# **Announcement of Federal Funding Opportunity**

# Summary

#### I. GENERAL INFORMATION

- **A. Title of Award:** Health Disparity Research Prostate Scholar Award (HDR).
- **B.** Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Prostate Cancer Research Program (PCRP).
- C. Funding Opportunity Number: DAMD17-PC03-HDR.
- **D. Agency Name:** US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.
- E. Agency Contact(s)
  - 1. Questions related to the Program, proposal format, or required documentation may be addressed to the CDMRP at:

Phone: 301-619-7079 Fax: 301-619-7792

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

Mail: Commander

US Army Medical Research and Materiel Command ATTN: MCMR-PLF (DAMD17-PC03-HDR)

1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

**2. Questions related to electronic submission:** The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website: <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a> (the proposal submission website)

E-mail: <u>help-proposals-cdmrp@cdmrp.org</u>

- F. Anticipated Instrument Type(s): Grants/Cooperative Agreements.
- **G.** Catalog of Federal Domestic Assistance (CFDA) Number(s): 12.420; Military Medical Research and Development.
- **H.** Website Address to Access Application Package: Proposals must be submitted electronically at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>. The website contains all the information, forms, documents, and links you will need to apply.

#### II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Health Disparity Research – Prostate Scholar Awards is to encourage investigators at the Assistant Professor or equivalent level to focus their research efforts on the disparate burden of prostate cancer in African Americans. These awards will require the active involvement of a collaborator who is an established prostate cancer researcher. The ultimate goal of these awards is to resolve the disparity in prostate cancer incidence, morbidity, and mortality between African Americans and other ethnic groups.

# III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- A total of approximately \$2 million (M) is available for this award mechanism.
- Depending on the number and quality of the applications, it is anticipated that approximately 5 proposals will be funded.
- Funding for Health Disparity Research Prostate Scholar Awards can be requested for up to a maximum of \$300,000 in direct costs for up to a 3-year performance period, plus indirect costs as appropriate.

# IV. ELIGIBILITY INFORMATION

- **A. Applicants:** Applicants must hold a position as an Assistant Professor or equivalent, and show a connection to, or effectiveness in working with, the African American community.
- **B.** Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution.
- C. Cost Sharing: Not required.
- **D. Other Eligibility Criteria:** Please see the Full Text of Program Announcement description for details regarding duplicate submissions, applications from Historically Black Colleges and Universities/Minority Institutions, and administrative compliance issues.

# V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

- **A. Proposal Information:** Applicants are required to submit the Proposal Information prior to upload of the proposal. Complete the Proposal Information as described at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>.
- **B.** Proposal Preparation: All proposals must be converted into an electronic PDF (Portable Document Format) file for electronic proposal submission. Please see the Full Text of Program Announcement for details
- **C. Submission Dates and Times:** Deadline Date: April 16, 2003. Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by 5:00 p.m. (Eastern time).

**D.** Electronic Submission Requirements: Electronic submission is required. No paper copy submissions will be accepted. Proposals must be submitted electronically at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>. Please see the Full Text of Program Announcement for details.

#### VI. PROPOSAL REVIEW INFORMATION

The CDMRP uses a two-tiered review process for proposals: scientific peer review, followed by programmatic review. Details of both tiers of review can be found in the Full Text of Program Announcement.

Health Disparity Research – Prostate Scholar Award applicants will have an opportunity to submit a written statement addressing the issues raised in their peer review summary statement. The written response will be forwarded to programmatic review along with the summary statement for consideration during the second tier of review.

# VII. AWARD ADMINISTRATION INFORMATION

- **A.** Award Notices and Administrative Requirements: Details of award notification procedures, and administrative requirements including Regulatory Compliance and Quality documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances, Research Involving Animals, and Safety Program Plan) can be found in the Full Text of Program Announcement.
- **B.** Reporting Requirements: Annual reporting requirements apply.

