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AUTHORITY

U.S. Army Medical Research and Materiel Command and Fort Detrick ltr., dtd October 17, 2001.

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Award Number: DAMD17-99-2-9005

TITLE: A Uniform Services Comprehensive Database and Tissue Repository for the Study of Epidemiological, Detection, Natural History and New Management Strategies for Prostate Cancer

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REPORT DATE: August 1999

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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_____ Narasimha Chavan Murthy 01/30/01

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13. ABSTRACT ***(Maximum 200 Words)***

The Tri-Service Project Working Group, under the direction of the US Army Medical Research and Development Command convened in the fall of 1997 and throughout early 1998 to develop an agenda for prostate cancer research. Members of the Tri-Service Project Working Group were composed of the US Army medical Research and Development Command, Armed Forces Institute of Pathology and various urologic military medical researchers from Army, Navy, and Air Force medical centers. The Director for Prostate Cancer Research, Congressionally Directed Medical Research Programs, US Army Medical Research and Development Command chaired the Tri-Service Project Working Group. The Tri-Service Project Working Group expressed a need for a centralized repository which would include sera, tissue and clinical data of prostate cancer patients which would serve as a national resource for prostate cancer research, and directed a scientific proposal be develop for submission to US Army Medical Research and Materiel Command for funding. The project was recommended for funding 22 September 1998 contingent upon resolution of the Peer and Programmatic reviews to be conducted in two phases. Phase I directed the hire of a study coordinator to assist the principal investigator in day-to-day management, and to develop and submit a revised proposal to address the weaknesses and deficiencies noted in peer and programmatic review. A revised proposal was submitted 1 June 1999 addressing the weaknesses and deficiencies noted in the peer and programmatic review. The project is currently waiting funding.

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FOREWORD

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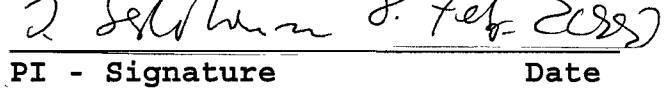

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INTRODUCTION

The Tri-Service Project Working Group, under the direction of the US Army Medical Research and Development Command convened in the fall of 1997 and throughout early 1998 to develop an agenda for prostate cancer research. Members of the Tri-Service Project Working Group were composed of the US Army Medical Research and Development Command, Armed Forces Institute of Pathology and various urologic military medical researchers from Army, Navy, and Air Force medical centers. The Director for Prostate Cancer Research, Congressionally Directed Medical Research Programs, US Army Medical Research and Development Command chaired the Tri-Service Project Working Group.

The major purpose of the Tri-Service Project Working Group was to advance an agenda for military medical prostate cancer research. The Tri-Service Project Working Group first listed goal was to develop a comprehensive relational database on individuals diagnosed with prostate cancer. This database would link clinicians treating cases of prostate cancer, pathologists in military medical centers, and the Armed Forces Institute of Pathology (AFIP) as part of a Department of Defense (DoD) network of prostate cancer data. The program would be designed to facilitate rapid multidisciplinary sharing and collaboration among clinicians, pathologists, and researchers of data collected on prostate cancer cases seen in DoD medical treatment facilities. The database will help to provide data useful for development of proposals for research projects of the type described in the DoD Prostate Cancer Research Program. Activities of the project would include coordination of a bank of tissue and serum samples from patients with prostate cancer, linkage of samples in the tissue and serum bank with clinical patient data, development of an infrastructure for rapid sharing of treatment outcomes, linkage with all Prostate Specific Antigen (PSA) test results, and linkage to existing stored tissue and serum samples from the same individuals.

The Tri-Service Prostate Cancer relational database would combine in a single, highly accessible source, the results of pathology exams, clinical staging, demographic factors such as race, ethnicity and place of birth, medical history, and lifetime military occupational history. It would catalog and identify the location and status of all available stored biological materials and clinical data from the patients in a single comprehensive database. The Tri-Service Prostate Cancer relational database would be updated to include the results of all medical, scientific and career events related to the patient, including hospitalizations, surgery, treatment, survival and results of all testing performed on tissue samples, serum, or other biological materials. All data will be accessible to clinicians, pathologists, and researchers. In addition, all patient data would be made available to the patient's physicians. The database will serve as a central resource of cases for multiple satellite research protocols from military medical centers with particular emphasis on the testing of new hypotheses and innovative epidemiological research on prostate cancer. The Armed Forces Institute of Pathology was selected as the central repository site.

BODY

The Tri-Service Project Working Group expressed a need for a centralized repository which would include sera, tissue and clinical data of prostate cancer patients which would serve as a national resource for prostate cancer research, and directed a scientific proposal be develop for submission to US Army Medical Research and Materiel Command for funding.

The Tri-Service Project Working Group selected Colonel Nancy Dawson, MC, Hematology/Oncology Service, Walter Reed Army Medical Center, as the overall principal investigator for the project. The Henry M. Jackson Foundation was asked to join the Tri-Service Cancer Working Group to provide it's administrative and management expertise in developing the technical proposal and managing the project. The following military sites were selected as participants to initiate this project:

Walter Reed Army Medical Center, Washington, D.C. (Army)
Malcolm Grow Medical Center, Andrews AFB, Maryland (USAF)
Madigan Army Medical Center, Tacoma, Washington (Army)
Naval Medical Center, San Diego, California (Navy)
Brooke Army Medical Center, Fort Sam Houston, Texas (Army)
Wright Patterson Medical Center, Wright Patterson AFB, Ohio (USAF)

The primary goal of this project was to establish a comprehensive serum and tissue repository utilizing the Armed Forces Institute of Pathology to archive all specimens and clinical data, and the Tri-Service network of military medical centers for patient recruitment for the study of the etiology of prostate cancer. The secondary goal of this project would be the incorporation of a demonstration project to illustrate the utility of the repository.

