MIPR NO: 90MM0581

TITLE: INDUCTION OF TNF-A AND IL-1 IN HUMAN TUBERCULOSIS (CIC3)

PRINCIPAL INVESTIGATOR: Greg T. Anders

CONTRACTING ORGANIZATION: Brooke Army Medical Center
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Fort Detrick, Frederick, Maryland 21702-5012

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other authorized documents.
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FOREWORD

For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR56.

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SUBJECT: Final Report for MIPR No. 9UM40581

Commander
U.S. Army Medical Research and Development Command
ATTN: SGRD-RMI-S
Fort Detrick, Frederick, MD 21702-5012

Judy Pawlus
Chief, Research Data Management Division

Dear Ms. Pawlus:

This correspondence is in response to a letter received from your office dated 3 January 1992 requesting final report for above-mentioned MIPR number. Attached is a final report format similar to previous quarterly report formats which have been submitted for this project. It should be noted that the undersigned has been the principal investigator for this project only from 15 August 1991 through 31 December 1991, and the attached report covers that interval period. Previously to that time, the principal investigator was Major Craig Smith who had submitted previous quarterly reports. It is apparent that previous work on this project prior to 15 August 1991 was conducted in a sporadic manner largely due to the deployment of Major Smith for Operation Desert Storm. The undersigned was approached by personnel from the Department of Clinical Investigation and the Infectious Disease Service, Department of Medicine, Brooke Army Medical Center, in late summer 1991 with a request that I assume the principal investigator position for this project of which I have agreed to do.

MIPR No. 9UM40581 bears significant similarity to previous work which I have conducted. The most recent publication regarding this work was published in the journal AIDS Research and Human Retroviruses, Volume 6, No. 1, 1990. This title of the work was "Production of Tumor Necrosis Factor-Alpha and Interleukin I by Alveolar Macrophages from HIV-infected Persons". This work was conducted under approved Clinical Investigation Protocol C-64-87 on file at the Brooke Army Medical Center.

From a scientific viewpoint, two patients have been currently enrolled in this study during the interval period 15 August 1991 to 31 December 1991. The initial data regarding these two patients was included in presentation involving other work at the Eighth Army Regional Subspecialty Meeting of the
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American College of Physicians, in San Francisco, California, on 26 October 1991. Although the data on these two patients is inadequate for complete evaluation, it does appear that the peripheral monocyte production of TNF-Alpha appears to be increased in patients with tuberculosis. It is important that the production of these cytokines in human tuberculosis be also evaluated in the particular subset with human tuberculosis as well as HIV infection. Ongoing work in this area as per other protocols continues.

With regard to expenditures, during the interval period of 15 August 1991 to 31 December 1991 a total of $12,311.01 was spent. This is broken down into $7,879.31 for expendable supplies and $4,431.70 for equipment. The three pieces of equipment that were purchased included an Olympus Inverted microscope, a power supply for same, and a GNA-100 gel applicator apparatus. These supplies and equipment are being used in ongoing work involving project 90MMS81. Although no specific publications regarding this particular project have yet evolved, we anticipate that continued work in this area will produce meaningful results.

I appreciate your understanding and if you have any further questions, please do not hesitate to contact me at (512) 221-0509/2336.

Sincerely,

GREGG T. ANDERS
Major, MC
Pulmonary Disease/Critical Care Service
Principal Investigator 90MMS81
FINAL REPORT

1. MIPR No. JUMHU581
2. Report Date 27 Jan 92
3. Reporting Period from 15 Aug 91 to 31 Dec 91
4. PI MAJ Gregg T. Anders
5. Telephone AV 471-0509
6. Agency Brooke Army Medical Center
7. Project Title: Induction of TNF-alpha and IL-1 in Human Tuberculosis
8. Current Staff, with Present Effort of each on project:
   MAJ Gregg T. Anders 10%  COL C. Kenneth McAllister 0%
   MAJ David P. Dooley 10%  MAJ Keith A. Konkol 0%
9. Approximate P.I. expenditure to date:
   Personnel Supplies $7,879.31
   Travel Other
   Equipment $4,431.70 Contracts
10. Comments on administrative and logistical matters: See attached correspondence.