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Foreword

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

General information about the USAMRMC can be obtained from the USAMRMC web site at http://mrmc-www.army.mil. Specific information about 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 3 on the following page) also can be downloaded from the CDMRP web site at http://cdmrp.army.mil.

1. 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

Mail: Commander

U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (PCRP00-Program Announcement)

1077 Patchel Street

Fort Detrick, MD 21702-5024

Applicants should submit any written questions regarding this program as early as possible. Every effort will be made to answer questions within 10 working days of receipt. Inquiries should be restricted to format issues only. Questions relating to technical proposal content or reasonableness/allowability of costs should be submitted in writing and will be forwarded to the U.S. Army Medical Research Acquisition Activity.

2. Research Involving Human Subjects and/or Anatomical Substances

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 HSSRB 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 Appendix H before funds can be awarded.

3. Forms

Associated forms (except for the Proposal Cover Booklet; see Section 3 on the following page) can be found in the Appendices of this Program Announcement and can be downloaded from the CDMRP web site at http://cdmrp.army.mil.

4. Proposal Cover Booklet (Bubble Sheet)

A Proposal Cover Booklet must be completed for each submission 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 Fax: 301-682-5521

E-mail: cdmrp.pa@det.amedd.army.mil

Mail: Commander

U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (PCRP00-Program Announcement)

1077 Patchel Street

Fort Detrick, MD 21702-5024

5. Proposal Submission

To be considered for award, submit the following documentation to the address at the end of this section:

Proposal: ONE clearly labeled original (binder-clipped) and THIRTY

collated photocopies (stapled or binder-clipped) of the **entire package. Every copy must match the original including reprints of any publications.** Do not use rubber bands, or

spiral or three-ring binders.

Proposal Cover Booklet: ONE original (binder clipped to the original proposal) and

THREE photocopies (**not** binder-clipped to proposal copies).

Letters of Recommendation: If required, binder-clipped to the front of the original proposal

under the original Proposal Cover Booklet. See individual

application instructions.

Abstract Pages: TWO additional copies of both the technical and the public

(nontechnical) abstracts in a manila clasp envelope along with a 3½" computer disk containing the abstract files (clearly labeled with the name of the principal investigator [PI], institution, and

word processing program). Format abstracts in Word,

WordPerfect, or ASCII.

Statement of Work: TWO additional copies of the Statement of Work in the same

manila clasp envelope with abstract copies and disk.

Packaging: Package only **ONE** complete proposal submission (original plus

all materials requested above) per box. If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with each submission. This postcard should state the

proposal title and PI's name.

Noncompliance: Noncompliance to established guidelines may be perceived as an

attempt to gain an unfair competitive advantage and may

therefore result in proposal rejection. Administrative reasons for **rejection** of all or part of proposals most frequently result from

failure to adhere to timelines, page limits, and font

requirements.

Submit the Proposal to: Commander

U.S. Army Medical Research and Materiel Command ATTN: MCMR-PLF (PCRP00-Program Announcement)

1076 Patchel Street (Building 1076) Fort Detrick, MD 21702-5024

6. Receipt Deadline

Deadlines for individual award mechanisms are provided in the Table of Award Mechanisms and Submission Requirements found on page vi.

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

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

- 3. it was placed into the control of a commercial courier service no later than 8:00 p.m. (local time at point of origination) the day before the proposal receipt deadline for delivery by 4:00 p.m. Eastern Time on the due date, or
- 4. the Government, in its sole discretion, decides to accept the late proposal if it determines that no competitive advantage has been conferred and that the integrity of the competitive grants process will not be compromised.

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

7. Timeline

The timeline for all awards is:

Proposal Receipt: May 17, 2000

Peer Review: July 2000

Request for Appendices: Approximately 2 weeks after the completion of peer review

Programmatic Review: October 2000

Notification: Approximately 2 weeks after the completion of programmatic

review

Award Date: No earlier than October 30, 2000 and no later than September 28,

2001

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 Prostate Cancer Research Program should 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.**

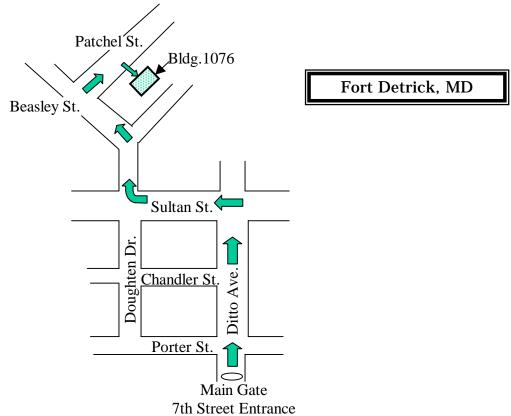


Table of Award Mechanisms and Submission Requirements

Award Mechanism	Experience of PI	Key Mechanism Elements	Dollars Available	Receipt Deadline	Instructions for Proposal Preparation
Postdoctoral Traineeship Awards	Recent doctoral graduates with 3 years or less of postdoctoral experience	 Prepares new scientists for careers in prostate cancer research Preliminary data not required 	\$98,000 for direct and indirect costs over a 2-year performance period	May 17, 2000 4:00 p.m. ET*	Section III
New Investigator Awards	Independent investigators with access to appropriate research facilities	Rewards innovative ideas and technology Preliminary data not required	\$225,000 for direct costs over a 3-year performance period	May 17, 2000 4:00 p.m. ET	Section IV
Idea Development Awards (with or without Nested Historically Black Colleges and Universities/ Minority Institutions (HBCU/MI) Traineeship Awards)	Independent investigators at the level of Assistant Professor or equivalent or above Nested HBCU/MI trainee: Predoctoral students and recent doctoral graduates with 3 years or less of postdoctoral experience	 Rewards innovative ideas and technology Preliminary data required With Nested HBCU/MI traineeships: prepares new scientists from HBCU/MI for careers in prostate cancer research 	\$375,000 for direct costs over a 3-year performance period Additional funds for nested HBCU/MI traineeships: for postdoctoral trainees, \$98,000 for direct and indirect costs over a 2-year performance period; for predoctoral students, \$44,000 for direct and indirect costs over a 2-year performance period	May 17, 2000 4:00 p.m. ET	Section V
Minority Population Focused Collaborative Training Awards	Assistant Professor or equivalent with minimal or no other support; collaboration with an established investigator is required	Develops a research concept that focuses on the disparity in prostate cancer incidence and mortality among different ethnic groups Preliminary data not required	\$75,000 for direct and indirect costs over a 1-year performance period	May 17, 2000 4:00 p.m. ET	Section VI
HBCU/MI Academic Development Awards	Advisor/mentor to the trainees and/or conference coordinator	Supports academic development related to prostate cancer by supporting conference cost and/or attendance by HBCU/MI pre- and postdoctoral trainees	\$20,000 for direct and indirect costs over a 1-year performance period	May 17, 2000 4:00 p.m. ET	Section VII

^{*} Eastern Time

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 directed toward specific diseases. Beginning in fiscal year 1992 (FY92), the U.S. Congress has directed the DOD to manage various extra- and intramural grant programs targeted toward specific research initiatives. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, \$1.5 billion has been targeted by Congress for research on breast, prostate, and 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 award opportunities that will enhance program research objectives without duplicating existing funding opportunities. 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 7-year 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, which consists of scientific merit review and programmatic review, as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on 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 developed for each award mechanism.

