, part 1.

STATEMENT OF ELIGIBILITY

Applicant's Name _____

Title of Proposal _____

Applicant's Organization Name: _____

Applicant's Organization Location: _____

Signature of Applicant: _____

STATEMENT OF ELIGIBILITY

For the purposes of the Department of Defense Congressionally Directed Medical Research Program's Prostate Cancer Research Program New Investigator Award category as outlined in the Announcement, the applicant fulfills all of the following criteria:

- Holds a position of Assistant Professor or equivalent;
AND
- Has access to appropriate research facilities;

I, _____ of _____
(printed name of Department Chair, Dean or equivalent official) (printed name of institution)

attest that the above-named investigator fulfills the requirements for a New Investigator Award.

Signature of Official _____ Date: _____

III-E. Reports

The award will require the timely delivery of several reports during the research effort. The recipient organization and the PI should realize that reports are necessary for the USAMRMC to monitor progress; however, a particular research project may require some variation.

The PIs of New Investigator Awards should plan on a requirement that consists of:

- an **ANNUAL** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and
- a **FINAL** report (submitted in the last year of the grant period) that details the findings and issues for the entire project.

The USAMRMC will notify PIs when these reports are due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by DOD must contact their contracting specialist and must follow the instructions concerning such activity in their contract.

IV. Idea Development Awards

IV-A. Idea Development Awards

The intent of Idea Development Awards is to encourage innovative approaches to prostate cancer research from established prostate cancer investigators and those investigators who want to move into the prostate cancer field. The research focus of Idea Development proposals should address an issue relevant to prostate cancer biology, prevention, and/or therapy. An Idea Development Investigator is defined as an independent investigator at the level of **Assistant Professor or above**. Idea Development proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative. All Idea Development proposals **must include preliminary data in prostate cancer research that are relevant to the proposed project** as well as a summary of the PI's research and professional experience in prostate cancer and/or their potential for contribution to the field of prostate cancer.

Funding for Idea Development Awards can be requested for up to \$375,000 for direct costs over a 3-year period of performance, plus indirect costs as appropriate. Funds can be requested for salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. A level of institutional support and commitment should be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. No more than one trip to a scientific meeting per award per year is funded. Please provide complete justification for expenses in any category.

Applicants may submit only one individual proposal in only one of the following categories: the New Investigator (Section III), Idea Development (Section IV), Post-doctoral Traineeship (Section V), or Minority Population Focused Collaborative Training Awards (Section VI). However, a similar or identical proposal may be incorporated into a Prostate Cancer Center Initiation submission (Section VII). Investigators should be cautioned that if both projects are recommended for funding, the individual proposal will not be funded but will be negotiated as part of the Prostate Cancer Center Initiation Award. Additionally, investigators submitting a Research Award proposal as part of a Prostate Cancer Center Initiation submission should understand that the intents of these two awards are different and will be evaluated by separate evaluation criteria.

IV-B. Scientific Peer Review Evaluation Criteria for Idea Development Awards

Idea Development proposals will be evaluated according to the following criteria:

- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms; develop new methodologies or technologies; or address underexplored or unexplored areas?
- **Scientific Relevance and Impact:** What will be the effect of these studies on the concepts or methods that drive this field? To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does this study address a critical problem in prostate cancer research? Does the proposal make a convincing case for the relevance of the research to prostate cancer?
- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Do the required preliminary data in prostate cancer research support the proposed project?
- **Principal Investigator:** Is the PI appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the prostate cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?
- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

IV-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a “Letter of Intent” form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). Please fax, e-mail, or mail the “Letter of Intent” form to:

Idea Development Awards

Fax: (301) 682-5521
E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil
Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

IV-D. Proposal Preparation

The following proposal preparation information is specific for the Idea Development Award category. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 7 pages and that the deadline for submission is March 10, 1999 at 4:00 p.m. Eastern Time.

1. Who May Apply – See Appendix B, part 1
2. Proposal Acceptance Criteria – See Appendix B, part 2
3. Proposal Cover Booklet – See Appendix B, part 3
4. Peer Review Referral Page – See Appendix B, part 4
5. Proposal Title Page – See Appendix B, part 5
6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
7. Proposal Abstracts – See Appendix B, part 7
8. Statement of Work – See Appendix B, part 8
9. Proposal Relevance and Impact Statement – See Appendix B, part 9
In addition to the instructions found in Appendix B, part 9, Idea Development applicants should state explicitly how the proposed work is innovative and relevant to prostate cancer research. Articulate how the combination of innovation and relevance in the proposal will have an impact upon and further the programmatic goals. Describe how the project will make a contribution to the goal of conquering prostate cancer and/or advancing research in the field.