# **Full Text of Program Announcement**

# I. GENERAL INFORMATION

- **A. Title of Award:** Health Disparity Research Prostate Scholar Award (HDR).
- **B.** Program Name: Department of Defense (DOD) Fiscal Year 2003 (FY03) Prostate Cancer Research Program (PCRP).
- C. Funding Opportunity Number: DAMD17-PC03-HDR.
- **D. Agency Name:** US Army Medical Research and Materiel Command (USAMRMC), Office of the Congressionally Directed Medical Research Programs (CDMRP), 1077 Patchel Street, Fort Detrick, Maryland 21702-5024.
- E. Agency Contact(s):
  - 1. Questions related to the Program, proposal format, or required documentation. Applicants should submit questions as early as possible. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079 Fax: 301-619-7792

E-mail: <a href="mailto:cdmrp.pa@det.amedd.army.mil">cdmrp.pa@det.amedd.army.mil</a>

Mail: Commander

US Army Medical Research and Materiel Command ATTN: MCMR-PLF (DAMD17-PC03-HDR)

1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: Help lines will be available to answer specific questions regarding the preparation of proposals for electronic submission, or the process of electronic submission. The help line phone numbers are provided on the web or may be requested by e-mail as follows:

Website: https://cdmrp.org/proposals (the proposal submission website)

E-mail: help-proposals-cdmrp@cdmrp.org

**F.** Anticipated Instrument Type(s): The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. More information on these funding instruments may be obtained by request from:

**Fax:** 301-619-2937

E-mail: q&a.baa@det.amedd.army.mil

Mail: Director

US Army Medical Research Acquisition Activity ATTN: MCMR-AAA 820 Chandler Street Fort Detrick, MD 21702-5014

- **G.** Catalog of Federal Domestic Assistance (CFDA) Number 12.420: Military Medical Research and Development.
- **H. Website to Access Application Package:** Proposals must be submitted electronically at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>. This website will contain all the information, forms, documents, and links you will need to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Section E.1 above.

# II. FUNDING OPPORTUNITY DESCRIPTION

# A. Program History

The Health Disparity Research – Prostate Scholar Award is part of the DOD PCRP, which was established in fiscal year 1997 (FY97) to promote innovative research directed toward eliminating prostate cancer. Appropriations for the PCRP since FY97 total \$480 million (M). The program history of the FY97-02 PCRP is shown in Table 1. The FY03 appropriation is \$85M.

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

Program History	FY97-00	FY01	FY02 <sup>1</sup>
Congressional Appropriations for PCRP	\$210M	\$100M	\$85M
Total Proposals Received	1, 951	782	699
Total Proposals Funded	439	212	150
Health Disparity Research Proposals Received	N/A <sup>2</sup>	6	10
Health Disparity Research Proposals Funded	N/A	1	5

Award negotiations will be finalized by September 2003.

- **B.** Program Objectives: The objectives of the FY03 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.
- **C. Award Mechanism Description:** The intent of the Health Disparity Research Prostate Scholar Awards is to encourage investigators at the Assistant Professor or equivalent level to focus their research efforts on the disparate burden of prostate cancer in African Americans. These awards will require the active involvement of a collaborator who is an established prostate cancer researcher. The ultimate goal of these awards is to resolve the disparity in prostate cancer incidence, morbidity, and mortality between African Americans and other ethnic groups.

Investigators must demonstrate a connection to, or effectiveness in working with, the African American community. Such demonstration might include previous experience working with the African American population and/or demonstrated cultural ties to the African American community.

<sup>&</sup>lt;sup>2</sup> N/A: Not applicable.

In addition, the proposal must explicitly state how the proposed research is related to a health disparity issue for prostate cancer.

Proposals must include a discussion regarding the institution's commitment to foster the applicant's prostate cancer research career as reflected by (1) the extent to which the applicant will be relieved of his or her academic or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) the opportunities for critical professional interaction with senior colleagues.

#### III. AWARD INFORMATION

Funding for Health Disparity Research – Prostate Scholar Awards can be requested for up to a maximum of \$300,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate. Projects requiring lower levels of funding may also be submitted. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings. The amount allotted for travel is \$1,800 per year. The nature of the PCRP does not allow for renewal of grants or supplementation of existing grants. Depending on the quality and the number of proposals received, the CDMRP expects to allot approximately \$2M of the \$85M FY03 PCRP appropriation to fund approximately five Health Disparity Research – Prostate Scholar Awards.

#### IV. ELIGIBILITY INFORMATION

**A. Applicants:** All eligible applicants to the Health Disparity Research – Prostate Scholar Awards must show a connection to, or effectiveness in working, with the African American community. To be eligible for this award, the applicant must hold a position as an Assistant Professor or equivalent.

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution as defined below.

- **B.** Institutions: Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).
- **C.** Cost Sharing: Cost sharing is not a requirement for this award.

