

AGENCY FOR INTERNATIONAL DEVELOPMENT <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 3
2. COUNTRY/ENTITY S&T Interregional		3. PROJECT NUMBER <input type="checkbox"/> 931-0453.36		
4. BUREAU/OFFICE S&T/Health		5. PROJECT TITLE (maximum 40 characters) <input type="checkbox"/> Malaria Immunology - Case Western U. <input type="checkbox"/>		
6. PROJECT ASSISTANCE COMPLETION DATE (PACD) MM DD YY 06 01 89		7. ESTIMATED DATE OF OBLIGATION (Under 'B.' below, enter 1, 2, 3, or 4) A. Initial FY <input type="checkbox"/> 84 <input type="checkbox"/> 85 <input type="checkbox"/> 86 <input type="checkbox"/> 87 <input type="checkbox"/> 88 <input type="checkbox"/> 89 B. Quarter <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 C. Final FY <input type="checkbox"/> 84 <input type="checkbox"/> 85 <input type="checkbox"/> 86 <input type="checkbox"/> 87 <input type="checkbox"/> 88 <input checked="" type="checkbox"/> 89		

8. COSTS (\$000 OR EQUIVALENT \$1 = )						
A. FUNDING SOURCE	FIRST FY 84			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	800		800	1,629		1,629
(Grant)	( 800 )	( )	( 800 )	( 1,629 )	( )	( 1,629 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S.	1.					
	2.					
Host Country						
Other Donor(s)						
<b>TOTALS</b>	<b>800</b>		<b>800</b>	<b>1,629</b>		<b>1,629</b>

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) ST/H	540	542		633		829		1,629	
(2)									
(3)									
(4)									
<b>TOTALS</b>				<b>633</b>		<b>829</b>		<b>1,629</b>	

10. SECONDARY TECHNICAL CODES (maximum 6 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 480 characters)

The purpose of this project is to conduct research on viral diseases occurring in Aotus monkeys and assist in classification of sporozoite antigens of the human malaria.

14. SCHEDULED EVALUATIONS						15. SOURCE/ORIGIN OF GOODS AND SERVICES			
Interim	MM	YY	MM	YY	Final	MM	YY		
	05	88				05	89		
						<input checked="" type="checkbox"/> 000 <input type="checkbox"/> 941 <input type="checkbox"/> Local <input type="checkbox"/> Other (Specify) _____			

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

This amendment extends the project of two years to integrate histopathological data on non-human primates into the human clinical trials of malaria vaccine candidates, and raises ZOP to \$ 1,629,243.00.

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

PROJECT AUTHORIZATION AMENDMENT NO. 1

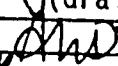
Name of Country: Worldwide  
Project Title: Malaria Immunity and Vaccination  
Project number: 931-0453.36 (Case Western University)  
Contract No. DPE-0453-A-00-4027-00

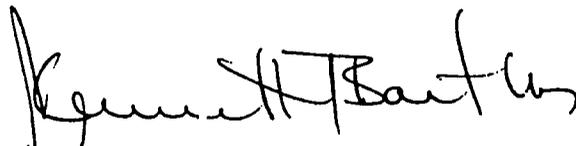
1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, the centrally-funded project, Malaria Immunity and Vaccination Research, was authorized on January 9, 1984. That authorization is hereby amended as follows:

Increase the life-of-project funding from \$800,000 to \$1,629,243. The life-of-project period is extended two years from FY 86 to FY 88. The Project Assistance Completion Date will be December 31, 1989.

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

Clearances:

S&T/H/CD, JHAustin		Date	8 May 87
S&T/H, GPettigrew	(draft)	Date	5/6/87
S&T/H, AVanDusen		Date	5/27/87
S&T/PO, GGower		Date	3 June 87
GC/CP, STisa	(draft)	Date	5/27/87



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

6 / 8 / 87

(Date)

S&T/H/CD: JEricksen:tns:3/27/87:4170t  
Revised:4/8/87; CMiller/JHeiby:tns:5/3/87  
*cm* *JH*

PLC136

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

MAY 15 1987

ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH

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

SUBJECT: Increased Funding Authority for Project 931-0453.36,  
Malaria Immunity and Vaccination - Research, Case Western  
University

Problem: Your approval is required to extend the Life of Project period and to increase the Life of Project funding for project 931-0453.36, Malaria Immunity and Vaccination Research, Case Western University. The life of project <sup>(acceleration)</sup> period would be extended from FY 86 to FY 88. The Project Assistance Completion Date would be extended to December 31, 1989. The life of project funding would be increased by \$829,243 for a new LOP of \$1,629,243. Of this, \$357,000 will be obligated in FY 87.

Discussion: Based upon the research progress outlined at the recent A.I.D. Malaria Vaccine Network Coordination Meeting (Urbana, May 5-8, 1986), the researchers at Case Western University have submitted an acceleration request. Although Dr. Aikawa submitted a three-year request, A.I.D. decided to move rapidly forward with two year extensions of several projects to give them LOP's of 5 years.

This acceleration is required because the amount of work required to study renal diseases and other histopathological problems has significantly increased as A.I.D. has expanded its animal models, bringing up two Peruvian Aotus models and the squirrel monkey model. All of these new models are in place and several vaccine candidates have been tested in them. The total number of monkeys in the network is rapidly increasing and the FDA requests for pathological data are increasing concomitantly.

