



**DEPARTMENT OF DEFENSE**

**FISCAL YEAR 2001  
PROSTATE CANCER RESEARCH PROGRAM  
PROGRAM ANNOUNCEMENT II**

*February 14, 2001*



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 2001 (FY01) PCRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

General information on the USAMRMC can be obtained from the USAMRMC web site at <http://mrmc-www.army.mil>. Specific information on the DOD PCRP can be obtained from the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil>. A copy of this program announcement and associated forms (except for the Proposal Cover Booklet; see Section 6 on page iii of this Foreword) also can be downloaded from the CDMRP web site at <http://cdmrp.army.mil/funding/default>. Information on the U.S. Army Medical Research Acquisition Activity can be obtained at <http://www-usamraa.army.mil>.

### **1. Highlights of Changes from the FY00 Program Announcement**

- Proposals for the FY01 PCRP are being requested through the publication of two separate program announcements. Program Announcement I released on December 13, 2000 requests proposals in three previously established PCRP award mechanisms: Idea Development Awards, New Investigator Awards, and Postdoctoral Traineeship Awards. This program announcement (Program Announcement II) requests proposals in five newly established PCRP award mechanisms: Clinical Trial Awards, Consortium Development Awards, Historically Black Colleges and Universities (HBCU) Collaborative Partnership Awards, and two types of Health Disparity Prostate Scholar Awards.
- A structured technical abstract using the headings in Appendix B, part 8 is required for all proposals.
- All letters of support should be included in the Administrative Documentation section of all proposal copies rather than submitted in a sealed envelope.
- All foreign language transcripts must be accompanied by an English translation.
- Appendices related to Regulatory Compliance and Quality (Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) have been extensively revised.

### **2. Who May Apply**

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit and nonprofit organizations, public and private, such as 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. Receipt Deadlines

Proposal receipt deadlines for individual award mechanisms are provided in Section 4 (Timelines) below, and in the Reference Table of Award Mechanisms and Submission Requirements on page II-3. See Appendix B, part 22 for additional details.

### 4. Timelines

**The timeline for Health Disparity Training – Prostrate Scholar, Health Disparity Research – Prostate Scholar, HBCU Collaborative Partnership, and Clinical Trial Awards is:**

Letter of Intent:	As soon as possible but no later than May 23, 2001
Proposal Receipt Deadline:	<b>June 6, 2001 at 4:00 p.m. Eastern Time</b>
Peer Review:	August 2001
Request for RCQ <sup>1</sup> Documents:	As early as August 2001
Programmatic Review:	October 2001
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2002

**The timeline for Consortium Development Awards is:**

Letter of Intent:	As soon as possible but no later than May 23, 2001
Proposal Receipt Deadline:	<b>August 29, 2001 at 4:00 p.m. Eastern Time</b>
Programmatic Review:	October 2001
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2002

### 5. Inquiries

Questions concerning the preparation of proposals, formats, 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](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (PCRP01-Program Announcement II)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

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

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<sup>1</sup> Regulatory Compliance and Quality

## **6. Proposal Cover Booklet (Bubble Sheet)**

A Proposal Cover Booklet must be completed for each proposal according to the instructions found in Appendix C. Proposal Cover Booklets can be requested via phone, fax, e-mail, or mail at the following addresses/numbers. Please allow sufficient time for delivery by regular mail.

Phone: 301-682-5501 (8:00 a.m.-5:00 p.m. Eastern Time)  
Fax: 301-682-5521  
E-mail: prequest@unitedis.com  
Mail: Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (PCRP01-Program Announcement II)  
1077 Patchel Street (Building 1077)  
Fort Detrick, MD 21702-5024

## **7. Proposal Submission**

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

**Send the Proposal to:** Commander  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-PLF (PCRP01-Program Announcement II)  
1076 Patchel Street (Building 1076)  
Fort Detrick, MD 21702-5024

## Driving Directions to Fort Detrick

### From Washington, DC

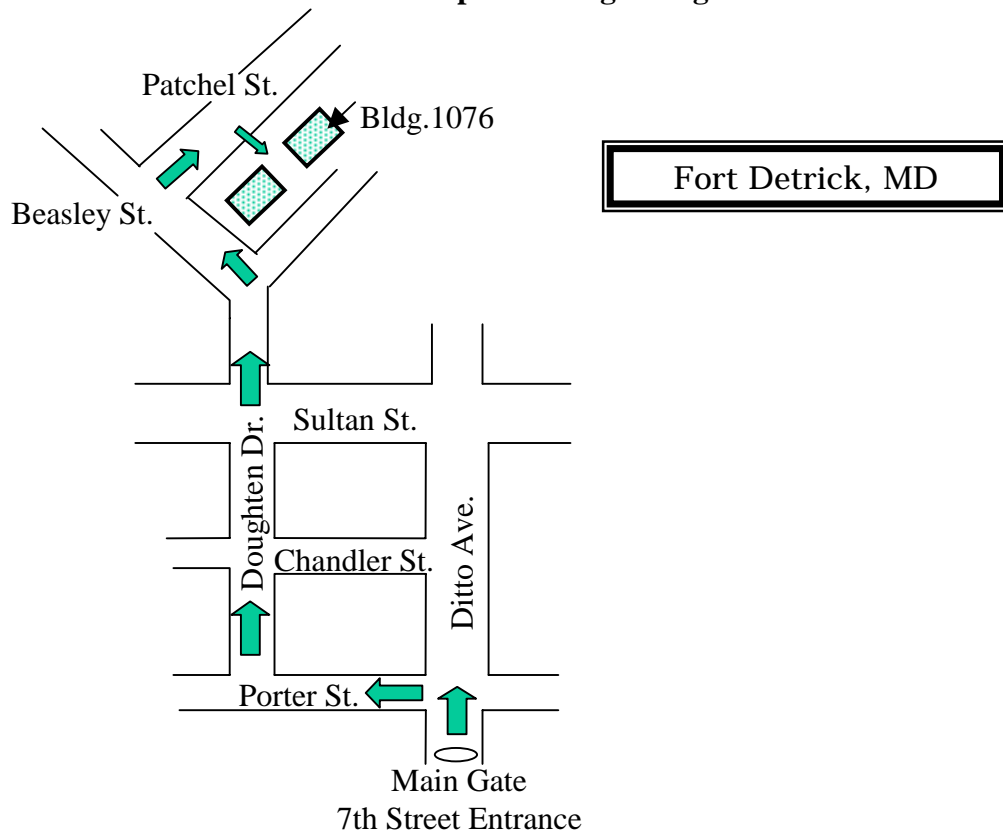
Take Interstate 495 to Interstate 270 North (exit 38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

### From Baltimore, MD

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

## Map of Fort Detrick

Packages to be delivered to the PCRP must be delivered to building 1076 as shown on the map below. To gain entry to Fort Detrick, you will be required to show your driver's license at the Main Gate. **Please allow at least 15 minutes to pass through the gate area.**



## **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 almost \$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 Sections III-B, IV-B, V-B, and VI-B). 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 as to make its completion implausible.

