

Program Announcement

I. GENERAL INFORMATION

This program announcement is being released before the receipt of Federal funds appropriated in a bill for this program; funding of proposals received in response to this program announcement is contingent on the receipt of these funds at the United States Army Medical Research and Materiel Command (USAMRMC).

A. Title of Award: *Prostate Cancer Research Program (PCRP) Clinical Consortium Award.*

B. Program Name: Department of Defense (DOD) Fiscal Year 2006 (FY06) PCRP.

C. Funding Opportunity Number: W81XWH-06-PCRP-CCA.

D. Agency Name: 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 announcement, 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@amedd.army.mil
Mail: Commander
US Army Medical Research and Materiel Command
ATTN: MCMR-ZB-C (PC06-CCA)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

2. Questions related to electronic submission: A help line for questions relating to proposal submission and the CDMRP eReceipt Online Proposal Submission System is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time at 301-682-5507. Help also is available on the CDMRP website or by e-mail as follows:

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

F. Anticipated Instrument Type(s): The USAMRMC executes 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@amedd.army.mil
Mail: Director
US Army Medical Research Acquisition Activity
ATTN: MCMR-AAA-R
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 at <https://cdmrp.org>. This website contains all the information, forms, documents, and links needed to apply. Applicants experiencing difficulty in downloading documents should contact the CDMRP as indicated in [Subsection I.E.2](#).

I. Award/Regulatory Approval: The applicant may not use funds from this award to directly support research involving human subjects, human biological substances, or laboratory animals.

II. FUNDING OPPORTUNITY DESCRIPTION

A. Program History: The Clinical Consortium Award is one of the mechanisms of the DOD PCRCP, which was established in FY97 to promote innovative research directed toward eliminating prostate cancer. Appropriations for the PCRCP from FY97 through FY05 totaled \$650 million (M). The Clinical Consortium Award was established in FY05, when the PCRCP received 11 Clinical Consortium Award proposals and funded 8. The FY06 appropriation is \$80M.

B. Program Objectives: The overall goal of the FY06 PCRCP is to find and fund innovative, high impact research that seeks 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 for their families.

C. Award Mechanism Description

1. General Information: The intent of the FY06 PCRCP Clinical Consortium Award is to recruit additional sites into the existing PCRCP Clinical Consortium, which facilitates the rapid execution of collaborative Phase II or Phase II-linked Phase I (Phase I/II) clinical trials testing therapeutic agents or approaches for the management or treatment of prostate cancer. The overarching goal of the PCRCP in establishing the Clinical Consortium is to combine the efforts of the nation's leading investigators to bring to market novel therapeutic interventions that will ultimately decrease the overall impact of the disease.

The PCRCP Clinical Consortium currently comprises seven Clinical Research Sites and one Coordinating Center, which jointly are responsible jointly for proposing, selecting, and

conducting Phase II and Phase I/II clinical trials focused on prostate cancer therapeutic interventions. The Coordinating Center, which functions as a Clinical Research Site, also serves as the consortium information and planning nexus providing administrative, operational, and data management support services to participant Clinical Research Sites to implement consortium clinical trials in a timely manner.

The Clinical Consortium organizational structure includes the following key features (see Figure 1 below):

- **Coordinating Center:** The Coordinating Center is required for the administration and day-to-day management of consortium operations, development of the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination. The Coordinating Center also functions as a Clinical Research Site,
- **Clinical Research Sites:** Clinical Research Sites conceive, develop, and conduct clinical trials in prostate cancer and serve as entry points for clinical trials from outside the consortium,
- **Clinical Consortium Committee:** This central committee is composed of the Principal Investigators from the Coordinating Center and Clinical Research Sites, for the clinical trial selection process, and for the continual development and operation of the consortium. A representative from the USAMRMC is to be invited to all formal meetings for the Clinical Consortium Committee, and
- **External Advisory Board (EAB):** The EAB, which includes members of the PCRP Integration Panel, the PCRP Program Manager and the CDMRP Grants Manager for the Clinical Consortium, provides scientific review, oversight, data monitoring, and evaluation.