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Proposal Body (7 page limit).....	___
References (no page limit).....	___
Biographical Sketches (3 page limit per PI and participating investigators)	___
Existing/Pending Support (no page limit).....	___
Facilities/Equipment Description (no page limit).....	___
Support Documentation (no page limit)	___
Detailed Cost Estimate (no page limit).....	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (2 document limit).....	___

Idea Development Awards

10. Proposal Body – See Appendix B, part 10

The body of Idea Development proposals is limited to 7 pages. Figures, tables, and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2). The inclusion of preliminary data is required for Idea Development proposals; investigators must submit promising and well-founded preliminary data in prostate cancer research that are relevant to the proposed project.

For Idea Development Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Describe the proposed project using the **general** outline provided below:

1. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
2. Hypothesis/Purpose: State the hypothesis to be tested and the expected results.
3. Objectives: State concisely the specific aims of the study.
4. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the synthesis. All figures, table, and diagrams must be included within the proposal body.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

Investigators must include a description of their experience in prostate cancer research as part of the Biographical Sketch.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15

16. Detailed Cost Estimate – See Appendix B, part 16

17. Instruments – See Appendix B, part 17

Idea Development Awards

18. Publications and Patent Abstracts – See Appendix B, part 18
19. Proposal Submission Address – See Appendix B, part 19
20. Proposal Submission Deadlines – See Appendix B, part 20
Please note that the deadline for submission for Idea Development awards is March 10, 1999 at 4:00 p.m. Eastern Time.
21. Notification – See Appendix B, part 21
22. Set-Aside for Historically Black Colleges and Universities and Minority Institutions – See Appendix B, part 1

IV-E. Reports

The award will require the timely delivery of several reports during the research effort. The recipient organization and the PI should realize that reports are necessary for the USAMRMC to monitor progress. However, a particular research project may require some variation.

The PIs of Idea Development Awards should plan on a requirement that consists of:

- an **ANNUAL** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and
- a **FINAL** report (submitted in the last year of the grant period) that details the findings and issues for the entire project.

The USAMRMC will notify PIs when these reports are due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by DOD must contact their contracting specialist and must follow the instructions concerning such activity in their contract.

V. Post-doctoral Traineeship Awards

V-A. Post-doctoral Traineeship Award Category

The intent of Post-doctoral Traineeship Awards is to enable recent doctoral degree graduates with limited post-doctoral experience (i.e., 3 years or less) either to extend ongoing research related to prostate cancer; or to broaden the scope of their research to include work relevant to prostate cancer under the guidance of a designated mentor. The research focus of Post-doctoral Traineeships should address an issue relevant to prostate cancer biology, prevention, and/or therapy.

Post-doctoral Traineeship proposals should be written and signed by the trainee as the PI and author of the proposal. Proposals will not be evaluated nor will awards be made for “to be named” trainees.

Post-doctoral Traineeships can be requested for up to \$84,000 for direct and indirect costs over a 2-year period of performance. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. No more than one trip to a scientific meeting per award per year is funded.

Applicants may submit only one individual proposal in only one of the following categories: the New Investigator (Section III), Idea Development (Section IV), Post-doctoral Traineeship (Section V), or Minority Population Focused Collaborative Training Awards (Section VI). However, a similar or identical proposal may be incorporated into a Prostate Cancer Center Initiation submission (Section VII). Investigators should be cautioned that if both projects are recommended for funding, the individual proposal will not be funded but will be negotiated as part of the Prostate Cancer Center Initiation Award.

V-B. Scientific Peer Review Evaluation Criteria for Post-doctoral Traineeships

Proposals will be evaluated according to the following criteria.

- **Candidate:** Do the candidate’s achievements to date (as assessed by background, academic performance, awards, and honors) make him or her a well-qualified candidate for post-doctoral training? Does the candidate have a record of previous research experience, publications, and/or related professional training that indicates suitability for a research career? What are the candidate’s stated goals? Do the letters of recommendation support the candidate’s abilities and potential for a productive research career?
- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the

Post-doctoral Traineeship Awards

candidate's training program? What is the mentor's previous research training experience with doctoral students?

- **Training Environment:** Does the post-doctoral training take place in an environment that is appropriate to accomplishing the candidate's goals? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to research training in prostate cancer?
- **Quality of the Research Training:** Will the training result in a valuable experience for the trainee in preparing him or her for an independent research career? Is the proposed training appropriate for the trainee? Would the described training further the trainee's goals to become an independent researcher?
- **Scientific Relevance:** Does the post-doctoral training relate to an important problem in prostate cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to prostate cancer research? Does the application make a convincing case for the relevance of the research to prostate cancer?
- **Budget:** Is the budget reasonable for the work proposed?

V-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a "Letter of Intent" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). Please fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521

E-mail: cdmrp_pa@ftdetrick-ccmail.army.mil

Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

V-D. Proposal Preparation

The following proposal preparation information is specific for Post-doctoral Traineeships. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 7 pages and that the deadline for submission is February 3, 1999 at 4:00 p.m. Eastern Time.

