

# Announcement of Federal Funding Opportunity

## Summary

### I. GENERAL INFORMATION

**A. Title of Award:** Clinical Consortium Award (CCA).

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

**C. Funding Opportunity Number:** PC05-CCA.

**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](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-ZB-C (PC05-CCA)  
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:

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

**F. Anticipated Instrument Type(s):** Assistance agreement.

**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:** *Not applicable to the Clinical Consortium Award.*

## **II. FUNDING OPPORTUNITY DESCRIPTION**

The PCRP Clinical Consortium Award will provide support to develop a consortium whose function will be to facilitate the rapid execution of collaborative Phase II or Phase II-linked Phase I (Phase I/II) clinical trials of promising new therapeutic agents or approaches for the management or treatment of prostate cancer. The overarching goal of the Clinical Consortium Award 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.

## **III. AWARD INFORMATION**

- Type of award: Assistance agreement.
- The PCRP plans to spend \$15 million (M) to fund the Clinical Consortium Award. A total of \$5M will be allocated from the FY05 budget with \$5M expected from each of the FY06 and FY07 budgets. **Funding beyond FY05 is contingent upon receipt of sufficient congressional appropriations to the PCRP.**
- Depending on the number and quality of the applications, it is anticipated that a single Coordinating Center and 8-10 Clinical Research Sites will be funded.
- Total funding for the Coordinating Center will be up to approximately \$5M (inclusive of direct and indirect costs) over a performance period of 3 years. These funds are for all Coordinating Center functions, administrative and clinical, as described in the Full Text of this Program Announcement. Funding will be disbursed in installments of up to approximately \$2M for the first year and up to approximately \$1.5M for each of the second and third years.
- Total funding for **all** the Clinical Research Sites will be up to approximately \$10M (inclusive of direct and indirect costs) over a performance period of 3 years. Awards for each Clinical Research Site are expected to be up to approximately \$300,000 (inclusive of direct and indirect costs) per year.

## **IV. ELIGIBILITY INFORMATION**

**A. Applicants:** Applicants must be independent investigators at the Assistant Professor level (or equivalent) or higher 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 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. 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. Submission Date and Time:** Deadline: June 7, 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. (See the Full Text of Program Announcement for details regarding supplementary clinical trial materials that are permissible to submit through August 26, 2005, 5:00 p.m. Eastern time.)

**E. 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**

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

## **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 and Safety Program Plan) can be found in the Full Text of Program Announcement.

**B. Consortium Award Reporting Requirements:** Clinical Consortium Award recipients will be required to provide annual written progress reports and a comprehensive final written progress report. Principal Investigators and Clinical Research Coordinators from the Coordinating Center and Clinical Research Sites also will be required to prepare oral and written semi-annual briefings to be presented at semi-annual 1-day meetings with an external advisory board and USAMRMC staff.

**C. Pre-Award Planning Meeting:** After notification of award status and prior to disbursement of funds, Clinical Consortium Award recipients will be required to attend a 1-day Pre-Award Planning Meeting in the Baltimore-Washington, DC area.

# Full Text of Program Announcement

## I. GENERAL INFORMATION

**A. Title of Award:** Clinical Consortium Award (CCA).

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

**C. Funding Opportunity Number:** PC05-CCA.

**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](mailto:cdmrp.pa@det.amedd.army.mil)  
Mail: Commander  
US Army Medical Research and Materiel Command  
ATTN: MCMR-ZB-C (PC05-CCA)  
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](mailto:help-proposals-cdmrp@cdmrp.org)

**F. Anticipated Instrument Type(s):** Assistance agreement. More information on this and other funding instruments may be obtained by request from:

Fax: 301-619-2937  
E-mail: [qa.baa@det.amedd.army.mil](mailto: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:** *Not applicable to the Clinical Consortium Award.*

## **II. FUNDING OPPORTUNITY DESCRIPTION**

**A. Program History:** The Clinical Consortium 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 Consortium Award is a new mechanism for the PCRP and is being offered for the first time in FY05.

**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**

**1. General Information:** The PCRP Clinical Consortium Award will provide support to develop a consortium whose function will be to facilitate 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 Clinical Consortium Award 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 consortium will consist of 8-10 Clinical Research Sites and one Coordinating Center. These participants will be responsible jointly for proposing, selecting, and conducting Phase II and Phase I/II clinical trials focused on prostate cancer therapeutic interventions. In addition to functioning as a Clinical Research Site, the Coordinating Center will serve as the

consortium information and planning nexus. Eligible applicants are defined as a single for-profit, nonprofit, public, or private institution or organization.

The Coordinating Center will have multidisciplinary expertise and extensive experience in developing and conducting multi-institutional clinical trials of innovative treatment approaches in support of prostate cancer research. In addition to functioning as a Clinical Research Site, the Coordinating Center will be responsible for providing administrative, operational, and data management support services to participant Clinical Research Sites to implement consortium clinical trials in a timely manner. The Coordinating Center also will be responsible for preparing two initial clinical trials for immediate implementation by the consortium at the start of the award. All sites (Clinical Research Sites and the Coordinating Center) will be required to participate in at least one of these two initial clinical trials. A procedure will be established for the selection of clinical trials to be implemented thereafter within the consortium.