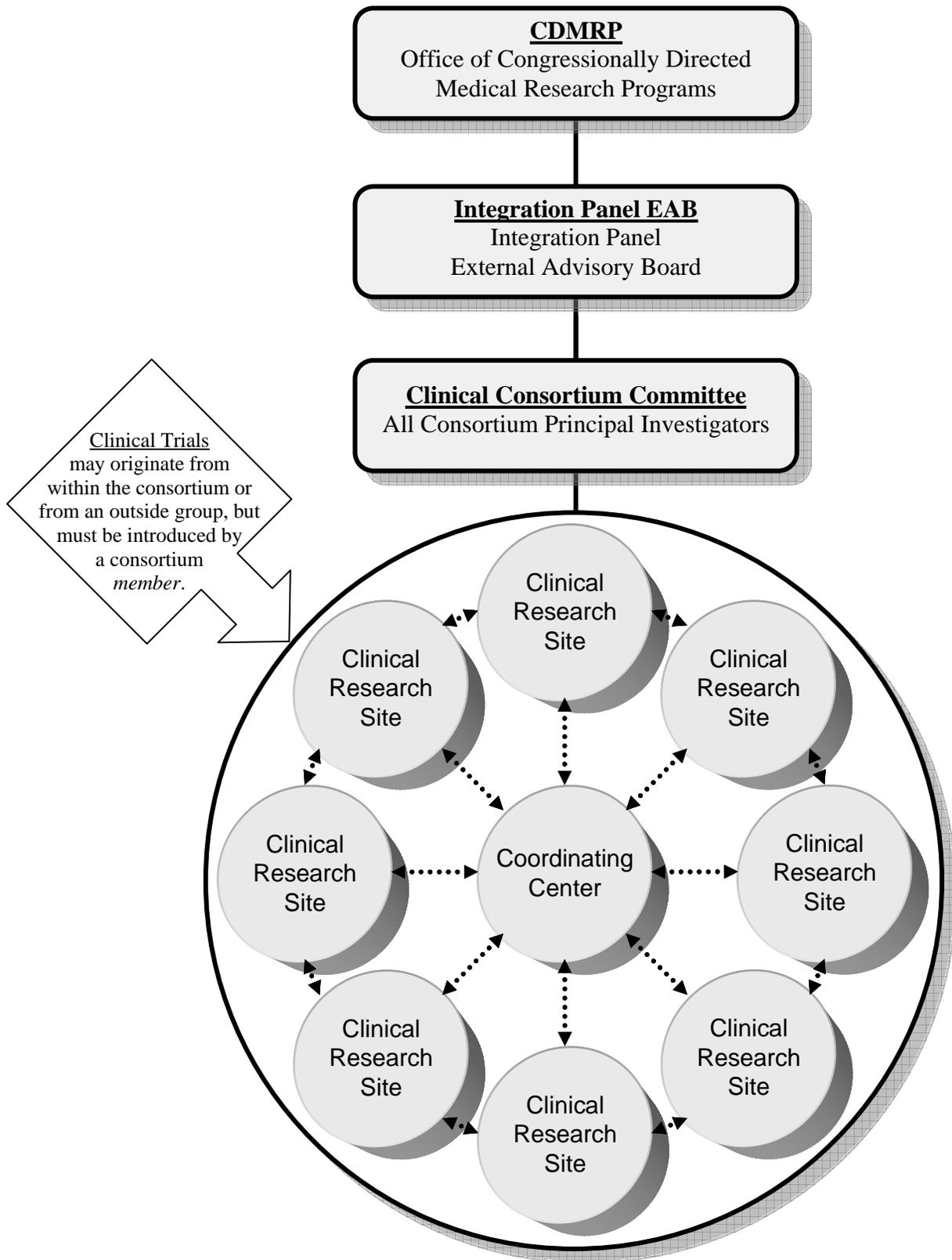


Figure 1. Basic Organizational Structure of the Clinical Consortium

All Consortium sites, including the Coordinating Center, are responsible for working collaboratively on the Clinical Consortium Committee to identify new clinical trials for implementation by the Consortium. Consortium members periodically propose new clinical trials to the Consortium, vote to decide which clinical trials will be implemented, and determine which Consortium institutions will participate. A representative from the USAMRMC must be invited to these sessions and any other formal meetings of the Consortium. Selected clinical trials are maintained in a queue and prepared for implementation as resources become available. All sites may serve as entry points for clinical trials that originate from outside the consortium. The Coordinating Center is responsible for facilitating this entire process. The Consortium is strongly encouraged to leverage the DOD investment whenever possible by including DOD-funded trials that meet the entry criteria established by the Clinical Consortium Committee.

The PCRIP Integration Panel, the PCRIP Program Manager, and the CDMRP Grants Manager for the Clinical Consortium function as an external advisory board to the Consortium by providing scientific review, consortium oversight, and data and progress review. Based on these reports and presentations, the EAB and USAMRMC staff will evaluate the progress, provide feedback, and invoke modifications and terminations as needed to facilitate the success of the consortium.

An important aspect of the Clinical Consortium Award is that **funding** for each participant site after the first year **is contingent upon** meeting the following consortium requirements:

- A minimum number of 35 patients accrued per year; however, the expectation is that accrual rates of 50 or more patients per year will be achieved;
- The presentation of at least one clinical trial to the consortium per year; however, the expectation is that two or more clinical trials will be proposed;
- Submission of an annual written progress report, semi-annual written briefings and presentations; and
- Timely submission of quality data as outlined by the Coordinating Center.

To assess data collection and accuracy, each participant site may be expected to participate in an on-site **audit** at the discretion of the Government by the Government or its designee.

Failure to achieve the minimum requirements outlined above may result in termination of individual award(s).
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The Clinical Consortium Award does not provide funding for research but rather provides the support to develop the collaborations and resources necessary for the consortium to rapidly execute Phase II and Phase I/II clinical trials.