# D. Other Eligibility Criteria:

1 B 1 (C)

- 1. **Duplicate Submissions:** Submission of the same research project to the FY03 PCRP under different award mechanisms is not allowed. This includes duplicate submissions under different award mechanisms by different PIs. The Government reserves the right to reject duplicative proposals.
- **2. HBCU/MI:** A goal of the DOD is to allocate funds for the CDMRP's peer reviewed research to fund proposals from HBCU/MI. This provision is based upon guidance from Executive Orders. Proposals submitted to the DOD are assigned HBCU/MI status if the submitting institution is so designated by the Department of Education on the date that the program announcement is released. The Department of

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<sup>&</sup>lt;sup>1</sup>Executive Orders 12876, 12900, and 13021

Education list is posted on the CDMRP website at <a href="http://cdmrp.army.mil/funding/pdf/mipcrp012703.pdf">http://cdmrp.army.mil/funding/pdf/mipcrp012703.pdf</a> under Minority Institutions.

**3.** Administrative Compliance Issues: Compliance guidelines have been designed to ensure the presentation of all proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

Failure to comply with any of the five items listed below will result in administrative rejection of the entire proposal prior to peer review:

- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is submitted after the deadline.
- Required administrative documentation is not included.

For any other sections of a proposal with a defined page limit, any pages over the specified limit will be removed from the proposal and not forwarded for peer review.

Unless specifically requested by the CDMRP, any material submitted after the submission deadline will not be forwarded for peer review.

#### V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

**A. Proposal Components Summary:** This subsection is a summary of submission requirements. Details, URLs, and other links are provided in the appropriate subsections of this program announcement.

The PI is responsible for uploading the following information:

- Proposal Information: The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- Statement of Work (SOW) and Proposal Abstracts: The SOW, Technical Abstract, and Public Abstract are each entered as a separate data field.
- **Proposal:** The proposal is uploaded as a PDF (Portable Document Format) file under the "File Upload" tab.
- Budget Information: The budget information is uploaded as a PDF file under the "File Upload" tab
- Regulatory Compliance and Quality (RCQ) Documents: The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance Form are each uploaded as separate PDF files under the "File Upload" tab.

The Contract Representative (or equivalent) from the applicant's institution is responsible for the following:

- US Army Medical Research Acquisition Activity (USAMRAA) Documents: The institute's currently negotiated "Rate Agreement," "Certifications and Assurances for Assistance Agreements," and the "Representations for Assistance Agreements" are to be uploaded as separate PDF files under the Contract Representative's "My Profile" tab.
- Approval: The Contract Representative must provide approval of all proposal components (Proposal Information, SOW, Abstracts, Proposal, Budget Information, and RCQ documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. (Eastern time) April 16, 2003. Otherwise, the entire proposal will be considered to be a "LATE" submission and will not be forwarded for review.
- **B. Proposal Information:** Applicants are required to submit the Proposal Information, Parts 1 and 2, (referred to in previous years as the "Proposal Cover Booklet") prior to upload of the proposal and the budget information. Complete the Proposal Information as described in <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>. The Proposal Information must include the e-mail address of a representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institute.
  - **Letter of Intent:** All applicants considering submission of a proposal in response to this program announcement are expected to submit an electronic Letter of Intent no later than 4 weeks prior to the April 16, 2003 deadline. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>, then save the information by clicking on the "Save and Forward Letter of Intent" button. This information may be changed at any time until the applicant submits the final Proposal Information by clicking on the "Submit Final" button.
- **C. SOW 11,400-character limit, including spaces (approximately 2 pages):** The SOW is captured as a data field under the "SOW/Abstract" tab in the CDMRP eReceipt system. To submit the SOW, the applicant may either type in the SOW, or "cut and paste" it from a word processing application into the data field. Sample SOWs can be found at <a href="https://cdmrp.org/samples.cfm">https://cdmrp.org/samples.cfm</a>.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each of the major goals or objectives of the proposed research/services will be accomplished during the timeline for which the USAMRMC will provide financial support.

As appropriate, the SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims),
- Identify the timeline and milestones for the work over the period of the proposed effort,
- Indicate the numbers of research subjects (animal or human) projected or required for each task,
- Identify methods, and
- Identify products/deliverables for each phase of the project.
- **D.** Proposal Abstracts 5,700-character limit, including spaces (approximately 1 page), for each abstract. Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to both the peer and programmatic review process.