After implementation of the initial clinical trials prepared by the Coordinating Center, all sites will be responsible for working collaboratively to identify new clinical trials for implementation by the consortium. Collectively, the consortium Principal Investigators (PIs) will constitute the Clinical Consortium Committee which will be responsible for selecting the clinical trials to be implemented by the consortium and for determining which consortium institutions will participate in each trial. A representative from USAMRMC must be invited to these sessions as well as any other formal meetings of the consortium. Selected clinical trials will be 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 will be responsible for facilitating this entire process. The consortium is strongly encouraged to leverage the DOD investment whenever possible by implementing DOD-funded trials. After the initial 6 months of the performance period of the award, the consortium is expected to have 10 or more clinical trials open at any given time. In addition, each participant site is expected to present two or more clinical trials each year for the consortium's consideration and maintain accrual of 50 or more patients per year.

The PCRIP Integration Panel (IP) and Program Manager will assume the role of an external advisory board (EAB) to the consortium. The role of the EAB will be to provide scientific review, consortium oversight, and data and progress review. PIs must present written and oral semi-annual briefings to the EAB and USAMRMC staff at 1-day meetings typically held in the Baltimore-Washington, DC area. Based on these reports and presentations, the EAB and USAMRMC staff will evaluate progress, provide feedback, and invoke modifications and terminations as needed to facilitate the success of the consortium. PIs also will be required to submit annual written progress reports and a final written comprehensive report.

**Funding** for each participant site in years 2 and 3 **will be contingent upon** meeting the following consortium requirements:

- A minimum number of 35 patients accrued per year; however, the expectation will be 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 will be that two or more clinical trials per year will be proposed;
- 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, at the discretion of the government, each participant site may be expected to participate in an on-site **audit** by the government or its designee.

**Failure to achieve the minimum requirements above may result in termination of individual assistance agreement(s).**

The Clinical Consortium Award mechanism will be used to select and fund both the Coordinating Center and the Clinical Research Sites. Applicants will be required to indicate whether the institution is applying as the Coordinating Center or as a Clinical Research Site. Applicants applying as the Coordinating Center have the option to be considered as a Clinical Research Site if not chosen as the Coordinating Center.

**Please note 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 the Consortium Participants:** Procedures for the consortium, while proposed by the Coordinating Center, will be fully developed and agreed upon by all participants working collaboratively at the Pre-Award Planning Meeting to be attended by representatives of the Coordinating Center, Clinical Research Sites, EAB, and USAMRMC.

**a. All Sites (Coordinating Center and Clinical Research Sites):** The responsibilities of each site 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 at least one of the initial clinical trials prepared by the Coordinating Center at the beginning of the award period;
- Presentation of at least one clinical trial for the consortium's consideration per year; however, the expectation is that two or more trials will be presented annually. (For the Coordinating Center, this requirement is **in addition to** the initial two clinical trials required at the beginning of the award.)



- 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;
- 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 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 Food and Drug Administration (FDA) requirements for investigational agents, as appropriate;
- Implementation of procedures established by the Coordinating Center to meet the local Institutional Review Board (IRB) requirements for the conduct of clinical trials and the protection of human subjects;
- Serving as a resource for the conduct of protocol-specified laboratory projects (such as tumor biology studies);
- Participation in consortium-developed procedures for the timely publication of major findings;
- Participation in consortium-developed procedures for resolving intellectual and material property issues among institutions participating in the consortium;
- Attend a Pre-Award Planning Meeting with all consortium members to develop the operational features of the consortium, the requirements for progress and evaluation, and the award negotiations process;
- Participation in the preparation of written and oral semi-annual briefings to the EAB and USAMRMC staff at 1-day meetings typically held in the Baltimore-Washington, DC area;

- Submission of annual written progress reports and a final written comprehensive report;
- Preparing for the possibility of a site visit audit; and
- Additional responsibilities based on recommendations and guidance from the consortium EAB and USAMRMC staff.

**b. Coordinating Center:** Responsibilities specific to the Coordinating Center 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;
- Provision of at least two initial Phase II or Phase I/II clinical trial protocols that are hypothesis-driven and seek to determine baseline activity of a new drug, or novel combination of existing drugs for implementation by the consortium at the beginning of the award period;
- 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 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).

**3. Clinical Consortium Award Proposal Requirements:** (See Section V for complete details.) All proposals for the PCRCP Clinical Consortium Award must indicate if the application is being submitted for consideration as a:

- Clinical Research Site, or
- Coordinating Center, or
- Coordinating Center with the option to be considered as a Clinical Research Site if the proposal is not selected for award as the single Coordinating Center.