Each scientific review panel is composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. The chair and scientific reviewers are recognized leaders in their fields and are chosen on the basis of their scientific expertise. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. Consumer reviewers are individuals who are affected by the disease, have been nominated by an advocacy organization, and have a demonstrated interest in and knowledge of the disease. Consumers augment the scientific merit 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-C, VI-B, and VII-C). 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 score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global score. 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 technical and public (nontechnical) abstracts (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 assist investigators in assessing research projects and are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier of the two-tiered review process is programmatic review. Programmatic review is accomplished by the IP, composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. With firsthand experience, consumer advocates enhance the review process by focusing attention upon critical patient issues and

outcomes. One of the functions of the IP is to conduct programmatic review to obtain a broad portfolio of grants across all disciplines and recommend an investment strategy for appropriated funds.

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 for programmatic review.

Programmatic review balances the potential outcomes and risks of scientifically excellent proposals. It should be emphasized that the IP is committed to funding a broad-based research portfolio. While the ratings and recommendations of peer review panels are important factors in programmatic review, the IP must also consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- ratings and recommendations of the peer review panels;
- programmatic relevance;
- scientific innovation;
- program portfolio balance with respect to research disciplines or specialty areas; and
- other equitable factors, e.g., geographic distribution and 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 will be 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 their funding status, along with a scientific summary critique of their proposal. The peer review summary statement will contain the criteria scores, the global score, and detailed comments that address the proposal's strengths and weaknesses with respect to each evaluation criterion. Notification letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

I-E. Reports

All awards will require the timely delivery of several reports during the research effort. The recipient organization and the principal investigator (PI) should realize that reports are necessary for the CDMRP to monitor progress. The CDMRP will notify PIs when these reports are due and provide format guidelines at that time.

The 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 grant period) that details the findings and issues for the entire project.

All investigators are strongly encouraged to publish their results in scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. For example, "This research, under DAMD..., was supported by the Department of Defense Prostate Cancer Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI must submit a copy of any manuscript or publication resulting from research to the CDMRP. In accordance with the Bayh-Dole Act (35 USC 200 et seq.), title to inventions and patents resulting from federally funded research may be held by the grantee, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must contact the contract specialist and follow the instructions in the contract concerning license agreements and patents.

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, including \$50M in FY99 and \$75M in FY00 to continue the peer-reviewed PCRP.

The program history of the FY97-99 PCRP is shown in Table II-1.

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

Program History	FY97/98	FY99 ¹
PCRP-Managed Appropriations for Peer-Reviewed Research	\$76M	\$50M
Number of Full Proposals Received	624	647
Number of Proposals Funded	193	105
Number of Training/Recruitment Awards Funded	23	23
Number of Research Awards Funded	170	78
Number of Cancer Center Awards Funded	N/A^2	4

¹Award negotiations will not be finalized until September 2000.

II-B. Overview of the Fiscal Year 2000 Prostate Cancer Research Program

The Congressionally Directed Medical Research Programs (CDMRP), through this Program Announcement, is soliciting applications on prostate cancer research and training. The overall goal of this funding effort is to promote research directed toward conquering prostate cancer. Within this context, the objectives of the PCRP are to (1) prevent prostate cancer, (2) detect prostate cancer in its earliest stages of development, (3) cure prostate cancer, and (4) improve the quality of life for individuals 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 PCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are

²Not applicable.

highly sought. Although the CDMRP wishes to encourage risk-taking research, such projects must, nonetheless, demonstrate solid scientific judgment and rationale.

Support for training of prostate cancer researchers, encouragement of established scientists in the field, and attraction of new scientific expertise from other fields are essential in the fight against prostate cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiological research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations may be submitted from any eligible institutional source. Proposals are encouraged from investigators working at Historically Black Colleges and Universities and Minority Institutions (HBCU/MI).

II-C. Fiscal Year 2000 Program Emphasis Areas

A total of \$75M was appropriated by Congress to fund the PCRP in FY00. Prior to receipt of these funds by the CDMRP, the DOD withholds approximately 9% for Congressionally mandated and DOD initiatives. Of that, 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 (up to 7 years). 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 82% of the original appropriation is therefore available to fund peer-reviewed research. Due to the high quality of proposals received in response to the FY99 Program Announcement and to rapidly commit FY00 funds to support highly meritorious research, approximately 8.5% of the available funds was used to fund FY99 proposals.

For FY00, approximately \$56.4M is available to fund a competitive peer-reviewed research program. Approximately \$32.1M will be used to fund proposals solicited in response to this Program Announcement. The programmatic strategy for FY00 is to fund proposals in two categories: (1) Research Awards and (2) Training/Recruitment Awards. Additionally, approximately \$24.3M will be used to support Dual Phase Research Awards. Unlike other proposal mechanisms, the Dual Phase Research Awards are a competitive continuation for those investigators who were funded in this mechanism in FY97/98, as described in the FY97 Broad Agency Announcement. Invited investigators will be provided with an invitational letter and Dual Phase Award Supplemental Instructions.

Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this Program Announcement carefully, as revisions to award mechanism definitions have been made.

II-C.1. Research Awards

Approximately \$30.55M will be allocated for Research Awards, which consist of New Investigator Awards (Section IV) and Idea Development Awards (with or without Nested HBCU/MI Traineeships) (Section V). The intent of both New Investigator and Idea Development Awards is to stimulate and reward creative research ideas that may be viewed as speculative but have the potential for high payoff. New Investigator Awards are targeted to investigators in the early phases of their careers and to investigators established in other fields who desire to move into prostate cancer but who have little or no preliminary data in prostate cancer. Idea Development Awards are aimed at giving established prostate cancer investigators and those investigators who want to move into prostate cancer and who have preliminary data relevant to prostate cancer research the necessary support and time to undertake underinvestigated areas of research. Idea Development Awards with Nested HBCU/MI Traineeships are being offered to assist in the research training of new HBCU/MI scientists for careers in prostate cancer research.

