Announcement of Federal Funding Opportunity

Summary

I. GENERAL INFORMATION

A. Title of Award: Clinical Trial Development Award (CTDA).

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Prostate Cancer Research Program (PCRP).

C. Funding Opportunity Number: PC05-CTDA.

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-ZB-C (PC05-CTDA) 1077 Patchel Street (Building 1077) Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: The help line phone number(s) is 301-682-5507 and is also provided on the Web. Other help desk contact information is:

Website:	https://cdmrp.org (User's Guide located in upper right corner of the proposal submission website)
E-mail:	help-proposals-cdmrp@cdmrp.org

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 https://cdmrp.org. The website contains all the information, forms, documents, and links needed to apply.

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward applied for written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

The intent of the Clinical Trial Development Award is to provide support to establish the necessary collaborations and develop the necessary research resources that will serve as a foundation for investigator-initiated clinical trials. The goal of these awards is the development of Phase I or Phase II clinical trial(s) that will have a major impact on the treatment, diagnosis, detection, or prevention of prostate cancer. As such, they should focus on new interventions and **not** on the refinements of existing interventions (e.g., optimizing timing or dosage regimens). Funds for Clinical Trial Development Awards will be disbursed in two installments, both of which can cover administrative support directly associated with planning, development, and review of the clinical trial or the clinical protocol and consent form. **Funds may not be used to support laboratory or preclinical research.**

III. AWARD INFORMATION

- Type of award: grant/cooperative agreement.
- Approximately $0.8 million (M) is available to fund the FY05 PCRP Clinical Trial Development Awards.
- Depending on the number and quality of the applications, it is anticipated that eight proposals will be funded.
- Funding for Clinical Trial Development Awards can be requested for a maximum of $100,000 for a 1-year performance period, inclusive of both direct and indirect costs. Funding will be disbursed in two equal installments: the first when the award is made and the second when the compliant proposal, clinical protocol and consent forms are submitted to either the FY06 PCRP Clinical Trial Award (pending receipt of funds) or to a clinical trial award mechanism from another nationally recognized funding source. **Funds may not be used to support laboratory or preclinical research.**
- Clinical Trial Development awardees will be required to submit a compliant proposal, clinical protocol, and consent form by February 2006 to either:

- The FY06 PCRP Clinical Trial Award according to guidance provided in the FY06 PCRP Clinical Trial Award Program Announcement (the FY06 Clinical Trial Award is anticipated to fund up to five awards for up to $1M per award over a 3-year period of performance, pending receipt of funds);

  OR

- A clinical trial award mechanism from another nationally recognized funding source. Official notice from the applicant's Sponsored Research Office (or equivalent) documenting the submission must be provided to the PCRP within 6 weeks of submission.

- Full Clinical Trial Award proposals may be submitted to the PCRP in FY06 without prior submission or receipt of a FY05 Clinical Trial Development Award.
- **Please note that there is no guarantee that funds will be available for Clinical Trial Awards in FY06.**

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent investigators at an eligible institution.

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, nonprofit, public, and private organizations. Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see "Major Equipment" located in Subsection V.G.2.c of the Full Text of Program Announcement for details.

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 https://cdmrp.org.

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 Date and Time: Deadline: February 8, 2005. 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 submissions will be accepted. Proposals must be submitted electronically at https://cdmrp.org. Please see the Full Text of Program Announcement for details.

VI. PROPOSAL REVIEW INFORMATION

Clinical Trial Development Award proposals will receive a single level of review. Proposals for the Clinical Trial Development Award will be reviewed by the PCRP Integration Panel to determine which proposals best fulfill the intent of the award mechanism.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices and Administrative Requirements: Details of award notification procedures and administrative requirements including regulatory documents (Certificate of Environmental Compliance, Research Involving Human Subjects and/or Anatomical Substances/Cadavers, 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: Clinical Trial Development Award (CTDA).

