

PD-AAZ-315

<b>AGENCY FOR INTERNATIONAL DEVELOPMENT</b> <b>PROJECT DATA SHEET</b>	1. TRANSACTION CODE <input type="checkbox"/> A = Add <input type="checkbox"/> C = Change <input type="checkbox"/> D = Delete	Amendment Number _____	DOCUMENT CODE <b>3</b>
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2. COUNTRY/ENTITY Worldwide	3. PROJECT NUMBER <input type="text" value="931-0453.55"/>
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4. BUREAU/OFFICE S&T/ H/CD <input type="checkbox"/> 10 <input type="checkbox"/>	5. PROJECT TITLE (maximum 40 characters) <input type="text" value="Malaria Immunology - USC"/>
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6. PROJECT ASSISTANCE COMPLETION DATE (PACD) MM DD YY <input type="text" value="06"/> <input type="text" value="15"/> <input type="text" value="89"/>	7. ESTIMATED DATE OF OBLIGATION (Under 'B.' below, enter 1, 2, 3, or 4) A. Initial FY <input type="text" value="86"/> B. Quarter <input type="text" value="4"/> C. Final FY <input type="text" value="88"/>
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8. COSTS (\$000 OR EQUIVALENT \$1 = )						
A. FUNDING SOURCE	FIRST FY			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	240		240	665		665
(Grant)	( 240 )	( )	( 240 )	( 665 )	( )	( 665 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
<b>TOTALS</b>	240		240	665		665

9. SCHEDULE OF AID FUNDING (\$000)									
A. APPRO- PRIATION	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) ST/H	540	542				665		665	
(2)									
(3)									
(4)									
<b>TOTALS</b>						665		665	

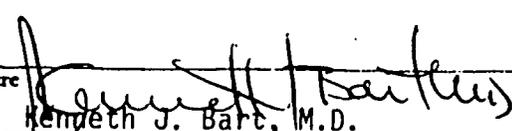
10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)	11. SECONDARY PURPOSE CODES
12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each) A. Code B. Amount	

13. PROJECT PURPOSE (maximum 480 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 <input type="text" value="11"/> <input type="text" value="78"/> <input type="text" value="77"/> <input type="text" value="78"/> Final MM YY <input type="text" value="06"/> <input type="text" value="89"/>	15. SOURCE/ORIGIN OF GOODS AND SERVICES <input checked="" type="checkbox"/> 000 <input type="checkbox"/> 941 <input checked="" type="checkbox"/> Local <input type="checkbox"/> Other (Specify) _____
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16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a \_\_\_\_\_ page PP Amendment.)

17. APPROVED BY	Signature  Kenneth J. Bart, M.D. Title Agency Director for Health	18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION Date Signed MM DD YY <input type="text" value="05"/> <input type="text" value="26"/> <input type="text" value="86"/>
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## PROJECT AUTHORIZATION

Name of Entity: Interregional  
Project Title: T-cell Immunity in Malarial Vaccination  
Project No.: 931-0453.55  
Grantee: The University of Southern California, Los Angeles, California

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the centrally-funded research project entitled "T-cell Immunity in Malarial Vaccination" involving not to exceed \$665,000 of S&T Bureau grant funds over a three-year period from the date of authorization subject to the availability of funds in accordance with the A.I.D. OYB/Allotment process, to help in financing the costs of the project.

2. This project will conduct research to investigate the cellular response to potential malaria vaccines through the activation of specific T-cells as well as stimulation of production of interleukins and interferons by the body. This includes the relative efficacy of macrophages, follicular dendritic cells and T-zone histiocytes in the presence of malaria antigens.

3. The agreement(s) which may be negotiated and executed by the officer(s) to whom such authority is delegated in accordance with A.I.D. regulations and delegations of authority shall be subject to the following terms and conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

4. Source and Origin of Commodities, Nationality of Services

- a. Commodities financed by A.I.D. under the project shall have their source and origin in the cooperating country\* or the United States except as A.I.D. may otherwise agree in

\*Each cooperating country where research, training, technical or other assistance takes place under the project shall be deemed to be a cooperating country for the purpose of permitting local cost financing.