This project is fundamental to our network in supporting the pathological component of the non-human primates. At this time, the staff is gearing up for the large NYU/WRAIR/CDC P. vivax trial as well as the Scripps/U. Hawaii P. falciparum Aotus trial. These two trials begin in April-May 1987 and involve 130 animals. Four other major trials are programmed for 1987.

As a result of discussions with you, we have removed the cost of the "electron microscope" which the investigator had requested, thereby reducing the cost of this two year acceleration by \$420,000.

Recommendation: That you: (1) approve the extension of the Life of Project period by two years from FY 86 to FY 88 for an overall 5-year Life of Project; and (2) approve \$829,243 increase in the Life of Project funding from \$800,000 to a new level of \$1,629,243 by signing the amended project authorization attached. All other terms and conditions of the project remain unchanged.

Attachments:

1. PAF Amendment
2. Case Western University Request.
3. Bi-Annual Report
4. External Team Evaluation

Clearances:

S&T/H/CD, JHAustin	<u>JHAustin</u>	Date	<u>8 May 87</u>
S&T/H, GPettigrew	<u>(draft)</u>	Date	<u>5/6/87</u>
S&T/PO, GGower	<u>GGower</u>	Date	<u>5 June 87</u>
GC/CP, STisa	<u>STisa</u>	Date	<u>5/15/87</u>

S&T/H/CD:JEricksen:tns:3/27/87:4170t  
Revised:CMiller/JHeiby:5/3/87

ca JH

AMERICAN INSTITUTE  
of BIOLOGICAL SCIENCES

MEMORANDUM

TO: AID, Dr. James Erickson

FROM: Dorothy Jordan *Dorothy*

DATE: October 7, 1986

SUBJECT: Review of Proposal - Dr. Masamichi Aikawa

Upon receiving the three year acceleration proposal from Dr. Masamichi Aikawa of Case Western Reserve University, I sent copies to two external expert reviewers for their comments. Today I received the second reviewers comments and am forwarding their comments to you for your information. As you will see, the reviewers basically agreed with the accelerated proposal, but one reviewer raised questions about one portion of the proposal.

If you have any questions, please do not hesitate to contact me.

Attachments: a/s



Centers for Disease Control  
Atlanta GA 30333  
October 1, 1986

Ms. Dorothy R. Jordan  
Project Director  
Malaria Immunity and Vaccination Research  
American Institute of Biological Sciences  
1800 N. Kent Street  
Suite 930  
Arlington, Virginia 22209

Dear Dorothy:

Re: Renewal of Project Proposal submitted by Dr. Masamichi Aikawa, Case  
Western Reserve.

I have reviewed the proposal submitted by Dr. Aikawa for an extension of his  
contract through June, 1990.

Without question, Dr. Aikawa's expertise and services to the AID Network are  
vital both in the areas of antigen localization by immunoelectron microscopy  
and renal pathology. His pathologic studies on experimental animals with  
regard to their responses to immunization and infection will contribute  
greatly as these studies progress to man. Even then, he should be a major  
asset to the Network.

Except for the initial expenditure for the new microscope, his requests are  
"modest". I strongly support the continuation of this work. I have some  
concern, however, over the "subcontract" with Dr. Suzuki of Gunma University,  
Japan. This particular area of research is not part of the AID Network effort  
and would probably receive little support from a scientific review committee.  
Immunization with attenuated parasites which give on a 6 percent maximum  
parasitemia is never going to get FDA (or other) support. The subcontract  
calls for a \$25,000 expenditure including a trip for Dr. Aikawa to Japan. I  
don't support this aspect of the proposal.

Don't  
know  
project

Sincerely yours,

William E. Collins, Ph.D.  
Deputy Branch Chief, Malaria Branch  
Division of Parasitic Diseases  
Center for Infectious Diseases



Pacific Northwest Laboratories  
P.O. Box 999  
Richland, Washington U.S.A. 99352  
Telephone (509)  
Telex 15-2874

September 12, 1986

Mrs. Dorothy R. Jordan  
Project Director  
American Institute of Biological Sciences  
Malaria Immunity and Vaccination Research  
1800 N. Kent Street, Suite 930  
Arlington, Virginia 22209

Dear Mrs. <sup>Dorothy</sup>Jordan:

As you requested in your letter dated 2 September, I have reviewed the 2 year acceleration proposal from Dr. Aikawa entitled "Studies on Malaria Antigens and Their Effects on Aotus Monkeys with Special Reference to the Nephrotic Syndrome."

My recommendation to USAID is that this proposal be fully funded as presented with only minor changes. It was the recommendation of the review team to Dr. Aikawa that he expand his scope of work to include the examination of Saimiri monkeys with reference to the nephrotic syndrome, since it appears likely that significant numbers of these animals will also be employed in future vaccine trials. I would recommend that this task be included in the new proposal. The review team also recommended to Dr. Aikawa, and he has indicated a willingness to do so, that he and his group become one of two USAID designated centers, the other being CDC, where other Network members can/will submit Aotus and Saimiri tissues taken at necropsy for histopathologic examination and SNÖVET coding. This too should be considered within the scope of this proposal in the context of staff requirements and related funding levels.

Technically, the scope of research contained within the proposal is sound, and I have every expectation that Dr. Aikawa and his colleagues will continue to make significant contributions to Network research efforts.

Thank you for the opportunity to review this proposal.

Sincerely,

*Dick*

Richard E. Weller, DVM  
Senior Research Scientist