The peer review summary statement is a product of scientific peer review. Each 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, 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;
- Program portfolio balance with respect to research disciplines or specialty areas; and
- Other equitable factors, e.g., adequate support for new investigators.

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 funding 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**

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving Regulatory Compliance and Quality (RCQ), budget, and Statement of Work. All documents related to RCQ (environmental compliance, human subjects/anatomical substance use, animal use, and safety plan documents) will be requested in the applicant's notification letter and reviewed by RCQ staff. All proposals submitted with research involving human subjects and/or anatomical substances must be approved by the appropriate local review board. Proposals must also be approved by the U.S. Army Human Subjects Research Review Board (HSRRB). 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. Therefore, all investigators submitting such proposals must comply with the requirements detailed in the RCQ documents dealing with Research Involving Human Subjects and/or Anatomical Substances **before funded research can begin.**

Concurrent with the RCQ review, a Contract Specialist from the U.S. Army Medical Research Acquisition Activity 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.**

## **I-F. 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-G. Publications and Patents**

All investigators are strongly encouraged to publish their results in the 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 to the CDMRP a copy of any manuscript or publication resulting from research funded under the award.

In accordance with the Bayh-Dole Act (35 USC<sup>1</sup> 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.

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<sup>1</sup>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 \$38M for peer reviewed prostate cancer research. An additional \$38M was appropriated in FY98 to continue the PCRP. FY98 funds were combined with the FY97 appropriation due to the high quality of research proposals received in FY97 as well as the enthusiasm from Congress and the scientific and advocacy communities to rapidly distribute funds to scientists. The Program's success has encouraged Congress to appropriate additional funds to the PCRP in subsequent years to continue the peer reviewed PCRP, including \$50M in FY99, \$75M in FY00, and \$100M in FY01.

The program history of the FY97-00 PCRP is shown in Table II-1.

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

<b>Program History</b>	<b>FY97-99</b>	<b>FY00<sup>1</sup></b>
PCRP-Managed Appropriations for Peer Reviewed Research	\$126M	\$75M
Number of Full Proposals Received	1,271	680
Number of Proposals Funded	297	141
Number of Training/Recruitment Awards Funded	46	16
Number of Research Awards Funded	247	125
Number of Cancer Center Awards Funded	4	N/A <sup>2</sup>

<sup>1</sup>Award negotiations will not be finalized until September 2001.

<sup>2</sup>Not applicable.

### II-B. Overview of the Fiscal Year 2001 Prostate Cancer Research Program: Two Program Announcements

The Congressionally Directed Medical Research Programs (CDMRP) is requesting proposals for prostate cancer research and training in two separate program announcements. This program announcement (Program Announcement II) requests proposals in five newly established PCRP award mechanisms: Prostate Cancer Clinical Trial Awards, Prostate Cancer Consortium Development Awards, Health Disparity Training – Prostate Scholar Awards, Health Disparity Research – Prostate Scholar Awards, and Historically Black Colleges and Universities Collaborative Partnership Training Awards. Program Announcement I (released on December 13, 2000) requests proposals in three previously established PCRP award mechanisms: Idea Development Awards, New Investigator Awards, and Postdoctoral Traineeship Awards.

The overall goal of both announcements is to promote research directed toward conquering prostate cancer. Within this context, the objectives of the FY01 PCRCP 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 living with prostate cancer and their families.

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 PCRCP 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 2001 PCRCP Award Opportunities**

A total of \$100M was appropriated by Congress to fund the PCRCP in FY01. Prior to receipt of these funds by the CDMRP, approximately 6% is withheld by the DOD for Congressionally mandated requirements and DOD initiatives. An additional 10% is set aside to manage the program, including costs for peer and programmatic review of proposals and administration of the grants/contracts throughout their entire performance period. The investment strategy that is then executed reflects the remaining funds, which are invested in research and training in peer reviewed prostate cancer research. Approximately 85% of the original appropriation is therefore available to fund peer reviewed research.

For FY01, approximately \$85M is available to fund a competitive peer reviewed research program. Approximately \$67M will be used to fund proposals requested in response to Program Announcement I, while the remaining \$18M will be used to fund proposals requested in response to Program Announcement II. The programmatic strategy for Program Announcement II is to fund proposals in three categories: (1) training/recruitment awards, (2) infrastructure awards, and (3) research awards.

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

## Reference Table of Award Mechanisms and Submission Requirements

Award Mechanism	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available	Receipt Deadline	Instructions for Proposal Preparation
Health Disparity Training – Prostate Scholar Awards	Predoctoral, Postdoctoral, and Postresidency	<ul style="list-style-type: none"> <li>Provides training opportunities to focus on the disparate burden of prostate cancer in African Americans</li> </ul>	\$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	June 6, 2001 4:00 p.m. ET*	Section III
Health Disparity Research – Prostate Scholar Awards	Assistant Professor or equivalent	<ul style="list-style-type: none"> <li>Supports researchers to focus on the disparate burden of prostate cancer in African Americans</li> </ul>	\$300,000 for direct costs over a 3-year performance period	June 6, 2001 4:00 p.m. ET	Section IV
Historically Black Colleges and Universities Collaborative Partnership Awards	Faculty member (with doctoral degree) working at an HBCU	<ul style="list-style-type: none"> <li>Fosters collaborations at an institutional level between an HBCU and another institution</li> <li>Provides support for infrastructure and training for HBCU faculty with the goal of establishing a sustained prostate cancer research training program at the HBCU</li> </ul>	\$600,000 for direct costs over a 3-year performance period	June 6, 2001 4:00 p.m. ET	Section V
Prostate Cancer Clinical Trial Awards	All levels of experience	<ul style="list-style-type: none"> <li>Funds prospective Phase I or Phase II clinical trials</li> <li>Focus on new therapeutics or treatments</li> <li>Collect correlative data that addresses the underlying mechanisms of clinical efficacy</li> </ul>	Up to \$2M for direct costs over a 3-year performance period, plus indirect costs as appropriate	June 6, 2001 4:00 p.m. ET	Section VI
Prostate Cancer Consortium Development Awards	Established Prostate Cancer Investigator with a record of leadership and scientific ability	<ul style="list-style-type: none"> <li>Provides support to establish necessary collaborations and develop preliminary infrastructure for a FY02 Prostate Cancer Consortium Award</li> <li>Prostate Cancer Consortium awards are intended to fund major, coordinated, goal/product-driven research effort that is national in scope</li> </ul>	\$150,000 inclusive of direct and indirect costs for Consortium Development Awards over a 1-year performance period (Consortium Awards will be for a maximum of \$15M over a 3-year performance period <b>pending availability of FY02 funds</b> )	August 29, 2001 4:00 p.m. ET	Section VII