II-C.2. Training/Recruitment Awards

Approximately \$1.55M will be allocated for Training/Recruitment Awards, which consist of Postdoctoral Traineeship Awards (Section III), Minority Population Focused Collaborative Training (MPFCT) Awards (Section VI), and HBCU/MI Academic Development Awards (Section VII). The intent of Postdoctoral Traineeship Awards is to prepare new scientists for careers in prostate cancer research. The goal of the MPFCT Awards is to increase research efforts focused on the disparity in prostate cancer incidence and mortality among different ethnic groups by fostering collaborative research and training in this area. The intent of the HBCU/MI Academic Development Awards is to provide education, training and/or scientific development in prostate cancer for HBCU/MI predoctoral and postdoctoral trainees.

III. Postdoctoral Traineeship Awards

III-A. Postdoctoral Traineeship Awards

The intent of Postdoctoral Traineeship Awards is to enable recent doctoral degree graduates with limited postdoctoral experience (i.e., 3 years or less at the time of proposal submission) either to extend ongoing research related to prostate cancer, or to broaden the scope of their research to include work relevant to prostate cancer under the guidance of a designated mentor. Eligible applicants must have successfully defended a doctoral thesis and completed all academic requirements at the time of award negotiation.

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

Approximately \$1M is available for Postdoctoral Traineeship Awards. Postdoctoral Traineeship Awards can be requested for a maximum of \$98,000 for direct and indirect costs over a 2-year performance period. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,500 per year. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

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

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

- **Applicant:** Do the applicant's achievements to date (as assessed by background, academic performance, awards, and honors) make him or her well-qualified for postdoctoral training? Does the applicant have a record of previous research experience, publications, and/or related professional training that indicates suitability for a research career? What are the applicant's stated goals in prostate cancer research? Do the letters of recommendation support the applicant's abilities and potential for a productive research career?
- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the training program? What is the mentor's previous research training experience with doctoral students?
- Quality of the Research Training: Will the training result in a valuable experience that will prepare the applicant for an independent research career in prostate cancer? Is the proposed training appropriate? Would the described training further the applicant's goal to become an independent researcher?

- **Training Environment:** Does the postdoctoral training take place in an environment that is appropriate to accomplishing the applicant's goals? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to research training in prostate cancer?
- **Scientific Relevance:** Will the postdoctoral training prepare the applicant to investigate an important problem in prostate cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to prostate cancer research? Does the application make a convincing case for the relevance of the training to prostate cancer?
- **Budget:** Is the budget reasonable for the training proposed?

III-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a "Letter of Intent" 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 web site at http://cdmrp.army.mil.

III-D. Proposal Preparation

The following proposal preparation information is specific for Postdoctoral Traineeship Awards. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 10 pages, inclusive of figures, tables, and graphs. Ensure that the proposal is received by **May 17, 2000 at 4:00 p.m. Eastern Time.**

- 1. Who May Apply See Appendix B, part 1.
- 2. Proposal Acceptance Criteria See Appendix B, part 2.
- 3. Proposal Cover Booklet See Appendix B, part 3 and Appendix C.
- 4. Peer Review Referral Page See Appendix B, part 4.
- 5. Proposal Title Page See Appendix B, part 5.
- 6. Table of Contents Tear out and use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
- 7. Checklist for Proposal Submission See Appendix B, part 7.

Principal Invest	igator:	 	 	
Proposal Title:_				

Postdoctoral Traineeship Award Proposal Table of Contents

Page Number Proposal Cover Booklet (12 pages) Peer Review Referral Page (no page limit)i Technical Abstract (1 page limit)4 Public Abstract (1 page limit)5 Statement of Work (2 page limit)6 Proposal Body (10 page limit) Abbreviations (1 page limit) References (no page limit) Biographical Sketches (3 page limit each for PI, mentor and collaborating investigators) Existing/Pending Support (no page limit)_____ Facilities/Equipment Description (no page limit) Administrative Documentation (no page limit) Detailed Cost Estimate (no page limit) Instruments (no page limit) Publications and Patent Abstracts (5 document limit)

Postdoctoral Traineeship Awards

- 8. Proposal Abstracts See Appendix B, part 8.
- 9. Statement of Work See Appendix B, part 9.
- 10. Proposal Relevance Statement See Appendix B, part 10.

In addition to the instructions found in Appendix B, part 10, Postdoctoral Traineeship Award applicants should describe explicitly the training value of the proposed research concept relative to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer will prepare the applicant for a career in the battle against prostate cancer.

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

The body of Postdoctoral Traineeship Award proposals is limited to 10 pages. Figures, tables, and graphs, if used, must be included within 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 such as coursework, laboratory techniques, conferences, and journal clubs. Describe the research concept to be explored. Provide a statement of the mentor's qualifications, including experience as a research supervisor.
- b. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career.
- 12. Abbreviations See Appendix B, part 12.
- 13. References See Appendix B, part 13.
- 14. Biographical Sketches See Appendix B, part 14.

Note that for Postdoctoral Traineeship Award proposals, biographical sketches should be prepared for the applicant, collaborating investigators, and the mentor. Each biographical sketch may not exceed three pages per investigator. The mentor's biographical sketch should include qualifications, especially in prostate cancer research, and previous experience in training students and postdoctoral fellows.

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

For Postdoctoral Traineeship Awards, it is especially important to provide documentation of existing/pending support involving the mentor to show that there is adequate support in the training environment for the postdoctoral trainee.

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

- 17. Administrative Documentation See Appendix B, part 17. Provide the following administrative documentation in the proposal submission:
 - A letter from the mentor describing the degree to which the applicant participated in idea development and proposal preparation, as well as the degree to which the applicant will participate in the execution of the proposal if funded. This letter should not be placed in an envelope and should be included in the Administrative Documentation section of the proposal.
 - A form signed by the Department Chair, Dean, or equivalent official verifying that the
 applicant has or will have successfully completed a doctoral degree at the time of award
 negotiation, has completed all academic requirements, and has no more than 3 years of
 postdoctoral training and therefore is an eligible applicant for this award type. The form
 on page III-9 should be used.
 - A letter of support from the mentor describing his or her commitment to the training/career development/mentorship of the applicant and the nature of the proposed collaboration/training. Emphasis should be placed on the training environment and the designated mentor. This letter is to be sent from the mentor to the applicant in a **sealed** envelope for forwarding, unopened, with the application. To ensure that the mentor's letter of support is not misplaced, the sealed envelope should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of support will not be accepted separately from the application.
 - Two additional letters of recommendation should accompany the application. These letters are to be sent from references to the applicant in **sealed** envelopes for forwarding, unopened, with the application. To ensure that the letters of recommendation are not misplaced, the sealed envelopes should be attached by binder clip to the original proposal underneath the Proposal Cover Booklet. Letters of recommendation will not be accepted separately from the application.