**a. All Applicants (Clinical Research Sites and Coordinating Center):** Proposals from each applicant must include:

- Descriptions of the applicant's commitment to and experience in prostate cancer clinical research;
- Description of the prostate cancer patient population and documentation of ability to enroll at least 35 evaluable individuals with prostate cancer per year into consortium-sponsored studies;
- Evidence of multidisciplinary clinical and laboratory expertise **within the applicant institution** that could serve as the basis for the implementation of clinical protocols by the consortium;
- Demonstration of adequate resources and expertise for data management and maintenance of data security/confidentiality;
- Evidence of institutional commitment to using facilities and resources in the conduct of consortium operations as required;
- Documentation of willingness to resolve intellectual and material property issues;

- A **named** institutional Clinical Research Coordinator who will interact with the Clinical Research Coordinators at other Clinical Research Sites 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; and
- Descriptions of procedures for ensuring compliance with FDA requirements for investigational agents, as appropriate.

**b. Coordinating Center Applicants:** Proposals from Coordinating Center applicants must include **all** the requirements noted in Subsection II.C.3.a above in addition to the requirements below:

- Evidence of institutional commitment to using facilities and resources in the conduct of consortium operations as required;
- Descriptions of the consortium organizational structure, a real-time communications plan, and standard operating procedures for proposing and determining which studies the consortium will pursue. The organizational structure should include the following key features (see Figure 1 below):
  - Coordinating Center for administration and day-to-day management of consortium operations, developing the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination, and performance as a Clinical Research Site,
  - Clinical Research Sites for conceiving, developing, and conducting clinical trials in prostate cancer, as well as serving as entry points for clinical trials from outside the consortium,
  - Clinical Consortium Committee composed of the PIs 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
  - An EAB comprised of members of the PCRIP and the PCRIP Program Manager for scientific review, oversight, data monitoring, and evaluation;