\*Eastern Time

**Important note regarding duplicate submissions:** Submission of the same research project to the FY01 PCRP under different award mechanisms in response to either Program Announcement I or Program Announcement II will not be allowed. This includes submissions under different award mechanisms from different principal investigators. All such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.

### III. Health Disparity Training – Prostate Scholar Awards

#### III-A. Health Disparity Training – Prostate Scholar Awards

African Americans have the highest prostate cancer incidence rates in the world.<sup>1</sup> Health Disparity Training – Prostate Scholar Awards (HDT-PSA) 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. It is the responsibility of the applicant to clearly articulate how the proposed research training addresses this disease disparity. **For the purposes 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.** 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, expenses including research supplies, 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, 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

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<sup>1</sup>American Cancer Society, *Cancer Facts & Figures – 2000*.

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, and travel to scientific meetings. The amount allotted for travel is \$1,500 per year.

**Submission of the same research project to the FY01 PCRP under different award mechanisms in response to either Program Announcement I or Program Announcement II will not be allowed. This includes submissions under different award mechanisms from different principal investigators (PIs). All such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.**

Approximately \$2.5M will be available for both types of Prostate Scholar Awards (i.e., HDT-PSA and Health Disparity Research – Prostate Scholar Awards [see Section IV]).

### **III-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:

- **Candidate:** Does the candidate demonstrate a connection to, or an effectiveness in working with, the African American community? Do the candidate'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 candidate? 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 take place in an environment that is appropriate to accomplishing the applicant's goals? 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 candidate's research program, and appropriate to the candidate's level? Is the candidate 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 reasonable? Are there sufficient overall financial resources to support the proposed training?

### **III-C. Programmatic Review Evaluation Criteria for Health Disparity Training – Prostate Scholar Awards**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, does the proposal meet the goals and intent of the HDT-PSA mechanism? Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

### **III-D. Letter of Intent**

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a Letter of Intent no later than 2 weeks prior to the receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil/default>

### **III-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.** Ensure that the proposal is received by **June 6, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1 and the Statement of Eligibility on page III-7. **In addition, applicants to the HDT-PSA must show a connection to, or effectiveness in working with the African American community.**
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Cover Booklet – 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).
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 prostate cancer. **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.** Due to the importance of the relevance to prostate cancer disparity, Relevance Statements will be forwarded to Programmatic Reviewers.
11. Proposal Body – See Appendix B, part 11.  
The body of HDT-PSA proposals is limited to **10 pages**. Figures, tables, graphs, and photographs, if used, must be included in this section.  
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. 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 specific aims and the research strategy of the project.
  - 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.
12. Abbreviations – See Appendix B, part 12.
  13. References – See Appendix B, part 13.
  14. Biographical Sketches – See Appendix B, part 14 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.
  15. Existing/Pending Support – See Appendix B, part 15.  
It is especially important to provide documentation of existing/pending support involving the mentor to document that there is adequate support in the training environment for the trainee.
  16. Facilities/Equipment Description – See Appendix B, part 16.
  17. Administrative Documentation – See Appendix B, part 17.  
Include the following items in this section of every copy of the proposal submission.
    - A list of all items included in the Administrative Documentation section. This list must be the first item in this section.
    - A Statement of Eligibility form (see page III-7) 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 from the mentor describing his/her commitment to the training/career development/mentorship of the candidate, the nature of the proposed collaboration/training, and his/her commitment to supporting research on prostate cancer disease disparity. This letter should also describe the degree to which the candidate participated in idea development and proposal preparation, as well as the degree to which the candidate 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/her experience in prostate cancer research and in training students and postdoctoral fellows. Note: Letters of support **will not** be accepted separately from the application.

- For Postresidency Traineeships, a letter of institutional support describing the level of institutional 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, equipment; and (3) opportunities for critical professional interaction with senior colleagues.
- Two additional letters of recommendation. Note: Letters of recommendation **will not** be accepted separately from the application.
- Letters of support from any collaborating investigators.

Note: Support documentation **will not** be accepted separately from the proposal submission.

**Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).**

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.  
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. Training awards frequently have a different institutional overhead charge. All training award investigators are encouraged to check with their institution concerning overhead costs. The amount allotted for travel is \$1,500 per year.
19. Instruments – See Appendix B, part 19.
20. Publications and Patent Abstracts – See Appendix B, part 20.
21. Proposal Submission – See Appendix B, part 21.
22. Receipt Deadline – See Appendix B, part 22.  
Please note that the **receipt deadline for all Health Disparity Training – Prostate Scholar Award proposals is June 6, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**
23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**STATEMENT OF ELIGIBILITY**  
**FY01 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: \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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Abbreviations (1-page limit) .....	___
References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
PI .....	___
Mentor .....	___
Collaborating Investigators .....	___
Existing/Pending Support (no page limit) .....	___
Facilities/Equipment Description (no page limit) .....	___
Administrative Documentation (no page limit) .....	___
List of items included in this section.....	___
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Graduate transcripts.....	___
Statement of Eligibility form.....	___
Letter from mentor .....	___
Two letters of recommendation.....	___
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Letters of support from collaborating individuals or institutions.....	___
Detailed Cost Estimate (no page limit) .....	___
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## **IV. Health Disparity Research – Prostate Scholar Awards**

### **IV-A. Health Disparity Research – Prostate Scholar Awards**

African Americans have the highest prostate cancer incidence rates in the world.<sup>1</sup> Health Disparity Research – Prostate Scholar Awards (HDR-PSA) 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. It is the responsibility of the applicant to clearly articulate how the proposed research addresses this disease disparity. **For the purposes 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.**

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 purposes of this program an HDR-PSA is intended for an individual who holds a position as an Assistant Professor or equivalent. Proposals must include a discussion of the level of institutional 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/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-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, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year.