B. Program Name: Department of Defense (DOD) Fiscal Year 2005 (FY05) Prostate Cancer Research Program (PCRP).

C. Funding Opportunity Number: PC05-CTDA.

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:	cdmrp.pa@det.amedd.army.mil
Mail:	Commander US Army Medical Research and Materiel Command ATTN: MCMR-ZB-C (PC05-CTDA) 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 number is 301-682-5507 and is also provided on the Web. Other help desk contact information is:

Website:	https://cdmrp.org (User's Guide located in upper right corner of 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:	qa.baa@det.amedd.army.mil
Mail:	Director US Army Medical Research Acquisition Activity ATTN: MCMR-ZB-A 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 https://cdmrp.org. This website will contain all the information, forms, documents, and links needed to apply. If you experience difficulties in downloading documents, contact the CDMRP as indicated in Subsection E.2 above.

I. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written permission from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward applied-for written approvals directly to the applicant.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Clinical Trial Development Award is part of the DOD PCRP, which was established in FY97 to promote innovative research directed toward eliminating prostate cancer. The FY05 appropriation is $85 million (M). Appropriations for the PCRP from FY97 to FY05 total $650M. The Clinical Trial Development Award was first offered in FY04, when 10 proposals were received and 7 were funded (award negotiations are expected to be finalized by December 2004).

B. Program Objectives: The objectives of the FY05 PCRP are to (1) prevent prostate cancer, (2) detect prostate cancer, (3) cure prostate cancer, and (4) improve the quality of life for individuals living with prostate cancer and their families.

C. Award Mechanism Description: PCRP will fund Phase I and/or Phase II clinical trials in two stages: the Clinical Trial Development Award in FY05 and, pending receipt of funds, the Clinical Trial Award in FY06. Proposals for the first award, the Clinical Trial Development Award, are being requested in this program announcement. Recipients of the Clinical Trial Development Award in FY05 will be required to submit proposals, clinical protocols, and consent forms to compete for the PCRP Clinical Trial Award in FY06 or for a clinical trial award mechanism from another nationally recognized funding source. However, the PCRP FY06 Clinical Trial Award will be open to all eligible applicants with clinical trial proposals relevant to prostate cancer treatment, diagnosis, detection, or prevention.

Due to the scope and magnitude of the PCRP Clinical Trial Award, the Clinical Trial Development Award has been instituted to provide support to establish the necessary collaborations and develop clinical protocols to provide a foundation for investigator-initiated clinical trials. The goal of these awards is to provide a foundation for the rapid execution of Phase I or Phase II clinical trial(s) that will have a major impact on the treatment, diagnosis, detection, or prevention of prostate cancer. As such, they should focus on new interventions and **not** on the refinements of existing interventions (e.g., optimizing timing or dosage regimens).

The Clinical Trial Development Award proposal should briefly describe:

- The objective and rationale of the proposed clinical trial, including any preclinical science and preliminary clinical research relevant to the trial;
- The relevance of the proposed clinical trial to prostate cancer treatment, diagnosis, detection, or prevention;
- The proposed intervention(s) to be tested in the clinical trial, with a brief description, as appropriate, of its:
    - Source,
    - Investigational New Drug (IND) status,
    - Availability of the substance in sufficient quantity under current Good Manufacturing Practices (cGMP) production,
    - Dosing,
    - Mechanisms of action, and
    - Preclinical/clinical evidence of efficacy;
- A preliminary estimate of sample size for the clinical trial, a preliminary patient accrual/recruitment schedule, and evidence of access to appropriate patient population(s);
- A plan for the development of a clinical protocol and consent form, and the outline of a plan for obtaining both internal scientific and local Institutional Review Board (IRB) reviews for the clinical protocol and consent form at the highest level possible within the institution, up to and including preliminary IRB approval if available at your institution, by the time of the Clinical Trial Award proposal submission;
- An outline of a clinical trial management plan; and
- Evidence of preliminary institutional commitment to the proposed clinical trial.

The Clinical Trial Development Award has been instituted to facilitate the funding of a quality clinical trial and the rapid accrual of patients into the trial through a well-developed clinical protocol. The purpose of the Clinical Trial Development Award is not to obtain preliminary data or to conduct studies to support the rationale for the proposed clinical trial; therefore, funds may not be used to support laboratory or preclinical research. Recipients of the Clinical Trial Development Award will be required to submit a proposal, clinical protocol, and consent form to compete for the PCRP Clinical Trial Award in FY06, pending receipt of funds, or for a clinical

trial award from another nationally recognized funding source. Funds from the Clinical Trial Development Award may be used to:

- Support meetings, teleconferences, and travel among participating investigators to develop the clinical trial and associated protocol and consent form;
- Furnish salary support during the clinical protocol development;
- Develop and implement a data management, real-time communications, or administration plan for the proposed clinical trial;
- Reimburse the Principal Investigator's (PI's) institution for costs associated with conducting the IRB review of the proposed clinical protocol and consent form;
- Provide other costs directly associated with planning and developing the clinical trial;
- Coordinate consent forms and other IRB issues between different institutions for multi-institutional trials;
- Resolve intellectual and material property rights among institutions, companies, and investigators;
- Develop definitive statistical plans; and
- Develop sources and obtain letters affirming intervention supply or availability.

