DEPARTMENT OF DEFENSE

FISCAL YEAR 2001
PROSTATE CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT I

December 13, 2000

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 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 fiscal year 2001 (FY01) 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

- Proposals for the FY01 PCRP will be requested through the publication of two separate program announcements. This program announcement (Program Announcement I) is requesting proposals in three previously established PCRP award mechanisms: Idea Development Awards, New Investigator Awards, and Postdoctoral Traineeship Awards. Program Announcement II will request proposals in four new PCRP award categories: clinical trials, research consortium development, institutional training, and scholar awards.
- A Letter of Support from a mentor (Postdoctoral Traineeship Awards) 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 to simplify some processes and clarify others. These revised appendices will be available on the CDMRP web site (http://cdmrp.army.mil/funding/default) by February 2001.

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.

3. Receipt Deadline

The receipt deadline for all proposals requested in this program announcement (Program Announcement I) is March 21, 2001 at 4:00 p.m. Eastern Time. See Appendix B, part 22 for additional details.

4. Timeline

The timeline for proposals requested in this program announcement is:

Letter of Intent:	As soon as possible but no later than March 7, 2001
Proposal Receipt Deadline:	**March 21, 2001 at 4:00 p.m. Eastern Time**
Peer Review:	May 2001
Request for RCQ[1] Documents:	As early as June 2001
Programmatic Review:	August 2001
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between November 2001 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
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP01-Program Announcement I)
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.

[1] 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: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (PCRP01-Program Announcement I)
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 I)
1076 Patchel Street (Building 1076)
Fort Detrick, MD 21702-5024

Driving Directions to Fort Detrick

From Washington, DC

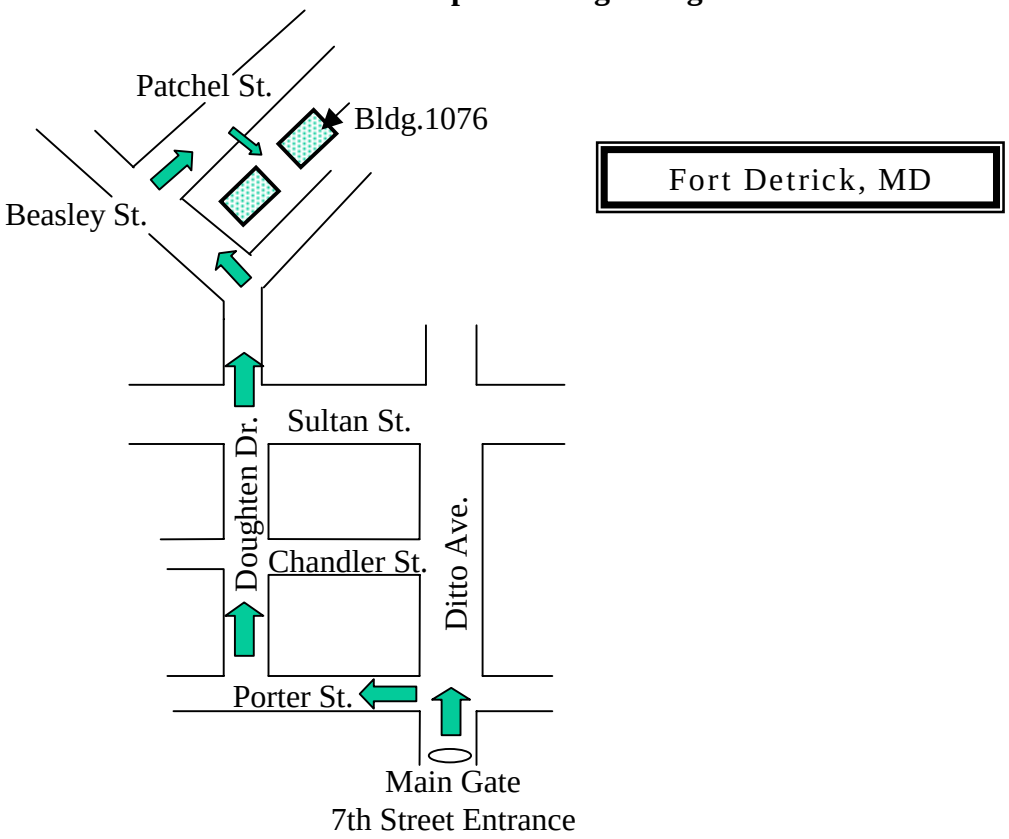
Take Interstate 495 to Interstate 270 North (exit 38) toward Rockville, Maryland. In Frederick, Interstate 270 ends and joins Route 15 North. Follow Route 15 North to the 7th Street exit. Turn right on 7th Street and proceed four blocks to Fort Detrick's Main Gate.