2. Responsibilities of Consortium Participants

a. Responsibilities of the Clinical Research Sites: These include:

- Full participation in the Consortium, including, but not limited to, clinical trial introduction and selection, patient accrual for consortium studies, data collection and timely submissions, meeting attendance, and adherence to the consortium's operating procedures;
- Participation in clinical trials selected by the Consortium;
- Provision for a Clinical Research Coordinator who will interact with the Clinical Research Coordinators of other Clinical Research Sites and the Supervising Clinical Research Coordinator of the Coordinating Center to expedite and guide clinical protocols through the regulatory approval processes and to coordinate patient accrual and study activities across sites;
- Implementation of the consortium's standardized procedures and participation in consortium functions;
- Meeting minimum accrual requirements of 35 patients per year; however, the expectation is that enrollment of 50 patients or more per year will be achieved annually;
- Implementation of the Consortium's core data collection methodology and strategies;
- Compliance with Consortium-developed quality assurance and quality control procedures, as appropriate, including:
 - Participation in an on-site monitoring program to be managed by the Coordinating Center,
 - Implementation of the Consortium-developed management plan for acquisition and aggregation of protocol-specified tumor specimens, biological fluids, and relevant clinical data to the appropriate laboratories for testing or storage necessary for the conduct and analyses of clinical trials during the performance period of the award,
 - Submission of appropriate data and materials to allow for verification and review of protocol-related procedures, for example, pathology, imaging techniques, surgical methods, and therapeutic use;
- Implementation of procedures established by the Coordinating Center for ensuring compliance with US Food and Drug Administration (FDA) requirements for investigational agents, as appropriate;
- Preparation and presentation of written and oral semi-annual briefings to the Integration Panel EAB and USAMRMC staff at 1-day meetings typically held in the Baltimore-Washington, DC area; and
- Additional responsibilities based on recommendations and guidance from the Consortium Integration Panel EAB and USAMRMC staff.

b. Responsibilities of the Coordinating Center: These include:

- Adherence to the responsibilities delineated above for a Clinical Research Site;
- Ensuring that at least 5 clinical trials are open at any given time, with the expectation that at least 10 clinical trials will be open at any given time;
- Development and maintenance of the consortium organizational structure;
- Management of consortium-developed procedures for review, selection, and implementation of clinical trials proposed by or through consortium members;
- Establishment and management of procedures to ensure compliance with the local Institutional Review Boards (IRBs) of all sites for the conduct of clinical trials and the protection of human subjects;
- Establishment and management of procedures for ensuring compliance with FDA requirements for investigational agents, devices, and procedures;
- Establishment and management of a communications plan and a real-time communications system between the Coordinating Center and Clinical Research Sites;
- Management of Consortium-developed quality assurance and quality control mechanisms for study monitoring, including:
 - On-site monitoring program,
 - Management plan for the handling, distribution, analysis, and banking of specimens and/or imaging products generated from Consortium studies necessary for the conduct and analyses of clinical trials during the performance period of the award;
 - Registration, tracking, and reporting of participant accrual,
 - Timely medical review and assessment of participant data,
 - Rapid reporting and communication of adverse events, and
 - Interim evaluation and consideration of measures of outcome;
- Management of Consortium-developed comprehensive data collection and data management systems that addresses the needs of all sites in terms of access to data, data security, and data integrity measures;
- Development of statistical plans for all Consortium clinical trials;
- Management of Consortium-developed intellectual and material property issues among institutions participating in the Consortium;
- Management of Consortium-developed procedures for the timely publication of major findings and other public dissemination of data;
- Development, organization, and submission of the written and oral semi-annual briefings to the EAB and USAMRMC staff at 1-day meetings typically held in the Baltimore-Washington, DC area; and

- Development, organization, and submission of the annual written progress reports and a final written comprehensive report to the USAMRMC (see [Subsection VII.E.1](#)).

III. AWARD INFORMATION

Funding for a FY06 PCRCP Clinical Consortium Award can be requested for a maximum of \$600,000 for direct costs over the performance period. The performance period can be requested for up to 2 years. Indirect costs should be added as appropriate. Proposals for projects requiring lower levels of funding may also be submitted. Funds from the FY06 PCRCP Clinical Consortium Award may be used to:

- Attend and support Consortium-related meetings and teleconferences;
- Purchase computers and general software required to participate in the Consortium;
- Furnish salary support for personnel needed to meet the goals of the Consortium such as the applicant (the Principal Investigator of the Clinical Protocol), Clinical Research Coordinator, Research Nurse, and Data/Informatics Coordinator;
- Support collaborations among Clinical Research Sites and the Coordinating Center to:
 - Implement data management, real-time communication, and/or administration plans for the Consortium,
 - Reimburse institutions for costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms, and
 - Provide other costs directly associated with planning, implementing, and supporting the Consortium; and
- Other costs directly associated with Consortium operations.