**Submission of the same research project to the FY01 PCRCP under different award mechanisms in response to either Program Announcement I or Program Announcement II will not be allowed. This includes submissions under different award mechanisms from different principal investigators (PIs). All such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.**

Approximately \$2.5M will be available for both types of Prostate Scholar Awards (i.e., HDR-PSA and Health Disparity Training – Prostate Scholar Award [see Section III]).

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<sup>1</sup>American Cancer Society, *Cancer Facts & Figures – 2000*.

## **IV-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:

- **Candidate:** Does the candidate demonstrate a connection to, or an effectiveness in working with, the African American community? Do the candidate'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?
- **Research Program:** Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed and well integrated for the candidate's research program? Is the candidate 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?
- **Scientific 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?
- **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 candidate 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 candidate's development of a research program addressing the disparity in prostate cancer?
- **Budget:** Is the budget reasonable?

## **IV-C. Programmatic Review Evaluation Criteria for Health Disparity Research – Prostate Scholar Awards**

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance. For example, does the proposal meet the goals and intent of the HDR-PSA mechanism? 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 a Letter of Intent no later than 2 weeks prior to the receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil/default>

#### **IV-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for HDR-PSA. 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.** Ensure that the proposal is received by **June 6, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1 and Statement of Eligibility on page VI-7.

**In addition, applicants to the HDR-PSA must show a connection to, or effectiveness in working with, the African American community.**

2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – 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).
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 the disparate burden of prostate cancer in African Americans. Applicants should describe their 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 Body – See Appendix B, part 11.

The body of HDR-PSA proposals is limited to **10 pages**. Figures, tables, graphs, and photographs, if used, must be included in this section.

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 specific aims of the study.
- d. **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for 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.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

Provide documentation of existing/pending support that reflects the commitment of the collaborating investigator or institutional commitment.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

Include the following items in this section of every copy of the proposal submission.

- A list of all items included in the Administrative Documentation section. This list must be the first item in this section.

- A Statement of Eligibility form (see page IV-7) signed by the applicant and the Department Chair, Dean, or equivalent official verifying that the applicant meets the relevant eligibility criteria.
- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution describing the level of institutional 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, equipment; and (3) opportunities for critical professional interaction with senior colleagues.
- Letter(s) of support from collaborator(s).

Note: Support documentation **will not** be accepted separately from the proposal submission.

**Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).**

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.  
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. The amount allotted for travel is \$1,800 per year.
19. Instruments – See Appendix B, part 19.
20. Publications and Patent Abstracts – See Appendix B, part 20.
21. Proposal Submission – See Appendix B, part 21.
22. Receipt Deadline – See Appendix B, part 22.  
Please note that the **receipt deadline for all Health Disparity Research-Prostate Scholar Award proposals is June 6, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**
23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**STATEMENT OF ELIGIBILITY**  
**FY01 Health Disparity Research – 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 requirements to be considered for a Health Disparity Research – Prostate Scholar Award and specifically meets the following criteria:

- Holds a faculty position at the assistant professor or equivalent level, and
- Has access to appropriate facilities and equipment.

Name of Official (*please print*): \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Signature of Official: \_\_\_\_\_ Date: \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

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PI .....	___
Collaborating Investigators .....	___
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## **V. Historically Black Colleges and Universities Collaborative Partnership Awards**

### **V-A. Historically Black Colleges and Universities Collaborative Partnership Awards**

African Americans have the highest prostate cancer incidence rates in the world.<sup>1</sup> Historically Black Colleges and Universities (HBCU) Collaborative Partnership Awards are institutionally based awards intended to intensify the commitment of the prostate cancer research community to investigate the disparate burden of prostate cancer in African American men. To effectively address this issue, these awards are directed at HBCU as a means to increase the number of HBCU scientists who are trained as prostate cancer researchers. The major goal of this award is to establish stable, long-term partnerships between an applicant HBCU and a collaborating non-HBCU institution to (1) provide mentorship and collaborative research opportunities for HBCU scientists, clinicians, and trainees; (2) develop, promote, and sustain independent, competitive research and training programs at the HBCU; and (3) increase the number of HBCU investigators focused on prostate cancer research. **Although the applicant and proposal submission must be from an HBCU, a strong institutional commitment must be demonstrated by both partners.** Established investigators from collaborating institutions must have a strong record of funding and achievement in prostate cancer research.

This award provides support to both the applicant HBCU and the collaborating partner to establish a prostate cancer training and research program at the HBCU. HBCU Collaborative Partnership Awards will provide investigators and trainees opportunities to collaborate, train, and acquire the knowledge and experience necessary to address significant and relevant problems in prostate cancer as they relate to the African American community. These awards should enhance the HBCU faculty's and trainees' skills and experiences to enable them to maintain a competitive and successful program in prostate cancer research. The focus of these awards should be on disease disparity, support and training of HBCU investigators, and the development of a sustainable research/training program. A key element of these proposals will be the project director, who must be an HBCU faculty member holding a doctoral degree who can demonstrate the ability to bring together the necessary collaborators and manage the partnership. Proposals should describe a plan to build a foundation and develop the necessary infrastructure for a research and training program at the HBCU that addresses disease disparity. Proposals may target any aspect of prostate cancer biology, etiology, prevention, detection, diagnosis, and/or treatment **provided there is a clear connection to the overarching problem of disease disparity in the African American population.** Site visits will be conducted at recipient institutions to monitor progress of the collaborative partnership.

Approximately \$2.25M will be available for awards under this mechanism. These awards can be requested for a maximum of \$600,000 in direct costs over a 3-year performance period. Direct costs for HBCU Collaborative Partnership Awards can cover salary support, postdoctoral traineeships, tuition for special training and/or education, consultation with established

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<sup>1</sup>American Cancer Society, *Cancer Facts & Figures – 2000*.

investigators, consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Collaborating institutions may receive up to 40% of first year total costs. However, no more than 25% of total costs for the full award can be granted to collaborating institutions during the lifetime of an award.