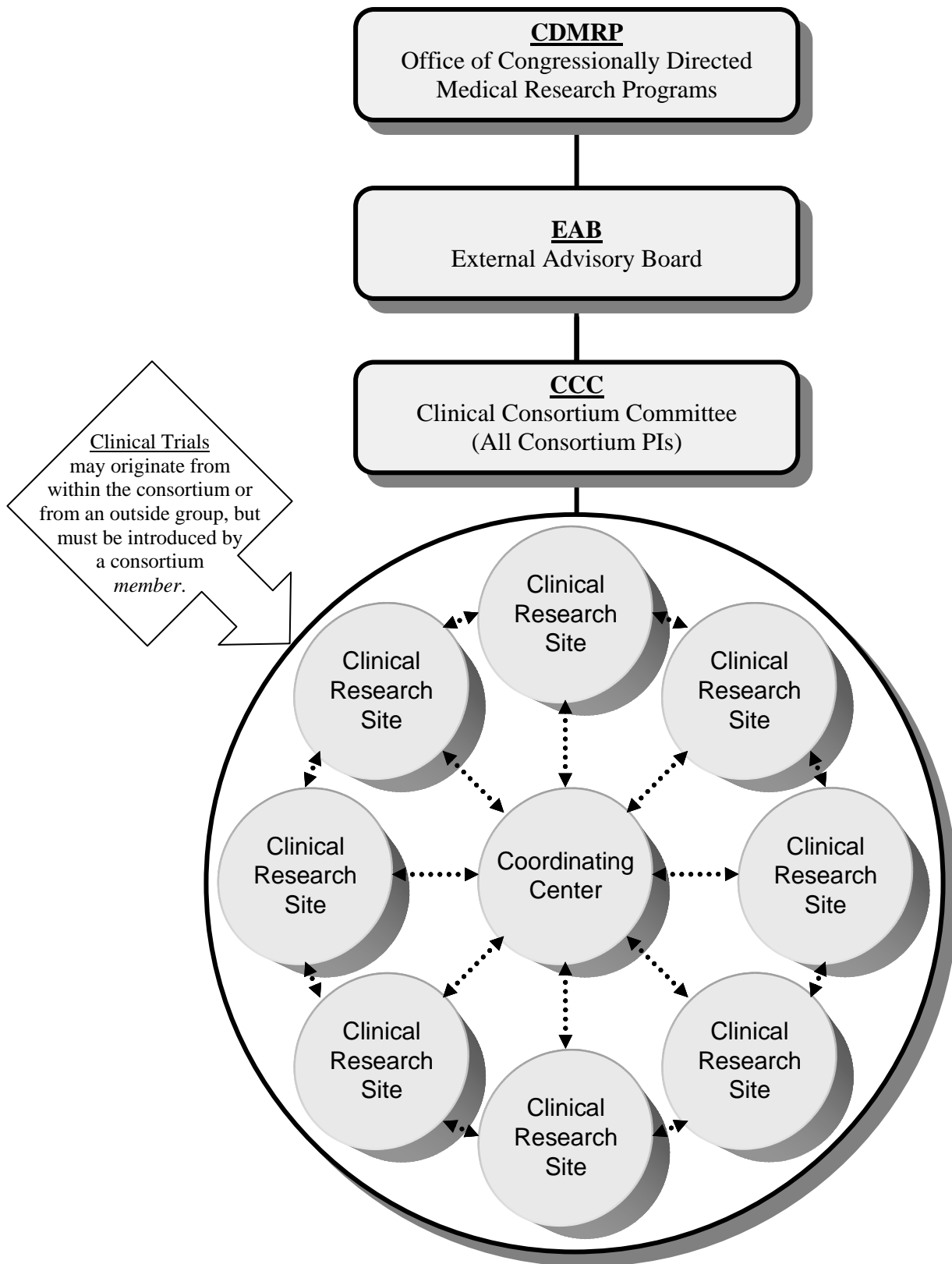


Figure 1: Basic Architecture of the Clinical Consortium

- An intellectual and material property plan for all participating institutions;
- Descriptions of procedures for coordinating the development and regulatory approval of consortium clinical protocols and associated clinical documents in a timely manner;
- Description of the two clinical trials to be conducted within the consortium at the beginning of the award period, including a brief description of clinical protocols and informed consent/assent form(s) that indicate the level of review achieved prior to submission of the Clinical Consortium Award;
- Descriptions of procedures for ensuring compliance with FDA requirements for investigational agents, as appropriate;
- A **named** Supervising Clinical Research Coordinator who will interact with and oversee all Clinical Research Coordinators to expedite and guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites;
- Plans for real-time communications among Clinical Research Sites and between Clinical Research Sites and the Coordinating Center; plans should address methods for information distribution within the consortium, how information technologies will be used to facilitate routine multi-institutional communication and provide real-time communication and data sharing;
- Descriptions of quality assurance, quality control, and study monitoring procedures;
- A comprehensive data management and statistical analysis plan including:
  - A discussion of the overall approach to data collection and management,
  - A statistical plan that includes sample size calculations, methods to monitor quality and consistency of data collection, and methods to measure outcomes,
  - A plan for real-time data transfer, and
  - Data security and integrity measures;
- Descriptions of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies, including a specimen handling and distribution plan for all institutions in the consortium; and
- Plans for ensuring rapid publication and other public dissemination of data generated by consortium-sponsored studies that address all relevant privacy issues.

**4. Use of Funds: The purpose of the PCRP Clinical Consortium Award is to provide the funding to establish the necessary collaborations and resources to rapidly execute clinical trials by the consortium and not to fund research or development of clinical protocols.**

**a. All Sites (Clinical Research Sites and Coordinating Center):** For all sites, funds from the Clinical Consortium Award may be used to:

- Attend and support consortium-related meetings;
- Purchase computers and general software required to participate in the consortium;
- Furnish salary support for personnel needed to meet the goals of the consortium for personnel such as the PI, 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.

**b. Coordinating Center:** In addition to the permissible use of funds from the Clinical Consortium Award described in Subsection II.C.4.a above, the Coordinating Center may use funds from this award to:

- Furnish salary support for personnel needed to meet the goals of the consortium, such as the PI, Consortium Clinical Research Coordinator, Administrative Assistant(s), Research Nurse(s), Statistician(s), Database Manager, and Informatics Manager;
- Implement consortium-developed standardization plan, data management program, and real-time communications system for the consortium;
- Support consortium-related meetings, teleconferences, and travel among participating investigators;
- Purchase computers, specialized software, and specialized software licenses pertinent to Coordinating Center-specific responsibilities for use at participating institutions;
- Coordinate preparation of informed consent/assent forms and other IRB required materials among different institutions;
- Manage the resolution of intellectual property and material rights among institutions;
- Develop definitive statistical plans;
- Develop sources for intervention supply or availability; and
- Other costs directly associated with planning and developing the consortium.

### III. AWARD INFORMATION

The PCRIP plans to spend \$15M to fund the Clinical Consortium Award. A total of \$5M will be allocated from the FY05 budget with \$5M expected from each of the FY06 and FY07 budgets. **Funding beyond FY05 is contingent on receipt of sufficient congressional appropriations to the PCRIP.** Of this total, funding for the Coordinating Center will be available for up to approximately \$5M (inclusive of direct and indirect costs) over a performance period of 3 years. These funds are for all Coordinating Center functions, administrative and clinical, as described in this announcement. Funding will be disbursed in installments of up to approximately \$2M for the first year and up to approximately \$1.5M for each of the second and third years. Funds for the Coordinating Center may cover administrative support including salary, consortium meetings and travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning and developing the consortium collaborations and resources. Funding also will be available for 8-10 Clinical Research Sites up to approximately \$10M total (inclusive of direct and indirect costs) for the 3-year period. Funding for each Clinical Research Site will be up to approximately \$300,000 per year (inclusive of direct and indirect costs). Funds for the Clinical Research Sites may cover administrative support including salary, consortium meetings and related travel among participating investigators, teleconferences, and other costs directly associated with planning and developing the consortium. Based on programmatic requirements, funding amounts may be tailored to produce the most efficient, cost-effective consortium possible; the PCRIP IP reserves the right to recommend modifications to budgets to meet the needs of the consortium.

All applicants must budget for travel to a consortium Pre-Award Planning Meeting in the Baltimore-Washington, DC area to be held some time after notification of award status and prior to disbursement of funds.