Based on programmatic requirements, funding amounts may be tailored to produce the most efficient, cost-effective consortium possible; the PCRCP Integration Panel reserves the right to recommend modifications to budgets to meet the needs of the Consortium. In addition, \$1,800 per investigator must be requested for travel to a PCRCP Awardees Meeting (tentatively scheduled for the fall of 2007).

The nature of the PCRCP does not allow for renewal of grants or supplementation of existing grants.

The CDMRP expects to allot approximately \$1.8M of the \$80M FY06 PCRCP appropriation to fund approximately three Clinical Consortium Awards depending on the quality and number of proposals received.

IV. ELIGIBILITY INFORMATION

A. Applicants: Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit proposals.

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 in [Subsection IV.B](#), “Institutions” below.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by conducting business only with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at <http://epls.arnet.gov>. (Reference Department of Defense Grant and Agreement Regulations (DODGAR) 25.110.)

B. Institutions: Eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies. The USAMRMC is especially interested in receiving applications from Historically Black Colleges and Universities/Minority Institutions (HBCU/MI).

A DOD goal is to allocate funds for the CDMRP peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders.¹ Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at <http://cdmrp.army.mil/spp> under “Minority Institutions.”

Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

C. Duplicate Submissions: Submission of the same research project to different FY06 PCR award mechanisms or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

¹Executive 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. Proposals will be evaluated according to peer and programmatic review criteria in [Section VI](#).

1. Applicant Responsibility: The applicant is responsible for entering and/or uploading the following information into the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>:

Item	Tab	Format	Action
Letter of Intent (LOI)	Proposal Information	Typed	Copy the LOI into the data field. Click the “Save and Forward Letter of Intent” button to automatically create the LOI.
Proposal Information	Proposal Information	Typed	Enter the appropriate information in data fields.
Proposal Contacts	Proposal Contacts	Typed	Enter contact information for the applicant and the Contract Representative at the applicant’s institution.
Collaborators and Conflicts of Interest (COI)	Collaborator/COI	Typed	Enter information about collaborators and others outside the scope of the proposal who may have a COI in the review of this proposal.
Proposal Abstracts, Impact Statement, and Statement of Work (SOW)	Abstract/Impact/SOW	Typed or Cut and Paste	Enter the Technical Abstract, Public Abstract, Impact Statement, and SOW in separate data fields.
Proposal Main Body	Required Files	PDF	Upload as a PDF file.
Supporting Documentation	Required Files	PDF	Upload as a PDF file.
Budget Information	Required Files	PDF	Upload as a PDF file.
Regulatory Documents	Required Files	PDF	Upload the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance forms.

2. Contract Representative Responsibility: The Contract Representative (CR) or institutional official responsible for sponsored program administration (or equivalent) at the applicant’s institution is responsible for the following:

Item	Tab	Format	Action
Contract Representative’s Contact Information Profile	My Profile for the CR	Typed	Complete before electronic approval of all submission components.
USAMRAA ^a -Required Documents	My Profile for the CR	PDF	Upload the Rate Agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements.
Approval	CR Approval	Click Approval Button	Click the button to approve the Proposal Information, Proposal Contacts, Collaborators and COI, Abstracts/Impact Statement/SOW, and Required Files <i>before</i> the submission deadline of 5:00 p.m. Eastern time, June 20, 2006.

^aUS Army Medical Research Acquisition Activity

B. Proposal Format: Proposals must be uploaded under the “Required Files” tab of the CDMRP eReceipt Online Proposal Submission System at <https://cdmrp.org>. Applicants unfamiliar with the preparation of PDF files are encouraged to acquire and learn to use the appropriate software well in advance of the submission deadline. The instructions in this subsection must be followed carefully to prepare proposals for PDF submission.

The main body of the proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on the computer screen and submitted via the CDMRP eReceipt Online Proposal Submission System.

- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (approximately 19.05 cm x 25.40 cm).

- **Color, High-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; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since 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. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Internet URLs:** URLs directing reviewers to websites containing significant additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are allowed.
- **Language:** English.

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.

C. 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. *Failure to adhere 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.*

The following will result in administrative rejection of the entire proposal before it reaches peer review:

- 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, pages exceeding the specified limit will be removed from the proposal and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

The electronic PDF file uploaded in the CDMRP eReceipt Online Proposal Submission System is the official proposal submission file. After conversion of word processing documents to PDF files and before electronic submission, applicants should review their files to ensure that the proposal complies with the preparation guidelines outlined in this program announcement.

D. Letter of Intent (LOI): An LOI (a brief description of the proposal) is entered in a data field under “My Proposals: Create New Proposal.” The LOI is saved when the “Save and

Forward Letter of Intent” button is selected. The LOI may be modified under “Proposal Information” at anytime before the applicant submits this information by clicking “Finalize for CR Approval.” The LOI should be submitted by *May 23, 2006* at <https://cdmrp.org>.