Only one HBCU Collaborative Partnership proposal may be submitted from any HBCU.

**Submission of the same research project to the FY01 PCRCP under different award mechanisms in response to either Program Announcement I or Program Announcement II will not be allowed. This includes submissions under different award mechanisms from different program investigators (PIs). All such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.**

## **V-B. Scientific Peer Review Evaluation Criteria for HBCU Collaborative Partnership Award Proposals**

HBCU Collaborative Partnership Award proposals will be evaluated according to the following criteria:

- **Project Director:** Is the Project Director an HBCU faculty member and does he/she have the appropriate qualifications and experience to coordinate and manage the partnership? Has the Project Director been able to establish appropriate collaborations? Does the project director devote an appropriate effort to this partnership?
- **Applicant Institution:** Will the collaboration advance the applicant institution's capability to develop a research/training program in prostate cancer? Does the applicant institution play the primary role in conception, design, and direction of the proposed partnership?
- **Collaborating Institution:** Does the collaborating institution have the background, qualifications, experience, and personnel in prostate cancer research to develop a productive collaboration with the applicant institution? Is the collaborating institution committed to the applicant institution's development both during and after the funding period of this award?
- **Training/Research Plan:** Is there a reasonable plan to develop an ongoing program in prostate cancer research and training at the HBCU by the end of the award period? Does the research plan address the disparate burden of prostate cancer in African Americans? Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed? How do the collaborating and applicant institutions propose to sustain the interactive environment necessary for the development of an effective program? Does the proposed partnership develop a credible environment at the applicant institution to increase the numbers of investigators focused on prostate cancer research?
- **Scientific Relevance:** Does the proposed research address the disparity in prostate cancer incidence, morbidity, and mortality between African Americans and other ethnic groups?

Do the proposed research and training concepts clearly focus on prostate cancer biology, etiology, prevention, detection, diagnosis, and/or treatment as they relate to the African American population?

- **Budget:** Is the budget reasonable for the work proposed?

### **V-C. Programmatic Review Evaluation Criteria for HBCU Collaborative Partnership 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. For example, is the award likely to train investigators at an HBCU to perform high quality research and become successful, independent prostate cancer researchers? Does the proposal meet the intent of the HBCU Collaborative Partnership Award mechanism? Additional details on programmatic review 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 a Letter of Intent no later than 2 weeks prior to the proposal receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the Congressionally Directed Medical Research Programs (CDMRP) web site at <http://cdmrp.army.mil/default>

### **V-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following proposal preparation information is specific for HBCU Collaborative Partnership Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of figures, tables, and graphs, and that the **receipt deadline is June 6, 2000 at 4:00 p.m. Eastern Time**.

1. Who May Apply – See Appendix B, part 1.  
The list of HBCU as recognized by the Department of Education is available at the CDMRP web site at <http://cdmrp.army.mil/default>
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Proposal Cover Booklet – See Appendix B, part 3 and Appendix C.
4. Peer Review Referral Page – See Appendix B, part 4.
5. Proposal Title Page – See Appendix B, part 5.  
**The project director should be the principal investigator on the title page.**
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).

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, HBCU Collaborative Partnership Award applicants should describe explicitly (within the 1-page limit) the plan for developing a prostate cancer research and training program at the HBCU. **Specifically state how the proposed partnership addresses the overarching problem of prostate cancer disparity in African Americans.** Articulate how the proposal’s combination of training and relevance to prostate cancer biology, etiology, prevention, detection, diagnosis, and/or therapy will prepare the HBCU participants as successful prostate cancer researchers.

11. Proposal Body – See Appendix B, part 11.

The body of HBCU Collaborative Partnership Awards proposals is limited to **10 pages**. Figures, tables, and graphs, if used, must be included within this section.

Describe the proposed partnership using the general outline provided below:

- a. Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the HBCU and the collaborating institution should be articulated. Qualifications and facilities of the collaborating institution should be addressed. Document the experience of the collaborating institution in developing institutional training and research programs and in acquiring funding in prostate cancer research. Include information on training/collaborations with HBCU investigators.
- b. Research/Training Program: Describe explicitly the value of the proposed research/training as it relates to the applicant institution’s plans for developing a prostate cancer research/training program that will increase the number of HBCU scientists working on prostate cancer disparity. Proposals must include a clearly articulated plan for a research/training program that focuses on biology, etiology, prevention, detection, diagnosis, and or treatment that addresses the disparity of prostate cancer in African Americans. Plans for supporting postdoctoral trainees can be included in this section. Articulate how the proposal will catalyze the applicant institution’s development of successful prostate cancer research training programs.
- c. Communication: Outline a plan for preparing reports issued between the applicant and the collaborating institutions and document progress showing how each institution is responding to problems, etc. Please note that these “status reports” cannot be used in lieu of actual meetings and the communications between the institutions’ faculties.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

For HBCU Collaborative Partnership Award proposals, biographical sketches should be prepared for the participants at the applicant institution, participants at the collaborating institution, and each of the key personnel, including all collaborating investigators listed on the budget page for the initial budget period.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

Include the following items in this section of every copy of the proposal submission.

- A list of all items included in the Administrative Documentation section. This list must be the first item in this section.
- A letter signed by the Department Chair, Dean, or equivalent official from the applicant institution assuring the commitment of the institution to the proposed program. This letter should reflect the extent to which the institution will support the collaboration by relieving participants of their academic and/or clinical responsibilities to have additional time for research and training, providing access to appropriate facilities, and providing opportunities for professional interactions with senior colleagues.
- The Statement of Eligibility form (see page V-7). This form is to be signed by the Department Chair, Program Director, Dean, or equivalent official at the applicant institution indicating that the project director holds a faculty position at an HBCU and possesses a doctoral level degree and therefore is an eligible applicant for this award.
- A letter signed by the Department Chair, Program Director, Dean, or equivalent official at the collaborating institution describing a commitment to the training/development/mentorship of the applicant institution and the nature of the proposed research/training.
- Letters of support from any additional consultants/collaborators or institutions that will be supplying essential assistance to the proposed project describing their roles in the research/training.

Note: Support documentation **will not** be accepted separately from the proposal submission.