The Tri-Service Project Working Group agreed that the serum and tissue repository be conducted in two (2) phases. It was agreed that phase I should be the establishment of a Tri-Service Tissue and Serum repository as a resource for both military and non-military investigators. Phase II should be the incorporation of a demonstration project to illustrate the utility of the repository.

Phase One:
In phase one, the primary objective would be to establish a prostate cancer serum and tissue repository as a resource for both military and non-military investigators. Initially, the tissue will consist of radical prostatectomy and lymph nodes specimens removed for prostatic carcinoma, which will be processed according to a defined protocol. The histological analysis will have local and central review. The project would encompass the utilization of six (6) peripheral, geographically dispersed military sites encompassing all branches of the services which would ship serum, tissue samples, and clinical information to the Armed Forces Institute of Pathology for the archiving of the data and tissue

samples. Additionally, standardized data collection instruments will be used at the designated centers by clinical research personnel and physicians to collect comprehensive prospective and retrospective information from men with prostate cancer. For geographic and service diversity, these sites include:

Phase Two:
Phase II will be the incorporation of a demonstration project to illustrate the utility of the repository. The primary objective of phase two will be the establishment of a centralized database at the Armed Forces Institute of Pathology that would incorporate the tissue, serum and clinical data and demonstrating the utility of the repository.

Assuming the success of phases I and II, additional military sites will be expanded to include additional peripheral, geographically dispersed military sites encompassing all branches of the services which will ship serum, tissue samples and clinical data to the Armed Forces Institute of Pathology for the archiving of the data samples.

Chronological History:

15 December 1997 – The Tri-Service Project Working Group finalized decisions for a Tri-Service Database Repository and directed the writing of a scientific proposal to be submitted to US Army Medical Research and Materiel Command.

15 April 1998 – The proposal entitled, " A Uniformed Services Comprehensive Database and Tissue Repository for the Study of Epidemiological, Detection, Natural History and New Management Strategies for Prostate Cancer" was submitted to US Army Medical Research and Materiel Command.

22 September 1998 – The proposal was recommend for funding, contingent upon resolution of the Peer and Programmatic reviews. US Army Medical Research and Materiel Command proposed to enter into a two-phase contract. During Phase I the Foundation was directed to hire a study coordinator to assist Dr. Dawson in day-to-day management and direction of the study. During Phase II the principal investigator would develop and submit a revised proposal to address the weaknesses and deficiencies noted in peer and programmatic review.

13 October 1998 – A revised budget and statement of work was submitted to US Army Medical Research and Materiel Command for Phase I.

12 November 1998 – A cooperative agreement for Phase I was signed between the Foundation and US Army Medical Research and Materiel Command in the amount of $108,113.00.

February 1999 – Dr. Dawson announced her retirement from military service, and that she would no longer serve as principal investigator. Dr. Isabell A. Sesterhenn, Armed Forces Institute of Pathology was selected as the principal investigator to replace Dr. Dawson.

1 June 1999 – A revised proposal addressing the weaknesses and deficiencies noted in the peer and programmatic review was submitted to US Army Medical Research and Materiel Command.

9 September 1999 – The revised proposal was recommended for funding at a reduced budget pending submission /approval of required appendices. The programmatic review panel proposed to fund this project for one year at a reduced budget of up to $300,000.

13 December 1999 – Additional guidance was received from US Army Medial Research Acquisition Activity regarding the submission of a revised budget. Up to $250,000 was proposed to initiate collection of materials and up to $50,000 was proposed to be utilized for consultation/outsourcing for the development and management of the database, forms, and work assignments.

31 January 2000 – A revised budget and Representations and Certifications packet was submitted to US Army Medical Research Acquisition Activity.

CONCLUSION:

Due to the ongoing nature of this contract, no conclusions have been reached at this time. We anticipate to be on contract by late February 2000 for the initial $300,000. Due to the initial budget guidance of $300,000, the following actions were necessary to meet the budget cap:

1. Elimination of Wright Patterson Medical Center, 74th Medical Group, Wright Patterson AFB, Ohio as a participating site in the study.
2. Defer purchasing equipment, blood/tissue collection supplies and office supplies for participating centers.
3. Defer overnight shipping contract for tissue/blood.
4. Defer hiring the histotechnician, data coordinator, and study coordinator.

Approximately, six months after receipt of funds, progress report will be submitted to US Army Medical Acquisition Activity. This progress report will be programmatically reviewed and pending the review, additional funds of up to $600,000 may be awarded.

Peer
10/29/2001

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND AND FORT DETRICK
810 SCHRIEDER STREET, SUITE 218
FORT DETRICK, MARYLAND 21702-5000

REPLY TO
ATTENTION OF:

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2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by e-mail at judy.pawlus@det.amedd.army.mil.

FOR THE COMMANDER:

PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

Enclosure