Programmatic review is based upon the Integration Panel's (IP's) review of these two abstracts as part of the peer review summary statements; therefore, it is paramount that the investigator submit abstracts that fully describe the proposed work.

Each abstract must contain the title of the proposal and the name of the PI. Each abstract must be submitted as a data field under the "SOW/Abstracts" tab of the CDMRP eReceipt system. Applicants can either type in their abstracts, or "cut and paste" them from a word processing application into the respective data fields. Do not include figures or tables in either abstract. Spell out all Greek or other non-English letters.

Abstracts of all funded proposals will be posted on the CDMRP website at <a href="http://cdmrp.army.mil/">http://cdmrp.army.mil/</a>. Thus, proprietary or confidential information should not be included in the abstract.

1. **Technical Abstract:** Sample technical abstracts can be found at <a href="https://cdmrp.org/samples.cfm">https://cdmrp.org/samples.cfm</a>. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective or hypothesis and its supporting rationale, specific aims of the study, study design, and significance of the proposed work to the program's goals.

Use the outline below for preparing the structured technical abstract.

- Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State concisely the specific aims of the study.
- Study Design: Briefly describe the study design.
- Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the program's goals. For example, how the study will cure, prevent or improve the detection or treatment of the disease.
- 2. Public Abstract: Sample public abstracts can be found at <a href="https://cdmrp.org/samples.cfm">https://cdmrp.org/samples.cfm</a>. The public abstract is intended to communicate the purpose of, and rationale for, the study to non-scientific audiences. The public abstract is an important component of the proposal review process because consumer advocates, who are part of the review and funding decision process, use this abstract as a part of their review. It must be composed in a way to make the scientific objectives and rationale for the proposal understandable to non-scientifically trained readers. The public abstract should not be a duplicate of the technical abstract, but should describe the goals and objectives of the research project, and its relevance to the program.

In addition to describing the project, the public abstract must answer the following questions:

- (1) What will the ultimate applicability of the research be?
  - What types of patients will it help and how?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a consumer-related outcome?
- (2) If the research is too basic for clinical applicability, what are the interim outcomes?
  - What types of contributions will this study make to advance research?
  - How will the research enhance this or other studies being conducted?

#### E. Proposal

1. Format: All proposals must be converted into an electronic PDF file for electronic submission. Proposals must be uploaded under the "File Upload" tab of the CDMRP eReceipt system. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire appropriate software and learn the process before the submission deadline. To prepare proposals for PDF submission, the instructions in this subsection must be followed carefully.

The proposal must be clear and legible and conform to the following guidelines:

- Type Font: 12 point, 10 pitch.
- Type Density: No more than 15 characters per inch. (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)
- Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch.
- Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.
- Color, Resolution, and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files, but applicants should keep in mind that some reviewers work from black and white printed copies. Applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white.
- Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations, and symbols.
- Language: English.
- Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm).
- **2. Title/Referral Page: No page limit.** Complete the Title/Referral Page, which can be downloaded from the CDMRP website at <a href="https://cdmrp.org/programAnnouncements.cfm">https://cdmrp.org/programAnnouncements.cfm</a>. Complete each section as described:
  - a. Proposal title (up to 160 characters).
  - b. Proposal log number (this will be automatically provided when the Proposal Information is completed and saved).
  - c. PI's full name (first, middle initial, last).
  - d. Submitting Institution.
  - e. Award mechanism: Type in "Health Disparity Research Prostate Scholar Award."
  - f. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that would best describe the technical aspects of the project.
  - g. Conflicts of interest: To avoid real and apparent conflicts of interest during the peer review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subcontractors. In addition, list the names of other individuals outside the scope of this proposal who may have a conflict of interest in review of this proposal. Provide the

following information for each participant: name, institutional affiliation(s), and role(s) on the proposed project or perceived conflicts of interest.