To document the sources of these letters, please include a list of the names, positions, and grant function (e.g., mentor, recommender) of authors of the letters in the Administrative Documentation section of the application. However, please attach the letters in sealed envelopes with a binder clip to the original proposal underneath the Proposal Cover Booklet. Finally, the Administrative Documentation section should also include any letters of support from any other collaborating investigators. Such letters should not be placed in envelopes and should be included in the Administrative Documentation section of the application.

- 18. Detailed Cost Estimate See Appendix B, part 18.

 Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.
- 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 Postdoctoral Traineeship Award proposals is May 17, 2000 at 4:00 p.m. Eastern Time.
- 23. Appendices See Appendix B, part 23.

STATEMENT OF	FELIGIBILITY
Applicant's Name:	
Title of Proposal:	
Applicant's Organization Name:	
Applicant's Organization Location:	
Signature of Applicant:	
STATEMENT OF	FELIGIBILITY
For the purposes of the Department of Defense Co Program's Prostate Cancer Research Program Pos outlined in the Program Announcement, the applic	tdoctoral Traineeship Award category as
 Has or will have successfully completed a doct Has or will have completed all academic requirements Has 3 years or less of postdoctoral experience. 	rements at the time of award negotiation; and
I,	of
(printed name of Department Chair, Dean, or equivalen	nt official) (printed name of institution)
attest that the above-named investigator fulfills the Postdoctoral Traineeship Award.	e requirements to be considered for a
Signature of Official:	Date:

IV. New Investigator Awards

IV-A. New Investigator Awards

The intent of New Investigator Awards is to promote and reward innovative ideas and technology from investigators in the early phases of their careers as well as those established investigators new to prostate cancer research who have little or no preliminary data in prostate cancer to conquer the disease. A New Investigator is defined as an independent investigator with access to appropriate research facilities.

In accordance with the challenge to be innovative, **proposals lacking pilot data will be competitive if they demonstrate sound scientific judgment and rationale.** New Investigator proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative. The proposed studies may be untested but have a high probability of revealing new avenues of investigation. Although this research is inherently risky in nature and does not require preliminary or pilot data, these proposals nonetheless should be based on a sound scientific rationale that is established through a critical review and analysis of the literature and logical reasoning. Table IV-1 delineates the differences between traditional research and New Investigator proposals.

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

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

Approximately \$10M is available for New Investigator Awards. Funding for New Investigator Awards can be requested for a maximum of \$225,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. A level of institutional support and commitment should be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. Please provide complete justification for expenses in all categories.

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

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

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Are they based on sound scientific rationale and logical reasoning? Does the applicant acknowledge potential problem areas and consider alternative tactics? (Preliminary data are not required but may be included.)
- **Scientific Relevance:** To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does this study address a critical problem in prostate cancer research? Does the proposal make a convincing case for the relevance of the research to prostate cancer?
- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms, develop new methodologies or technologies, or address underexplored or unexplored areas?
- **Principal Investigator (PI):** Does the PI show potential for contributing to the prostate cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?
- **Environment:** Is the scientific environment appropriate for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?
- **Budget:** Is the budget reasonable for the research proposed?

IV-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a "Letter of Intent" 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 web site at http://cdmrp.army.mil.

IV-D. Proposal Preparation

The following proposal preparation information is specific for New Investigator Awards. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement.

Please note that the body of the proposal is limited to 10 pages, inclusive of figures, tables, and graphs. Ensure that the proposal is received by **May 17, 2000 at 4:00 p.m. Eastern Time.**

- 1. Who May Apply See Appendix B, part 1.
- 2. Proposal Acceptance Criteria See Appendix B, part 2.
- 3. Proposal Cover Booklet See Appendix B, part 3 and Appendix C.
- 4. Peer Review Referral Page See Appendix B, part 4.
- 5. Proposal Title Page See Appendix B, part 5.
- 6. Table of Contents Tear out and use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
- 7. 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.
- 10. Proposal Relevance Statement See Appendix B, part 10.

 In addition to the instructions found in Appendix B, part 10, New Investigator Award applicants should state explicitly how the proposed work is innovative and relevant to prostate cancer research. Describe how the combination of innovation and relevance in the proposal will make a contribution to the goal of conquering prostate cancer and advancing research in the field.
- 11. Proposal Body See Appendix B, part 11.

The body of New Investigator Award proposals is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section. Presentation of preliminary or pilot data is not required for New Investigator Award proposals but can be included if available.

For New Investigator Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Principal Investigator:			
Proposal Title:			
•			

New Investigator Award Proposal Table of Contents

Page Number

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

- a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
- b. Hypothesis/Purpose: State the hypothesis to be tested and the expected results.
- c. Objectives: State concisely the specific aims of the study.
- d. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for all proposed syntheses. Outline and document the routes to each synthesis. All figures, tables, and graphs must be included within the proposal body.
- 12. Abbreviations See Appendix B, part 12.
- 13. References See Appendix B, part 13.
- 14. Biographical Sketches See Appendix B, part 14.
- 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. Provide the following administrative documentation in the proposal submission:
 - A letter from the applicant describing the degree to which the applicant and any collaborators participated in proposal development. This letter should not be placed in an envelope and should be included in the Administrative Documentation section of the proposal.
 - A form signed by the Department Chair, Dean, or equivalent official verifying that the applicant is an independent investigator with access to appropriate research facilities and therefore is an eligible applicant for this award type. The form on page IV-9 should be used.
- 18. Detailed Cost Estimate See Appendix B, part 18.
- 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 New Investigator Award proposals is May 17, 2000 at 4:00 p.m. Eastern Time.**
- 23. Appendices See Appendix B, part 23.