The proposal, clinical protocol, and consent form must all be submitted as part of the application for the PCRP Clinical Trial Award in FY06. Failure to submit a proposal to the PCRP or to another funding source in FY06 after receipt of a FY05 Clinical Trial Development Award will result in a forfeit of the second installment of the Clinical Trial Development Award funding. Selection to receive a FY05 Clinical Trial Development Award and submission of an FY06 Clinical Trial Award proposal do not guarantee receipt of a FY06 Clinical Trial Award. The FY06 Clinical Trial Award will be open to all eligible applicants with clinical trials relevant to prostate cancer treatment, diagnosis, detection, or prevention, irrespective of submission or receipt of a FY05 Clinical Trial Development Award.

III. AWARD INFORMATION

Funding for Clinical Trial Development Awards can be requested for a maximum of $100,000 inclusive of both direct and indirect costs for up to a 1-year performance period. Funds will be disbursed in two equal installments: the first when the award is made and the second when the compliant proposal, protocol, and consent forms are submitted. Funds from both installments of the Clinical Trial Development Award can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning, development, and review of the clinical trial or the clinical protocol and consent form. Travel costs may not exceed $1,800 per investigator. **Funds may not be used to support laboratory or preclinical research.**

Disbursement of the Clinical Trial Development Award funds will be made in two equal installments. The first installment will be made at the time of the award; the second installment will be made after the submission of a compliant clinical trial award proposal, clinical protocol, and consent form to either the PCRP or to another nationally recognized funding organization that funds clinical trials. **Failure to submit a clinical trial proposal to the PCRP or to a similar funding agency in FY06 after receipt of a FY05 Clinical Trial Development Award will result in a forfeit of the second installment of the Clinical Trial Development Award funding.**

Clinical Trial Development awardees will be required to submit a compliant proposal, clinical protocol, and consent form by February 2006 to either:

- The FY06 PCRP Clinical Trial Award according to guidance provided in the FY06 PCRP Clinical Trial Award Program Announcement the FY06 Clinical Trial Award in FY06 is anticipated to fund up to five awards for up to $1M per award over a 3-year period of performance, pending receipt of funds;

  OR

- A clinical trial award mechanism from a nationally recognized funding source. Official notice from the applicant's Sponsored Research Office (or equivalent) documenting this submission must be provided to the PCRP within 6 weeks of submission.

The nature of the PCRP does not allow for renewal of grants or supplementation of existing grants. The CDMRP expects to allot approximately $0.8M of the $85M FY05 PCRP appropriation to fund approximately eight Clinical Trial Development Awards.

Please note that there is no guarantee that funds will be available for Clinical Trial Awards in FY06.

IV. ELIGIBILITY INFORMATION

A. Applicants: Applicants must be independent investigators at an eligible institution.

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, nonprofit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI). Agencies of local, state, and federal governments are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies will be expected to explain how their proposals do not overlap with their intramural programs.

C. Cost Sharing: It is expected that institutions will cost share. Please see full details under "Major Equipment" in Subsection V.G.2.c.

D. Other Eligibility Criteria

1. Duplicate Submissions: Submission of the same research project to the FY05 PCRP under different award mechanisms or to other CDMRP programs is discouraged. 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 on guidance from Executive Orders.[1] 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 the program announcement is released. The Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp 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. 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.

The following will result in administrative rejection of the entire proposal prior to review:

- Font size is less than 12 point.
- Font type is not Times New Roman.
- Line spacing is greater than six lines per vertical inch.
- Margins are less than 0.5 inch on any side.
- Proposal body exceeds page limit.
- Proposal body is missing.
- Detailed cost estimate is missing.
- Proposal is incomplete after the deadline.

