DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
PROSTATE CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT

February 21, 2002

Headquarters, U.S. Army Medical Research and Materiel Command
MCMR-PLF, 1077 Patchel Street
Fort Detrick, Maryland 21702-5024

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Foreword

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed to continue the Department of Defense (DOD) Prostate Cancer Research Program (PCRP). The deadline, format, and other criteria specified for proposals in this DOD Fiscal Year 2002 (FY02) PCRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

Please note that the signing of the FY02 appropriation was delayed until January 2002, which requires the announcement, evaluation, and decision process to commence before the actual receipt of funding at this Command for these projects. However, this Command's study of the appropriation and its knowledge of the history of these programs lead it to believe that the DOD will provide the funds for these projects.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity (USAMRAA), the Congressionally Directed Medical Research Programs (CDMRP), and the DOD PCRP can be obtained from the CDMRP web site at http://cdmrp.army.mil. A copy of this program announcement and associated forms also can be downloaded from the CDMRP web site (for information on completing the Proposal Information, see Section 6, page iv of this Foreword).

1. Highlights of Changes from the FY01 Program Announcement

- An authorized Administrative Representative from the Sponsored Programs Office at the applicant's organization is **required to submit one electronic version of the applicant's proposal as a PDF (Portable Document Format) file through the Internet (electronic submission)**; the electronic PDF file will serve as the official proposal submission. Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

- Margins for proposal preparation and acceptance have been changed to a minimum of **0.5-inch top, bottom, right,** and **1-inch left**.

- The proposal submission deadline is different for each mechanism. Please check the submission date for the award mechanism of interest in Section 4, page iii of this Foreword or in the section pertaining to the mechanism of interest.

- Letters of Intent to submit proposals to the FY02 PCRP must be submitted electronically through http://cdmrp.army.mil.

- The paper Proposal Cover Booklet has been replaced by Proposal Information found online at http://cdmrp.org/proposals.

- Proposals that were declined for funding in a previous year may be resubmitted to the PCRP using a new process. The resubmission should contain a 2-page section that addresses the major issues identified in the previous summary statement; a copy of the summary statement from the unfunded application should also be included. However, resubmissions must specifically adhere to the proposal preparation requirements specified in this program announcement for the mechanism to which the proposal is submitted.

- FY02 Health Disparity Training and Health Disparity Research applicants must **explicitly express how the proposed research is related to health disparity** within the Proposal Relevance Statement section. Failure to do so may be grounds for administrative withdrawal of the proposal without further review.

- FY02 Health Disparity Training and Health Disparity Research applicants will have an opportunity to submit a written statement addressing the issues raised in the peer review summary statement. The written response will be forwarded to programmatic review along with the summary statement for consideration during the second tier of review.

- To be eligible for the New Investigator Award, applicants may not have received non-mentored funding from any of the following: the National Institutes of Health (NIH), the American Cancer Society (ACS), the National Science Foundation (NSF), or the DOD. Applicants will also need to provide evidence that they are within 6 years of their last fellowship or postdoctoral position.
- Documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002 and will be requested in the applicant's notification letter.
- All submissions to the PCRP that involve human subjects should provide medical care for research-related injuries at no cost to the subject. Investigators should plan on budgeting for such costs.

2. Who May Apply

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. Please refer to sections on individual mechanisms for additional eligibility criteria.

3. Submission Deadlines

The proposal submission deadline is different for each award mechanism. Please check the following timelines or the award mechanism of interest for more details. An electronic PDF version of your proposal, which will serve as the official proposal submission, must be sent

through the Internet by an authorized Administrative Representative of the Sponsored Programs Office (or equivalent) of your organization by **11:59 p.m. (applicant's local time) on the day of the submission deadline**. See Appendix B, part 23, and Appendix C for additional details.

4. Timelines

a. The timeline for Idea Development Awards is:

Electronic Letter of Intent:	As soon as possible but no later than April 29, 2002
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet by **11:59 p.m. (applicant's local time) on May 14, 2002.**
Peer Review:	July 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	October 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	**Between December 2002 and September 2003**

b. The timeline for Postdoctoral Traineeship Award and New Investigator Awards is:

Electronic Letter of Intent:	As soon as possible but no later than April 29, 2002
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**
Peer Review:	July 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	October 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	**Between December 2002 and September 2003**

c. The timeline for Health Disparity Training – Prostate Scholar and Health Disparity Research – Prostate Scholar Awards is:

Electronic Letter of Intent:	As soon as possible but no later than April 29, 2002
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**
Peer Review:	July 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Summary Statement to PI[1]	By August 28, 2002
PI Reply to Summary Statement	Returned to CDMRP by September 10, 2002
Programmatic Review:	October 2002

[1] Principal Investigator

Notification:	Approximately 2 weeks after programmatic review
Award Date:	**Between December 2002 and September 2003**

5. Inquiries

Questions concerning the **proposal format or required documentation** can be addressed to the CDMRP at:

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP02-Program Announcement)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

Applicants should submit questions regarding this program via e-mail or in writing as early as possible. Every effort will be made to answer questions within 5 working days.

Help lines will be available by April 15, 2002 to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (http://cdmrp.army.mil) and the proposal submission web site (http://cdmrp.org/proposals). Alternately, help can be obtained by e-mail, at help-proposals-cdmrp@cdmrp.org

6. Proposal Submission

Applicants should refer to sections on individual award mechanisms and Appendix B for appropriate submission requirements.

Proposals will be submitted electronically at http://cdmrp.org/proposals. The web site will be available for proposal submission by April 15, 2002. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must submit one electronic PDF version of the applicant's proposal, which will count as the official proposal submission.

Several steps are critical for successful electronic submission of the applicant's proposal:

1. The applicant is required to submit Proposal Information (referred to in previous years as the Proposal Cover Booklet) online at http://cdmrp.org/proposals, to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf. **The Proposal Information must be submitted prior to submission of the proposal. We encourage applicants to**

begin this part of the submission process early.

2. Once the applicant has submitted the online Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.

3. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Applicants are encouraged to coordinate early with their Sponsored Programs Office.

4. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. The Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the web site (http://cdmrp.org/proposals) no later than **11:59 p.m. (applicant's local time) on the due dates specified on page iii for the specific mechanism for which you are applying.** Detailed instructions for electronic submissions will be available by April 15, 2002 at http://cdmrp.org/proposals.

I. Overview of the Congressionally Directed Medical Research Programs

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

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received more than $2.2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense Women's Health, osteoporosis, and other specified areas.

The CDMRP exists to support research that will positively impact the health of all Americans. The CDMRP strives to identify gaps in funding and provide opportunities that will enhance program research objectives without duplicating existing funding. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that addresses individual program objectives.

I-B. Investment Strategy

For each program, the CDMRP has developed and refined a flexible execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to the program, establish an appropriate investment strategy, and perform programmatic review as described in Section I-C.2. Based upon this investment strategy, each program then uses a variety of award mechanisms to address the most urgent needs of the research community.