OF ELIGIBILITY
OF ELIGIBILITY
te Congressionally Directed Medical Research New Investigator Award category as outlined in fills all of the following criteria:
es.
ofof
ivalent official) (printed name of institution)
s the requirements to be considered for a New
Date:

V. Idea Development Awards (with or without Nested HBCU/MI Traineeship Awards)

V-A. Idea Development Awards without Nested HBCU/MI Traineeship Awards

The intent of Idea Development Awards is to encourage innovative approaches to prostate cancer research from established prostate cancer investigators and those investigators who want to move into the prostate cancer field. An Idea Development Award investigator is defined as an independent investigator at the level of **Assistant Professor or above.**

Idea Development Award proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative. All Idea Development Award proposals **must include preliminary data relevant to prostate cancer research and the proposed project** as well as a summary of the principal investigator's (PI's) research and professional experience in prostate cancer and/or potential for contribution to the field of prostate cancer.

Approximately \$20.55M is available for Idea Development Awards. Funding for Idea Development Awards can be requested for a maximum of \$375,000 for direct costs over a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,800 per year. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. A level of institutional support and commitment should be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment. Please provide complete justification for expenses in all categories.

V-B. Idea Development Awards with Nested HBCU/MI Traineeship Awards

Nested Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Traineeship Awards are being offered as an optional part of the Idea Development Award mechanism. The intent of the traineeships is to prepare new scientists from HBCU/MI for careers in prostate cancer research under the mentorship of an experienced PI. **The PI can be from any institution, but the trainee must be from an HBCU/MI.**

It is expected that the training will offer a valuable opportunity to further develop the experience necessary to advance the trainee's research career in prostate cancer. While the trainee may not train for the duration of the award in the mentoring laboratory, it is anticipated that the PI of the Idea Development Award will sustain an interactive, ongoing mentorship with the trainee throughout the duration of the award. Therefore, all PIs of Idea Development Awards with

Nested HBCU/MI Traineeship Awards must furnish an annual documentation of performance of the training experience for the HBCU/MI trainee. The Congressionally Directed Medical Research Programs (CDMRP) will notify PIs when these reports are due and provide format guidelines at that time (refer to Section I-E).

A trainee is defined as a predoctoral student or a recent doctoral degree graduate with limited postdoctoral experience (i.e., 3 years or less at the time of proposal submission). Eligible postdoctoral candidates must have successfully defended a doctoral thesis and completed all academic requirements at the time of award negotiation. These Nested HBCU/MI Pre- and Postdoctoral Traineeship Awards can only be obtained as part of the Idea Development Award mechanism.

Applicants must submit a biographical sketch of no more than three pages for each trainee and include it in the biographical sketch section (see Appendix B, part 14). To Be Named (TBN) trainees are acceptable for the proposal. When TBN trainees are ultimately selected, the CDMRP must be notified and the name and biographical sketch of each candidate must be provided.

Approximately \$750K is available for Nested HBCU/MI Traineeship Awards. Up to **two** trainees, i.e. two predoctoral trainees, two postdoctoral trainees, or one of each can be nested in a single proposal. Funding for Nested HBCU/MI Predoctoral Traineeship Awards can be requested for a maximum of \$44,000 each for direct and indirect costs over a 2-year performance period. Funding for Nested HBCU/MI Postdoctoral Traineeship Awards can be requested for a maximum of \$98,000 each for direct and indirect costs over a 2-year performance period. These funds can cover tuition, stipend, salary, expenses including research supplies, and travel to scientific meetings. The amount allotted for travel is \$1,500 per year per trainee. Expenses relevant to the traineeship should be listed under the "Other" category on the "Detailed Cost Estimate" form (see Appendix B, part 18). It is requested that indirect charges related to the traineeship be at the lowest possible rates. Please provide complete justification for expenses in all categories.

V-C. Scientific Peer Review Evaluation Criteria for Idea Development Awards

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

• **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Do the required preliminary data in prostate cancer research support the proposed project?

- **Scientific Relevance:** To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does this study address a critical problem in prostate cancer research? Does the proposal make a convincing case for the relevance of the research to prostate cancer?
- **Innovation:** Does the research employ novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms, develop new methodologies or technologies, or address underexplored or unexplored areas?
- **Personnel:** Is the PI appropriately trained and well suited to carry out this work? Does the PI show potential for contribution to the prostate cancer field? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is appropriate expertise available to conduct the study successfully? **For Nested HBCU/MI Traineeship Awards,** are the PI and other scientific personnel well qualified to conduct training for the trainees? Is there a senior staff member who is identified and responsible for the trainee? Will the PI sustain an interactive, ongoing mentorship with the trainee?
- Environment: Is the scientific environment an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support? For Nested HBCU/MI Traineeship Awards, is the research training properly structured and balanced to ensure that the trainee will acquire the knowledge and necessary skills relevant to the scientific area being studied?
- **Budget:** Is the budget reasonable for the research proposed?

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 receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the CDMRP web site at http://cdmrp.army.mil.

V-E. Proposal Preparation

The following proposal preparation information is specific for Idea Development Awards. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 10 pages, inclusive of figures, tables, and graphs. Ensure that the proposal is received by **May 17, 2000 at 4:00 p.m. Eastern Time.**

- 1. Who May Apply See Appendix B, part 1.
- 2. Proposal Acceptance Criteria See Appendix B, part 2.

- 3. Proposal Cover Booklet See Appendix B, part 3 and Appendix C.
- 4. Peer Review Referral Page See Appendix B, part 4.
- 5. Proposal Title Page See Appendix B, part 5.
- 6. Table of Contents Tear out and use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
- 7. 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.
- 10. Proposal Relevance Statement See Appendix B, part 10. In addition to the instructions found in Appendix B, part 10, Idea Development Award applicants should state explicitly how the proposed work is innovative and relevant to prostate cancer research. Articulate how the combination of innovation and relevance in the proposal will have an impact upon and further the programmatic goals. Describe how the project will make a contribution to the goal of conquering prostate cancer and/or advancing research in the field.
- 11. Proposal Body See Appendix B, part 11.
 - a. Idea Development Award Proposal Body.

The body of Idea Development Award proposals is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section. The inclusion of preliminary data is required for Idea Development proposals; investigators must submit promising and well-founded preliminary data relevant to prostate cancer research and the proposed project.