All applicants must provide evidence of sufficient institutional support and commitment for the proposed clinical trial. Consideration of cost sharing with other funding sources is encouraged. The nature of this award mechanism does not allow for renewal of assistance agreements or supplementation of existing assistance agreements with DOD funds. **Funding beyond FY05 is contingent upon receipt of sufficient FY06 and FY07 appropriations by the PCRIP.**

### IV. ELIGIBILITY INFORMATION

**A. Applicants: Applicants must be independent investigators at the Assistant Professor level (or equivalent) or higher 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 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 PCRFP 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.<sup>1</sup> 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. Peer reviewers expect to see a consistent, prescribed format for each proposal. Nonadherence to format requirements makes proposals difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in proposal rejection or a lower global priority score.

The following will result in administrative rejection of the entire proposal prior to peer 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.

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

- 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 peer review.

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

## V. PROPOSAL PREPARATION AND SUBMISSION INFORMATION

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

The PI is responsible for uploading the following information:

- **Proposal Information:** The Proposal Information consists of two parts, both of which are entered as data fields. A Letter of Intent is generated when Part 1 of the Proposal Information is saved.
- **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 June 7, 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 May 17, 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 <https://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;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

**E. Proposal Abstracts – *No abstracts are required for the Clinical Consortium Award.*** Please enter “Not required for Clinical Consortium Awards” in the technical abstract and public

abstract fields. These entries are captured as separate data fields under the “SOW/Abstract” tab in the CDMRP eReceipt system and are required for final submission of your proposal.

## 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).

<p><b>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 peer review.</b></p>
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- 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: Indicate whether the application is being submitted as a Clinical Research Site, Coordinating Center, or Coordinating Center with the option to be considered as a Clinical Research Site if not selected as the Coordinating Center by typing in **one** of the following:
- "Clinical Consortium Award – Clinical Research Site," or
  - "Clinical Consortium Award – Coordinating Center only," or
  - "Clinical Consortium Award – Coordinating Center with option."
- f. Indicate this is a NEW proposal.
- g. Keyword descriptive technical terms: To assist the staff in assigning proposals to the appropriate scientific peer review panel, please specify the subject area of the proposal. Also, list specific keywords and descriptive technical terms that 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 [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: *Not applicable to the Clinical Consortium Award.***

**5. Proposal Resubmission Statement: *Not applicable to the Clinical Consortium Award.***

**6. Main Body**

**a. All Applicants: (Clinical Research Sites and Coordinating Center): Start section on a new page; 30-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 the qualifications of the research team and institution to participate as a

Clinical Research Site or Coordinating Center in the consortium. (**Coordinating Center applicants also need to complete Subsections V.F.6.b and V.F.6.c.**)

Provide evidence that the research team and institution fulfill each of the following criteria for participation in the consortium:

- **Commitment to and Experience in Prostate Cancer Clinical Research**
  - Describe specific areas of clinical research interest, such as novel designer drugs, combinatorial therapy schedules, surgical interventions, imaging techniques and immunotherapies. Include overall scope of program and demonstration of integration of basic and/or correlative science into the program, and
  - 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.F.14).
- **Consortium Resources**
  - 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.
- **Institutional Resources**
  - Provide evidence of expertise in Clinical Trials within the applicant institution and describe the experience in the development and conduct of prostate cancer clinical trials; as appropriate, describe any additional 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 for data management and maintenance of data security/confidentiality, and
  - Provide evidence of institutional commitment to using facilities and resources in the conduct of consortium operations.

**b. Coordinating Center Applicants Only: Start section on a new page; 30-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 the ability of his or her group to serve as the consortium Coordinating Center and support the design and conduct of consortium clinical trials. (Coordinating Center applicants also must provide the information described in Subsections V.F.6.a and V.F.6.c.)

Describe the qualifications of the group and plans for the development of key features of the consortium Coordinating Center using the following general outline:

- **Commitment to and Experience in Multidisciplinary and Multi-Institutional Prostate Cancer Clinical Research:** Describe previous experience and accomplishments related to the design, administration, and fiscal management of multi-institutional prostate cancer clinical trials, with particular emphasis on Phase II clinical trials. Describe previous experience with establishing communications systems and data management resources for multi-institutional projects. Reference relevant publications and submit reprints with the proposal (see Subsection V.F.14).
- **Institutional Resources:** Provide evidence of institutional commitment to provide the necessary resources needed to develop and support standardized data collection, data management and analysis, and data security and integrity for the consortium participants.
- **Consortium Organizational Structure:** Provide a detailed description of the overall consortium organization, plans for communications, procedures for transference of funds, and standardized operating procedures for selection and implementation of clinical trials. The organizational structure should include the following key features (see also Figure 1 in Subsection II.C.3.b):
  - Coordinating Center for administration and day-to-day management of consortium operations, developing the clinical trial selection process, protocol coordination, regulatory coordination, study management and monitoring, data collection, management and statistics, and intellectual/material property coordination, and performance as a Clinical Research Site,
  - Clinical Research Sites for conceiving, developing, and conducting clinical trials in prostate cancer, as well as serving as entry points for clinical trials from outside the consortium,
  - Clinical Consortium Committee composed of the PIs 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
  - An EAB comprised of members of the PCRP IP and the PCRP Program Manager for scientific review, oversight, data monitoring, and evaluation.