E. Proposal Information: Applicants are required to submit the Proposal Information as described in <https://cdmrp.org> before uploading the proposal, supporting documentation, and budget information.

- A *Title/Referral Page* for the proposal will be generated from the information uploaded in eReceipt and appended to the proposal electronically by the CDMRP eReceipt system.

F. Proposal Contacts: The Proposal Contacts *must* include the e-mail address of a Contract Representative authorized to negotiate on behalf of the applicant’s institution. The Proposal Contacts must be approved by the Contract Representative at the applicant’s institution.

G. Collaborators and Conflicts of Interest (COI): To avoid COI during the review process, list the names of all scientific participants in the proposal including collaborators and consultants. In addition, list the names of individuals outside the scope of this proposal who may have a COI in reviewing this proposal.

H. Proposal Abstracts: *Not applicable for the Clinical Consortium Award.*

I. Impact Statement: *Not applicable for the Clinical Consortium Award.*

J. Statement of Work – 11,400-character limit including spaces (approximately two pages): The SOW is captured as a data field under the “Abstract/Impact/SOW” tab in the CDMRP eReceipt system. Applicants can type the SOW into the data field or “cut and paste” it from a word processing application.

The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal’s SOW must include DOD-funded tasks only. Sample SOWs can be found at <https://cdmrp.org/samples.cfm>.

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 performance period for the proposed effort;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

K. Proposal Main Body: Start section on a new page; 30-page limit inclusive of any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, and other information needed to judge the proposal.

The proposal main body is uploaded as a PDF file under the “Required Files” tab of the CDMRP eReceipt system.

It is the applicant’s responsibility to clearly articulate the qualifications of the research team and institution to participate as a Clinical Research Site. Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

1. Commitment to and Experience in Prostate Cancer Clinical Research

- Describe commitment to prostate cancer clinical research, which may include levels of effort, funding, and interactions with consumer advocacy groups.
- Describe experience in conducting multi-institutional clinical trials that demonstrates the applicant’s willingness and ability to function in the Consortium.
- Describe specific areas of clinical research interest such as novel designer drugs, combinatorial therapy schedules, surgical interventions, imaging techniques, and immunotherapies. Include the overall scope of the program and a demonstration of integration of basic and/or correlative science into the program;
- Provide details of ongoing or completed prostate cancer-relevant clinical trials, particularly Phase II clinical trials, with an emphasis on clinical trials that might be brought into the Consortium. Reference relevant publications and submit reprints with the proposal (see [Subsection V.L.7](#));
- Describe procedures for ensuring compliance with FDA requirements for investigational agents.

2. Consortium Resources

- Include a named institutional Clinical Research Coordinator who will interact with the Clinical Research Coordinators at other consortium Clinical Research Institutions and the Supervising Clinical Research Coordinator at the Coordinating Center to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites,
- Describe the prostate cancer population (including size, age range, and clinical manifestations) and provide evidence of ability to enroll at least 35 evaluable individuals with prostate cancer per year into Consortium-sponsored studies, and
- Provide evidence of successful multi-center clinical trial collaborations.

3. Institutional Resources

- Provide evidence of expertise in clinical trials in the applicant institution and describe the experience in the development and conduct of prostate cancer clinical trials; as

appropriate, describe any additional multidisciplinary clinical and/or laboratory expertise that could serve as the basis for the development of clinical trials by the consortium,

- Describe the resources and expertise available for the collection and processing of specimens from Consortium-sponsored studies,
- Describe the resources and expertise available for data management and maintenance of data security and confidentiality, and
- Provide evidence of institutional commitment to using facilities and resources in the conduct of Consortium operations.

L. Supporting Documentation: Submit only material specifically requested in this program announcement. *This section is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.* Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed; submitting such material may be grounds for administrative rejection of the proposal.

Supporting Documentation must be uploaded as a single PDF file under the “Required Files” tab of the CDMRP eReceipt system. All documents or letters that require signatures must be signed and incorporated into the supporting documentation file before it is submitted.

The first item in the Supporting Documentation file is the [Checklist/Table of Contents](#) page. The requested, allowable items in this section must be listed in the Checklist/Table of Contents; these include:

- 1. Abbreviations: Start section on a new page; one-page limit.** Provide a list of all acronyms, abbreviations, and symbols used in the main body of the proposal.
- 2. 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).
- 3. Biographical Sketches: Four-page limit per individual.** Include biographical sketches for all key personnel 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 proposal scores. 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.
- 4. Existing/Pending Support: Start section on a new page; no page limit.** List the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the applicant and key personnel on a separate page. If no support exists, enter “None.” Proposals submitted under this program announcement should not duplicate other funded research projects.

5. Facilities/Equipment Description: No page limit. Describe the facilities available for performing 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 whether Government-owned facilities or equipment are proposed for use.