For Idea Development Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

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

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

Principal Investigator:	•			
Proposal Title:		 		

Idea Development Award with or without a Nested HBCU/MI Traineeship Award Proposal Table of Contents

Page Number Proposal Cover Booklet (12 pages) Peer Review Referral Page (no page limit)i Table of Contents (1 page limit) ______2 Technical Abstract (1 page limit)4 Proposal Relevance Statement (1 page limit)8 Idea Development Proposal Body (10 page limit)_____ Nested HBCU/MI Proposal Body, if applicable (1 page limit for each trainee) Abbreviations (1 page limit) References (no page limit) Biographical Sketches (3 page limit each for PI and participating investigators)_ Existing/Pending Support (no page limit) Facilities/Equipment Description (no page limit) Administrative Documentation (no page limit) Detailed Cost Estimate (no page limit) Instruments (no page limit) Publications and Patent Abstracts (5 document limit)

- iii. Objectives: State concisely the specific aims of the study.
- iv. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the synthesis. All figures, tables, and graphs must be included within the proposal body.
- b. Nested HBCU/MI Traineeship Award Proposal Body. The body of the Nested HBCU/MI Traineeship Award proposal is limited to one page per trainee. Identify the staff member who is responsible for the trainee. Describe the research training in which the trainee will participate such as research, coursework, laboratory techniques, conferences, and journal clubs. Briefly describe how the training will promote the trainee's career development and how the PI will sustain an interactive, ongoing mentorship with the trainee.
- 12. Abbreviations See Appendix B, part 12.
- 13. References See Appendix B, part 13.
- 14. Biographical Sketches See Appendix B, part 14. Investigators must include a description of their experience in prostate cancer research as part of the biographical sketch. A biographical sketch of no more than three pages must be included in this section for each named trainee.
- 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. Provide the following administrative documentation in the proposal submission:
 - A letter from the applicant describing the degree to which the applicant and any
 collaborators participated in proposal development. This letter should not be placed in an
 envelope and should be included in the Administrative Documentation section of the
 proposal.
 - If applicable, a form signed by the Department Chair, Dean, or equivalent official verifying that the Nested HBCU/MI postdoctoral trainee has or will have successfully completed a doctoral degree at the time of award negotiation, has completed all academic requirements, and has no more than 3 years of postdoctoral training and therefore is an eligible applicant for this award type. The form on page V-9 should be used.

- 18. Detailed Cost Estimate See Appendix B, part 18.
- 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 Idea Development Award proposals is May 17, 2000 at 4:00 p.m. Eastern Time.
- 23. Appendices See Appendix B, part 23.

STATEMENT OF ELIGIBILITY
Applicant's Name:
Title of Proposal:
Applicant's Organization Name:
Applicant's Organization Location:
Signature of Applicant:
STATEMENT OF ELIGIBILITY
For the purposes of the Department of Defense Congressionally Directed Medical Research Program's Prostate Cancer Research Program Nested Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Postdoctoral Traineeship Award category as outlined in the Program Announcement, the applicant fulfills all of the following criteria:
 Has or will have successfully completed a doctoral thesis at the time of award negotiation; Has or will have completed all academic requirements at the time of award negotiation; and Has 3 years or less of postdoctoral experience.
I,ofofof
attest that the above-named investigator fulfills the requirements to be considered for a Nested HBCU/MI Postdoctoral Traineeship Award.
Signature of Official: Date:

VI. Minority Population Focused Collaborative Training Awards

VI-A. Minority Population Focused Collaborative Training Awards

There is a clear disparity in prostate cancer incidence and mortality among different ethnic groups. Minority Population Focused Collaborative Training (MPFCT) Awards are intended to initiate and increase research efforts investigating this disparity. Further, MPFCT Awards are intended to attract new investigators to this research area and to foster collaborations between applicants and researchers established in the field of prostate cancer research. An MPFCT Award investigator is defined as an independent investigator at the level of Assistant Professor or equivalent with minimal or no other support.

MPFCT Awards enable investigators to design and initiate a prostate cancer research concept that focuses on the disparity in prostate cancer incidence and mortality among different ethnic groups. One of the goals of these awards is to establish and foster collaborations between applicant principal investigators (PIs) and established investigators; **therefore**, **applications are required to include a collaboration with an established investigator**. Collaborations between investigators who are working at different institutions are especially encouraged. Both the applicant PI and collaborating investigator should contribute to the planned project. This award is intended to provide concept development and research support for researchers who have access to research facilities but have minimal or no other funding. Therefore, the award is intended to support the planning and development of a program of research, not necessarily the completion of the proposed program. Awards will provide investigators the opportunity to collaborate, train, and acquire the experience, resources, and preliminary data needed to design a fundable plan for prostate cancer research. The long-term goal of this award mechanism is to increase research efforts in this area by preparing investigators to submit competitive, well-developed research proposals to funding agencies.

Approximately \$0.5M is available for MPFCT Awards. Funding for MPFCT Awards can be requested for a maximum of \$75,000 for direct and indirect costs over a 1-year performance period. These funds can cover salary, expenses including research supplies, tuition for special training and/or education, costs related to arranging a collaboration with an established investigator (to include salary support if needed), consultation with scientific and/or technical experts (e.g., statisticians, editors), administrative and technical assistance, purchase of essential equipment or equipment rental, office supplies, and travel. The amount allotted for travel is \$1,500. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories.

-

¹American Cancer Society, Cancer Facts & Figures – 1999.

VI-B. Scientific Peer Review Evaluation Criteria for Minority Population Focused Collaborative Training Awards

MPFCT Award proposals will be evaluated according to the following criteria:

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

VI-C. Letter of Intent

All applicants considering submission of a proposal in response to this Program Announcement are requested to submit a "Letter of Intent" 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 web site at http://cdmrp.army.mil.

VI-D. Proposal Preparation

The following proposal preparation information is specific for MPFCT Awards. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement.

Please note that the body of the proposal is limited to 10 pages, inclusive of figures, tables, and graphs. Ensure that the proposal is received by **May 17, 2000 at 4:00 p.m. Eastern Time.** If funded, applicants may delay the start of the award to allow the institution to sufficiently relieve the investigator of academic or clinical responsibilities.

- 1. Who May Apply See Appendix B, part 1.
- 2. Proposal Acceptance Criteria See Appendix B, part 2.
- 3. Proposal Cover Booklet See Appendix B, part 3 and Appendix C.
- 4. Peer Review Referral Page See Appendix B, part 4.
- 5. Proposal Title Page See Appendix B, part 5.
- 6. Table of Contents Tear out and use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
- 7. Checklist for Proposal Submission See Appendix B, part 7.
- 8. Proposal Abstracts See Appendix B, part 8.
- Statement of Work See Appendix B, part 9.
 A sample MPFCT Award Statement of Work is provided on page VI-11.
- 10. Proposal Relevance Statement See Appendix B, part 10. In addition to the instructions found in Appendix B, part 10, MPFCT Award applicants should describe explicitly the training value of the proposed research concept relative to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer in the proposal will prepare the applicant for a career in the battle against prostate cancer.
- 11. Proposal Body See Appendix B, part 11.