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

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

[1] Executive Orders 12876, 12900, and 13021

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.
- **Proposal Contacts:** Contact information for the PI and the Contract Representative are required to complete the proposal submission process.
- **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 "Required Files" tab.
- **Budget Information:** The budget information is uploaded as a PDF file under the "Required Files" tab.
- **Regulatory Documents:** The Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form are each uploaded as separate PDF files under the "Required Files" tab.

The Contract Representative or institutional official responsible for sponsored program administration (or equivalent) from the applicant's institution is responsible for the following:

- **The Contract Representative's Contact Information Profile: This must be completed prior to electronic approval of all proposal components.**
- **US Army Medical Research Acquisition Activity (USAMRAA)-Required Documents:** The institution'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 or institutional official responsible for sponsored program administration (or equivalent) must provide approval of all proposal components (Proposal Information, Proposal Contacts, SOW, Abstracts, Proposal, Budget Information, and regulatory documents). Contract Representative approval must occur prior to the submission deadline of 5:00 p.m. Eastern time February 8, 2005. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time deadline.

B. Proposal Information: Applicants are required to submit the Proposal Information, Parts 1 and 2, prior to upload of the proposal and the budget information. Complete the Proposal

Information as described in https://cdmrp.org. The Proposal Information may be "Verified & Saved" for editing purposes until "Submit Final" for approval by their Sponsored Programs Office's (or equivalent's) representative.

- **Letter of Intent:** An electronic Letter of Intent should be submitted by January 12, 2005. To accomplish this, the applicant should complete Part 1 of the Proposal Information section at https://cdmrp.org, 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. Proposal Contacts: The Proposal Contacts **must** include the e-mail address of a representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution. The Proposal Contacts must be "Finalized" for approval by the applicant's Sponsored Programs Office's (or equivalent) representative.

D. SOW – 11,400-character limit, including spaces (approximately two 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 http://cdmrp.org/samples.cfm.

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 number of research subjects (animal or human) projected or required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

E. Proposal Abstracts – 5,700-character limit, including spaces (approximately one page), for each abstract: Both a structured technical abstract and a public (nontechnical) abstract are required. These abstracts are vitally important to the review process.

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 https://cdmrp.army.mil. Thus, proprietary or confidential information should not be included in the abstract.

1. Technical Abstract: Sample technical abstracts can be found at http://cdmrp.org/samples.cfm. The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, intervention and its supporting rationale, trial design, and relevance of the proposed clinical trial 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 clinical trial. Briefly describe the studies that led to the proposed clinical trial.
- Intervention: State the intervention to be tested. Provide evidence or rationale that supports the intervention.
- Trial Design: Briefly describe the proposed clinical trial, including proposed patient sample size, accrual, and outcome measures. Indicate the phase (I, I/II, or II) of the clinical trial.
- Relevance: Provide a brief statement explaining the relevance of the proposed clinical trial to prostate cancer treatment, diagnosis, detection, or prevention.

2. Public Abstract: Sample public abstracts can be found at http://cdmrp.org/samples.cfm. 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 are the ideas and reasoning behind the proposed clinical trial?

(2) What will be the ultimate applicability of the clinical trial to prostate cancer?

- 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?

F. Proposal

1. Format: All proposal components (proposal body, biographical sketches, publications, letters of support, etc.) must be converted into a single PDF file for electronic submission. Proposals must be uploaded under the "Required Files" 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.

Please Note New Format Requirements

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

- **Font size: 12 point or larger.**
- **Font type: Times New Roman.**
- **Spacing: Single-spaced between lines of text, no more than six lines of type within a vertical inch.**
- **Margins: Minimum of 0.5 inch in all directions.**
- **Print area: 7.5 inches x 10.0 inches (approximately 19 cm x 25.5 cm).**

Failure to adhere to the requirements for font size, font type, spacing, margins, and print area will result in administrative rejection of the entire proposal prior to review.

- 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.
- Language: English.