I-C. Proposal Evaluation

The CDMRP uses a two-tiered review process for proposal evaluation as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a scientific 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 program goals.

I-C.1. Scientific Peer Review

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

Scientific peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. For the breast, prostate, and ovarian cancer research programs, consumer reviewers are cancer survivors and representatives of consumer advocacy organizations. For the neurofibromatosis research program, consumer reviewers are individuals with neurofibromatosis or their family members and representatives of consumer advocacy organizations. Consumer reviewers are nominated by an advocacy organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the scientific peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see Section B of each award mechanism). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement. Summary statements are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The 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. One of the functions of programmatic review is to select 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 peer review summary statements, which include the proposal abstracts, to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded to programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and evaluations of scientific peer review panels are primary factors in programmatic review; the IP also must consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation; and
- Program portfolio balance with respect to research disciplines or specialty areas.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

I-D. Notification

Following completion of the two-tiered evaluation process, every applicant will receive a letter indicating the award status of his/her proposal, along with the peer review summary statement. Letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

I-E. Negotiation of the Award

Please note that the signing of the FY02 appropriation was delayed until January 2002, which requires the announcement, evaluation, and decision process to commence before the actual receipt of funding at this Command for these projects. However, this Command's study of the appropriation, and its knowledge of the history of these programs, leads it to believe that the DOD will provide the funds for these projects.

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving the U.S. Army Medical Research Acquisition Activity (USAMRAA) and Regulatory Compliance and Quality (RCQ). A Contract Specialist from USAMRAA will contact the Administrative Representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.
Please note that the award start date will be determined during the negotiation process.

Concurrent with the USAMRAA discussions, RCQ will review the environmental compliance, safety plan, animal use, and human subjects/anatomical substance use documents to ensure that Army regulations are met. All documents related to RCQ will be requested in the applicant's notification letter and will be reviewed by RCQ staff. All documents related to RCQ should be available on the CDMRP web site by April 2002.

I-F. Human Use Requirements Unique to Department of Defense-funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects, a second, DOD review and approval is also required. The Human Subjects Research Review Board (HSRRB), administered by the USAMRMC Office of Regulatory Compliance and Quality, is responsible for conducting this second level of review. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. **All research protocols involving human subjects and/or anatomical substances must be approved by both the appropriate local review board and by the HSRRB before funding can begin and prior to initiation of the research protocol.**

Two requirements specific to DOD-funded research that the applicant must specifically address, if applicable, in the development of a research proposal for submission to the DOD are outlined below.

- Medical Care for Research-Related Injuries. For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Part 7, Appendix F for more details.

- Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

More information regarding research involving human subjects can be found in the RCQ Document, "Research Involving Human Subjects and/or Anatomical Substances," which will be available on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

I-G. Annual and Final Reports

All awards will require the timely delivery of several reports during the research effort. These reports are necessary for the CDMRP to monitor progress and evaluate program outcomes.

The Principal Investigator (PI) should plan on a reporting requirement consisting 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 award period) that details the findings and issues for the entire project.

I-H. Publications and Patents

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. For example, "This research, under award number DAMD…, was supported by the Department of Defense Prostate Cancer Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI must submit a copy of any manuscript or publication resulting from research funded under the award to the CDMRP.

In accordance with the Bayh-Dole Act (35 USC[1] 200 et seq.), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

[1] United States Code

II. Department of Defense Prostate Cancer Research Program

II-A. History of the Prostate Cancer Research Program

The Department of Defense (DOD) Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative, multi-institutional, multidisciplinary, and regionally focused research directed toward eliminating prostate cancer. Congressional direction for FY97 specified $38 million (M) for peer reviewed prostate cancer research. An additional $38M was appropriated in FY98 to continue the PCRP. The Program's success has encouraged Congress to appropriate additional funds to the PCRP in subsequent years to continue the peer reviewed PCRP. Appropriations since FY97 have totaled $386M. The program history of the FY97-01 PCRP is shown in Table II-1.

Table II-1: History of the DOD's Peer Reviewed PCRP

Program History	FY97-00	FY01[1]
PCRP-Managed Appropriations for Peer Reviewed Research	$201M	$100M
Number of Full Proposals Received	1, 950	782
Number of Proposals Funded	437	213
Number of Training/Recruitment Awards Funded	62	32
Number of Research Awards Funded	371	176
Number of Infrastructure Awards Funded	N/A[2]	5
Number of Cancer Center Awards Funded	4	N/A

[1]Award negotiations will not be finalized until September 2002.
[2]Not applicable.

II-B. Overview of the Fiscal Year 2002 Prostate Cancer Research Program

The Congressionally Directed Medical Research Programs (CDMRP) is requesting proposals on prostate cancer research and training through this program announcement. Proposals will be requested in five previously established PCRP award mechanisms: Idea Development Awards, New Investigator Awards, Postdoctoral Traineeship Awards, Health Disparity Training – Prostate Scholar Awards, and Health Disparity Research – Prostate Scholar Awards. In addition, investigators chosen for funding through the Consortium Development Award in FY01 received supplemental instructions to submit proposals for the Consortium Award in FY02.

The overall goal of this announcement is to promote research directed toward conquering prostate cancer. Within this context, the objectives of the FY02 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 CDMRP is challenging the scientific community to design innovative prostate cancer research that will foster new directions, address neglected issues, and bring new investigators into the field. 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. Fiscal Year 2002 PCRP Program Announcement Award Opportunities

This command anticipates that $75.9M will be available to fund competitive, peer reviewed prostate cancer research proposals (Table II-2).

Table II-2: Estimated FY02 PCRP Budget

Allocations	FY02
Congressional Appropriation	$85.0M
Less: Congressional/DOD Withholds[1]	($5.4M)
Appropriation Received	$79.6M
Less: Approximate PCRP Management Costs[2]	($3.7M)
Amount Available for FY02 Research	$75.9M
Training Awards	$3.0M
Research Awards	$52.9M
Infrastructure Awards[3]	$20.0M

[1]Withholds include Small Business Innovation Research (SBIR)/U.S. Army Medical Research and Materiel Command (USAMRMC).
[2]Any cost savings from management cost will be applied to research funding.
[3]Consortium Award: proposal submission is open only to recipients of FY01 Consortium Development Awards.

FY02 PCRP budget data are estimated based on prior years' experience and information available for the current year. The only data known at the time of publication of this Program Announcement is the congressional appropriation in the amount of $85M. Until funds are received by the USAMRMC, a final budget for withholds, management costs, or research cannot be quantified nor can research funding availability be guaranteed.

Prospective applicants that are familiar with the CDMRP program requirements from previous years are urged to review this program announcement carefully because revisions have been made.

