

PD-AAZ-575

AGENCY FOR INTERNATIONAL DEVELOPMENT
PROJECT DATA SHEET

1. TRANSACTION CODE A - Add C - Change D - Delete
Amendment Number 1
DOCUMENT CODE 3

ENTRY/ENTITY: Worldwide
BUREAU/OFFICE: Office of Health 10

3. PROJECT NUMBER: 931-0453.55 ISN 62150
3. PROJECT TITLE (maximum 40 characters): Malaria Immunology - USC

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)
MM DD YY
07 30 90

7. ESTIMATED DATE OF OBLIGATION
(Under "B." below, enter 1, 2, 3, or 4)
A. Initial FY 86 B. Quarter 4 C. Final FY 90

8. COSTS (\$000 OR EQUIVALENT \$1 =)

A. FUNDING SOURCE	FIRST FY <u>86</u>			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	240		240	681		681
(Grant)	(240)	()	(240)	(681)	()	(681)
(Loan)	()	()	()	()	()	()
Other U.S.	1.					
	2.					
Host Country						
Other Donor(s)						
TOTALS	240		240	681		681

9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1) HE	540	542		631		50		681	
(2)									
(3)									
(4)									
TOTALS				631		50		681	

10. SECONDARY TECHNICAL CODES (maximum 8 codes of 3 positions each)
11. SECONDARY PURPOSE CODE
12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)
A. Code
B. Amount
13. PROJECT PURPOSE (maximum 400 characters)

The purpose of this research project is to study the cellular responses to malaria immunization and to examine the potential need for immunomodulators in future malaria vaccine.

14. SCHEDULED EVALUATIONS
Interim MM YY MM YY Final MM YY
06 89 02 90
15. SOURCE/ORIGIN OF GOODS AND SERVICES
 000 941 Local Other (Specify)

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a _____ page PP Amendment)

The purpose of this amendment is to increase life of project funding from \$665,000 to \$681,000 and to extend the PACD from 6-15-89 to 7-30-90.

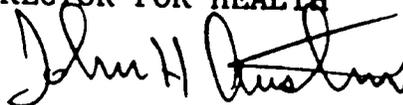
17. APPROVED BY: Kenneth J. Bart
Signature: Kenneth J. Bart
Title: Kenneth J. Bart, M.D. Agency Director for Health
Date Signed: MM DD YY 07 11 89
18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION
MM DD YY 11 11 89

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

JUL 7 1989

ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH

FROM: S&T/H/WVC, John H. Austin



SUBJECT: Increase funding authority and extend the Project Assistance Completion Date for the Malaria Vaccine Development Program - the University of Southern California, project No. 931.0453.55

Action: Your approval is required to increase life of project funding to \$680,672 and extend the Project Assistance Completion Date (PACD) to 7/31/90 in accordance with Section 104 of the Foreign Assistance Act of 1961, as amended, for project 931-0453.55, Malaria Immunity and Vaccination Research (MIVR), the University of Southern California (USC), Los Angeles, California.

Discussion: This project has been a fundamental component of the Agency's malaria vaccine program for studying immunity to malaria and screening of malarial vaccine preparations using T-lymphocyte assays.

Under the direction of Dr. John Martin, this research contract included three objectives to strengthen the MIVR's capacity to study cell-mediated immunity against the malaria parasite and to screen vaccine candidates for their ability to boost cell-mediated immunity. Specifically, these objectives were to (1) determine proliferative responses of functionally distinct subpopulations of human T-cells to purified Plasmodium falciparum sporozoite and merozoite stage antigens, (2) determine the requirements for interleukin and interferon synthesis in achieving optimal activation of early T-cell subsets, and (3) clone phenotypically characterized malarial antigen-specific T-cells for: a) use in functional studies and b) for identification of immunologic epitopes on malarial parasites.

The contract extension will continue on-going work in objective 3, focussing on the characterization of the immune response to a certain Plasmodium vivax circumsporozoite peptide. Work on this objective is unique and has been rather productive. As a service to the MIVR Project, Dr. Martin's group has plans to train other scientists in immunologic assays developed in his laboratory that are relevant to understanding protection against malaria and evaluating prototype malaria vaccines. The USC also has access to patients with Plasmodium vivax infections, which is a relatively rare resource in the United States for immune cells and sera to study this type of malaria. For these reasons, it would be very difficult for another contractor to assume and complete studies and services developed at USC.

The current contract will expire at the end of September 1989, however an unsolicited proposal from USC for a new agreement was not acceptable in its entirety after external peer review. The PI has requested a contract extension and supplemental funding for those aspects of the proposal found to be meritorious. These services and research activities are on-going and any disruption of services would cause serious delays in the vaccine development effort.

Justification to the Congress: Project Funding is included in the FY 1989 Congressional Presentation, Annex IV, Centrally Funded Programs, page 120.

Clearances Obtained: After a competitive scientific review of a new proposal from USC, interim funding for the services and certain studies outlined in a scope of work (attached) was recommended by an A.I.D. external expert panel on the basis of scientific methodology, qualifications and experience of the proposed investigators, and the institutional capability in accordance with FAR 15.506.2, FAR 15.507 (b) (1).

Recommendation: That you (1) sign the attached authorization to increase the life of project funding to \$681,000 and extend the Project Assistance Completion Date to July 31, 1990 and (2) sign the justification and Authorization for Other Than Full and Open Competition (O.F.O.C.).

Attachments:

1. Project Authorization
2. Scope of Work and Budget
3. Justification and Authorization of O.F.O.C.

Clearances

S&T/H: CDiggs	<i>CDiggs</i>	Date	7 July 89
GPettigrew	<i>GPettigrew</i>	Date	7-7-89
AVandusen	<i>AVandusen</i>	Date	7-7-89
S&T/PO: DSheldon	<i>DSheldon</i>	Date	7/10/89
GC/CP: STisa	<i>STisa</i>	Date	6-26-89

Drafter: S&T/H: EPeterson: ps: x4601: 5/31/89: wang#1816s
revised EP/ASF 5/31/89

PROJECT AUTHORIZATION AMENDMENT NO. 1

Name of Country: Worldwide

Project Title: Malaria Immunity and Vaccine Research

Project Number: 931-0453.55, The University of Southern California, Los Angeles California: Malaria T Cell Immunity in Malaria Vaccination

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, the centrally-funded project, "T Cell Immunity In Malarial Vaccination" was authorized on May 26, 1986. That authorization is hereby amended as follows:

a) Increase the life-of-project funding by \$16,000 from \$665,000 to \$681,000 and

b) Extend the Project Assistance Completion Date to July 31, 1990.

2. The authorization cited above remains in effect except as modified herein.

Approved Kenneth Trantun

Disapproved _____

Date 7/11/89

Clearances:

S&T/H:JAustin	<u>[Signature]</u>	Date	<u>7 July 89</u>
CDiggs	<u>[Signature]</u>	Date	<u>7 July 89</u>
GPettigrew	<u>[Signature]</u>	Date	<u>7-7-89</u>
AVanDusen	<u>[Signature]</u>	Date	<u>7-7-89</u>
S&T/PO:DSheldon	<u>[Signature]</u>	Date	<u>7/10/89</u>
GC/CP:STisa	<u>Phone [Signature]</u>	Date	<u>6-20-89</u>

M