2. Title/Referral Page: No page limit. Complete the Title/Referral Page. Please note that all forms are available on the "Summary Tab" of eReceipt. 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 "Clinical Trial Development Award." (Indicate the clinical trail phase (Phase I, I/II, or II).

f. Indicate that this is a NEW proposal.

g. Keyword descriptive technical terms: To assist the staff in assigning proposals, 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.

h. Conflicts of interest: To avoid real and apparent conflicts of interest during the review process, list the names of all scientific participants in the proposal including consultants, collaborators, and subawardees. In addition, list the names of other individuals outside the scope of this proposal that may have a conflict of interest in the review of this proposal. Provide the following information for each participant: name, institutional affiliation(s), and, if applicable, his or her role(s) on the proposed project.

3. Table of Contents/Checklist: Start section on a new page; one-page limit. Prepare a Table of Contents/Checklist, with page numbers. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Please note that headers should not be included, as the proposal log number will be electronically captured on each page of the proposal after receipt.

4. Proposal Relevance Statement: Start section on a new page; one-page limit. Applicants should state explicitly how the proposed work will have a major impact on the treatment of prostate cancer. If this proposal is duplicative of a proposal submitted to another FY05 CDMRP program announcement, provide a strong justification for submitting duplicate proposals and the proposal's relevance to prostate cancer.

5. Proposal Resubmission Statement: Not applicable to Clinical Trial Development Award proposals.

6. Main Body: Start section on a new page; six-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other relevant information needed to judge the proposal. It is the investigator's responsibility to clearly articulate how the proposed plan for a clinical trial meets the intent of the mechanism. The proposal body should address the review criteria as outlined in Subsection VI.B of this program announcement.

Describe the proposed clinical trial using the outline provided below:

a. Objective: State the objective and rationale of the proposed clinical trial, including any preclinical science and preliminary clinical research relevant to the trial;

b. Relevance: State the relevance of the proposed clinical trial to prostate cancer treatment, diagnosis, detection, or prevention;

c. Interventions: As appropriate, describe the proposed intervention(s) to be tested in the clinical trial, with a brief description of its source, IND status, availability of the substance in sufficient quantity under cGMP production, dosing, mechanism(s) of action, and preclinical/clinical efficacy;

d. Patient Population(s): Provide a description of the patient population(s), an estimated sample size for the clinical trial, and a preliminary patient accrual/recruitment schedule;

e. Clinical Protocol: Outline the plan for the development of a clinical protocol and consent form and for obtaining both internal scientific and local IRB reviews at the highest level possible within the institution, up to and including preliminary IRB approval if available at your institution, by the time of the Clinical Trial Award proposal submission;

f. Management Plan: Describe the preliminary management plan for the clinical trial, including key participants and their contributions (additional information on collaborators can be included in the Biographical Sketch section, see item 9 below).

g. Institutional Support: Provide some evidence that the institution will support the proposed clinical trial.

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: Four-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 a lower global priority score. The Biographical Sketch form 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. 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. Administrative Documentation: No page limit. Submit only material specifically requested or required in this program announcement. **This section is not for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other relevant information needed to judge the proposal.** 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.

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

Provide the following:

- Letter(s) of support from any collaborating individuals or institutions.
- Letter(s) of commitment from institutions proposing to participate in the clinical trial.

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.

14. 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 reviewed.

G. Budget Information: Budget Information includes the Detailed Cost Estimate form and Budget Justification form. Budget Information is uploaded under the "Required Files" tab of the CDMRP eReceipt system.

1. Funding Restrictions: Funding for Clinical Trial Development Awards can be requested for a maximum of $100,000 inclusive of both direct and indirect costs for up to a 1-year performance period. Funds will be disbursed in two installments: the first when the award is made and the second when the compliant proposal, clinical protocol, and consent forms are submitted to either the FY06 PCRP Clinical Trial Award (pending receipt of funds) or to a clinical trial award mechanism from another nationally recognized funding source. Funds from both installments can cover administrative support including salary, meetings and related travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning, development and review of the clinical trial or the clinical

protocol and consent form. Travel costs may not exceed $1,800 per investigator. **Funds may not be used to support laboratory or preclinical research**.

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in review, and applicants are cautioned to use discretion in budget requests. Budgets also will be reviewed during award negotiations. **Organizations must provide sufficient detail and budget justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research.** The Detailed Cost Estimate form and Budget Justification for your proposal must be uploaded as a PDF file, separate from the proposal.