Important note regarding duplicate submissions: Submission of the same research project to the FY02 PCRP under different award mechanisms is **not** allowed, and all such duplicate submissions may be administratively withdrawn. This includes duplicate submissions under different award mechanisms by different Principal Investigators. The Government reserves the right to reject any proposal.

Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available	Submission Deadline	Instructions for Proposal Preparation
Postdoctoral Traineeship Awards	Recent doctoral graduates with 3 years or less of postdoctoral experience	• Prepares new scientists for careers in prostate cancer research • Preliminary data not required	$98,000 for direct and indirect costs over a 2-year performance period	May 16, 2002 11:59 p.m. ALT[1]	Section III
Health Disparity Training – Prostate Scholar Awards	Predoctoral, Postdoctoral, and Postresidency	• Provides training opportunities to focus on the disparate burden of prostate cancer in African Americans	$90,000 for Predoctoral, $147,000 for Postdoctoral, and $300,000 for Postresidency Traineeships inclusive of direct and indirect costs over a 3-year performance period	May 16, 2002 11:59 p.m. ALT	Section IV
Health Disparity Research – Prostate Scholar Awards	Assistant Professor or equivalent	• Supports researchers to focus on the disparate burden of prostate cancer in African Americans	$300,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate	May 16, 2002 11:59 p.m. ALT	Section V
New Investigator Awards	Independent investigators within 6 years of last fellowship or postdoctoral position with access to appropriate research facilities and no previous non-mentored awards from the DOD, NIH[2], NSF[3], or ACS[4]	• Emphasis on innovative ideas and technology • Preliminary data not required	$225,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate	May 16, 2002 11:59 p.m. ALT	Section VI
Idea Development Awards	Independent investigators at the level of Assistant Professor or equivalent or above	• Emphasis on innovative ideas and technology • Preliminary data required	$375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate	May 14, 2002 11:59 p.m. ALT	Section VII

[1] Applicant's Local Time
[2] National Institutes of Health
[3] National Science Foundation
[4] American Cancer Society

III. Postdoctoral Traineeship Awards

III-A. Postdoctoral Traineeship Awards

The intent of Postdoctoral Traineeship Awards is to enable recent doctoral degree graduates with limited postdoctoral experience (i.e., 3 years or less at the time of proposal submission) 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 focus of these awards is on the applicant, the mentor, and the training environment. Eligible applicants must have successfully defended a doctoral thesis and completed all academic requirements for their degree at the time of award negotiation.

Postdoctoral Traineeship Award proposals, with appropriate direction from the mentor, should be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees.

Submission of the same research project to the Fiscal Year 2002 (FY02) Prostate Cancer Research Program (PCRP) under different award mechanisms is not allowed, and all such duplicate submissions may be administratively withdrawn. This includes duplicate submissions under different award mechanisms by different PIs. The Government reserves the right to reject any proposal.

Postdoctoral Traineeship Awards can be requested for a maximum of $98,000 for direct and indirect costs over a 2-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,500 per year.

III-B. Scientific Peer Review Evaluation Criteria for Postdoctoral Traineeship Award Proposals

Postdoctoral Traineeship Award proposals will be evaluated according to the following criteria:

- **Applicant:** Do the applicant's achievements to date (as assessed by background, academic performance, awards, and honors) make him or her well qualified for postdoctoral training? Does the applicant have a record of previous research experience, publications, and/or related professional training that indicates suitability for a career in prostate cancer research? Are the applicant's stated goals focused on prostate cancer research? Do the letters of recommendation support the applicant's abilities and potential for a productive research career in prostate cancer?

- **Mentor:** Does the mentor have the background, qualifications, resources, and time to supervise the training program? Does the mentor's previous research training experience with doctoral students demonstrate suitability to serve as a mentor?

- **Training and Environment:** Will the training prepare the applicant for an independent research career in prostate cancer? Is the proposed training appropriate? Would the described training further the applicant's goal to become an independent researcher? Does the postdoctoral training take place in an environment that is appropriate to accomplishing the applicant'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?

- **Relevance:** Will the postdoctoral training prepare the applicant to investigate 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 training 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 methods/tactics? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data?

- **Budget:** Is the budget appropriate for the training proposed?

III-C. Resubmission of Previous Years Proposals

Proposals that have been declined for funding in a previous year may be resubmitted to the PCRP. The resubmission should meet the FY02 submission requirements and format guidelines for this award mechanism but may also contain a 2-page section that addresses the major issues identified in the previous summary statement; a copy of the summary statement from the unfunded application should also be included. The resubmission statement should highlight and summarize deletions, additions, and other significant changes to the current submission, and be responsive to all aspects of the critique from the previous peer and programmatic reviews. Reference should be made to any new preliminary data included. Resubmissions that have not clearly taken into account the major comments or concerns resulting from the prior peer and programmatic reviews will be reviewed accordingly. See Appendix B, parts 3 and 11 for additional details.

III-D. Programmatic Review Evaluation Criteria for Postdoctoral Traineeship Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

III-E. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than 2 weeks prior to the award mechanism's receipt deadline. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02pcrp1.htm by April 15, 2002.
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III-F. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Postdoctoral Traineeship Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1 and the Statement of Eligibility, page III-8. In addition, eligible applicants for the Postdoctoral Traineeship Awards must have successfully defended a doctoral thesis, or completed all academic requirements for their degree at the time of award negotiation, and have 3 years or less postdoctoral experience at the time of award submission.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number generated by the Proposal Information.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Postdoctoral Traineeship Award applicants should describe explicitly (within the 1-page limit) the training value of the proposed research relative to the applicant's career goals. Describe how the combination of training value and relevance to prostate cancer will prepare the applicant for a career in the battle against prostate cancer.

11. Proposal Resubmission Statement – If applicable; see Appendix B, part 11

12. Proposal Body – See Appendix B, part 12.
    The body of Postdoctoral Traineeship Award proposals is limited to **6 pages**, inclusive of figures, tables, graphs, and photographs, if used.

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

    a. 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 experience as a research supervisor.

    b. Description of Research Project: Describe the proposed project using the **general** outline provided below:

        i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

        ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

        iii. Objectives: State concisely the project's specific aims and research strategy.

iv. Methods: Describe the experimental design and methodology.

c. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career in prostate cancer research.

13. Abbreviations – See Appendix B, part 13.

14. References – See Appendix B, part 14.

15. Biographical Sketches – See Appendix B, part 15 and Appendix E.
Note that for Postdoctoral Traineeship Award proposals, biographical sketches should be included for the applicant, the mentor, and all collaborating investigators. Each biographical sketch may not exceed 3 pages.

16. Existing/Pending Support – See Appendix B, part 16.
For Postdoctoral Traineeship Awards, it is especially important to provide documentation of existing/pending support involving the mentor in order to document that there is adequate support in the training environment for the postdoctoral trainee.

17. Facilities/Equipment Description – See Appendix B, part 17.

18. Administrative Documentation – See Appendix B, part 18.
Provide the following items in the Administrative Documentation section of the proposal.