- **Clinical Trials Implementation**
  - Describe plans for coordinating the submission of proposed clinical trials, review, selection, and implementation of clinical trials within the consortium;
  - Outline plans for coordinating IRB submissions and approvals at participating sites; and
  - Outline plans for developing procedures to ensure compliance with FDA requirements for investigational agents, as appropriate.
- **Study Management and Monitoring**
  - Describe plans for real-time communication among all institutions participating in the consortium,
  - Include a **named** Supervising Clinical Research Coordinator who will interact with and oversee the Clinical Research Site clinical coordinators to guide clinical protocols through the regulatory approval processes, coordinate participant accrual, and coordinate study activities across sites;
  - Outline procedures for quality assurance, quality control, and study monitoring; and
  - Describe plans for the development of methods for the handling, distribution, analysis, banking, and security of specimens and/or imaging products generated from consortium-sponsored studies.
- **Data Management:** Outline a strategy for the development and implementation of a data management plan, including:
  - Descriptions of the overall approach to data collection and management,
  - A statistical plan that includes methods to monitor quality and consistency of data collection and methods to measure outcomes,
  - A plan for real-time data transfer, and
  - Data security and integrity measures.
- **Publication and Data Dissemination:** Describe plans for ensuring rapid publication and other public dissemination of data while maintaining participant privacy.
- **Fiscal Administration:** Describe previous experience with the financial management of multi-institutional clinical research studies.

**c. Coordinating Center Applicants Only — Two Initial Clinical Trials: Start section on a new page; 10-page limit.** Provide brief descriptions of two currently funded Phase II or Phase I/II prostate cancer clinical trials proposed for immediate implementation by the consortium. It is expected that most, if not all, of the patients for these studies will be accrued from within the consortium. Therefore, the two initial clinical trials must be ready to initiate patient accrual just prior to or at the initiation of the award. The proposed studies will be evaluated at both peer and programmatic reviews (see Subsections VI.B.1 and VI.B.2 for additional information on review



criteria). (Coordinating Center applicants also must provide the information described in Subsections V.F.6.a and V.F.6.b.)

Include the following information for each of the two proposed clinical trials:

- Clinical trial title: Provide the title of each clinical trial;
- Phase: Designate the clinical trial as Phase I/II or II;
- Personnel: List the names of all personnel (including the PI) who will have significant involvement in the clinical trials; include their practice license (e.g., M.D. or RN), highest degree(s), job title, and employing institution;
- Location of study: List all centers, clinics, or laboratories where the studies are to be conducted; include details as to how consortium Clinical Research Sites will be integrated into these trials;
- Background: Describe the rationale for conducting the study, as well as the study's relevance and applicability of findings; include descriptions of preliminary studies, Phase I results, or other findings;
- Objectives: Describe the purpose, goals, and endpoint of the study;
- Drug or device: Describe the drugs or devices to be used in the studies; include Investigational New Drug (IND)/Investigational Device Exemption (IDE) numbers, sponsors, and sources, if applicable;
- Study population: Describe the target population and the proposed sample size and provide patient accrual rate requirements;
- Protocol design: Describe the type of study to be performed (prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology;
- Funding and IRB approval status: Provide evidence of funding status of the initial clinical trial(s); describe the status of IRB approval for the initial clinical trial(s) (note that applicants may submit supplementary materials documenting changes in funding or IRB approval status under "Regulatory and Other Documents" in eReceipt through August 26, 2005, 5:00 p.m. Eastern time); and

**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:** *Not applicable to the Clinical Consortium Award.* Coordinating Center applicants: Detailed protocols are not required with proposal submission. Please see Subsection V.F.6.c for further details.

**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:

- Letters of support from any collaborating individuals or institutions in this section of the proposal.
- 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.
- Consortium Coordinating Center: Documentation of funding and IRB approval status for the two initial clinical trials.

All administrative documentation must be incorporated into the electronic PDF version of the proposal. Support documentation will not be accepted separately from the electronic proposal submission, except supplementary materials documenting changes in funding or IRB approval status for the two initial clinical trials, which may be submitted through

5:00 p.m. Eastern time August 26, 2005. 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 for Clinical Research Site applicants, ten document limit for Coordinating Center applicants. Include up to five relevant publication reprints and/or patent abstracts. Coordinating Center applicants are allowed an additional five documents if they are applicable to the Coordinating Center specific portion of the application (see Subsection V.F.6.b). A patent abstract should provide a non-proprietary description of the patent application. If more than the specified number of items is included in the submission, the extra items will not be peer 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:** The PCRIP plans to spend \$15M to fund the Clinical Consortium Award. A total of \$5M will be allocated from the FY05 budget, with \$5M expected from each of the FY06 and FY07 budgets. **Funding beyond FY05 is contingent on receipt of sufficient congressional appropriations to the PCRIP.** Of this total, funding for the Coordinating Center will be up to approximately \$5M (inclusive of direct and indirect costs) over a performance period of 3 years. These funds are for all Coordinating Center functions, administrative and clinical, as described in this announcement. Funding will be disbursed in installments of up to approximately \$2M for the first year and up to approximately \$1.5M for each of the second and third years. Funds for the Coordinating Center may cover administrative support including salary, consortium meetings and travel among participating investigators, database generation and software development, purchase of computers, design of websites, teleconferences, and other costs directly associated with planning and developing the consortium collaborations and resources. Total funding for 8-10 Clinical Research Sites will be up to approximately \$10M inclusive of direct and indirect costs over 3 years. Funding will be disbursed in annual installments of approximately \$300,000 per site inclusive of direct and indirect costs. Funds for the Clinical Research Sites may cover administrative support including salary, consortium meetings and related travel among participating investigators, teleconferences, and other costs directly associated with planning and developing the consortium. Based on programmatic requirements, funding amounts may be tailored to produce the most efficient, cost-effective consortium possible; the PCRIP IP reserves the right to recommend modifications to budgets to meet the needs of the consortium.