1. Who May Apply – See Appendix B, part 1
2. Proposal Acceptance Criteria – See Appendix B, part 2
3. Proposal Cover Booklet – See Appendix B, part 3
4. Peer Review Referral Page – See Appendix B, part 4
5. Proposal Title Page – See Appendix B, part 5
6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
7. Proposal Abstracts – See Appendix B, part 7
8. Statement of Work – See Appendix B, part 8
9. Proposal Relevance and Impact Statement – See Appendix B, part 9
In addition to the instructions found in Appendix B, part 9, Post-doctoral applicants should describe explicitly the training value of the proposed research concept relative to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer will prepare the applicant for a career in the battle against prostate cancer.

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Biographical Sketches (3 page limit for PI, mentor and collaborating investigators)	___
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Instruments (no page limit).....	___
Publications and Patent Abstracts (2 document limit).....	___

Post-doctoral Traineeship Awards

10. Proposal Body – See Appendix B, part 10

The body of Post-doctoral Traineeship proposals is limited to 7 pages. Figures, tables and graphs should be included within this section. However, submission of color figures, tables, graphs, and photographs is not recommended (see Appendix B, part 2).

Describe the proposed project using the **general** outline provided below:

1. Description of the Research Training: Describe the research training in which the applicant will participate such as coursework, laboratory techniques, conferences, and journal clubs. Describe the research concept to be explored. Provide a statement of the mentor's qualifications, including his or her experience as a research supervisor.
2. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

Note that for Post-doctoral Traineeship proposals, biographical sketches should be prepared for the applicant, collaborating investigators, and the mentor. The mentor's biographical sketch should include his or her qualifications, especially in prostate cancer research, and previous experience in training students and post-doctoral fellows.

13. Existing/Pending Support – See Appendix B, part 13

For Post-doctoral Traineeships, it is especially important to provide documentation of existing/pending support involving the mentor to show that there is adequate support in the training environment for the post-doctoral trainee.

14. Facilities/Equipment Description – See Appendix B, part 14

15. Support Documentation – See Appendix B, part 15

The following support documentation should be provided in the proposal submission:

- ❖ A letter signed by the Department Chair, Dean, or equivalent verifying the applicant has completed the degree and has no more than 3 years of post-doctoral training. This letter is to be sent to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that this letter is not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet.

Post-doctoral Traineeship Awards

- ❖ A letter of support from the mentor describing his or her commitment to the training/career development/mentorship of the applicant, and the nature of the proposed collaboration/training. Emphasis should be placed on the training environment and the designated mentor. This letter is to be sent from the mentor to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that the mentor's letter of support is not misplaced, the sealed envelope should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support will not be accepted separately from the application.
- ❖ Two additional letters of recommendation should accompany the application. These letters are to be sent from the references to the applicant in **sealed** envelopes for forwarding, unopened, with the application. To ensure that the letters of reference are not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of recommendation will not be accepted separately from the application.

To document the sources of these letters, please include in the Support Documentation section of the application a list of the names, positions, and grant function (e.g., mentor, recommender) of authors of the letters. However, please attach the letters in sealed envelopes with a binder clip to the original proposal underneath the Proposal Cover Booklet.

Finally, the Support Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Support Documentation section of the application.

16. Detailed Cost Estimate – See Appendix B, part 16

Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Proposal Submission Address – See Appendix B, part 19

20. Proposal Submission Deadlines – See Appendix B, part 20

Please note that the deadline for submission for Post-doctoral Traineeship Awards is February 3, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

22. Set-Aside for Historically Black Colleges and Universities and Minority Institutions – See Appendix B, part 1

V-E. Reports

The award will require the timely delivery of several reports during the research effort. The recipient organization and the PI should realize that reports are necessary for the USAMRMC to monitor progress. However, a particular research project may require some variation.

The PIs of Post-doctoral Traineeships will be required to submit one 2-5 page **ANNUAL** summary and one **FINAL** report. These summaries should present a description of the training and research accomplishments. The USAMRMC will notify PIs when these reports are due. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by DOD must contact their contracting specialist and must follow the instructions concerning such activity in their contract.