- Official transcripts from undergraduate and graduate institutions. All foreign language transcripts must be accompanied by an English translation.

- A Statement of Eligibility form (page III-8) signed by the applicant and the Department Chair, Dean, or equivalent official verifying that the applicant has or will have successfully completed a doctoral degree at the time of award negotiation, has completed all academic requirements, and has no more than 3 years of postdoctoral training and therefore is eligible for this award.

- 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. **This letter should also describe the degree to which the applicant participated in idea development and proposal preparation, as well as the degree to which the applicant will participate in the execution of the proposal if funded.** Emphasis should be placed on the training environment and the designated mentor, and should include qualifications, especially in prostate cancer research, and previous experience in training students and postdoctoral fellows. This letter is to be sent with the application and included in the Administrative Documentation section of all copies of the proposal.

- Two additional letters of recommendation should accompany the application.

- Letters of support from any collaborating investigators.

Note: The signed Statement of Eligibility form, letters of recommendation, and letters of support from collaborating investigators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

Proposals lacking the above-mentioned administrative documentation may be considered noncompliant and therefore may not be forwarded for review (see Appendix B, part 22).

19. Detailed Cost Estimate – See Appendix B, part 19 and Appendix F.
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Training awards frequently have a different institutional indirect charge. All training award investigators are encouraged to check with their institution concerning indirect costs. Postdoctoral Traineeship Awards can be requested for a maximum of $98,000 for direct and indirect costs over a 2-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,500 per year.

For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See part 7 of Appendix F for more details.

20. Instruments – See Appendix B, part 20.

21. Publications and/or Patent Abstracts – See Appendix B, part 21.

22. Proposal Submission – See Appendix B, part 22.

23. Submission Deadline – See Appendix B, part 23.
Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

24. Regulatory Compliance and Quality Requirements – See Appendix B, part 24.
    All documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002. See Appendix B, part 24 for more details.

STATEMENT OF ELIGIBILITY

FY02 PCRP Postdoctoral Traineeship Award

Applicant's Name:_____

Title of Proposal:_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of Applicant:_____

I certify that the above-named investigator fulfills the requirements to be considered for a Postdoctoral Traineeship Award and specifically meets all of the following criteria:

- Has or will have completed all academic requirements for a doctoral degree at the time of award negotiation;
- Has or will have successfully completed a doctoral thesis at the time of award negotiation; and
- Has 3 years or fewer of postdoctoral experience at the time of award submission.

Name of Official (*please print*):_____

Title:_____

Organization: _____

Signature of Official:_____ Date:_____

Proposal Log Number: _____

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

Postdoctoral Traineeship Award Proposal
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IV. Health Disparity Training – Prostate Scholar Awards

IV-A. Health Disparity Training – Prostate Scholar Awards

African Americans have the highest prostate cancer incidence rates in the world.[1] Health Disparity Training – Prostate Scholar Awards (HDT-PSAs) are intended to provide investigators in the **early stages** of their careers with training opportunities (under the guidance of a designated mentor) that focus on the disparate burden of prostate cancer in African Americans. The ultimate goal of these awards is to resolve the disparity in prostate cancer incidence, morbidity, and mortality between African Americans and other ethnic groups.

For the purpose of this award, investigators **must** demonstrate a connection to, or effectiveness in working with, the African American community. Such demonstration might include previous experience working with the African American population, and/or demonstrated cultural ties to the African American community. **In addition, the proposal must explicitly express how the proposed research is related to a health disparity issue.**

HDT-PSA proposals, with appropriate direction from the mentor, should be written and signed by the trainee/applicant as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees.

These awards require the active involvement of a mentor who is an established prostate cancer researcher. Under this award mechanism, investigators may apply for Predoctoral Traineeships, Postdoctoral Traineeships, or Postresidency Traineeships.

Predoctoral Traineeship Awards
The intent of these awards is to support doctoral students studying the disparate burden of prostate cancer in African Americans. Eligible applicants must be enrolled full-time in an accredited doctoral program at the time of proposal submission. Predoctoral Traineeship Awards can be requested for a maximum of $90,000 for direct and indirect costs over a 3-year performance period. These funds can cover salary, tuition, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,500 per year.

Postdoctoral Traineeship Awards
The intent of these awards is to enable recent doctoral graduates to obtain research experience studying the disparity in prostate cancer in African Americans. Eligible applicants must have successfully defended a doctoral thesis and completed all academic requirements for their degree at the time of award negotiation and must have 3 or fewer years of postdoctoral experience at the time of award submission. Individuals with a Ph.D., M.D., or equivalent degree are encouraged to apply. Postdoctoral Traineeship Awards can be requested for a maximum of $147,000 for direct and indirect costs over a 3-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see

[1]American Cancer Society, *Cancer Facts & Figures – 2002*.

Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,500 per year.

Postresidency Traineeship Awards
The intent of these awards is to train physicians in research that focuses on the disparity of prostate cancer in African Americans. Eligible applicants must be within 6 years of completing postgraduate medical education at the time of proposal submission. Postresidency traineeship proposals should include a discussion of the level of institutional commitment that exists to foster the applicant's prostate cancer research career as reflected by (1) the extent to which the applicant will be relieved of his/her academic and/or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) the opportunities for critical professional interaction with senior colleagues. Postresidency Traineeship Awards can be requested for a maximum of $300,000 for direct and indirect costs over a 3-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,500 per year.

Submission of the same research project to the Fiscal Year 2002 (FY02) Prostate Cancer Research Program (PCRP) under different award mechanisms is not allowed, and all such duplicate submissions may be administratively withdrawn. This includes duplicate submissions under different award mechanisms by different PIs. The Government reserves the right to reject any proposal.

IV-B. Scientific Peer Review Evaluation Criteria for Health Disparity Training – Prostate Scholar Award Proposals

HDT-PSA proposals will be evaluated according to the following criteria:

- **Applicant:** Does the applicant demonstrate a connection to, or effectiveness in working with, the African American community? Do the applicant's previous training, experience, and achievements (e.g., academic performance, awards, publications) indicate a solid potential for a successful career in prostate cancer research? Does the training outlined in the proposal enhance the probability that the applicant will pursue a career in prostate cancer research that addresses disease disparity?

- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the applicant? Does the mentor have a strong record in prostate cancer research? Does the mentor's previous research training experience with doctoral students, fellows, or residents demonstrate suitability to serve as a mentor? Is the mentor involvement appropriate for the level of the award?

- **Relevance:** Does the work outlined in the proposal address the disparity in incidence, morbidity, or mortality of prostate cancer in African Americans? Does the application make a convincing case for the relevance of the research to disease disparity?

- **Training and Environment:** Will the training help prepare the applicant for an independent research career in prostate cancer? Is the proposed training appropriate? Does the training address an issue related to prostate cancer health disparity in the African American community? Are the training 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?