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, and V-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 Regulatory Compliance and Quality documents dealing with Research Involving Human Subjects and/or Anatomical Substances **before funds can be awarded.**

Concurrent with the RCQ review, a Contract Specialist from the U.S. Army Medical Research Acquisition Activity (USAMRAA) will contact the administrative representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

Please note that the award start date will be determined during the negotiation process.

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

[1] United States Code

II. Department of Defense Prostate Cancer Research Program

II-A. History of the Prostate Cancer Research Program

The Department of Defense (DOD) Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative, multi-institutional, multidisciplinary, and regionally focused research directed toward eliminating prostate cancer. Congressional direction for FY97 specified $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

Program History	FY97-99	FY00[1]
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[2]

[1]Award negotiations will not be finalized until September 2001.
[2]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 on prostate cancer research and training in two separate program announcements. This program announcement (Program Announcement I) requests proposals in three previously established PCRP award mechanisms: Idea Development Awards, New Investigator Awards, and Postdoctoral Traineeship Awards (see Section II-C for additional details). Program Announcement II (anticipated to be released in January 2001) will request proposals in four new award categories aimed at executing clinical trials, developing research consortia, establishing

institutional training grants at Historically Black Colleges and Universities, and training minority investigators through scholar awards.

The overall goal of both announcements is to promote research directed toward conquering prostate cancer. Within this context, the objectives of the FY01 PCRP are to (1) prevent prostate cancer, (2) detect prostate cancer in its earliest stages of development, (3) cure prostate cancer, and (4) improve the quality of life for individuals and their families living with prostate cancer.

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

II-C. Fiscal Year 2001 PCRP Program Announcement I Award Opportunities

A total of $100M was appropriated by Congress to fund the PCRP 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 this program announcement, while the remaining $18M will be used to fund proposals requested in response to PCRP Program Announcement II, anticipated to be released in January 2001. The programmatic strategy for Program Announcement I is to fund proposals in two categories: (1) research awards and (2) training/recruitment 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.

II-C.1. Training/Recruitment Awards

Approximately $2M will be allocated for training/recruitment awards, which consist of Postdoctoral Traineeship Awards (Section III). The intent of Postdoctoral Traineeship Awards is to prepare new scientists for careers in prostate cancer research.

II-C.2. Research Awards

Approximately $65M will be allocated for research awards, which consist of New Investigator Awards (Section IV) and Idea Development Awards (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 high risk but have the potential for high return in scientific and clinical knowledge. New Investigator Awards are targeted to investigators in the early phases of their careers and to investigators established in other fields with limited or no experience in the prostate cancer field (as indicated by publications and research funding) who desire to move into prostate cancer research. Preliminary data are not required for New Investigator Awards. 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. One of the goals of both mechanisms is to recruit investigators to prostate cancer research. Investigators without significant preliminary data relevant to prostate cancer should apply for the New Investigator Award. Investigators with significant preliminary data should apply for the Idea Development Award.

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
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	March 21, 2001 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	March 21, 2001 4:00 p.m. ET	Section IV
Idea Development Awards	Independent investigators at the level of Assistant Professor or equivalent or above	• Rewards innovative ideas and technology • Preliminary data required	$375,000 for direct costs over a 3-year performance period	March 21, 2001 4:00 p.m. ET	Section V

* Eastern Time

Important note regarding duplicate submissions: Submission of the same research project under different award mechanisms will **not** be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different principal investigators. The Government reserves the right to reject any proposal.