6. Letters of Support: Provide the following:

- Letters of support from all collaborating individuals or institutions.
- Documentation of willingness to resolve intellectual and material property issues with other institutions involved in the consortium. Documentation must be signed by an authorized senior official at the applicant institution.
- Letter of commitment from a senior administrator at the applicant institution.

7. 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 publications are included in the submission, the extra items will not be peer reviewed.

M. Budget Information: Applicants must complete the [Detailed Cost Estimate form and the Budget Justification form](#), and upload them as a single PDF file under the “Required Files” tab of the CDMRP eReceipt system. When a proposal requesting funding as part of a larger study is submitted, the proposal’s budget justification should include only DOD-funded tasks.

1. Funding Restrictions: Funding for a FY06 PCRCP Clinical Consortium Award can be requested for a maximum of \$600,000 for direct costs over the performance period. The performance period can be requested for up to 2 years. Indirect costs should be added as appropriate. Proposals for projects requiring lower levels of funding may also be submitted. Funds from the FY06 PCRCP Clinical Consortium Award may be used to:

- Attend and support Consortium-related meetings and teleconferences;
- Purchase computers and general software required to participate in the Consortium;
- Furnish salary support for personnel needed to meet the goals of the Consortium such as the applicant (the Principal Investigator of the Clinical Protocol), Clinical Research Coordinator, Research Nurse, and Data/Informatics Coordinator;
- Support collaborations among Clinical Research Sites and the Coordinating Center to:
 - Implement data management, real-time communication, and/or administration plans for the Consortium,
 - Reimburse institutions for costs associated with conducting the IRB review of the clinical protocols and informed consent/assent forms, and
 - Provide other costs directly associated with planning, implementing, and supporting the Consortium; and
- Other costs directly associated with Consortium operations.

Based on programmatic requirements, funding amounts may be tailored to produce the most efficient, cost-effective consortium possible; the PCRIP Integration Panel reserves the right to recommend modifications to budgets to meet the needs of the consortium. In addition, \$1,800 per investigator must be requested for travel to a PCRIP Awardees Meeting (tentatively scheduled for the fall of 2007).

2. Detailed Cost Estimate Form and Budget Justification Instructions: Budget is an important consideration in both peer review and programmatic 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.* All costs must be entered in U.S. dollars.

The USAMRMC encourages in-kind contributions and cost-sharing for CDMRP-supported research. In-kind contributions may include support of services (e.g., laboratory services and salaries of personnel), real property and equipment, and/or supplies (e.g., drugs, devices, reagents) directly benefiting and specifically identifiable to the research project. *It is expected that institutions will share the cost of equipment purchased for this research proposal. Please see full details under “Major Equipment” in [Subsection V.M.2.c](#).*

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).

Follow the instructions below when providing the information requested in the Detailed Cost Estimate form.

a. Personnel

- i. Name:** Beginning with the applicant, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and

support staff. *The applicant must be identified as the Principal Investigator of the proposal.*

ii. Role on Project: Identify the role of each participant listed. 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 Government 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 applicant's qualifications 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. List the percentage of each appointment to be spent on this project for each key staff member. Include the percent effort of all unpaid collaborators and consultants.

Clinical studies must have a clinical coordinator who has sufficient time dedicated to the project to carry out the record keeping, coordination, and/or other administrative duties the project entails.

vi. Salaries Requested: Enter the salaries in whole U.S. dollars for each position for which funds are requested. Calculate the salary request by multiplying an individual's institutional base salary by the percentage of effort on the project.

vii. Fringe Benefits: Fringe benefits for each position may be requested in accordance with institutional guidelines, provided the costs for all sponsors are treated consistently by the applicant's organization. Provide documentation to support the fringe benefits.

viii. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

b. Consultant Costs: Provide the names and organizational affiliations of all consultants whether or not funds are requested.

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 where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be negotiated separately.

- i.** If the purchase of equipment for this research project is requested, it is expected that the applicant's institution will share 50% of the cost.
 - ii.** Permanent equipment is any article of nonexpendable tangible property having a useful life of 2 years or longer and an acquisition cost of \$5,000 or more per unit.
 - iii.** The basis for the cost of each item of permanent equipment included in the budget must be disclosed.
 - iv.** Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations whose primary purpose is the conduct of scientific research. Normally the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.
- d. Materials, Supplies, and Consumables:** A general description and estimated total cost of supplies are required. Itemize supplies in separate categories. Categories in amounts less than \$1,000 do not need to be itemized.
- e. Travel Costs:** Costs for travel to scientific/technical meetings may not exceed \$1,800 per year. Additional travel funds of \$1,800 per investigator must be requested to attend a PCRPA Awardees Meeting (tentatively scheduled for the fall of 2007).
- Travel costs associated with the execution of the proposed work should be entered in this section. If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly \$1,800 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the U.S. requires prior approval from the US Army Medical Research Acquisition Activity (USAMRAA).
- f. Research-Related Subject Costs:** *Not applicable to the Clinical Consortium Award.*
- 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:** *Not applicable to the Clinical Consortium Award.*
- 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 in 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. Directs costs, indirect costs, and the total cost for the entire proposed period of support should equal the amount entered in the “Required Files” tab at <https://cdmrp.org>.