 The body of MPFCT Award proposals is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section.

Describe the proposed research concept 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 established investigator and the applicant should be articulated. Qualifications and facilities of the established investigator should be addressed.

Principal Investigator:			-
Proposal Title:			
•			

Minority Population Focused Collaborative Training Award Proposal Table of Contents

Page Number Proposal Cover Booklet (12 pages) Public Abstract (1 page limit) 5 Proposal Body (10 page limit) Abbreviations (1 page limit) References (no page limit) Biographical Sketches (3 page limit for PI and each collaborating investigator)...... Existing/Pending Support (no page limit)________ Facilities/Equipment Description (no page limit) Administrative Documentation (no page limit) Detailed Cost Estimate (no page limit) Instruments (no page limit) Publications and Patent Abstracts (5 document limit)_____

- b. Career Development: Describe explicitly the value of the proposed training as it relates to the applicant's career goals. Articulate how the combination of training value and relevance to prostate cancer in the proposal will catalyze the applicant's development as an independent prostate cancer investigator.
- c. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Proposals must present a plan for research concept development that focuses on the disparity in prostate cancer incidence and mortality rates in one or more ethnic groups. Cite relevant literature references.
- 12. Abbreviations See Appendix B, part 12.
- 13. References See Appendix B, part 13.
- 14. Biographical Sketches See Appendix B, part 14. For MPFCT Award proposals, biographical sketches should be prepared for the applicant and the established, collaborating investigator. Each biographical sketch may not exceed three pages. Investigators must include a description of their experience in prostate cancer research as part of the biographical sketch.
- 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. Provide the following administrative documentation in the proposal submission:
 - A letter from the applicant describing the degree to which the applicant and any
 collaborators participated in proposal development. This letter should not be placed in an
 envelope and should be included in the Administrative Documentation section of the
 proposal.
 - A letter signed by the Department Chair, Dean, or equivalent official from the applicant
 institution describing the commitment of the institution to the applicant's research career,
 as reflected by the extent to which the applicant will be relieved of his or her academic
 and/or clinical responsibilities to have additional time for collaboration and training,
 access to appropriate facilities, and opportunities for professional interactions with senior
 colleagues.
 - A form signed by the Department Chair, Dean, or equivalent official indicating that the applicant is an Assistant Professor or equivalent, has access to appropriate research facilities and therefore is an eligible applicant for this award type. The form on page VI-9 should be used.

- A letter from the collaborating established investigator describing his/her commitment to the training/career development/mentorship of the applicant and the nature of the proposed collaboration/training.
- Letters of support from any additional consultants/collaborators who will be supplying essential assistance to the proposed project describing their role on the concept development.
- 18. Detailed Cost Estimate See Appendix B, part 18.

 Training awards frequently have a different institutional overhead charge. All training investigators are encouraged to check with their institution concerning overhead costs.
- 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 MPFCT Award proposals is May 17, 2000 at 4:00 p.m. Eastern Time.**
- 23. Appendices See Appendix B, part 23.

STATEMENT OF E	LIGIBILITY
Applicant's Name:	
Title of Proposal:	
Applicant's Organization Name:	
Applicant's Organization Location:	
Signature of Applicant:	
STATEMENT OF E	LIGIBILITY
For the purposes of the Department of Defense Congram's Prostate Cancer Research Program Minori Training Award category as outlined in the Program A following criteria:	ty Population Focused Collaborative
 Holds a position of Assistant Professor or equivale Has access to appropriate research facilities. 	ent; and
I,	of
attest that the above-named investigator fulfills the rec Population Focused Collaborative Training Award.	
Signature of Official:	Date:

Minority Population Focused Collaborative Training Award

Sample Statement of Work

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

<u>Phase 1</u>: Project Startup and Parameter Development (Months 1-3)

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

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

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

<u>Phase 3</u>: Formulation of Research Questions for Idea Award proposal in Response to the Department of Defense Prostate Cancer Research Program Announcement (Months 8-12)

• Consolidate information obtained during Phase 2

VII. HBCU/MI Academic Development Awards

VII-A. HBCU/MI Academic Development Awards

The intent of Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Academic Development Awards is to provide education, training and/or scientific development in prostate cancer for pre- and postdoctoral trainees currently attending or working at HBCU/MI. This mechanism seeks to accomplish this by providing funding for travel to scientific meetings and/or to encourage the development of scientific conferences on topics such as research design and grant writing to strengthen the trainees' potential for developing successful careers in prostate cancer research.

All institutions or organizations eligible for funding from the Congressionally Directed Medical Research Programs (CDMRP), including scientific or professional societies, are encouraged to apply.

Institutions may apply for this award in one of three ways:

- 1. by requesting **travel support** for HBCU/MI pre- and postdoctoral trainees to attend a major national scientific meeting relevant to prostate cancer,
- 2. by requesting **conference support** for a conference, or
- 3. by requesting **travel and conference support** for a conference hosted in conjunction with an organized scientific meeting.

Note that for purposes of this award, a conference is defined as a workshop, seminar, symposium, or other organized, formal event designed to disseminate information, provide training or instruction, or discuss topics relevant to prostate cancer research.

Participation by a minimum of five HBCU/MI trainees is required for conference support whether or not funding for travel is requested. Therefore, funding will not be provided for conference support unless trainee participation is ensured.

The principal investigator (PI) is expected to serve as an advisor and mentor for participating trainees and/or as the conference coordinator. Advisory and mentorship functions may include duties such as accompanying trainees to the conference, overseeing and directing trainee participation in the conference, and conducting follow-up discussions related to the conference. Conference coordinator functions may include organizing, overseeing, and directing the conference. In both cases, the PI must ensure that the meeting content is appropriate to the intent of this award and that appropriate trainee selection and recruitment criteria are developed and implemented.

A trainee is defined as a predoctoral student or a recent doctoral degree graduate with limited postdoctoral experience (i.e., 3 years or less at the time of proposal submission). Eligible

postdoctoral candidates must have successfully defended a doctoral thesis and completed all academic requirements at the time of award negotiation.

A biographical sketch of no more than three pages must be submitted for each trainee and included in the biographical sketch section (see Appendix B, part 14). Up to three To Be Named (TBN) trainees may be included in the proposal. When TBN trainees are ultimately selected, the CDMRP must be notified and the name and biographical sketch of each candidate must be provided.