- **Research Program:** Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed, well integrated for the applicant's research program, and appropriate to the applicant's level? Is the applicant aware of potential problem areas, and are potential solutions proposed? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data?

- **Budget:** Is the budget appropriate? Are there sufficient overall financial resources to support the proposed training?

IV-C. Programmatic Review Evaluation Criteria for Health Disparity Training – Prostate Scholar Awards

Prior to programmatic review, applicants for the FY02 Health Disparity Training – Prostate Scholar Awards will have an opportunity to submit a written reply to the issues raised in the peer review summary statement. Summary statements from peer review will be sent to the PI by August 28, 2002. The PI can provide a response to the summary statement, not to exceed 3 pages, excluding biographical sketches for any new personnel, reprints or preprints of accepted manuscripts, and revised budget pages, if appropriate. The response should concentrate on those sections of the application needing revision or more development, not on elements rated highly by the peer reviewers. The response must be returned to the Congressionally Directed Medical Research Programs (CDMRP) by September 10, 2002 so it can be appended to the summary statement for the second tier of review, programmatic review.

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

IV-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than 2 weeks prior to the award mechanism's receipt deadline. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02pcrp1.htm by April 15, 2002.

IV-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for HDT-PSAs. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1 and the Statement of Eligibility on page IV-9. All eligible applicants to the HDT-PSA must show a connection to, or effectiveness in working, with the African American community.
   a. Predoctoral Traineeship applicants must be enrolled full-time in an accredited doctoral program.
   b. Postdoctoral Traineeship applicants must (1) have or will have completed all academic requirements for a doctoral degree at the time of award negotiations, (2) have or will have successfully completed a doctoral thesis at the time of award negotiation, and (3) have 3 or less years of postdoctoral experience at the time of award submission.
   c. Postresidency Traineeship applicants must be within 6 years of completing postgraduate medical education at the time of proposal submission.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Information – See Appendix B, part 4 and Appendix C.
5. Title/Referral Page – See Appendix B, part 5.
6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the

Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number generated by the Proposal Information.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
In addition to the instructions found in Appendix B, part 10, HDT-PSA applicants should describe explicitly (within the 1-page limit) the training value of the proposed research relative to the applicant's career goals. Describe how the combination of training value and relevance to prostate cancer disease disparity will prepare the applicant for a career in the battle against prostate cancer. **Applicants must demonstrate a connection to, or effectiveness in working with, the African American community.** Due to the importance of the relevance to prostate cancer disparity, Relevance Statements will be forwarded to programmatic reviewers.

11. Proposal Resubmission Statement – If applicable; see Appendix B, part 11.
This section is not applicable for HDT-PSA submissions.

12. Proposal Body – See Appendix B, part 12.
The body of HDT-PSA proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used.

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

    a. Description of the Research Training: Describe the research training in which the applicant will participate. For predoctoral and postdoctoral traineeships, include a description of coursework, laboratory techniques, conferences, and journal clubs. Describe the research concept to be explored.

    b. Description of Research Project: Describe the proposed project using the general outline provided below:

        i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

        ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

        iii. Objectives: State concisely the project's specific aims and research strategy.

        iv. Methods: Describe the experimental design and methodology.

    c. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career in the area of prostate cancer disease disparity.

13. Abbreviations – See Appendix B, part 13.

14. References – See Appendix B, part 14.

15. Biographical Sketches – See Appendix B, part 15 and Appendix E.
    Note that for all proposals, biographical sketches should be included for the applicant, the mentor, and all collaborating investigators. Each biographical sketch may not exceed 3 pages.

16. Existing/Pending Support – See Appendix B, part 16.
    It is especially important to provide documentation of existing/pending support involving the mentor in order to document that there is adequate support in the training environment for the trainee.

17. Facilities/Equipment Description – See Appendix B, part 17.

18. Administrative Documentation – See Appendix B, part 18.

    Provide the following items in the Administrative Documentation section.

    - A Statement of Eligibility form (see page IV-9) signed by the applicant and the Department Chair, Dean, or equivalent official verifying that the applicant meets the relevant eligibility criteria.

    - Official transcripts from undergraduate (required for predoctoral traineeships only) and graduate institutions. All foreign language transcripts must be accompanied by an English translation.

    - A letter of support signed by the mentor describing his or her commitment to the training, career development, and/or mentorship of the applicant, the nature of the proposed collaboration/training, and his or her commitment to supporting research on prostate cancer disease disparity. **This letter should also describe the degree to which the applicant participated in both the idea development and the proposal's preparation, as well as the degree to which the applicant will participate in the execution of the proposal if funded.** The training environment should be clearly and concisely described. The qualifications of the designated mentor should be addressed, especially his or her experience in prostate cancer research and in training students and postdoctoral fellows. Note: Letters of support **will not** be accepted separately from the electronic application.

    - For Postresidency Traineeships, a letter of institutional support describing the institution's commitment to fostering the applicant's research career, as reflected by (1) the extent to which the applicant will be relieved of other academic and clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues.

    - Two additional letters of recommendation should accompany the application. Note:

Letters of recommendation **will not** be accepted separately from the electronic application.

- Letters of support from any collaborating investigators.

Note: The signed Statement of Eligibility form, letters of recommendation, and letters of support from institutions or collaborating investigators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

Proposals lacking required administrative documentation may be considered noncompliant and therefore may not be forwarded for review (see Appendix B, part 22).

19. Detailed Cost Estimate – See Appendix B, part 19 and Appendix F.
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Training awards frequently have different institutional indirect costs. All training award investigators are encouraged to check with their institution concerning indirect costs. The amount allotted for travel is $1,500 per year.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See part 7 of Appendix F for more details.

20. Instruments – See Appendix B, part 20.

21. Publications and/or Patent Abstracts – See Appendix B, part 21.

22. Proposal Submission – See Appendix B, part 22.

23. Submission Deadline – See Appendix B, part 23.
Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

24. Regulatory Compliance and Quality Requirements – See Appendix B, part 24.
All documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002. See Appendix B, part 24 for more details.

STATEMENT OF ELIGIBILITY

FY02 PCRP Health Disparity Training – Prostate Scholar Award

Applicant's Name: _____

Title of Proposal: _____

Applicant's Organization Name: _____

Applicant's Organization Location: _____

_____

Signature of Applicant: _____

I certify that the above-named investigator fulfills the following requirements for the award mechanism checked below:

☐ Predoctoral Traineeship: The applicant is enrolled full-time in an accredited doctoral program.

☐ Postdoctoral Traineeship: The applicant (1) has or will have completed all academic requirements for a doctoral degree at the time of award negotiation, (2) has or will have successfully completed a doctoral thesis at the time of award negotiation, and (3) has 3 or fewer years of postdoctoral experience at the time of award submission.

☐ Postresidency Traineeship: The applicant is within 6 years of completing postgraduate medical education at the time of proposal submission.