**Proposals lacking required administrative documentation may be considered noncompliant and thus not be forwarded for review (see Appendix B, part 21).**

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

HBCU Collaborative Partnership Awards can be requested for an average of \$200,000 per year, for a maximum of \$600,000 over 3 years for direct costs. Collaborating institutions may receive up to 40% of first year total costs. However, no more than 25% of total costs for the full award can be granted to collaborating institutions during the lifetime of an award. Direct costs for HBCU Collaborative Partnership Awards can cover salary support, tuition for special training and/or education, consultation with established investigators, consultation

with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, and expenses including research supplies, office supplies, and travel. Funds may be requested for postdoctoral trainees. Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs. Funds also may be used to establish formal technical assistance programs in which experienced and well-funded investigators provide consultation and mentoring in grant writing and grantsmanship. The amount allotted for travel is \$1,800 per year for senior investigators and \$1,500 per year for postdoctoral trainees from the HBCU to attend scientific/technical meetings.

It is the policy of the Department of Defense that all commercial and nonprofit recipients provide the equipment needed to support proposed research (see Appendix F). However, the need for equipment support at an HBCU institution is recognized and will be taken into consideration during the review and negotiation process.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for HBCU Collaborative Partnership Award proposals is June 6, 2001 at 4:00 p.m. Eastern Time.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**STATEMENT OF ELIGIBILITY**  
**FY01 HBCU Collaborative Partnership 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 an HBCU Collaborative Partnership Award and specifically meets the following criteria:

- Holds a faculty position at an HBCU, and
- Holds a doctoral degree (M.D., Ph.D., D.V.M., or equivalent).

Name of Official (*please print*): \_\_\_\_\_

Title: \_\_\_\_\_

Organization: \_\_\_\_\_

Signature of Official: \_\_\_\_\_ Date: \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_  
Last Name First Name MI

**Proposal Title:** \_\_\_\_\_  
\_\_\_\_\_

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**Health Disparity Research – Prostate Scholar Award Proposal  
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References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
Project Director .....	___
Participating Investigators at HBCU.....	___
Participating Investigators at Collaborating Institution .....	___
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## VI. Prostate Cancer Clinical Trial Awards

### VI-A. Prostate Cancer Clinical Trial Awards

The intent of Prostate Cancer Clinical Trial (Clinical Trial) Awards is to fund prospective Phase I or Phase II clinical trials in the areas of prostate cancer therapy, diagnosis, detection, and prevention. The particular target, pathway, molecule, or device that is the focus of the clinical trial must be clearly identified. These awards are intended to focus on clinical trials of new therapeutics or treatments rather than refining administration of existing therapies (e.g., optimizing timing or dosage regimens). Proposals must include a strategy to collect correlative data that addresses the underlying mechanisms of clinical efficacy. Clinical Trial Awards are for the support of projects that are likely to have a major impact on the prevention, diagnosis, or treatment of prostate cancer by applying promising and well-founded laboratory or other preclinical findings to the care of patients with prostate cancer. ***Applicants must include data to support the feasibility of their hypotheses and approaches, along with a plan to conduct a prospective clinical trial or study.*** The inclusion of a clear experimental and appropriately powered statistical plan to perform a prospective clinical trial or study is a requirement for consideration. The clinical trial proposed as part of the submission must be ready for patient enrollment upon receipt of funds. These awards are intended to support both new and established scientists across a broad spectrum of disciplines.

Approximately \$12.5M is available for Clinical Trial Awards. Support for Phase I trials and correlative studies can be requested for a maximum of \$1M in direct costs over a 2-year performance period, plus indirect costs as appropriate. Support for Phase II or Phase I/Phase II trials and correlative studies can be requested for a maximum of \$2M in direct costs over a 3-year performance period, plus indirect costs as appropriate. Investigators should document supplemental support as appropriate, e.g., provision of drugs by the pharmaceutical company or other sources. The focus of the award should be on the clinical trial and the corresponding correlative mechanistic work.

**Submission of the same research project to the FY01 PCRP under different award mechanisms in response to either Program Announcement I or Program Announcement II will not be allowed. This includes submissions under different award mechanisms from different principal investigators (PIs). All such duplicate submissions may be administratively withdrawn. The Government reserves the right to reject any proposal.**

### VI-B. Scientific Peer Review Evaluation Criteria for Prostate Cancer Clinical Trial Award Proposals

- **Trial Design:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed, well integrated, and innovative? Is there adequate laboratory and other pre-clinical evidence to support the clinical feasibility and promise of the approach? Does the proposal emphasize mechanistic studies of a correlative nature, i.e., does the study address underlying mechanisms as they relate to clinical efficacy? Will the clinical trial proposed as

part of the submission be ready for patient enrollment upon receipt of funds? Does the applicant acknowledge potential problem areas and consider alternative approaches? Have the availability of subjects for the trial and the likelihood of subject attrition been addressed? Is the recruitment schedule reasonable?

- **Clinical Relevance and Impact:** Does the study address an important problem in the area of prostate cancer therapy, diagnosis, detection, or prevention? If the aims of the application are achieved, are they likely to have a *substantial clinical impact*?
- **Statistical Plan:** Is the design of the clinical trial sound and sufficiently well developed with the *required statistical power* to lead to meaningful results? Is there a clear statistical plan, including power analysis, outlined in the proposal? Is the appropriate statistical expertise represented on the research team?
- **Personnel:** Does the PI have expertise in prostate cancer research and experience conducting clinical trials? Are the other scientific personnel well qualified to participate in the project? Is there representation from all the areas of expertise needed to conduct the study successfully?
- **Environment:** Is the scientific environment an appropriate setting for the proposed research? Are the pre-clinical and clinical requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Are letters of commitment included from the participating centers? Are there assurances that the therapies to be evaluated are available?
- **Budget:** Is the budget reasonable for the research proposed?

## VI-C. Programmatic Review Evaluation Criteria for Prostate Cancer Clinical Trial Awards

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-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than 2 weeks prior to proposal receipt deadline. This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default>

## **VI-E. Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Clinical Trial Awards. Please note that the body of the proposal is limited to **25 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that the proposal is received by **June 6, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – 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).
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, Clinical Trial Award applicants should state explicitly (within the 1-page limit) how the proposed work meets the intent of the Clinical Trial Award mechanism.
11. Proposal Body – See Appendix B, part 11.  
The body of Clinical Trial Award proposals is limited to **25 pages**. Figures, tables, and graphs, if used, must be included within this section.  
Describe the proposed project using the general outline below:
  - a. **Background:** Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to the proposal; provide an overview of the state of the science, and the relevance of the trial. Cite relevant literature references as appropriate.
  - b. **Hypothesis/Rationale/Purpose:** State the hypothesis to be tested and the expected results.
  - c. **Objectives:** State concisely the specific aims of the study.