Approximately \$50,000 is available for HBCU/MI Academic Development Awards. Funding can be requested for a maximum of \$20,000 for direct and indirect costs over a 1-year performance period (inclusive of travel and conference support as appropriate). The amount allotted for travel is \$1,500 per trainee. Budget is a key consideration in both peer and programmatic review; applicants are cautioned to use discretion in budget requests. Please provide complete justification for expenses in all categories. Documentation verifying conference dates and focus is required. Include this information in the Administrative Documentation section (see Appendix B, part 17).

VII-A.1. Travel Support

Applications requesting travel support must include travel funding for a minimum of five HBCU/MI pre- and/or postdoctoral trainees. All trainees supported by these awards are encouraged to present their research findings at the conference.

VII-A.2. Conference Support

Conference support may be requested to provide support for the conference. Participation by a minimum of five HBCU/MI trainees is required. Allowable costs are described in Section VII-B. Conference support will be designated specifically to provide trainees with information pertinent to the development of successful careers in prostate cancer research.

VII-A.3. Travel and Conference Support

Applications requesting both travel and conference support may be submitted. Travel costs must be included to ensure conference participation by a minimum of five HBCU/MI trainees. Other allowable costs are described in Section VII-B.

VII-B. Allowable Costs

The following expenses can be requested in an HBCU/MI Academic Development Award proposal:

• **Travel and Lodging:** Travel for HBCU/MI trainees selected to participate in the meeting; travel and lodging of staff and speakers identified in the proposal, and approved at the time of award.

- **Conference Services:** Recording and transcriptions of proceedings, simultaneous translations, rental equipment, and other related services.
- Consultant Services: Consultant fees and supporting costs.
- **Honoraria:** Speakers fees for services rendered.
- **Advertisement/Publication Costs:** Partial or complete publication of proceedings, pamphlets, diagrams, printing, distribution, mailing, postage, and general handling.
- **Registration Fees:** Registration fees, when paid by the grantee to other organizations on behalf of attendees.
- **Supplies:** Supplies required to support the activities of the conference.

VII-C. Scientific Peer Review Evaluation Criteria for HBCU/MI Academic Development Awards

HBCU/MI Academic Development Awards will be evaluated according to the following criteria:

- **Trainees:** Are the qualifications of the trainees appropriate for the type of meeting to be attended? Have the trainees demonstrated research potential and academic achievements appropriate to their level? Is the selection process for all trainees appropriate?
- **Training Value:** Is the conference for which the trainees are receiving travel funds related to the trainees' research training in prostate cancer research? Will the trainees benefit from attending the conference? Will the trainees present research findings at the meeting? To what extent will the PI enhance the trainees' experience?
- **Conference:** Is the topic relevant to prostate cancer and will it benefit the HBCU/MI trainees' prostate cancer research careers? Are the organizers qualified to conduct the conference? How appropriate are the speakers for the conference?

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 the receipt deadline. This form can be found in Appendix A and submitted as directed, or completed and submitted via the CDMRP web site at http://cdmrp.army.mil.

VII-E. Proposal Preparation

The following proposal preparation information is specific for HBCU/MI Academic Development Awards. Specific instructions for proposal preparation are found in Appendix B of this Program Announcement. Please note that the body of the proposal is limited to 10 pages,

inclusive of figures, tables, and graphs. Ensure that the proposal is received by May 17, 2000 at 4:00 p.m. Eastern Time.

- 1. Who May Apply See Appendix B, part 1.
- 2. Proposal Acceptance Criteria See Appendix B, part 2.
- 3. Proposal Cover Booklet See Appendix B, part 3 and Appendix C.
- 4. Peer Review Referral Page See Appendix B, part 4.
- 5. Proposal Title Page See Appendix B, part 5.
- 6. Table of Contents Tear out and use the table of contents on the following page in your proposal submission. As listed, number all pages of the sections consecutively at the bottom center, beginning with the Proposal Title Page.
- 7. 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.
- 10. Proposal Relevance Statement See Appendix B, part 10. In addition to the instructions found in Appendix B, part 10, HBCU/MI Academic Development Award applicants should state explicitly how the proposed conference is relevant to prostate cancer research and explain thoroughly the training value for HBCU/MI trainees.
- 11. Proposal Body See Appendix B, part 11.

The body of HBCU/MI Academic Development Award proposals is limited to 10 pages. Figures, tables, and graphs, if used, must be included within this section.

For HBCU/MI Academic Development Award proposals, it is the responsibility of the investigator to describe how the proposed conference will promote training of HBCU/MI trainees.

Describe the proposed conference and travel using the **general** outline provided below:

- a. Background: Provide a brief statement regarding the need for and timeliness of the conference.
- b. Purpose: State the purpose of the conference.
- c. Objectives: State concisely the educational aims of participation in the meeting and the expected training value.

Principal Investigato	r:	 	
Proposal Title:			

(HBCU/MI Academic Development Award Proposal) Table of Contents

Page Number

Proposal Cover Booklet (12 pages)
Peer Review Referral Page (no page limit)i
Proposal Title Page (1 page limit)
Table of Contents (1 page limit)2
Checklist for Proposal Submission (1 page)
Technical Abstract (1 page limit)4
Public Abstract (1 page limit)5
Statement of Work (2 page limit)6
Proposal Relevance Statement (1 page limit)8
Proposal Body (10 page limit)
Abbreviations (1 page limit)
References (no page limit)
Biographical Sketches (3 page limit each for PI and participating investigators)
Existing/Pending Support (no page limit)
Facilities/Equipment Description (no page limit)
Administrative Documentation (no page limit)
Detailed Cost Estimate (no page limit)
Instruments (no page limit)
Publications and Patent Abstracts (5 document limit)

- d. Methods: Describe the selection process for the trainees. If conference support is requested, give details about the meeting organization, focus, and agenda with specific emphasis on the training component. Provide a list of speakers if appropriate.
- 12. Abbreviations See Appendix B, part 12.
- 13. References See Appendix B, part 13.
- 14. Biographical Sketches See Appendix B, part 14. Biographical sketches should be prepared for pre- and postdoctoral trainees as well as the meeting coordinator, collaborating investigators, and invited speakers if appropriate.
- 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. Provide the following administrative documentation in the proposal submission:
 - A letter from the applicant describing the degree to which the applicant and any
 collaborators participated in proposal development. This letter should not be placed in
 an envelope and should be included in the Administrative Documentation section of the
 proposal.
 - A document verifying conference dates and focus is required from the sponsoring institution or organization and must be included in this section.
- 18. Detailed Cost Estimate See Appendix B, part 18.
- 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/MI Academic Development Award proposals is May 17, 2000 at 4:00 p.m. Eastern Time.
- 23. Appendices See Appendix B, part 23.