VI. Minority Population Focused Collaborative Training Awards

VI-A. Minority Population Focused Collaborative Training Awards

There is a clear disparity in prostate cancer incidence and mortality among different ethnic groups.¹ Minority Population Focused Collaborative Training (MPFCT) Awards are intended to initiate and increase research efforts investigating this disparity. Further, MPFCT Awards are intended to attract new investigators to this research area and to foster collaborations between applicants and researchers established in the field of prostate cancer research. MPFCT Awards enable investigators to design and initiate a prostate cancer research concept that focuses on the disparity in prostate cancer incidence and mortality among one or more ethnic groups. The research focus should address an issue relevant to prostate cancer biology, prevention, and/or therapy. One of the goals of these awards is to establish and foster collaborations between applicant PIs and established investigators; **therefore, applications are required to include a collaboration with an established investigator.** Collaborations between investigators who are working at different institutions are especially encouraged. Both the applicant PI and collaborating investigator should contribute to the planned project. This award is intended to provide concept development and research support for researchers who have access to research facilities but have minimal or no other funding. Awards will provide investigators the opportunity to collaborate, train, and acquire the experience, resources, and preliminary data needed to design a fundable plan for prostate cancer research. The long-term goal of this award mechanism is to increase research efforts in this area by preparing investigators to submit competitive, well developed research proposals to funding agencies.

Funding for MPFCT Awards can be requested for a maximum of \$75,000, inclusive of direct and indirect costs, for up to 1 year. These funds can include salary support, expenses including research supplies, tuition for special training and/or education, costs related to arranging a collaboration with an established investigator, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, office supplies, and travel.

Applicants may submit only one individual proposal in only one of the following categories: the New Investigator (Section III), Idea Development (Section IV), Post-doctoral Traineeship (Section V), or Minority Population Focused Collaborative Training Awards (Section VI). However, a similar or identical proposal may be incorporated into a Prostate Cancer Center Initiation submission (Section VII). Investigators should be cautioned that if both projects are recommended for funding, the individual proposal will not be funded but will be negotiated as part of the Prostate Cancer Center Initiation Award.

¹ American Cancer Society, Cancer Facts & Figures - 1998

VI-B. Scientific Peer Review Evaluation Criteria for MPFCT Awards

Proposals will be evaluated according to the following criteria

- **Applicant:** Do the applicant's previous training, prior research experience, and publication record indicate promising achievements to date? Will the training/collaboration offer a valuable opportunity to further develop necessary experience to advance the applicant's research career in prostate cancer? Does the applicant have a need for funding due to limited research support?
- **Collaborating Investigator:** Does the collaborating investigator have the background, qualifications, and time to develop a productive collaboration with the applicant? Is the collaborating investigator committed to the applicant's career development?
- **Research Concept Development:** Does the proposed idea develop a new area of research or a novel application of existing research for studying the disparity in prostate cancer occurrence among men of different ethnic groups? Do both the applicant and the collaborating investigator contribute to the planned project?
- **Scientific Relevance:** Does the proposed concept and research clearly focus on the disparity in prostate cancer incidence among men of different ethnic groups? Does the application make a convincing case for the relevance of the concept to prostate cancer?
- **Resources/Environment:** Will the collaboration support the applicant's planned program of research? Are the proposal requirements adequately supported by the scientific environment, necessary resources, and collaborative arrangements (of both the collaborator and the applicant)? Is there a strong institutional commitment to relieve the applicant of other academic or clinical responsibilities in order to permit time for collaboration and concept development? Is there a strong institutional commitment to the applicant's career development?
- **Budget:** Is the budget reasonable for the work proposed?

VI-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a "Letter of Intent" form as soon as possible. This form can be found in Appendix A, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). Please Fax, e-mail, or mail the "Letter of Intent" form to:

Fax: (301) 682-5521

E-mail: cdmrp_pa@ftdetrck-ccmail.army.mil

Mail: Commander, U.S. Army Medical Research and Materiel Command

Minority Population Focused Collaborative Training Awards

ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

VI-D. Proposal Preparation

The following proposal preparation information is specific for MPFCT Award category. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 7 pages and that the deadline for submission is March 10, 1999 at 4:00 p.m. Eastern Time. If funded, applicants may delay the start of the award to allow the institution to relieve the investigator of his/her academic or clinical responsibilities. Proposed start dates should be no earlier than May 1999 and no later than December 1999.

1. Who May Apply – See Appendix B, part 1
2. Proposal Acceptance Criteria – See Appendix B, part 2
3. Proposal Cover Booklet – See Appendix B, part 3
4. Peer Review Referral Page – See Appendix B, part 4
5. Proposal Title Page – See Appendix B, part 5
6. Table of Contents – Use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
7. Proposal Abstracts – See Appendix B, part 7
8. Statement of Work – See Appendix B, part 8
A sample MPFCT Award Statement of Work is provided on page VI-8.

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Biographical Sketches (3 page limit for PI and each collaborating investigator)	___
Existing/Pending Support (no page limit).....	___
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Support Documentation (no page limit)	___
Detailed Cost Estimate (no page limit).....	___
Budget for Entire Proposed Period (no page limit)	___
Budget Justification (no page limit)	___
Instruments (no page limit).....	___
Publications and Patent Abstracts (2 document limit).....	___

Minority Population Focused Collaborative Training Awards

9. Proposal Relevance and Impact Statement – See Appendix B, part 9

In addition to the instructions found in Appendix B, part 9, MPFCT applicants should describe explicitly the training value of the proposed research concept relative to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer in the proposal will prepare the applicant for a career in the battle against prostate cancer.