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

4. Federal Agency Financial Requirement: Proposals from Federal agencies *must* provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

Start the plan on a new page at the end of the Budget Information section. The Federal Agency Financial Plan must be uploaded as part of the budget information before the submission deadline of **5:00 p.m. Eastern time, June 20, 2006.**

N. 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.

O. USAMRAA-Required Documents: The Contract Representative at the applicant’s institution must upload the current version of the institution’s negotiated Rate Agreement, the [Certifications and Assurances for Assistance Agreements](#), and the [Representations for Assistance Agreements](#). These documents must be uploaded as separate PDF files under the Contract Representative’s “My Profile” tab of the CDMRP eReceipt system by the proposal submission deadline.

P. Submission Date and Time: Proposals must be approved on the CDMRP eReceipt system by the Contract Representative at the applicant’s institution by the deadline. Proposals that are incomplete or not approved electronically before the deadline 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, June 20, 2006 deadline.

The timeline for the Clinical Consortium Award is:

Online Letter of Intent:	Expected by May 23, 2006
Online Proposal Information:	Required prior to proposal submission
Proposal Submission/Approval Deadline:	5:00 p.m. Eastern time, June 20, 2006
Peer Review (First Tier):	July 2006
Programmatic Review (Second Tier):	September 2006
Request for Additional Documents:	As early as 2 weeks after the completion of programmatic review
Notification Letter:	Approximately 4 weeks after the completion of programmatic review
Award Start Date:	Anticipated between December 2006 and September 2007

Q. Electronic Submission Requirements: Electronic submission is required. Only proposals submitted as PDF files through the CDMRP eReceipt system at <https://cdmrp.org> will be accepted.

Several steps are critical to successful proposal submission:

- The Proposal Information must be “Finalized for CR Approval” before the proposal is submitted. Applicants are encouraged to begin this part of the submission process early.
- Proposal Contacts must be “Finalized for CR Approval” before the proposal is submitted. The e-mail address of a Contract Representative at the applicant’s institution must be included in the Proposal Contacts. Applicants are encouraged to begin this part of the submission process early.
- Applicants are encouraged to coordinate with their Contract Representative early in the application process.
- The Contract Representative authorized to negotiate on behalf of the applicant’s 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, June 20, 2006 deadline.
- Some items in the proposal including figures, tables, graphs, letters, or publications will need to be scanned electronically. These documents should be scanned at a resolution of 300 dpi or less.
- Applicants are encouraged to retain a date and time-stamped copy of the proposal component files as prepared by word processing software (e.g., Microsoft Word, WordPerfect) as well as the original PDF conversion file.
- The Detailed Cost Estimate form and the Budget Justification form must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

- The regulatory documents required at submission include a completed and signed Certificate of Environmental Compliance and a completed and signed Principal Investigator Safety Program Assurance form. These forms must be uploaded under the “Required Files” tab of the CDMRP eReceipt system.

VI. PROPOSAL REVIEW INFORMATION

A. Proposal Review and Selection Overview

1. Process: The CDMRP uses a two-tier review process for proposal evaluation. The two tiers differ fundamentally. The first tier is a scientific peer review of proposals against established criteria for determining 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 and overall goals of the program.

2. Peer Review: Peer review is conducted by scientific and consumer reviewers. The primary responsibility of the peer reviewers is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Scientific reviewers are selected for their subject matter expertise and 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 process by bringing the patient perspective to the assessment of science and the relevance of the research.

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: Programmatic review is conducted by the Integration Panel, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the Integration Panel represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. A function of programmatic review is to structure 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. Integration Panel members base programmatic review primarily on the peer review summary statements and the proposal abstracts. The Integration Panel also may review SOWs and impact statements. Full proposals are not forwarded to programmatic review.

HBCU/MI proposals are reviewed concurrently with others in the same research area during scientific peer review. However, they may be evaluated separately during programmatic review. Consistent with the CDMRP’s goal, recommendations for funding HBCU/MI proposals are based on scientific excellence and program relevance.