Costs proposed must conform to the following regulations and principles:

- **Commercial Firms:** Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31 (http://farsite.hill.af.mil), Contract Cost Principles and Procedures.
- **Educational Institutions:** Office of Management and Budget (OMB) Circular A-21, Cost Principles for Educational Institutions (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **Nonprofit Organizations:** OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations (http://www.whitehouse.gov/omb/grants/grants_circulars.html).
- **State, Local, and Tribal Governments:** OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments (http://www.whitehouse.gov/omb/grants/grants_circulars.html).

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 Budget 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%, note this with an asterisk (*) and provide a full explanation in the Budget 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 for all sponsors. 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 nonprofit recipients provide the equipment needed to support proposed research. In those rare cases in which specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated. Moreover, it is expected that institutions will share 50% of the cost of equipment purchased for this research proposal when individual equipment costs are equal to or exceed $5,000.

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., office supplies). Categories in amounts less than $1,000 do not need to be itemized.

e. Travel Costs: Travel costs to scientific/technical meetings may not exceed $1,800 per investigator.

f. Research-Related Subject Costs: Not applicable to Clinical Trial Development Award proposals.

g. Other Direct Costs: 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. Subaward 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 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 Budget 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 equal the amount previously entered online in the Proposal Information https://cdmrp.org.

3. Budget Justification (third page of the Detailed Cost Estimate form): Each item in the budget should be clearly justified under the Budget Justification section of the Detailed Cost Estimate form.

H. Regulatory Requirements: Completed and signed copies of the Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance form must be uploaded under the "Required Files" tab of the CDMRP eReceipt system as separate PDF files.

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

I. USAMRAA-Required Documents: The most current version 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 (or equivalent). These documents must be uploaded as separate PDF files under the Contract Representative's "My Profile" tab of the CDMRP eReceipt system prior to negotiations.

J. Submission Date and Time: 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 either incomplete or not approved electronically before the deadline, it will not be considered for review. The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time February 8, 2005 deadline.

The timeline for the Clinical Trial Development Award is:

Online Letter of Intent:	Expected by **January 12, 2005**
Online Proposal Information:	Prior to proposal submission
Proposal Submission/Approval Deadline:	**5:00 p.m. Eastern time February 8, 2005**
Proposal Review:	March 2005
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:	Anticipated between May 2005 and September 2005

K. Electronic Submission Requirements: Electronic submission is required. Proposals will be accepted only as PDF files submitted through the CDMRP eReceipt system at https://cdmrp.org.

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.
- Proposal Contacts must be submitted prior to submission of the proposal. The e-mail address of a Contract Representative from the Sponsored Programs Office (or equivalent) must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate early with their Sponsored Programs Office (or equivalent).

- The Contract Representative from the Sponsored Programs Office (or equivalent) who is authorized to negotiate on behalf of the institution is required to provide final approval before the proposal is accepted.
- The eReceipt system will **not** accept data entry, file uploads, or approvals submitted after the 5:00 p.m. Eastern time February 8, 2005 deadline.
- 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 "Required Files" tab of the CDMRP eReceipt system.
- The regulatory documents required at submission include a completed, signed Certificate of Environmental Compliance and a completed, signed Principal Investigator Safety Program Assurance form. These must be uploaded under the "Required Files" tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review Process: Clinical Trial Development Award proposals will receive a single level of review by the PCRP Integration Panel (IP) to determine which proposals best fulfill the intent of the award mechanism. The IP, which is composed of scientists, clinicians, and consumer advocates, represents diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. The PCRP IP will use the full Clinical Trial Development proposal to assess the scientific/technical merit and relevance of the submission to prostate cancer treatment, diagnosis, detection, or prevention.

B. Review Criteria: Clinical Trial Development Award proposals will be evaluated according to the following criteria:

- **Clinical Relevance:** Does the applicant provide a clear scientific rationale for the proposed clinical trial? Do existing preclinical science and/or preliminary clinical research support the relevance of the clinical trial to prostate cancer? Does the proposed clinical trial address an important problem related to the treatment, diagnosis, detection, or prevention of prostate cancer, and is it likely to have a substantial clinical impact?
- **Intervention:** Is the proposed intervention to be tested in the clinical trial adequately described and available? Is the intervention novel?
- **Clinical Trial:** Is the plan for the development of a clinical protocol within the time of the Clinical Trial Development Award appropriate? Is there a plan for obtaining both internal scientific review and local IRB approval(s) for the clinical protocol and consent form at the highest level possible within the institution, up to and including preliminary IRB approval, by the time of a Clinical Trial Award proposal submission? Are the

preliminary sample sizes and patient accrual plans reasonable? Does the PI present evidence of access to an appropriate patient population? Is the outline of a clinical trial management plan present, and is it appropriate to the proposed clinical trial?