- d. Preliminary Studies: A presentation of the studies that led to the proposed clinical trial is required. Data from pilot studies and additional supporting data from other research that support the necessity, feasibility, and potentiality of the trial should also be provided.
- e. Correlative Studies: Present a plan to collect correlative data that addresses the underlying mechanism of clinical efficacy.
- f. Clinical Protocol: Include a discussion of the following topics.
  - Study design for the intervention(s) to be used.
  - Potential biases in the research protocol and how they will be addressed.
  - Clinical, behavioral, laboratory, and physiological tests and protocols.
  - Patient recruitment, including (1) patient availability; (2) inclusion and exclusion criteria; (3) methods for recruiting, retention, and follow-up; (4) data to support recruitment/retention estimates; (5) patient assignment to experimental groups and methods of randomization (if any); and (6) study endpoints.
  - Data management, including the (1) overall approach to data management; (2) a statistical plan that includes sample size calculations and methods to monitor quality and consistency of both the intervention(s) and data collection; and (3) data security measures.
  - Methods of analysis (primary and secondary endpoints should be clearly defined and related to the power calculation).
  - Any issues that may lead to concern for the welfare of human subjects and confidentiality.
  - A study organization and management plan, including an organizational chart and timetable.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support-See Appendix B, Part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.

Include the following items in this section of every copy of the proposal submission.

- A list of all items included in the Administrative Documentation section. This list must be the first item in this section.

- Letters of support from proposed collaborating individuals or institutions confirming collaborative efforts that are necessary for the projects success. Also include letters documenting outside support (e.g., the provision of a drug by a drug company).

Note: Support documentation **will not** be accepted separately from the proposal submission.

**Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).**

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.

Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. A budget for the entire trial and data analysis period must be provided. If some costs of the trial are to be funded through other sources, provide detailed information about these sources. Budgets should clearly delineate which portions are being requested for support by this program and which are to be supported by other sources. A total overall budget as well as itemized, individual budgets for each year of support requested must be prepared. If multiple centers are proposed or if any subcontract(s) for personnel or facilities exist, separate itemized budgets must be prepared for each year of the study. Direct costs can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year per PI to attend scientific/technical meetings.

19. Instruments – See Appendix B, part 19.

20. Publications and Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Receipt Deadline – See Appendix B, part 22.

Please note that the **receipt deadline for Prostate Cancer Clinical Trial Award proposals is June 6, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.

**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

\_\_\_\_\_

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References (no page limit) .....	___
Biographical Sketches (3-page limit each)	
PI .....	___
Key Personnel (including collaborating investigators, individuals in training, and support staff) .....	___
Existing/Pending Support (no page limit) .....	___
Facilities/Equipment Description (no page limit) .....	___
Administrative Documentation (no page limit) .....	___
Letters of support from collaborating individuals or institutions .....	___
Letters documenting outside support .....	___
Detailed Cost Estimate (no page limit) .....	___
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## **VII. Prostate Cancer Consortium Awards and Consortium Development Awards**

The intent of Prostate Cancer Consortium (Consortium) Awards is to develop a major, coordinated, goal/product-driven research effort that involves the nation's leading prostate cancer researchers and focuses on an overarching problem relevant to the prevention, detection, diagnosis, treatment, or cure of prostate cancer. Unlike other mechanisms, the Consortium Award will be executed through two separate awards, the Prostate Cancer Consortium Development (Consortium Development) Award in fiscal year 2001 (FY01) and, pending receipt of funds for FY02, the Prostate Cancer Consortium (Consortium) Award in FY02. Proposals for the first award, the Consortium Development Award, are being requested in this program announcement. Recipients of the Consortium Development Award in FY01 will be required to submit proposals to compete for the Consortium Award in FY02. Funding for the Consortium Development Award in FY01 is up to \$150,000 per award inclusive of both direct and indirect costs for 1 year. Funding for the Consortium Award in FY02 is anticipated to be up to \$15M per award over a 3-year period of performance.

### **VII-A. Prostate Cancer Consortium Awards**

Descriptions of the scope and intent of the Consortium Award are provided here to assist investigators in preparing proposals for the Prostate Cancer Consortium Development Award. Consortium Awards are intended to involve the nation's leading prostate cancer researchers and to support goal/product-driven research efforts focused on a common theme that represents a critical area of prostate cancer research. Each consortium should comprise a multidisciplinary/multi-institutional (a minimum of two institutions) research team made up of scientists and/or clinicians who have made significant contributions or have specific expertise related to the central research theme addressed in the proposal. These awards should accelerate research progress through real-time communication and problem solving, and by incorporating multiple, overlapping, parallel projects that approach the research problem from a variety of perspectives. Collaborations established through the consortium should result in a synergistic research project rather than an additive set of subprojects (i.e., the combined efforts of the whole consortium provide greater benefit than the sum of individual research initiatives). The overall goal of these awards is to accelerate advances in prostate cancer research and to support the Prostate Cancer Research Program (PCRP) goal of eliminating prostate cancer. The development of effective means of coordinating research progress and results in real time across all disciplines and all institutions involved is central to the success of the consortium. The PCRP Integration Panel will serve as an external advisory board for the consortium.

Consortium Award proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiological research, including basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Although a clinical trial may be a part of the consortium plan, inclusion of a clinical trial is not a requirement. The items below illustrate the scope and theme of projects that may be appropriate for the focus of Consortium awards. These are examples only and

should not be considered indicative of preferred or more desirable research areas. Applicants are encouraged to identify original research problems that might best be addressed through development of a research consortium.

- A consortium focused on developing specific drugs aimed at androgen receptor (AR) changes in androgen-independent (AI) prostate cancer. Questions that might be addressed by consortium participants include identification and relevance of genetic changes in AR, identification of structural or functional differences in AR, identification of biomarkers for changes in AR, development of drugs targeting changes in AR and AR signaling that may prevent AI cell proliferation, and development of plans for clinical trials and patient accrual.
- A consortium focused on development of antibody-based immunotherapy for prostate cancer. Problems that might be addressed by this consortium include identification or creation of optimum prostate cancer-related antigens, development of anti-prostate cancer antibodies coupled with novel therapeutic agents, development of strategies for the localization or time-release of antibody delivery, optimization of novel immunostimulatory strategies, and development of plans for clinical trials and patient accrual.