B. Review Criteria

1. Peer Review: FY06 PCRCP Clinical Consortium Award proposals will be evaluated by peer reviewers according to the following criteria. The reviewers will evaluate:

- **Participant Recruitment**
 - The appropriateness of the size of the accessible prostate cancer patient population.
 - The appropriateness of the range of diseases affecting the accessible prostate cancer patient population.
 - The success of the institution in recruiting patients for clinical trials.
- **Collaborations**
 - The appropriateness of the applicant's background and expertise in collaborative prostate cancer clinical research.
 - How successful the applicant has been in previous collaborations.
 - How well the applicant's institution has facilitated the applicant's collaborations.
- **Personnel**
 - Whether the applicant meets the eligibility requirements.
 - The appropriateness of the research team's background and expertise with respect to its ability to perform multi-institutional prostate cancer clinical research.
 - Whether the research team has the ability and experience to contribute substantially to the design and conduct of consortium clinical trials.
 - The appropriateness of the named institutional Clinical Research Coordinator experience in guiding clinical protocols through the regulatory approval processes and his or her ability to interact with other Consortium Clinical Research Coordinators.
 - The appropriateness of the levels of effort for successful conduct of the proposed work.
- **Institutional Resources and Commitment**
 - The appropriateness of the institution's commitment to working with the Consortium.
 - How the applicant is supported by the availability of and accessibility to facilities and resources, especially in regard to specimen collection and processing.
 - The appropriateness of the institution's resources and expertise for data management and maintaining security and confidentiality.
 - The willingness of the institution to resolve intellectual and material property issues with other institutions in the Consortium.

- **Budget**
 - How the budget is appropriate for the proposed research.

2. Programmatic Review: Criteria used by the Integration Panel to make funding recommendations that maintain the PCRCP's broad portfolio include:

- Ratings and evaluations of the peer reviewers (scientific and consumer),
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

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 Integration Panel and recommended for funding to the Commanding General, USAMRMC.

VII. AWARD ADMINISTRATION INFORMATION

A. Award Notices: Each applicant will receive notification of the award status of his or her proposal. A copy of the peer review summary statement will be posted to the CDMRP eReceipt system. Applicants can expect to receive notification approximately four weeks after programmatic review.

B. Administrative Requirements: Awards are made to organizations, not individuals. An applicant must 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. A prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, 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) to be eligible for an award. ***Any organization requesting receipt of an award through 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>.***

Proposals from Federal agencies ***must*** provide a plan delineating how all funds will be obligated by September 30, 2007, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as administrative agreements with foundations, non-Federal institutions, and universities.

For Clinical Consortium Awards, no changes in the institution, the applicant, or the SOW will be allowed once the proposal has been submitted.

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 authorized to negotiate contracts and grants at the applicant's institution. Additional documentation and justifications related to the budget may be required as part of the negotiation process.

For multi-institutional studies, collaborating institutions must be willing to resolve potential intellectual and material property issues and remove institutional barriers to achieving high levels of cooperation to ensure the successful establishment and maintenance of the research project. An intellectual and material property plan agreed to by all participating institutions may be required during award negotiations.

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.

2. Certificate of Environmental Compliance: The [Certificate of Environmental Compliance](#) must be submitted with the proposal. If multiple research sites/institutions are funded in the 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 required; it will be requested at a later date. A Facility Safety Plan from the applicant's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at <https://mrmc.detrick.army.mil/crprcsohdfsplan.asp>. If the applicant's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at <https://mrmc.detrick.army.mil/docs/rcq/FY02FSPAAppendix.doc>.

If multiple research sites/institutions are funded in the proposal, 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: *Not applicable to Clinical Consortium Awards.*

5. Research Involving Human Subjects/Biological Substances/Cadavers: *Not applicable to Clinical Consortium Awards.*

6. Award/Regulatory Approval: *Not applicable to Clinical Consortium Awards.*

E. Reporting Requirements: The Government requires reports to be submitted for continuation of the research and funding. The specific reports due to the Government will be described in each award instrument. (Full USAMRMC reporting requirements can be found at <https://mrmc-www.army.mil>, under “Links and Resources.”) ***Failure to submit required reports by the required date may result in a delay in or termination of award funding.***

Reporting requirements include the following:

- 1. Research Progress Reports:** 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. Copies of all scientific publications and patent applications resulting from CDMRP funding should be included in the progress reports. PIs also must prepare written and oral semi-annual briefings to the EAB at semi-annual meetings typically held in the Baltimore-Washington, DC area.
- 2. Fiscal Reports:** 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 submitting 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 are not 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. All other sources also should be consulted to the extent practical for the same purpose.

D. Inquiry Review Panel: Applicants may 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 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 seq²), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US 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.

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.

²Title 35 of the United States Code, Section 200 etc.

IX. ACRONYM LIST

AVI	Audio Video Interleave
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
COI	Conflict of Interest
CR	Contract Representative
DOD	Department of Defense
DODGAR	Department of Defense Grant and Agreement Regulations
EPLS	Excluded Parties List System
FAR	Federal Acquisition Regulations
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
HSRRB	Human Subjects Research Review Board
IRB	Institutional Review Board
JPEG	Joint Photographic Experts Group
M	Million
MB	Megabyte
MPEG	Moving Picture Experts Group
OMB	Office of Management and Budget
PCRP	Prostate Cancer Research Program
PDF	Portable Document Format
SOW	Statement of Work
TIFF	Tagged Image File Format
URL	Uniform Resource Locator
USAMRAA	US Army Medical Research Acquisition Activity
USAMRMC	US Army Medical Research and Materiel Command
USC	United States Code
WAV	Waveform