- **3.** Table of Contents/Checklist: Start section on a new page. Prepare a <u>Table of Contents/Checklist</u>, with page numbers, using the form provided. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. If possible, provide headers throughout the proposal that include the PI's name (last name, first name, middle initial) and proposal log number (this will be automatically provided when the electronic Proposal Information is saved).
- **4. Proposal Relevance Statement: Start section on a new page; one-page limit.** Health Disparity Research Prostate Scholar Award applicants should describe explicitly how the proposed research addresses a health disparity issue. The applicant should also state how the proposed research focuses on an issue related to the disparate burden of prostate cancer in African Americans. Applicants must demonstrate a connection to, or effectiveness in working with, the African American community. Due to the importance of the relevance to prostate cancer disparity, Relevance Statements will be forwarded to programmatic reviewers.
- **5. Proposal Resubmission Statement:** Not applicable for Health Disparity Research Prostate Scholar Awards submissions.
- 6. Main Body: Start section on a new page; 10-page limit inclusive of any figures, tables, graphs, and photographs. Describe the proposed project using the outline provided below:
  - a. Background: Briefly describe the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.
  - b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.
  - c. Objectives: State concisely the project's specific aims and research strategy.
  - d. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation. For synthetic chemistry proposals, include a clear statement of the rationale for all proposed syntheses. Outline and document the routes to each synthesis.
  - e. Collaborative Arrangement: Detail the proposed collaborative arrangement and emphasize the specific goals. A concise description of the proposed interaction between the established investigator and the applicant should be articulated. Qualifications and facilities of the established investigator should be addressed. Document the experience of the collaborating investigator in training prostate cancer researchers and include information on training/collaborations with minority investigators.
  - f. Career Development Plan: Briefly describe the applicant's career development plan and how the proposed research will promote the applicant's career in the area of prostate cancer disease disparity.
- **7. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used.
- **8.** References: Start section on a new page; no page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **9. Biographical Sketches:** Three-page limit per individual. Biographical sketches should be included for each of the key personnel listed on the budget page, including collaborating investigators and support staff. These documents are a critical component of the review process. Incomplete or missing biographical sketches may result in lower priority scores. The <u>Biographical Sketch form</u> may be used. Use of this form is not mandatory, but the information requested shall be presented in a similar format.
- **10.** Existing/Pending Support: Start section on a new page; no page limit. List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the PI and key personnel.

It is especially important to provide documentation of existing/pending support that reflects the commitment of the collaborating investigator or institutional commitment. If no support exists, state "none." Proposals submitted under this program announcement should not duplicate other funded research projects.

- 11. Facilities/Equipment Description: No page limit. Describe the facilities available for performance of the proposed research/services. Describe the institutional commitment, including any additional facilities or equipment proposed for purchase or available for use at no cost to the USAMRMC. Indicate if government-owned facilities or equipment are proposed for use.
- **12. Questionnaires, Survey Instruments, or Clinical Protocols: No page limit.** Include an appropriately titled page listing the documents you have included in this section.
- 13. Publications and/or Patent Abstracts: Five-document limit. Include up to five relevant publication reprints and/or patent abstracts. A patent abstract should provide a non-proprietary description of the patent application. If more than five such items are included in the submission, the extra items will not be peer reviewed.
- **14.** Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. This section is not for additional data, figures, or other similar information. Unrequested material that is submitted may be construed as an attempt to gain a competitive advantage and will be removed; it may be grounds for administrative rejection of the proposal.

All administrative documentation must be incorporated into the electronic PDF version of your proposal. Support documentation will not be accepted separately from the electronic proposal submission. All documents or letters requiring signatures must be signed and then incorporated into the submitted proposal.

The first item in this section must be a list of all the items included in the Administrative Documentation section. Provide the following in the Administrative Documentation section of the proposal.

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

- **F. Budget Information:** Budget Information includes the <u>Detailed Cost Estimate forms and Budget Instification</u>. Budget Information is uploaded under the "File Upload" tab of the CDMRP eReceipt system.
  - 1. Funding Restrictions: Funding for Health Disparity Research Prostate Scholar Awards can be requested for up to a maximum of \$300,000 for direct costs for up to a 3-year performance period, plus indirect costs as appropriate. These funds can cover salary, expenses including research supplies, and travel to scientific/technical meetings. The amount allotted for travel is \$1,800 per year.
  - **2. Detailed Cost Estimate Forms and Justifications Instructions:** Budget is an important consideration in both peer and programmatic review, and applicants are cautioned to use discretion in budget requests. Budgets will also be reviewed during award negotiations. Complete justification must be provided for expenses in all categories. The Detailed Cost Estimate form and Justification for your proposal must be uploaded as a PDF file, separate from the proposal.

