

PD-AAZ-636

AGENCY FOR INTERNATIONAL DEVELOPMENT  
**PROJECT DATA SHEET**

1. TRANSACTION CODE  
 A = Add  
 C = Change  
 D = Delete  
 Amendment Number: 15N 62233

DOCUMENT CODE: 3

2. COUNTRY/ENTITY: WORLDWIDE

3. PROJECT NUMBER: 931-0453.90

4. BUREAU/OFFICE: Office of Health

5. PROJECT TITLE (maximum 40 characters): Mal Inm & Vacc Res (Case Western Univ)

6. PROJECT ASSISTANCE COMPLETION DATE (FACD)  
 MM DD YY: 05 31 92

7. ESTIMATED DATE OF OBLIGATION (Under "B." below, enter 1, 2, 3, or 4)  
 A. Initial FY: 89  
 B. Quarter: 1  
 C. Final FY: 91

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

A. FUNDING SOURCE	FIRST FY 89			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	871		871	1,700		1,700
(Grant)	( 871 )	( )	( 871 )	( 1,700 )	( )	( 1,700 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
<b>TOTALS</b>	871		871	1,700		1,700

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				1,700		1,700	
(2)									
(3)									
(4)									
<b>TOTALS</b>						1,700		1,700	

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)

This project will conduct research on the pathology of various organs in monkeys before and after immunization with malaria vaccines and challenges, and the pathological effects of various adjuvants in primates before immunization. In addition, the project will characterize protective malaria antigens by immunoelectron microscopy.

14. SCHEDULED EVALUATIONS

Interim: MM YY MM YY Final: MM YY: 05 92

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)

17. APPROVED BY: KENNETH J. BART, M.D., Agency Director for Health

Signature: [Handwritten Signature]

Date Signed: MM DD YY: 06 24 89

18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION: MM DD YY

## AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C. 20523

JUN 9 1989

## ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH

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

SUBJECT: Malaria Immunity and Vaccine Research--Authorization of Subproject Activity "Studies on Malaria Antigens and Their Pathological Effects on Primates" under malaria project 931-0453

Problem: Your approval is requested for a \$1,700,000, 35-month project entitled "Studies on Malaria Antigens and Their Pathological Effects on Primates."

Background: A research proposal was received from Case Western Reserve University to study malaria antigens and their pathological effects on primates. The proposal was reviewed by an external panel of scientific experts, the Scientific Consultants Group, and S&T/H malaria staff both for scientific merit and program relevance. As a result of the reviews, the proposal was recommended for funding with minor modifications. Specific project objectives include: (1) Characterization of protective antigens of P. falciparum and other plasmodia by immunoelectron microscopy; (2) Study of the pathology of various organs, particularly kidneys in Aotus and Saimiri monkeys before and after immunization with malaria vaccines and challenges; and (3) Study of the pathological effects of various adjuvants in primates before immunization.

Discussion: Over the past few years the Principal Investigator has been studying renal diseases occurring in P. falciparum infected and uninfected Aotus monkeys and characterizing protective antigens of P. falciparum and P. vivax by immunoelectron microscopy. The work has been accomplished in collaboration with numerous malaria research laboratories funded by A.I.D. The work has provided valuable feedback to research laboratories and primate testing facilities, directing and accelerating malaria vaccine development.

The proposed work does not duplicate or overlap with other work funded by the Malaria Vaccine Research and Development Project. The work expands and extends research carried out in basic research and provides a unique resource for malaria vaccine research. We propose to award a three year non-competitive Cooperative Agreement for this activity. The proposal is attached for further information and details of specific experimental design.

2

Research Involving Testing of Animals and Human Subjects:  
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."

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 approve funding in the amount of \$1,700,000 over a three-year period for the subproject activity entitled "Studies on Malaria Antigens and Their Effects on Primates" by signing the attached Project Authorization.

Attachments:

1. PAF Amendment
2. Case Western Reserve University Proposal
3. Letter from Principal Investigator responding to reviewer's comments
4. Scope of Work and Budget
5. Justification for Non-Competitive Procurement

Clearances:  
S&T/H:JAustin Edon In Date: 7-1-89  
S&T/H:CDiggs Edon Date: 7-1-89  
S&T/H:GPettigrew Edon Date: 6/8/89  
S&T/PO:DSheldon Edon Date: 6/24/89

Drafter:CMiller:fyh:5/18/89

PROJECT AUTHORIZATION

Name of Country: Worldwide  
Project Title: Studies on Malaria Antigens and their  
Pathological Effects on Primates  
Project Number: 931-0453

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the centrally-funded project, "Studies on Malaria Antigens and their Pathological Effects on Primates," not to exceed \$1,700,000 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 cost of the project.
2. This project will conduct research on the pathology of various organs in monkeys before and after immunization with malaria vaccines and challenges the pathological effects of various adjuvants in primates before immunization. In addition, the project will characterize protective malaria antigens by immunoelectron microscopy.
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 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;

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\*Each 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 of goods and services required for the activity conducted in such country.

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.

Approve R H Van Dusen  
Disapproved \_\_\_\_\_  
Date June 23 1989

Clearances:	S&T/H/WVC:JAustin	<u>[Signature]</u>	Date	<u>5/1/89</u>
	S&T/H/M:CDiggs	<u>[Signature]</u>	Date	<u>5/1/89</u>
	S&T/H:GPettigrew	<u>[Signature]</u>	Date	<u>6/9/89</u>
	AVanDusen	<u>[Signature]</u>	Date	<u>6/9/89</u>
	S&T/PO:DSheldon	<u>[Signature]</u>	Date	<u>6/21/89</u>
	GC/CP:STisa	<u>[Signature]</u>	Date	<u>6-14-89</u>

Drafter:S&T/H/M:CMI Mer:ps:x4601:5/31/89:wang#1817s