Name of Official (*please print*):_____

Title:_____

Organization:_____

Signature of Official: _____ Date:_____

Proposal Log Number: _____

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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V. Health Disparity Research – Prostate Scholar Awards

V-A. Health Disparity Research – Prostate Scholar Awards

African Americans have the highest prostate cancer incidence rates in the world.[1] Health Disparity Research – Prostate Scholar Awards (HDR-PSAs) are intended to encourage investigators at the assistant professor or equivalent level to focus their research efforts on the disparate burden of prostate cancer in African Americans. These awards will require the active involvement of a collaborator who is an established prostate cancer researcher. The ultimate goal of these awards is to resolve the disparity in prostate cancer incidence, morbidity, and mortality between African Americans and other ethnic groups.

For the purpose of this award, investigators **must** demonstrate a connection to, or effectiveness in working with, the African American community. Such demonstration might include previous experience working with the African American population, and/or demonstrated cultural ties to the African American community. **In addition, the proposal must explicitly express how the proposed research is related to a health disparity issue.**

HDR-PSAs are intended to encourage scientists or physicians who have postdoctoral and/or fellowship training, but are not yet established researchers to focus their research efforts on the disparate burden of prostate cancer in African Americans. For the purpose of this program, a HDR-PSA is intended for an individual who holds a position as an Assistant Professor or equivalent. Proposals must include a discussion regarding the institution's commitment to foster the applicant's prostate cancer research career as reflected by (1) the extent to which the applicant will be relieved of his or her academic or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) the opportunities for critical professional interaction with senior colleagues. HDR-PSAs can be requested for a maximum of $300,000 in direct costs over a 3-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

Submission of the same research project to the Fiscal Year 2002 (FY02) Prostate Cancer Research Program (PCRP) under different award mechanisms is not allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms by different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

[1] American Cancer Society, *Cancer Facts & Figures – 2002*

V-B. Scientific Peer Review Evaluation Criteria for Health Disparity Research – Prostate Scholar Award Proposals

HDR-PSA proposals will be evaluated according to the following criteria:

- **Applicant:** Does the applicant demonstrate a connection to, or effectiveness in working with, the African American community? Do the applicant's previous training, experience, and achievements indicate a solid potential for a successful career in prostate cancer research? Does the research outlined in the proposal enhance the probability that the applicant will pursue a career in prostate cancer research that addresses disease disparity?

- **Disease Relevance:** Does the proposed research address the disparity in incidence, morbidity, and mortality of prostate cancer in African Americans? If the aims of this research are achieved, will there be a potential benefit to the African American population? Does the application make a convincing case for the relevance of the research to disease disparity?

- **Research Program:** Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed and well integrated for the applicant's research program? Is the applicant aware of potential problem areas, and are potential solutions proposed?

- **Collaborator:** 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? Does the collaborating investigator have a strong record of funding in prostate cancer research? Does the collaborating investigator have experience training individuals from diverse backgrounds?

- **Institutional Commitment:** Is there an institutional commitment to provide access to laboratory facilities and equipment? Are there opportunities for critical professional interaction with senior colleagues? Will the applicant be provided with sufficient relief from academic or clinical responsibilities to permit substantially increased time for research activities? Is there a strong institutional commitment to the applicant's development of a research program addressing the disparity in prostate cancer?

- **Budget:** Is the budget appropriate?

V-C. Programmatic Review Evaluation Criteria for Health Disparity Research – Prostate Scholar Awards

Prior to programmatic review, applicants for the FY02 HDT-PSAs will have an opportunity to submit a written reply to the issues raised in the peer review summary statement. Summary statements from peer review will be sent to the PI by August 28, 2002. The PI can provide a response to the summary statement, not to exceed 3 pages, excluding biographical sketches for any new personnel, reprints or preprints of accepted manuscripts, and revised budget pages, if

appropriate. The response should concentrate on those sections of the application needing revision or more development, not on elements rated highly by the peer reviewers. The response must be returned to the Congressionally Directed Medical Research Programs (CDMRP) by September 10, 2002 so it can be appended to the summary statement for the second tier of review, programmatic review.

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

V-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than 2 weeks prior to the award mechanism's receipt deadline. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02pcrp1.htm by April 15, 2002.

V-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for HDR-PSAs. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1.
   In addition, applicants to the HDR-PSA must hold a position as an Assistant Professor or equivalent, show a connection to, or effectiveness in working with, the African American community, and demonstrate an area of research that is clearly related to an issue in health disparity.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and proposal log number generated by the Proposal Information.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, HDR-PSA applicants should describe explicitly (within the 1-page limit) how the proposed research addresses a health disparity issue. The applicant should also state how proposed research focuses on an issue related to the disparate burden of prostate cancer in African Americans. **Applicants must demonstrate a connection to, or effectiveness in working with, the African American community.** Due to the importance of the relevance to prostate cancer disparity, Relevance Statements will be forwarded to programmatic reviewers.

11. Proposal Resubmission Statement – See Appendix B, part 11
    This section is not applicable for HDR-PSA submissions.

12. Proposal Body – See Appendix B, part 12.
    The body of HDR-PSA proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used.

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

    a. Background: Briefly describe the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the project's specific aims and research strategy.

    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 all proposed syntheses. Outline and document the routes to each synthesis.

e. 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. Document the experience of the collaborating investigator in training prostate cancer researchers and include information on training/collaborations with minority investigators.

f. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed research will promote the applicant's career in the area of prostate cancer disease disparity.

13. Abbreviations – See Appendix B, part 13.

14. References – See Appendix B, part 14.

15. Biographical Sketches – See Appendix B, part 15 and Appendix E.

16. Existing/Pending Support – See Appendix B, part 16.
Provide documentation of existing/pending support that reflects the commitment of the collaborating investigator or institutional commitment.

17. Facilities/Equipment Description – See Appendix B, part 17.

18. Administrative Documentation – See Appendix B, part 18.
Provide the following items in the Administrative Documentation section of the proposal.

- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution describing the institution's commitment to fostering the applicant's research career as reflected by (1) the extent to which the applicant will be relieved of other academic and/or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues.

- Letter(s) of support from collaborator(s).

Note: The signed letter of institutional commitment and letter(s) of support from collaborating investigators **will not** be accepted separately from the electronic submission. All letters must be signed and then scanned into the submitted proposal.

Proposals lacking required administrative documentation may be considered noncompliant and therefore may not be forwarded for review (see Appendix B,

part 22).

19. Detailed Cost Estimate – See Appendix B, part 19 and Appendix F.
    Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. HDR-PSA awards can be requested for a maximum of $300,000 in direct costs over a 3-year performance period. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See part 7 of Appendix F for more details.

20. Instruments – See Appendix B, part 20.

21. Publications and/or Patent Abstracts – See Appendix B, part 21.

22. Proposal Submission – See Appendix B, part 22.

23. Submission Deadline – See Appendix B, part 23.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

24. Regulatory Compliance and Quality Requirements – See Appendix B, part 24.
    All documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002. See Appendix B, part 24 for more details.