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. The focus of these awards is on the applicant, the mentor, and the training environment. Eligible applicants must have successfully defended a doctoral thesis and completed all academic requirements for their degree at the time of award negotiation.

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

Submission of the same research project under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

Approximately $2M 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.

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

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

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

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

- **Training and Environment:** Will the training prepare the applicant for an independent research career in prostate cancer? Is the proposed training appropriate? Would the described training further the applicant's goal to become an independent researcher? Does the postdoctoral training take place in an environment that is appropriate to accomplishing the applicant's goals? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to research training in prostate cancer?

- **Relevance:** Will the postdoctoral training prepare the applicant to investigate an important problem in prostate cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to prostate cancer research? Does the application make a convincing case for the relevance of the training to prostate cancer?

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well-integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data?

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

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

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

III-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

III-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Postdoctoral Traineeship Awards. Please note that the body of the proposal is limited to **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 **March 21, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1 and Statement of Eligibility.

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, Postdoctoral Traineeship Award applicants should describe explicitly (within the 1-page limit) the training value of the proposed research relative to the applicant's career goals. Describe how the combination of training value and relevance to prostate cancer will prepare the applicant for a career in the battle against prostate cancer.

11. Proposal Body – See Appendix B, part 11.
    The body of Postdoctoral Traineeship Award 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 such as coursework, laboratory techniques, conferences, and

journal clubs. Describe the research concept to be explored. Provide a statement of the mentor's qualifications, including experience as a research supervisor.

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

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

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

   iii. Objectives: State concisely the 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.

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 Postdoctoral Traineeship Award proposals, biographical sketches should be included for the applicant, the mentor, and all collaborating investigators. Each biographical sketch may not exceed 3 pages.

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 document 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.
    A list of all items included in the Administrative Documentation section is to be the first item in this section.

    Provide the following items in the Administrative Documentation section of each copy of the proposal submission. To document the sources of letters of support, 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:

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

- A Statement of Eligibility form (page III-7) signed by the applicant and the Department Chair, Dean, or equivalent official verifying that the applicant has or will have successfully completed a doctoral degree at the time of award negotiation, has completed all academic requirements, and has no more than 3 years of postdoctoral training and therefore is eligible for this award.

- A letter of support from the mentor describing his or her commitment to the training/ career development/mentorship of the applicant and the nature of the proposed collaboration/training. This letter should also describe the degree to which the applicant participated in idea development and proposal preparation, as well as the degree to which the applicant will participate in the execution of the proposal if funded. Emphasis should be placed on the training environment and the designated mentor, and should include qualifications, especially in prostate cancer research, and previous experience in training students and postdoctoral fellows. This letter is to be sent with the application and included in the Administrative Documentation section of all copies of the proposal. 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 with the application and included in the Administrative Documentation section of all copies of the proposal. Letters of recommendation **will not** be accepted separately from the application.

- The Administrative Documentation section can also include letters of support from any collaborating investigators.

Proposals lacking the above-mentioned 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.

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 March 21, 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 PCRP Postdoctoral Traineeship

Applicant's Name:_____

Title of Proposal:_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of Applicant:_____

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

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

Name of Official (*please print*):_____

Title:_____

Organization:_____

Signature of Official:_____ Date:_____

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

Proposal Title:_____

_____

Postdoctoral Traineeship Award Proposal
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IV. New Investigator Awards

IV-A. New Investigator Awards

The intent of New Investigator Awards is to promote and reward innovative ideas and technology related to prostate cancer. New Investigator Awards are targeted to investigators in the early phases of their careers and to investigators established in other fields with limited or no experience in the prostate cancer field (as indicated by publications and research funding) who desire to move into prostate cancer research. To be eligible for this award, the applicant must be an independent investigator with access to appropriate research facilities.