All applicants must budget for travel to a consortium Pre-Award Planning Meeting in the Baltimore-Washington, DC area to be held some time after notification of award status and prior to disbursement of funds.

**There is no guarantee that funds will be available for the Clinical Consortium Award in FY06 or FY07.**

**2. Detailed Cost Estimate Form and Budget Justification Instructions:** Budget is an important consideration in both peer 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.** 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](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](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](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. **Coordinating Center Applicants:** Coordinating Center funds are for both the administrative and clinical responsibilities. As such, the Coordinating Center budget must indicate approximately \$900K for Clinical Research Site responsibilities and approximately \$4.1M for the Coordinating Center responsibilities. Please provide these details in separate sections of the submitted budget.

**a. Personnel**

- i. Name:** Starting with the PI, list the names of all participants who will be involved in the consortium-related activities during the initial budget period, regardless of whether salaries are requested. Include all collaborating investigators, Clinical Research Coordinators, 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 in the consortium. 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 consortium are important factors in selecting proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on the consortium.

**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 \$10,000.

**d. Materials, Supplies, and Consumables:** A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories. Categories in amounts less than \$1,000 do not need to be itemized.

**e. Travel Costs:** Applicants must budget for travel to a consortium Pre-Award Planning Meeting in the Baltimore-Washington, DC area to be held some time after notification of award status and prior to disbursement of funds. Travel costs also must include travel to the semi-annual progress review meetings (see Subsection II.C.1).

**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:** 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.

**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 June 7, 2005 deadline. **Coordinating Center applicants may provide supplemental material indicating any change of funding or IRB approval status for the two initial clinical trials through 5:00 p.m. August 26, 2005.**

**The timeline for the Clinical Consortium Award is:**

Online Letter of Intent:	Expected by May 17, 2005
Online Proposal Information:	Prior to proposal submission
<b>Proposal Submission/Approval Deadline:</b>	<b>5:00 p.m. Eastern time June 7, 2005</b>
Peer Review:	July 2005
Clinical Trial Supplementary Materials:	5:00 p.m. Eastern time August 26, 2005
Programmatic Review:	September 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 October 2005 and September 2006

**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 June 7, 2005 deadline, except supplementary materials documenting changes in funding or IRB approval status of the two initial clinical trials, which may be submitted through August 26, 2005, 5:00 p.m. Eastern time.
- 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 and Selection Overview**

**1. Process:** The CDMRP uses a two-tier review process for proposal evaluation. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on scientific merit as well as overall program goals.

**2. Peer Review:** Peer review is conducted by panels organized according to scientific discipline or specialty area. The primary responsibility of the peer review panels is to provide unbiased, expert advice on the scientific/technical merit and relevance of proposals based on the review criteria published for each award mechanism.

Peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting scientific review administrator. Scientific reviewers are selected based on their expertise and their experience with scientific peer review. Consumer reviewers are nominated by an advocacy or support organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the peer review by bringing the patient perspective to the assessment of science and to the relevance of research.



Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see below). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed that its completion is implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the peer review scores and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement.

**3. Programmatic Review:** The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The scientific members of the IP represent diverse disciplines and specialty areas, and the consumer members represent national advocacy constituencies. One of the functions of programmatic review is to maintain a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals from multiple research areas compete in a common pool. IP members primarily use the peer review summary statements and the proposal abstracts. SOWs may also be reviewed. Full proposals are not forwarded to programmatic review.

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

## **B. Review Criteria**

**1. Peer Review:** Clinical Consortium Award proposals will be evaluated according to the following criteria:

### **a. All Applicants (Clinical Research Sites and Coordinating Center)**

- **Personnel:** How have the PI and other key personnel demonstrated experience and excellence in multi-institutional prostate cancer clinical research? Is the PI currently involved in prostate cancer clinical research? Do the PI and other key personnel have the ability and experience to substantially contribute to the design and conduct of consortium clinical trials? Is the named institutional Clinical Research Coordinator appropriately experienced to guide clinical protocols through the regulatory approval processes and interact with other consortium Clinical Research Coordinators? Are all participating personnel willing to commit adequate time, resources, and subjects to consortium clinical trials?