10. Proposal Body – See Appendix B, part 10

The body of MPFCT Awards is limited to 7 pages. Describe the proposed research concept using the **general** outline provided below:

- ❖ **Collaborative Arrangement:** Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the established investigator and the applicant should be articulated. Qualifications and facilities of the established investigator should be addressed.
- ❖ **Career Development:** Describe explicitly the value of the proposed training as it relates to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer in the proposal will catalyze the applicant's development as an independent prostate cancer investigator.
- ❖ **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Proposals must present a clearly articulated plan for research concept development that focuses on the disparity in prostate cancer incidence and mortality rates in one or more ethnic groups. State the specific aims of the study. Briefly describe the methods to be used. Cite relevant literature references.

11. References – See Appendix B, part 11

12. Biographical Sketches – See Appendix B, part 12

For MPFCT Award proposals, biographical sketches should be prepared for the applicant, established investigator, and each of the key personnel, including collaborating investigators listed on the budget page for the initial budget period, and may not exceed 3 pages per investigator. Investigators must include a description of their experience in prostate cancer research as part of the Biographical Sketch.

13. Existing/Pending Support – See Appendix B, part 13

14. Facilities/Equipment Description – See Appendix B, part 14

Minority Population Focused Collaborative Training Awards

15. Support Documentation – See Appendix B, part 15

The following support documentation is to be contained within the MPFCT Award proposal submission, as follows:

- ❖ A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution describing the commitment of the institution to the applicant's research career, as reflected by the extent to which the applicant will be relieved of his or her academic and/or clinical responsibilities to have additional time for collaboration and training, access to appropriate facilities, and opportunities for professional interactions with senior colleagues.
- ❖ A form signed by the Department Chair, Program Director, or Dean indicating that the PI is an Assistant Professor or equivalent and, therefore, an eligible applicant for this award type. The form on the following page should be used.
- ❖ A letter from the collaborating established investigator describing his/her commitment to the training/career development/mentorship of the applicant, and the nature of the proposed collaboration/training.
- ❖ Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project describing their role on the concept development.

16. Detailed Cost Estimate – See Appendix B, part 16

Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.

17. Instruments – See Appendix B, part 17

18. Publications and Patent Abstracts – See Appendix B, part 18

19. Proposal Submission Address – See Appendix B, part 19

20. Proposal Submission Deadlines – See Appendix B, part 20

Please note that the deadline for submission for MPFCT Awards is March 10, 1999 at 4:00 p.m. Eastern Time.

21. Notification – See Appendix B, part 21

22. Set-aside for Historically Black Colleges and Universities and Minority Institutions – See Appendix B, part 1

STATEMENT OF ELIGIBILITY

Applicant's Name _____

Title of Proposal _____

Applicant's Organization Name: _____

Applicant's Organization Location: _____

Signature of Applicant: _____

STATEMENT OF ELIGIBILITY

For the purposes of the Department of Defense Congressionally Directed Medical Research Program's Prostate Cancer Research Program Minority Population Focused Collaborative Training Award category as outlined in the Announcement, the applicant fulfills all of the following criteria:

- Holds a position of at least an Assistant Professor or equivalent;
AND
- Has access to appropriate research facilities;

I, _____ of _____
(printed name of Department Chair, Dean or equivalent official) (printed name of institution)

attest that the above-named investigator fulfills the requirements for a Minority Population Focused Collaborative Training Award.

Signature of Official _____ Date: _____

MPFCT Award Sample Statement of Work

Waters, Sugar E.

Statement of Work

Exploring the Correlation between Glucose Intake and Prostate Cancer Progression by Analyzing Trends in “University of Somewhere” Prostate Cancer Patient Database

Phase 1: Project Startup and Parameter Development (Months 1-3)

- Meet with collaborating established investigator
- Hire a biostatistician for statistical analyses of data
- Purchase computer to assist in information processing
- Review current database for parameters relating to diet and prostate specific antigen measurements
- Enroll in advanced biochemistry course

Phase 2: Information Consolidation and Project Development through Consultative Interactions (Months 4-8)

- Consult an epidemiologist to determine appropriate research design for a clinical trial
- Consult a nutritionist to plan diet alternatives for future study groups
- Consult a urologist to determine methods to recruit subjects
- Complete course work for advanced biochemistry course
- Attend Association for the Advancement of Prostate Research course on “Design of Clinical Trials”

Phase 3: Formulation of Research Questions for Idea Award proposal in response to the DOD PCRP Announcement (Months 8-12)

- Consolidate information obtained during Phase 2
- Submit final report summarizing the efforts accomplished

IV-E. Reports

The award will require the timely delivery of a report of the research effort. The recipient organization and the PI should realize that reports are necessary for the USAMRMC to monitor progress. However, a particular research project may require some variation.