The following section provides instructions for preparing the Detailed Cost Estimate form. All amounts entered should be in U.S. dollars.

#### a. Personnel

- **i.** Name: Starting with the PI, list the names of all participants who will be involved in the project during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff. Only **ONE** person may be identified as the PI of the proposal.
- **ii. Role on Project:** Identify the role of each individual listed on the project. Describe his or her specific functions in the "Justification" section of the Detailed Cost Estimate form.
- **iii. Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50 percent, note this with an asterisk (\*) and provide a full explanation in the "Justification" section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- iv. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project.
- v. Percentage of Effort on Project: The qualifications of the PI and the amount of time that he or she and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.
- vi. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.
- vii. Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant

organization as a direct cost to all sponsors. A copy of the rate agreement or other documentation to support the fringe benefits should be provided.

- viii. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.
- **b.** Consultant Costs: Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants.
- **c. Major Equipment:** It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.
- **d.** Materials, Supplies, and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than \$1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.
- e. Travel Costs: Travel costs may not exceed \$1,800 per year.
- **f.** Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.
- **g.** Other Expenses: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution.
- **h. Subcontract Costs:** A description of services or materials that are to be awarded by subcontract or subgrant is required. For awards totaling \$10,000 or more, provide the following specific information:
  - Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
  - Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
  - Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
  - The proposed acquisition price.
- i. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed.

- j. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section of the Detailed Cost Estimate form. Note with an asterisk (\*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should agree with the amount previously entered on-line in the Proposal Information <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>.
- **3. Justification (third page of the Detailed Cost Estimate form):** Each item in the budget should be clearly justified under the "Justification" section of the Detailed Cost Estimate form.
- **G. RCQ Requirements:** Completed and signed copies of the "<u>Certificate of Environmental Compliance</u>" and "<u>Principal Investigator Safety Program Assurance Form</u>" must be uploaded under the "File Upload" tab of the CDMRP eReceipt system as separate PDF files.

Do not submit other RCQ Documents (Research Involving Human Subjects and/or Anatomical Substances; Research Involving Animals) with the proposal. Instead, the applicant should provide these documents to the USAMRMC only upon request.

- **H. USAMRAA Documents:** A copy of the institution's negotiated "Rate Agreement," the "Certifications and Assurances for Assistance Agreements", and the "Representations for Assistance Agreements" must be uploaded by the Contract Representative from the Sponsored Programs Office. These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system.
- **I.** Submission Dates and Times: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant's institution's Sponsored Programs Office (or equivalent) by the deadline. If your proposal is submitted and approved electronically after the deadline, it will not be considered for review.

# The timeline for Health Disparity Research – Prostate Scholar Awards is:

On-Line Letter of Intent: As soon as possible but no later than March 19, 2003.

On-Line Proposal Information: Prior to proposal submission.

Proposal Submission/Approval Deadline: 5:00 p.m. Eastern time April 16, 2003.

Peer Review: June 2003.

Summary Statements available to Applicant: By August 28, 2003 Applicant Response Deadline: By September 10, 2003

Programmatic Review: October 2003.

Request for Additional Documents: As early as 2 weeks after the completion of

programmatic review.

Notification Letter: Approximately 4 weeks after programmatic review.

Award Start Date: Between November 2003 and September 2004.

**J. Electronic Submission Requirements:** Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at <a href="https://cdmrp.org/proposals">https://cdmrp.org/proposals</a>.

Several steps are critical to successful proposal submission.

- The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early.
- The e-mail address of a Contract Representative from the Sponsored Programs Office must be included.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office.
- The Contract Representative from the Sponsored Programs Office who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- If final approval is not accomplished by the submission deadline, the proposal will be considered to be a "LATE" submission and will not be considered for review.
- Any supporting documentation that the applicant includes with the proposal must be incorporated into the PDF file prior to upload.
- Some items to be included in the proposal will need to be scanned. These items might include figures, tables, letters, or publications. All scanned documents, including figures, tables, and graphs, should be scanned at a resolution of 300-400 dpi or less.
- Budget Information includes the Detailed Cost Estimate form and the Budget Justification form.
   Budget Information must be uploaded under the "File Upload" tab of the CDMRP eReceipt system.
- The RCQ documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed PI Safety Program Assurance Form. These must be uploaded under the "File Upload" tab of the CDMRP eReceipt system.