The Consortium Director, i.e., the principal investigator (PI) on the proposal, should have a proven track record of leadership and scientific ability to direct and oversee the overall research effort and have experience in managing multifaceted projects. Each Consortium should maximize the utilization of resources and minimize unnecessary duplication among consortium members; e.g., experimental techniques, databases, models, animal models, antibodies, etc. should be shared resources for all consortia members.

## **VII-B. Prostate Cancer Consortium Development Awards**

Due to the scope and magnitude of the consortium awards, the Consortium Development Award is intended to provide support to establish the necessary collaborations and develop the preliminary infrastructure, including a coordination core, that will provide the foundation for a Consortium Award. One product of the Consortium Development Award will be the submission of a proposal for a Consortium Award in spring of 2002. Approximately \$600K is available in FY01 for Consortium Development Awards. Individual awards can be requested for a maximum of \$150,000 inclusive of both direct and indirect costs for 1 year. These funds can cover administrative support including salary, meetings and related travel among consortium participants, database generation and software development, purchase of computers, design of web sites, teleconferences, and other costs directly associated with planning and developing the consortium. **Funds may not be used to support laboratory research.**

Investigators interested in applying for a Consortium Development Award must submit a proposal no **later than August 29, 2001 at 4:00 p.m. Eastern Time**. Unlike other proposals submitted to the PCRP, Consortium Development Awards will only receive a single level of review. Proposals for Consortium Development Awards will be reviewed by the PCRP Integration Panel, as described below, to determine which proposals best fulfill the intent of the award mechanism. Notification is expected to occur in December 2001. Consortium

Development awardees will be required to submit a proposal for the Consortium Award in the Spring of 2002 according to guidance provided in Prostate Cancer Consortium Award Supplemental Instructions, which will be provided following receipt of FY02 funds.

**Please note there is no guarantee that funds will be available for Consortium Awards in FY02.**

### **VII-C. Proposal Review Evaluation Criteria for Consortium Development Award Proposals**

Proposals competing for the Prostate Cancer Consortium Development Award will be reviewed by the PCRP Integration Panel according to the following guidelines:

*Overarching Theme:*

- The extent to which the goal/product-driven research addresses a critical issue in prostate cancer research that would best be answered by a national research strategy representing a multidisciplinary, multi-institutional team of scientists working together.
- The specific research theme and end product's relevance and impact to the prevention, detection, diagnosis, and/or treatment of prostate cancer.

*Project Management:*

- The outline of a project management plan for the timely integration of the results from the various components of the consortium, and a proposed timeline.
- The outline of a plan for a multi-institutional, multidisciplinary consortium to address an appropriate problem to include a description of the individual components of the consortium and the resources available.
- The outline of an effective communications plan to support the multi-institutional consortium.

*Personnel:*

- The PI's qualifications and ability to organize, administer, and manage a well-qualified team of multidisciplinary, multi-institutional researchers in the consortium to solve a critical problem in prostate cancer research.
- The commitment of key personnel who are the best suited individuals for addressing the critical prostate cancer question.
- Qualifications of other key investigators and consortium participants.

### **VII-D. Letter of Intent**

All applicants considering submission of a proposal in response to this program announcement are requested to submit a Letter of Intent no later than 2 weeks prior to proposal receipt deadline.

This form can be found in Appendix A and submitted as directed or completed and submitted via the Congressionally Directed Medical Research Programs web site at <http://cdmrp.army.mil/funding/default>

## **VII-E. Consortium Development Award Proposal Preparation**

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Consortium Development 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.** Ensure that the proposal is received by **August 29, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1.
2. Proposal Acceptance Criteria – See Appendix B, part 2.
3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.
4. Proposal Cover Booklet – 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).
7. Checklist for Proposal Submission – See Appendix B, part 7. *Not required for this proposal and will not be forwarded for review if submitted.*
8. Proposal Abstracts – See Appendix B, part 8. *Not required for this proposal and will not be forwarded for review if submitted.*
9. Statement of Work – See Appendix B, part 9 and Appendix D.
10. Proposal Relevance Statement – See Appendix B, part 10. *Not required for this proposal and will not be forwarded for review if submitted.*
11. Proposal Body – See Appendix B, part 11.  
The body of Consortium Development Award proposals is limited to **6 pages**. Figures, tables, and graphs, if used, must be included within this section.

The proposal body should consist of **three parts**. It is the responsibility of the investigator to clearly articulate how the proposed consortium plan meets the intent of the mechanism. The proposal should address the evaluation criteria as outlined in Section VII-C.

- a. Description of the overarching theme, end products, and relevance.
  - b. Management and communication plan (for both the Consortium Development Award and the Consortium Award).
  - c. Key participants and their contributions (additional information on collaborators can be included in the Biographical Sketch section, see item 14 below).
12. Abbreviations – See Appendix B, part 12.
  13. References – See Appendix B, part 13.
  14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
  15. Existing/Pending Support – See Appendix B, part 15. *Not required for this proposal and will not be forwarded for review if submitted.*
  16. Facilities/Equipment Description – See Appendix B, part 16. *Not required for this proposal and will not be forwarded for review if submitted.*
  17. Administrative Documentation – See Appendix B, part 17.  
Include in this section letters of commitment from institutions that will be participating in the consortium.
- Note: Support documentation **will not** be accepted separately from the proposal submission.
- Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 21).**
18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.  
Budget is a consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.
  19. Instruments – See Appendix B, part 19. *Not required for this proposal and will not be forwarded for review if submitted.*
  20. Publications and Patent Abstracts – See Appendix B, part 20. *Not required for this proposal and will not be forwarded for review if submitted.*
  21. Proposal Submission – See Appendix B, part 21.
  22. Receipt Deadline – See Appendix B, part 22.  
Please note that the **receipt deadline for Consortium Development Award proposals is August 29, 2001 at 4:00 p.m. Eastern Time. Receipt of a proposal after the deadline may be grounds for proposal rejection.**
  23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.



**Principal Investigator:** \_\_\_\_\_  
*Last Name* *First Name* *MI*

**Proposal Title:** \_\_\_\_\_

\_\_\_\_\_

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