The PIs of MPFCT Awards will be required to submit a 2-5 page **FINAL** summary. This summary should present a description of the training and research accomplishments. The USAMRMC will notify PIs when this report is due and provide format guidelines at that time. Additionally, all awardees will be required to enter research progress and accomplishments into a Government-provided software program.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. PIs must submit a copy of any manuscripts or publications resulting from their research to the USAMRMC. Furthermore, investigators who contemplate filing licensing agreements or patent applications arising from the research funded by DOD must contact their contracting specialist and must follow the instructions concerning such activity in their contract.

VII. Prostate Cancer Center Initiation Awards

VII-A. Prostate Cancer Center Initiation Awards

The intent of the Prostate Cancer Center Initiation Awards is to invigorate the research community, bring new investigators into the field of prostate cancer, and make great strides toward conquering prostate cancer by engaging experts from multiple disciplines to establish regional centers for the study and treatment of prostate cancer. Prostate Cancer Center Initiation Awards will provide institutions the opportunity to acquire the experience, resources, data, and services needed to compete for funding from other resources.

The overall proposal must represent an innovative, multidisciplinary approach that is integrated around a common theme relevant to prostate cancer biology, prevention, and/or therapy. These awards must contain at least two, but no more than three, research projects and must contain only one single core facility to support the proposed work. A core facility provides shared resources or services that are utilized by all the projects in the center. The core facility can include administrative support, pathology and laboratory services, animal facilities, information management systems, and/or training. The overall Prostate Cancer Center Principal Investigator (PCC-PI) should have a proven track record of leadership and scientific ability to direct and oversee the overall research effort as well as a record of experience in managing multifaceted projects. A proven track record of scientific research and an institutional commitment of resources and space are required for successful competition in this category.

Unlike other proposal categories, investigators interested in applying for a Prostate Cancer Center Initiation Award should submit a short pre-proposal, due no later than March 10, 1999 at 4:00 p.m. Eastern Time. Prostate Cancer Center Initiation Award pre-proposals will be screened to determine which projects best fulfill the intent of the award category. Following completion of the pre-proposal screening process, all submitters will receive a letter indicating whether their pre-proposal has been selected for additional consideration. Invited institutions will then be requested to submit a full Prostate Cancer Center Initiation proposal according to the guidance provided in the Prostate Cancer Center Initiation Supplemental Instructions, which will be provided with the invitational letter. Invitations to submit a full Prostate Cancer Center Initiation proposal will be extended no later than April 25, 1999. The full Prostate Cancer Center Initiation proposal will be due no later than July 7, 1999 at 4:00 p.m. Eastern Time.

The allocation for Prostate Cancer Center Initiation Awards is approximately \$18M. Funding can be requested for a maximum of \$2.5M, inclusive of direct and indirect costs, over a 3-year period of performance.

VII-B. Selection Criteria for Pre-proposals

Pre-proposals will be evaluated according to the criteria listed below:

- how well the pre-proposal describes a Prostate Cancer Center Initiation program integrated around a common theme relevant to prostate cancer biology, prevention, and/or therapy;
- the identification of at least two, but no more than three, research projects and only one single core facility;
- the demonstration of a multidisciplinary effort;
- evidence of institutional commitment to sustain the long-term goals of the effort;
- a proven track record of prostate cancer research and scholarship for the PCC-PI;
- the potential to have a major impact on prostate cancer biology, prevention, and/or therapy; and
- the demonstration of only one application per institution.

VII-C. Letter of Intent

All applicants considering submission of a pre-proposal in response to this Program Announcement are encouraged to submit a “Letter of Intent” form as soon as possible. Please use the form on the following page for this Letter of Intent. Please fax, e-mail, or mail the “Letter of Intent” form to:

Fax: (301) 682-5521

E-mail: cdmrp_pa@ftdetrick-ccmail.army.mil

Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

**Letter of Intent
to Submit a Pre-Proposal in Response to the
FY 99 Department of Defense Prostate Cancer Research Program
Prostate Cancer Center Initiation Award**

Please fill out one of these request forms for the single core and for each project in the Prostate Cancer Center Initiation Award pre-proposal you plan to submit.

Fax this form to (301) 682-5521.