#### VI. PROPOSAL REVIEW INFORMATION

#### A. Proposal Review and Selection Overview

- 1. **Process:** The CDMRP uses a two-tiered review process for proposal evaluation. 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 scientific merit as well as overall program goals.
- **2. Peer Review:** Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals, based upon the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the 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 below). 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 peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the 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.

**3. Programmatic Review:** The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. 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 primarily use the peer review summary statements, and the proposal abstracts. SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals will be reviewed concurrently with all others in the same research area during scientific peer review, but may be evaluated separately during programmatic review. Consistent with the CDMRP's goal, recommendations for funding HBCU/MI submissions will be based upon scientific excellence and program relevance.

#### **B.** Review Criteria

- **1. Peer Review:** Health Disparity Research Prostate Scholar Award proposals will be evaluated according to the following criteria:
  - Applicant: Does the applicant demonstrate a connection to, or effectiveness in working with, the African American community? Do the applicant's previous training, experience, and achievements indicate a solid potential for a successful career in prostate cancer research? Does the research outlined in the proposal enhance the probability that the applicant will pursue a career in prostate cancer research that addresses disease disparity?
  - **Disease Relevance:** Does the proposed research address the disparity in incidence, morbidity, and mortality of prostate cancer in African Americans? If the aims of this research are achieved, will there be a potential benefit to the African American population? Does the application make a convincing case for the relevance of the research to disease disparity?
  - Research Program: Are the conceptual framework, concepts, hypothesis, design, methods, and analyses of the research adequately developed and well integrated for the applicant's research program? Is the applicant aware of potential problem areas, and are potential solutions proposed?
  - Collaborator: Does the collaborating investigator have the background, qualifications, and time to develop a productive collaboration with the applicant? Is the collaborating investigator committed to the applicant's career development? Does the collaborating investigator have a strong record of funding in prostate cancer research? Does the collaborating investigator have experience training individuals from diverse backgrounds?
  - **Institutional Commitment:** Is there an institutional commitment to provide access to laboratory facilities and equipment? Are there opportunities for critical professional interaction with senior

colleagues? Will the applicant be provided with sufficient relief from academic or clinical responsibilities to permit substantially increased time for research activities? Is there a strong institutional commitment to the applicant's development of a research program addressing the disparity in prostate cancer?

- **Budget:** Is the budget feasible for the work proposed?
- 2. PI Response to the Peer Review Summary Statement: Prior to programmatic review, applicants for the FY03 Health Disparity Research Prostate Scholar Award will have an opportunity to submit a written reply to the issues raised in the peer review summary statement. Summary statements from peer review will be available to the PI by August 28, 2003. The PI can provide a response to the summary statement, not to exceed 3 pages, excluding biographical sketches for any new personnel, reprints or preprints of accepted manuscripts, and revised budget pages, if appropriate. The response should concentrate on those sections of the application needing revision or more development, not on elements rated highly by the peer reviewers. The response must be returned to the CDMRP by September 10, 2003 so it can be appended to the summary statement for the second tier of review, programmatic review.
- **3. Programmatic Review:** The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to establish the PCRP's broad portfolio. The criteria the IP uses to make funding recommendations are:
  - Ratings and evaluations of the scientific peer review panels;
  - Programmatic relevance;
  - Relative innovation; and
  - Program portfolio balance with respect to research disciplines or specialty areas.

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

# VII. AWARD ADMINISTRATION INFORMATION

- **A.** Award Notices: After the two-tiered evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review summary statement. Applicants can expect to be notified of the agency's decision in November 2003.
- **B.** Administrative Requirements: All awards are made to organizations, not individuals. A PI should submit a proposal through, and be employed by or affiliated with, a university, college, non-profit research institute, commercial firm, or government agency (including military laboratories) in order to receive support. To be eligible for award, a prospective recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (Office of Management and Budget Circular A-110).

Any change in the institution, the PI, and/or the SOW will require that the PI resubmit contact information. Any delay in the submission of updated information could result in a delay in the contracting and regulatory review and a subsequent delay in payment.

**C. Award Negotiation:** Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist from USAMRAA will contact the Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications related to the proposed Statement of Work and associated budgets may be required.