Proposal Log Number: _____

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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VI. New Investigator Awards

VI-A. New Investigator Awards

The intent of New Investigator Awards (NIAs) is to promote and reward investigators in the early years of their career who have innovative ideas and new technologies applicable to prostate cancer research and treatment. **NIAs are specifically targeted to investigators within 6 years of their last fellowship or postdoctoral position.** To be eligible for this award, the applicant must be an independent investigator with access to appropriate research facilities. In keeping with the intent of attracting new investigators, the applicant may not have received non-mentored funding as a Principal Investigator (PI) or co-PI from the National Institutes of Health (NIH), the American Cancer Society (ACS), the National Science Foundation (NSF), or the Department of Defense (DOD).

Innovation is a significant feature of the NIA. Research that is innovative may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including the following:

- Study concept – investigation of a novel idea and/or unique research question
- Research method or technology – use of novel research methods or new technologies to address a research question
- Clinical interventions – use of a novel method or technology for preventing, diagnosing, or treating prostate cancer
- Adaptations of existing methods or technologies – application or adaptation of existing methods or technologies for research or clinical purposes that are fundamentally different from those originally intended, and/or for use under novel research or clinical purposes.

This list is not all-inclusive, but is intended to serve as a foundation on which to frame and present the innovative features of the proposal.

In accordance with the challenge to be innovative and capture novel ideas in their early stages of development, **proposals are not required to have preliminary data.** Although this research is inherently risky and does not require preliminary data, these proposals should nonetheless be based on a sound scientific rationale that is established through logical reasoning and/or a critical review and analysis of the literature. **It is the responsibility of the investigator to clearly and explicitly state how the proposed research is innovative and applicable to prostate cancer.**

Funding for NIAs can be requested for a maximum of $225,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year. Evidence should be supplied that there is institutional support and commitment to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and

equipment.

Submission of the same research project to the Fiscal Year 2002 (FY02) Prostate Cancer Research Program (PCRP) under different award mechanisms is not allowed, and all such duplicate submissions may be administratively withdrawn. This includes duplicate submissions under different award mechanisms by different PIs. The Government reserves the right to reject any proposal.

VI-B. Scientific Peer Review Evaluation Criteria for New Investigator Award Proposals

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

- **Innovation:** Is the proposed research innovative in one or more of the following areas: study concept or question; research methods or technologies; clinical interventions; adaptations of existing methods or technologies? Is it innovative in other ways? Are the aims original? Does the project propose new paradigms, or challenge existing paradigms? Is innovation necessary for the project?

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental design, methods, and analyses adequately developed and well integrated to the aims of the project? Is there a clear-cut rationale supporting the research provided? Are the aims based on logical reasoning? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? If included, do the preliminary data support the scientific rationale for the study?

- **Disease Relevance:** Does this study address a critical problem in prostate cancer research? 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 the proposal make a convincing case for the relevance of the research to prostate cancer?

- **Personnel:** Does the PI show potential for contributing to the prostate cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if applicable)? Is there appropriate expertise available to conduct the study successfully? Is the PI within 6 years of last fellowship or postdoctoral position? Has the PI received previous non-mentored funding as a PI or co-PI?

- **Environment:** Is there evidence that the scientific environment is 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 provided with the proposal?

- **Budget:** Is the budget appropriate for the research proposed?

VI-C. Resubmission of Previous Year Proposals

Proposals that have been declined for funding in a previous year may be resubmitted to the PCRP. The resubmission should meet the FY02 submission requirements and format guidelines for this award mechanism, but may also contain a 2-page section that addresses the major issues identified in the previous summary statement; a copy of the summary statement from the unfunded application should also be included. The resubmission statement should highlight and summarize deletions, additions, and other significant changes to the current submission, and be responsive to all aspects of the critique from the previous peer and programmatic reviews. Reference should be made to any new preliminary data included. Resubmissions that have not clearly taken into account the major comments or concerns resulting from the prior peer and programmatic reviews will be reviewed accordingly. See Appendix B, parts 3 and 11 for additional details.

VI-D. Programmatic Review Evaluation Criteria for New Investigator Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VI-E. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than 2 weeks prior to the award mechanism's receipt deadline. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02pcrp1.htm by April 15, 2002.

VI-F. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for NIAs. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1 and Statement of Eligibility form on page VI-8.
   In addition, New Investigator Award applicants must (1) be independent investigators, (2) be within 6 years or last fellowship of postdoctoral training, (3) have access to appropriate research facilities, and (4) have not received non-mentored funding as a PI or co-PI from the NIH, ACS, NSF, or the DOD.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number generated by the Proposal Information.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, NIA applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to prostate cancer research. Describe how the combination of innovation and relevance of the proposal will contribute to the goals of conquering prostate cancer and advancing research in the field.

11. Proposal Resubmission Statement – If applicable; see Appendix B, part 11.

12. Proposal Body – See Appendix B, part 12.
    The body of NIA proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used.

    For NIA proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Presentation of preliminary data is **not** required. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a

sound scientific rationale established through a critical review and analysis of the literature.

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/Rationale/Purpose: State the hypothesis to be tested and the expected results.

c. Objectives: State concisely the project's specific aims and research strategy.

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 all proposed syntheses. Outline and document the routes to each synthesis.

13. Abbreviations – See Appendix B, part 13.

14. References – See Appendix B, part 14.

15. Biographical Sketches – See Appendix B, part 15 and Appendix E.

16. Existing/Pending Support – See Appendix B, part 16.
For FY02 NIA, the applicant may not have received non-mentored funding as a PI or co-PI from the NIH, ACS, NSF, or the DOD.

17. Facilities/Equipment Description – See Appendix B, part 17.

18. Administrative Documentation – See Appendix B, part 18.
Provide the following items in the Administrative Documentation section of the proposal.

- A Statement of Eligibility form (page VI-8) signed by the applicant and Department Chair, Dean, or equivalent official, verifying that the applicant is an independent investigator within 6 years of their last fellowship or postdoctoral position who has not have received non-mentored funding as a PI or co-PI from the NIH, ACS, NSF, or the DOD and has access to appropriate research facilities and therefore is an eligible applicant for this award type.

- Letters of support from the institution and/or collaborating individuals.

Note: The signed Statement of Eligibility form and letters of support from the institution and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

Proposals lacking required administrative documentation may be considered noncompliant and therefore may not be forwarded for review (see Appendix B, part 18).

19. Detailed Cost Estimate – See Appendix B, part 19 and Appendix F.
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Funding for NIAs can be requested for a maximum of $225,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See part 7 of Appendix F for more details.

20. Instruments – See Appendix B, part 20.

21. Publications and/or Patent Abstracts – See Appendix B, part 21.

22. Proposal Submission – See Appendix B, part 22.

23. Submission Deadline – See Appendix B, part 23.
Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 16, 2002. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

24. Regulatory Compliance and Quality Requirements – See Appendix B, part 24.
All documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002. See Appendix B, part 24 for more details.