In accordance with the challenge to be innovative and capture novel ideas in their early stages of development, **proposals lacking preliminary data must demonstrate sound scientific judgment and rationale to be competitive.** This research may represent a new paradigm, challenge existing paradigms, or look at an existing problem from a new perspective. Thus, New Investigator proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of prostate cancer. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Although this research is inherently risky and does not require preliminary data, these proposals should nonetheless be based on a sound scientific rationale that is established through logical reasoning and/or a critical review and analysis of the literature.

Submission of the same research project under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different principal investigators (PIs). The Government reserves the right to reject any proposal.

Approximately $20M 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. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment.

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

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

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental 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 evaluated if included.)

- **Scientific Relevance:** Does this study address a critical problem in prostate cancer research? To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does the proposal make a convincing case for the relevance of the research to prostate cancer?

- **Innovation:** Does the research involve 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:** 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 expertise available to conduct the study successfully?

- **Environment:** 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. Programmatic Review Evaluation Criteria for New Investigator Award Proposals

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

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 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

IV-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for New Investigator Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and

photographs. **Proposals exceeding specified page limits may be administratively withdrawn prior to peer review.** Ensure that the proposal is received by **March 21, 2001 at 4:00 p.m. Eastern Time.**

1. Who May Apply – See Appendix B, part 1 and Statement of Eligibility.

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, New Investigator Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to prostate cancer research. Describe how the combination of innovation and relevance in the proposal will contribute to the goals 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, graphs, and photographs, if used, must be included in this section.

    For New Investigator Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Presentation of preliminary data is **not** required. However, for the proposal to be competitive, investigators must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature.

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

a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

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

c. Objectives: State concisely the 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.

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.
    Provide the following items in the Administrative Documentation section of each copy of the proposal submission:

    - A Statement of Eligibility form (page IV-7) signed by the applicant and 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.

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

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.

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 March 21, 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 PCRP New Investigator Award

Applicant's Name:_____

Title of Proposal:_____

Applicant's Organization Name:_____

Applicant's Organization Location:_____

_____

Signature of Applicant:_____

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

- Is an independent investigator; and
- Has access to appropriate research facilities.

Name of Official (*please print*):_____

Title:_____

Organization:_____

Signature of Official:_____ Date:_____

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

Proposal Title:_____

_____

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V. Idea Development Awards

V-A. Idea Development Awards

The intent of Idea Development Awards is to encourage innovative approaches to prostate cancer research from established prostate cancer investigators and established investigators in other fields who want to move into prostate cancer research. To be eligible for an Idea Development Award, an applicant must be an independent investigator at the level of **Assistant Professor or equivalent or above.**

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.

Submission of the same research project under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

Approximately $45M 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. Institutional support and commitment must be evident to foster the applicant's research career, such as the provision of access to adequate laboratory facilities and equipment.

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

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

- **Research Strategy:** Are the conceptual framework, hypotheses, experimental 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 relevant to prostate cancer research support the proposed project?

- **Scientific Relevance:** Does this study address a critical problem in prostate cancer research? To what extent will the project, if successful, make an original and important contribution to the goal of conquering prostate cancer and/or advancing research in the field? Does the proposal make a convincing case for the relevance of the research to prostate cancer?

- **Innovation:** Does the research involve 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?

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

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

V-C. Programmatic Review Evaluation Criteria for Idea Development Award Proposals

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

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 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

V-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Development Awards. Please note that the body of the proposal is limited to **10 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn**

prior to peer review. Ensure that the proposal is received by **March 21, 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, Idea Development Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to prostate cancer research. Describe how the combination of innovation and relevance in the proposal will contribute to the goal of conquering prostate cancer and/or advancing research in the field.

11. Proposal Body – See Appendix B, part 11.
    The body of Idea Development Award proposals is limited to **10 pages**. Figures, tables, graphs, and photographs, if used, must be included in this section. The inclusion of promising and well-founded preliminary data relevant to prostate cancer research and the proposed project is required for Idea Development proposals. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

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

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. 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 the proposed syntheses. Outline and document the routes to the synthesis.

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

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.

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 March 21, 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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