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

# D. RCQ Review

- 1. Overview: Concurrent with the USAMRAA negotiations, RCQ will review the Certificate of Environmental Compliance, and PI Safety Program Assurance form submitted with the proposal, as well as RCQ documents related to Research Involving Animal Use and Research Involving Human Subjects/Anatomical Substance Use submitted upon request to ensure that Army regulations are met.
- **2.** Certificate of Environmental Compliance: The Certificate of Environmental Compliance should be submitted with the proposal. If multiple research sites/institutions are funded in your proposal, then a Certificate of Environmental Compliance for each site will be requested at a later date.
- **3. Safety Program Documents:** The <u>Principal Investigator Safety Assurance Form</u> should be submitted with the proposal.

A Facility Safety Plan is also required and will be requested at a later date. However, your institution may already have an approved Facility Safety Plan. To determine the status of approval, check the USAMRMC website at <a href="http://mrmc-www.army.mil/crprcqsohdfsplan.asp">http://mrmc-www.army.mil/crprcqsohdfsplan.asp</a>. If your institution is not listed on the aforementioned website, contact your Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Safety Program Plan can be found at <a href="http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc">http://mrmc-www.army.mil/docs/rcq/FY02FSPAppendix.doc</a>.

If multiple research sites/institutions are funded in your proposal, then a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

- **4. Research Involving Animal Use:** Animal use documents should not be submitted with the proposal and will be requested at a later date. Specific requirements for research involving animals can be found at <a href="http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc">http://mrmc-www.army.mil/docs/rcq/FY02AnimalAppendix.doc</a>.
- **5. Research Involving Human Subjects/Anatomical Substances:** Human Subjects and/or Anatomical Substances use documents should not be submitted with the proposal and will be requested at a later date. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects and/or anatomical substances, a second tier of review and approval is also required by the DOD. This second review is conducted by the Human Subjects Research Review Board (HSRRB), which is administered by the USAMRMC Office of Regulatory Compliance and Quality. 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. For example:
  - Intent to Benefit. In the development of a research protocol for submission to the DOD, the applicant must specifically address, if applicable, the Intent to Benefit. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be

- aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.
- The DOD considers cell lines of human origin to be human anatomical substances. Use of these cell lines is subject to HSRRB review and approval.

Specific requirements for research involving human subjects and/or anatomical substances can be found at <a href="http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf">http://mrmc-www.army.mil/docs/rcq/HSAppendix19Feb02.pdf</a>. An informed consent form template can be located at <a href="http://mrmc-www.army.mil/docs/rcq/consentform">http://mrmc-www.army.mil/docs/rcq/consentform</a> template.pdf

**E. Reporting:** All research awards will require the timely delivery of several reports during the research effort. Reporting requirements consist 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.

#### VIII. OTHER INFORMATION

- **A. Disclosure of Proprietary Information outside the Government:** By submission of a proposal, the applicant understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding will not be subject to public release.
- **B.** Government Obligation: Applicants are cautioned that only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. Applicants who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.
- **C. Information Service:** Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.
- **D. Inquiry Review Panel:** Applicants can submit a letter of inquiry to the USAMRMC in response to funding decisions made for a given proposal. Members of the CDMRP staff, USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel and review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.
- **E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq. <sup>2</sup>), 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.

<sup>&</sup>lt;sup>2</sup> Title 35, United States Code, Section 200 et seq.

# IX. ACRONYM LIST

AVI Audio Video Interleave

CDMRP Congressionally Directed Medical Research Programs

CFDA Catalog of Federal Domestic Assistance

CPA HBCU Collaborative Partnership Training Award

DOD Department of Defense

EHD Exploration – Hypothesis Development Award ERD Exploration – Resource Development Award

FY Fiscal Year

HBCU Historically Black Colleges and Universities

HBCU/MI Historically Black Colleges and Universities/Minority

Institutions

HDR Health Disparity Research – Prostate Scholar Award HDT Health Disparity Training – Prostate Scholar Award

HSRRB Human Subjects Research Review Board

IDEA Idea Development Award

IP Integration Panel

IRB Institutional Review Board

M Million

MPEG Moving Picture Experts Group NIA New Investigator Award

PCRP Prostate Cancer Research Program

PDF Portable Document Format PI Principal Investigator

POSTDOC Postdoctoral Traineeship Award
PRT Physician Research Training Award
RCQ Regulatory Compliance and Quality

SOW Statement of Work

USAMRAA US Army Medical Research Acquisition Activity
USAMRMC US Army Medical Research and Materiel Command

USC United States Code

WAV Wave