STATEMENT OF ELIGIBILITY

FY02 PCRP New Investigator Award

Applicant's Name:_____

Title of Proposal:_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of` Applicant:_____

I certify that the above-named investigator fulfills the requirements to be considered for a New Investigator Award and specifically meets all of the following criteria:

- Is an independent investigator;
- Is within 6 years or last fellowship or postdoctoral training;
- Has access to appropriate research facilities; and
- Has not have received non-mentored funding as a PI or co-PI from the National Institutes of Health, American Cancer Society, the National Science Foundation, or the Department of Defense

Name of Official (*please print*): _____

Title: _____

Organization: _____

Signature of Official:_____ Date:_____

Proposal Log Number: _____

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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VII. Idea Development Awards

VII-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 established investigators in other fields who want to move into prostate cancer research. To be eligible for an Idea Development Award, an applicant must be an independent investigator at the level of **Assistant Professor (or equivalent) or above.** All Idea Development Award proposals **must include preliminary data relevant to prostate cancer research and the proposed project** as well as a summary of the Principal Investigator's (PI's) research and professional experience in prostate cancer and/or potential for contribution to the field of prostate cancer.

Innovation is a significant feature of the Idea Development Award. Idea Development Award proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. Research that is innovative may represent a new paradigm, may challenge existing paradigms, or may look at existing problems from new perspectives. As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including the following:

- Study concept – investigation of a novel idea and/or unique research question
- Research method or technology – use of novel research methods or new technologies to address a research question
- Clinical interventions – use of a novel method or technology for preventing, diagnosing, or treating prostate cancer
- Adaptations of existing methods or technologies – application or adaptation of existing methods or technologies for research or clinical purposes that are fundamentally different from those originally intended, and/or for use under novel research or clinical purposes.

This list is not all-inclusive, but is intended to serve as a foundation on which to frame and present the innovative features of the proposal.

Funding for Idea Development Awards can be requested for a maximum of $375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment.

Submission of the same research project to the Fiscal Year 2002 Prostate Cancer Research Program (PCRP) under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms by different PIs. The Government reserves the right to

reject any proposal.

VII-B. Scientific Peer Review Evaluation Criteria for Idea Development Award Proposals

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

- **Innovation:** Is the proposed research innovative in one or more of the following areas: study concept or question; research methods or technologies; clinical interventions; adaptations of existing methods or technologies? Is it innovative in other ways? Are the aims original? Does the project propose new paradigms, or challenge existing paradigms? Is innovation necessary for the project?

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental design, methods, and analyses adequately developed and well integrated to the aims of the project? Is there a clear-cut rationale supporting the research provided? Does the applicant acknowledge potential problem areas and consider methods/alternative tactics? Do the required prostate cancer-relevant preliminary data support the proposed project?

- **Disease Relevance:** Does this study address a critical problem in prostate cancer research? 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 the proposal make a convincing case for the relevance of the research to prostate cancer?

- **Personnel:** 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 applicable)? Is appropriate expertise available to conduct the study successfully?

- **Environment:** Is the scientific environment appropriate for the proposed research? Do necessary resources and appropriate collaborative arrangements adequately support the research requirements? Is there evidence of institutional support provided with the proposal?

- **Budget:** Is the budget appropriate for the research proposed?

VII-C. Resubmission of Previous Year Proposals

Proposals that have been declined for funding in a previous year may be resubmitted to the PCRP. The resubmission should meet the FY02 submission requirements and format guidelines for this award mechanism, but may also contain a 2-page section that addresses the major issues identified in the previous summary statement; a copy of the summary statement from the unfunded application should also be included. The resubmission statement should highlight and summarize deletions, additions, and other significant changes to the current submission, and be responsive to all aspects of the critique from the previous peer and programmatic reviews.

Reference should be made to any new preliminary data included. Resubmissions that have not clearly taken into account the major comments or concerns resulting from the prior peer and programmatic reviews will be reviewed accordingly. See Appendix B, parts 3 and 11 for additional details.

VII-D. Programmatic Review Evaluation Criteria for Idea Development Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VII-E. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than 2 weeks prior to the award mechanism's receipt deadline. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02pcrp1.htm by April 15, 2002.

VII-F. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Development Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Ensure that one electronic PDF (Portable Document Format) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 14, 2002.**

Applicants unfamiliar with the preparation of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

1. Who May Apply – See Appendix B, part 1.
   Eligible Idea Development Award applicants must be independent investigators at the Assistant Professor level (or equivalent) or above.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and the proposal log number generated by the Proposal Information.

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Idea Development Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to prostate cancer research. Describe how the combination of innovation and relevance in the proposal will contribute to the goal of conquering prostate cancer and/or advancing research in the field.

11. Proposal Resubmission Statement – If applicable, see Appendix B, part 11.

12. Proposal Body – See Appendix B, part 12.
    The body of Idea Development Award proposals is limited to **10 pages**, inclusive of figures, tables, graphs, and photographs, if used. The inclusion of promising and well-founded preliminary data relevant to prostate cancer research and the proposed project is required for Idea Development 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. Include preliminary data relevant to prostate cancer research. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the project's specific aims and study design.

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.

13. Abbreviations – See Appendix B, part 13.

14. References – See Appendix B, part 14.

15. Biographical Sketches – See Appendix B, part 15 and Appendix E.

16. Existing/Pending Support – See Appendix B, part 16.

17. Facilities/Equipment Description – See Appendix B, part 17.

18. Administrative Documentation – See Appendix B, part 18.
Provide the following items in the Administrative Documentation section.

    Provide letter(s) of support from the institution and/or collaborating investigators in the Administrative Documentation section of each copy of the proposal submission.

    Note: The signed letter(s) of support from the institution and/or collaborators **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the submitted proposal.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

19. Detailed Cost Estimate – See Appendix B, part 19 and Appendix F.
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. In addition, budgets will be reviewed during award negotiations. Please provide complete justification for expenses in all categories. Idea Development Awards can be requested for a maximum of $375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, research-related injury medical costs (if applicable; see Part 7 of Appendix F), and travel to scientific meetings. The amount allotted for travel is $1,800 per year.

    For all Department of Defense-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See part 7 of Appendix F for more details.

20. Instruments – See Appendix B, part 20.

21. Publications and/or Patent Abstracts – See Appendix B, part 21.

22. Proposal Submission – See Appendix B, part 22.

23. Submission Deadline – See Appendix B, part 23.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) on May 14, 2002. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

24. Regulatory Compliance and Quality Requirements – See Appendix B, part 24.
    All documents related to Regulatory Compliance and Quality issues (RCQ) should be available on the CDMRP web site by April 2002. See Appendix B, part 24 for more details.

Proposal Log Number: _____

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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