- **Institutional Resources and Commitment:** How does the institution demonstrate commitment to working with all selected sites? Does the institution have the necessary resources and expertise for specimen collection and processing? Does the institution have the necessary resources and expertise for data management and maintaining security/confidentiality? Is the evidence of willingness to resolve intellectual and material property issues with other institutions in the consortium appropriate?
- **Participant Recruitment:** Is there evidence of access to an appropriate and sufficiently large prostate cancer patient population? How successful has the institution been in recruiting patients for clinical trials?
- **Collaborations:** Will the applicant integrate well into the consortium and be a contributing team player? Does the PI have a proven track record of successful collaborations? Does the institution provide any unique resource(s) that may be of benefit to the consortium?
- **Budget:** Is the budget appropriate for the proposed program?

**b. Coordinating Center (to be reviewed in addition to the criteria in Subsection VI.B.1.a above)**

- **Personnel:** How does the PI or other key personnel demonstrate expertise in the design and administration of multi-institutional prostate cancer clinical trials? How successful have they been in acquiring funding for clinical trials? Do the PI and other key personnel have appropriate expertise in prostate cancer? Is there a named Supervising Clinical Research Coordinator who will interact with all Clinical Research Coordinators to coordinate regulatory approvals and consortium activities?
- **Consortium Components:** Does the proposal include all required consortium components (e.g., EAB, Clinical Consortium Committee, Coordinating Center, and Clinical Research Sites)? How clearly has the applicant outlined how each component will function as an integrated unit?
- **Study and Data Management:** How will the strategies for the development and implementation of data management and statistical plans provide access to data, data security, and data integrity? Is there an outline of an appropriate study management plan, including plans for real-time communication, quality control, and quality assurance? Are there plans for the development of specimen handling, distribution, analysis, and banking methods? Are there plans for rapid publication and other public dissemination of data generated by the consortium, and have all relevant privacy issues been addressed?
- **Financial Management:** Do the PI and/or other key personnel have appropriate experience and expertise in fiscal administration of multisite studies, including the distribution and management of funds?

**c. Coordinating Center Initial Two Clinical Trials:**

- **Personnel (applicable if a clinical trial(s) originates from outside the consortium and key personnel have not been previously listed, as described in Subsection VI.B.1.a):** Have the PI and other key personnel in the clinical trial been named and do they have the appropriate expertise in prostate cancer? How has the PI demonstrated success in completing clinical trials?
- **Study Design:** Are the trials focused on therapeutic interventions? Has the study population been adequately described? Have the investigational drugs or devices been adequately described? If from outside the consortium, where does the clinical trial(s) originate? How do the proposed timelines, with and without consortium support, adequately describe the impact of the consortium to facilitate clinical trials?
- **Regulatory Process:** Will the trials be initiated at a time appropriate for implementation by the consortium? Are there plans for the coordination of IRB submissions and approvals at participating sites? Is there a plan for developing procedures to ensure compliance with FDA regulations for investigational agents? Have the appropriate IND/IDE numbers been provided?
- **Relevance:** Are the types of studies to be performed appropriate? Do the trials address an important problem in prostate cancer? Is the intervention or device to be tested likely to have a substantial impact on prostate cancer?

**2. Programmatic Review:** The ratings and evaluations of scientific peer review panels are primary factors in programmatic review. The IP also considers other criteria to maintain the PCRCP's broad portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels,
- Programmatic relevance,
- Relative innovation,
- 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 IP and recommended to the Commanding General, USAMRMC, for funding.

**Based on programmatic requirements, funding amounts may be tailored to produce the most efficient, cost-effective consortium possible; the PCRCP IP reserves the right to recommend modifications to budgets to meet the needs of the consortium.**

## VII. AWARD ADMINISTRATION INFORMATION

**A. Award Notices:** After the two-tier evaluation process is completed, every applicant will receive notification of the award status of his or her proposal and a copy of the peer review

summary statement. Applicants can expect to be notified of the agency's decision in November 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/crpreqsohdfsplan.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:** *Not applicable to the Clinical Consortium Award.*

**5. Research Involving Human Subjects/Anatomical Substances/Cadavers:** *Not applicable to the Clinical Consortium Award.*

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

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

**1. Research Progress Report Requirements:** PIs are required to submit annual written reports that present a detailed summary of scientific issues and accomplishments and a final comprehensive written report (submitted in the last year of the award period) that details the findings and issues for the entire project. 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 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. Consortium members can expect at least one on-site audit during the 3-year term of the award

## 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 in either peer or programmatic review have occurred, and if so, what action should be taken.

**E. Title to Inventions and Patents:** In accordance with the Bayh-Dole Act (35 USC 200 et seq.<sup>2</sup>), title to inventions and patents resulting from such federally funded research may be held by the contractee 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.

**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.

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

## **IX. ACRONYM LIST**

AVI	Audio Video Interleave
CCA	Clinical Consortium Award
CCC	Clinical Consortium Committee
CCR	Central Contractor Registration
CDMRP	Congressionally Directed Medical Research Programs
CFDA	Catalog of Federal Domestic Assistance
DOD	Department of Defense
EAB	External Advisory Board
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
FY	Fiscal Year
HBCU/MI	Historically Black Colleges and Universities/Minority Institutions
IDE	Investigational Device Exemption
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
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