Overall Principal Investigator's Name: _____

Project/Core Director's Name: _____

Institution: _____

Institution's Address: _____

Phone Number: _____

Fax Number: _____

Which of the three research areas will be addressed (biology, prevention, and/or therapy) in the proposal: _____

Content area that will be addressed in the proposal/project/core (please check a maximum of five areas):

- | | | |
|---|--|--|
| <input type="checkbox"/> Alternative Medicine | <input type="checkbox"/> Gene Expression | <input type="checkbox"/> Prevention |
| <input type="checkbox"/> Behavioral/Social Sciences | <input type="checkbox"/> Gene Sequencing/Mapping | <input type="checkbox"/> Protein-nucleic Acid Interactions |
| <input type="checkbox"/> Biological Response Modifiers | <input type="checkbox"/> Immunologic Sciences | <input type="checkbox"/> Radiologic Sciences |
| <input type="checkbox"/> Cell Biology | <input type="checkbox"/> Health Care Delivery | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> Clinical/Experimental Therapeutics | <input type="checkbox"/> Medical Genetics | <input type="checkbox"/> Technology Development |
| <input type="checkbox"/> Endocrinology | <input type="checkbox"/> Molecular Genetics | <input type="checkbox"/> Tumor Biology/Progression |
| <input type="checkbox"/> Epidemiology/Biostatistics | <input type="checkbox"/> Pathobiology | <input type="checkbox"/> Virology |
| | <input type="checkbox"/> Pharmacology/Toxicology | |

Other, please specify _____

Provide the title for your Center, Project, or Core; and briefly describe your proposed research:

Use additional pages if needed. Please include the name of PI and applicant institution for form tracking.

Does your Prostate Cancer Center Initiation submission include a similar or identical proposal also submitted to another award mechanism for the FY 99 PCRP?

No Yes

VII-D. Pre-proposal Preparation

VII-D.1. Pre-proposal Acceptance Criteria

Compliance guidelines have been designed to present the pre-proposal in an organized and easy to follow manner to the panel responsible for screening it. Reviewers will expect a consistent, prescribed format for each reviewed pre-proposal. Non-adherence to format guidelines (such as font size, margins, and line spacing) makes pre-proposals difficult to read. Also, an unusual format may be perceived as giving applicants an unfair competitive advantage, and may result in proposal rejection.

It is recommended that the instructions in this section be followed carefully. The application should be clear, legible, and conform to the following spacing, font size, margins, and printing guidelines:

- Language: English
- Margins: Minimum of 0.5 inch top, bottom, right, and left
- Paper Size: 8.5 x 11.0 inches (Note to international applicants: A4 paper will be accepted if the text of the proposal does not exceed 7.5 x 10.0 inches [approximately 19 cm x 25.5 cm].)
- Printing: Single-sided (Double-sided printed pages are not accepted, with the exception of article reprints.)
- Spacing: Single-spaced between lines of text, no more than 5 lines of type within a vertical inch
- Type Color: Black ink including all graphs, diagrams, tables, and charts. The application should contain only material that can be photocopied. Submitting investigators should be cautioned that if color graphs or photographs are included, they may not reproduce in subsequent photocopies. Therefore, submission of color figures, tables, graphs, or photographs is not recommended and is at the investigator's own risk.
- Type Density: No more than 15 characters per inch (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Type Font: 12 point, 10 pitch, no more than 15 characters per inch and 114 characters per line.

To assist applicants, the following example is included.

This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing. This demonstrates the minimum font size and margins, and the required line spacing.

VII-D.2. Pre-proposal Preparation

The following four parts are required as part of the Prostate Cancer Center Initiation Award pre-proposal and should be included in the following order:

1. Pre-proposal Title Page - Start section on a new page - 1 page limit

The **Pre-proposal Title Page** should include the following information:

- Pre-proposal title
- Prostate Cancer Center Initiation overall Principal Investigator's (PCC-PI's) full name, including middle initial
- PCC-PI's phone and fax numbers
- Organization's name and location (including city, state, zip or postal code, and country)

2. Pre-proposal Body - Start section on a new page - 5 page limit

This **Pre-proposal Body** is limited to 5 pages, and should include the following information:

- Describe the Prostate Cancer Center Initiation organization: the research projects (not less than two, nor more than three) and the single core, and how they will interact.
- Describe the theme relevant to prostate cancer biology, prevention, and/or therapy, how this theme is integrated throughout the Cancer Center, and describe the multidisciplinary aspects of the proposal.
- Discuss how the individual projects and core are relevant to, and have the potential to have a major impact on, prostate cancer biology, prevention, and/or therapy.
- Discuss the PCC-PI's and the individual Project and Core Director's proven track records of prostate cancer research and scholarship. For the purposes of this Program Announcement, the PCC-PI is the investigator responsible for the oversight of the overall effort, while the Project or Core Directors are responsible for the direction of an individual research project or core.
- Describe the institution's previous, current, and future commitment to sustaining the long-term effort of the Initiation Center's goals.

3. References - Start section on a new page - 1 page limit

List relevant **references** in alphabetical order by first author. Use a standard reference format that includes the full citation and gives the authors, year published, title of reference, source of reference, volume, chapter, and page numbers in the Reference List.