- **Principal Investigator and Personnel:** Does the PI have expertise in clinical prostate cancer research? Are the PI and other key personnel appropriately trained and well suited to carry out this work? Is there representation from all the areas of expertise needed to conduct the clinical trial successfully?
- **Institutional Commitment:** Is there evidence of institutional commitment to the proposed clinical trial at each participating institution?

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 evaluation process is completed, every applicant will receive notification of the award status of his or her proposal. Applicants can expect to be notified of the agency's decision in May 2005.

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, nonprofit research institution, commercial firm, or government agency (including military laboratories) to receive support. To be eligible for an 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 (OMB Circular A-110 and DOD Grant and Agreement Regulations). *Any organization requesting receipt of an award from this announcement must be registered in the Central Contractor Registration (CCR) database. Access to the CCR online registration is through the CCR homepage at http://www.ccr.gov.*

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 and/or representative from the 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 SOW and associated budgets may be required.

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

D. Regulatory Review

1. Overview: Concurrent with the USAMRAA negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form submitted with the proposal. The applicable USAMRMC regulatory office will review documents related to research involving animal use, human subjects/anatomical substance use, and cadaver use submitted upon request to ensure that Army regulations are met.

2. Certificate of Environmental Compliance: The Certificate of Environmental Compliance must 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 Principal Investigator Safety Program Assurance form must 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 https://mrmc.detrick.army.mil/crprcqsohdfsplan.asp. 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 https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAppendix.doc.

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 https://mrmc.detrick.army.mil/docs/rcq/FY05AnimalAppendix.doc.

5. Research Involving Human Subjects/Anatomical Substances/Cadavers: (See Subsection V.H for information pertaining to the submission of documents related to the use of human subjects, human anatomical substances, and/or cadavers.) In addition to local IRB approval to conduct research involving human subjects and/or anatomical substances or cadavers, a second tier of IRB 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 Research Protections (ORP) (formerly 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. Before writing a research protocol, investigators must consider the requirements of Title 10 United States Code 980, which are applicable to DOD-sponsored research. Title 10 United States Code 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

  Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained prior to the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. Investigators 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/cadavers. Use of these cell lines is subject to HSRRB review and approval.

All PCRP FY06 Clinical Trial Award protocols must undergo review and approval by the HSRRB prior to implementation of the study; therefore, DOD and HSRRB requirements should be considered by recipients of the Clinical Trial Development Award during the development of protocols.

Specific requirements for research involving human subjects, human anatomical substances, and/or cadavers can be found at https://mrmc.detrick.army.mil/docs/rcq/HumanSubjectsAppendix(13May04).doc. An informed consent form template can be located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

6. Award/Regulatory Approval: Once an award is made, the applicant may not use, employ, or subcontract for the use of any human subjects, human anatomical substances/cadavers, or laboratory animals without written approval from the applicable USAMRMC regulatory office. The applicable USAMRMC regulatory office will forward the applied-for written approvals directly to the applicant.

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

1. Research Progress Report Requirements: 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.

2. Fiscal Report Requirements: Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research 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 used. 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, the 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 have occurred in the review process, 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.[2]), 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.

[2]Title 35, United States Code, Section 200 et seq.

F. J-1 Visa Waiver: It is the responsibility of the awardee to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

IX. ACRONYM LIST

AVI	Audio Video Interleave
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
cGMP	Current Good Manufacturing Practices
CTDA	Clinical Trial Development Award
DOD	Department of Defense
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IND	Investigational New Drug
IP	Integration Panel
IRB	Institutional Review Board
M	Million
MPEG	Moving Picture Experts Group
PCRP	Prostate Cancer Research Program
OMB	Office of Management and Budget
ORP	Office of Research Protections (formerly Regulatory Compliance and Quality)
PDF	Portable Document Format
PI	Principal Investigator
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