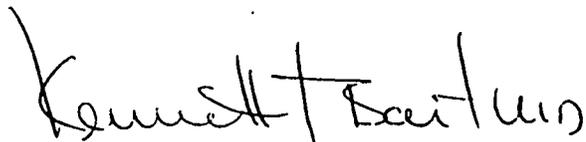
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writing. Except for ocean shipping, the suppliers of commodities or services shall have the cooperating country or the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

- b. Ocean shipping financed by A.I.D. under the project shall, except as A.I.D. may otherwise agree in writing, be financed only on flag vessels of the United States.

Clearances:

S&T/H, GShivers	<u>GS</u>	Date	<u>5/21/86</u>
S&T/H, AVanDusen	<u>AVD</u>	Date	<u>5/21/86</u>
GC/CP, STisa	Draft	Date	<u>5/23/86</u>
S&T/PO, GGower	<u>KGm for</u>	Date	<u>5/22/86</u>



Kenneth J. Bart, M.D.  
Agency Director for Health

5/26/86  
(Date)

  
S&T/H:JErickson:tns:5/15/86:2698t:X5-8934

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

May 21, 1986

ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH

FROM: S&T/H, Ann Van Dusen *Ann Van Dusen*

SUBJECT: Malaria Vaccine Development - the University of Southern California, Los Angeles, California

Action: Your approval is required for a grant of \$665,000 from Section 104 of the Foreign Assistance Act of 1961 as amended for project 931-0453.55, Malaria Immunity and Vaccination Research, the University of Southern California, Los Angeles, California.

We have reviewed a research proposal from the University of Southern California, proposing a three-year program, primarily to assess the immunogenicity of malarial vaccine preparations using a T-lymphocyte activation assays. This project is extremely important to the Agency's overall malaria vaccine effort because it is the only one looking at the cellular stimulation of interleukins and interferon(s) which may be very important immunomodulators in immunocompromised people, especially children in Africa. The specific project objectives include: (1) determining the proliferative response of functionally distinct subpopulations of human T-cells to purified Plasmodium falciparum sporozoite and merozoite stage antigens; (2) determining the requirements for interleukin and interferon synthesis in achieving optimal activation of early T-cell subsets; and, (3) cloning phenotypically characterized, malarial antigen-specific T-cells for use in functional studies and for the identification of immunologic epitopes on malaria parasites under Good Laboratory Practice (GLP) regulations to facilitate incorporation of the results directly into IND and NDA applications.

In the past two years, the researchers, while at USUHS in Bethesda, Maryland, have been able to isolate and test different sub-populations of antigen-presenting cells for their capacity to activate specific types of T-cells. They have completed the development of an interleukin-I assay utilizing human cultured T-cells. This breakthrough will allow the researchers to quickly complete the interleukin-II assay which will be critical to the human vaccines trials that will be implemented shortly. In addition, this laboratory has focused on the Epstein-Barr virus relationships to malaria which it seems is somewhat related to the HTLV-III virus that causes AIDS. These studies will be extremely important if the CDC report to the Malaria Network Coordination Meeting May 9, 1986 proves a direct link between malaria and the lymphotropic type viruses.

The research proposal is attached for further information and details of the specific experimental design. Also please see below.\*

Justification to the Congress: Project Funding is included in the FY 1986 Congressional Presentation, Annex V, Centrally Funded Programs, page 87.

Clearances Obtained: This project was approved by the 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) (i).

Recommendation: That you sign the attached authorization.

Attachments:

1. Project Authorization
2. USC Proposal

Clearances:

S&T/H, GShivers	<u>AS</u>	Date	<u>5/21/86</u>
GC/CP, STisa	<u>Draft</u>	Date	<u>5/23/86</u>
S&T/PO, GGower	<u>Km fu</u>	Date	<u>5/22/86</u>

S&T/H:  :tns:5/15/86:2960t

\*The following is incorporated as part of this memo per Steve Tisa's clearance: Research involving testing of animals and human subjects will comply with the following DHHS guidelines: "Guide for the Care and Use of Laboratory Animals" - U.S. Department of Health and Human Services (DHHS) Publication No. (NIH) 85-23;" and "Guide for the Safety of Human Subjects in Research - U.S. Department of Health and Human Services (DHHS) - Human Research Subjects - 45 CFR,-PT46."

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