4. Biographical Sketches - Start section on a new page - 3 page limit per investigator

Biographical sketches should be prepared for the PCC-PI and individual Project/Core Directors and should not exceed 3 pages per investigator. The “Biographical Sketch” form can be found in Appendix D, or it can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil>). Curricula vitae may not be substituted for a biographical sketch.

VII-E. Prostate Cancer Center Initiation Pre-proposal Submission

VII-E.1. Submission Address

Submit the following documentation to the address listed below:

Pre-proposal: 1 original bound with a binder clip and 30-collated photocopies, stapled or bound with binder clips

Send the Pre-proposal to: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP99-Announcement)
524 Palacky Street
Fort Detrick, MD 21702-5024

Please package only **ONE** pre-proposal per box. If an acknowledgment of pre-proposal receipt is desired, enclose a self-addressed, stamped postcard with the pre-proposal. The postcard should state the pre-proposal title and PCC-PI's name.

VII-E.2. Deadline

The submission deadline for Prostate Cancer Center Initiation pre-proposals is March 10, 1999 at 4:00 p.m. Eastern Time.

Any pre-proposal received after the exact time specified for receipt shall not be considered unless it is received before award is made, and it:

Prostate Cancer Center Initiation Awards

1. was sent by mail and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation, or
2. was sent by U.S. Postal Service Express Mail Next Day Delivery (Post Office to Addressee: ***Do not send Second Day Delivery***) and postmarked no later than 8:00 p.m. (local time at origination point) on March 9, 1999, or
3. was placed into the control of other commercial courier service for next day delivery no later than 8:00 p.m. (local time at origination point) on March 9, 1999.

Investigators are advised that documentation of receipt by the delivery agent may be necessary if a problem should occur.

VII-F. Scientific Peer Review Evaluation Criteria for the Full Prostate Cancer Center Initiation Award Proposal

As noted above, Prostate Cancer Center Initiation pre-proposals will be screened to determine which projects best fulfill the intent of the award category. Based upon the pre-proposal screening, selected investigators will be invited to submit a full Prostate Cancer Center Initiation proposal. Specific directions for preparation of the full proposal will be sent to participating applicants at the time of invitation. Scientific merit review of invited, full proposals will involve two phases: each project and the single core will be evaluated separately according to the criteria listed below; after each project and the single core have been evaluated, the overall proposal will be evaluated according to the criteria listed below. To be eligible for funding, a minimum of two scientifically meritorious projects must be included with each Center application.

➤ Evaluation Criteria for Individual Research Projects within the Overall Proposal

Each project within the overall program will be evaluated according to the following criteria:

- **Scientific Relevance:** Is the project likely to advance our understanding in prostate cancer biology, prevention, and/or therapy? Does the project have the potential to have a major impact on prostate cancer biology, prevention, and/or therapy?
- **Research Strategy:** Are the hypothesis, rationale, design, and methods valid? Are they well integrated in the aims of the project? Is the proposed project innovative and original?
- **Personnel:** Are the Project Director and key staff well qualified to perform the proposed research? Is there sufficient expertise included to support the research projects and the activities of the core?
- **Budget:** Is the budget reasonable for the research proposed?

➤ **Evaluation Criteria for the Single Core Facility**

Each proposed core will be evaluated according to the following criteria:

- **Integration and Function:** Is the proposed core well integrated with each research project and the overall goals of the Center? Does the core provide high quality service required by the research projects? Are the facilities adequate to provide these services?
- **Personnel:** Are the Core Director and key staff well qualified to perform the core services and functions? How will the personnel ensure integration and delivery of core services and functions to each project?
- **Budget:** Is the budget reasonable for the proposed core services and functions?

➤ **Evaluation Criteria for the Overall Proposal**

The overall proposal will be evaluated according to the criteria below:

- **Scientific Relevance:** Is the proposed research theme likely to generate a new understanding of prostate cancer biology, prevention, and/or therapy? Does the proposed Initiation Center have the potential to have a major impact on prostate cancer biology, prevention, and/or therapy? Is the proposed research multidisciplinary?
- **Research Management Plan:** Does the proposed Center present a solid plan to integrate individual research projects and the core into a cohesive overall effort/linking of individual research projects and core goals to the overall research strategy?
- **Qualifications of the Center Director:** Is there evidence that the proposed Prostate Cancer Center overall PI has the leadership, experience, and scientific ability to successfully lead the proposed Center?
- **Research Environment/Institutional Commitment:** Is there evidence of a strong institutional commitment to sustain the long-term goals of the effort? Have adequate resources been allocated to the Center to support the overall research goals of the Center? Is the institutional research environment supportive of the Center effort?
- **Budget:** Is the budget reasonable for the proposed research? Are each project and the core adequately funded to perform the research as presented? Are adequate funds requested to ensure success of the entire Center?