

PL-112-333

AGENCY FOR INTERNATIONAL DEVELOPMENT PROJECT DATA SHEET		1. TRANSACTION CODE <input checked="" type="checkbox"/> A = Add C = Change D = Delete	Amendment Number 1	DOCUMENT CODE 3
2. COUNTRY/ENTITY S&T Interregional		3. PROJECT NUMBER 931-0453.42		
4. BUREAU/OFFICE S&T/H/CD		5. PROJECT TITLE (maximum 40 characters) Malaria Immunology - Battelle		
6. PROJECT ASSISTANCE COMPLETION DATE (PACD) MM DD YY 08 29 91		7. ESTIMATED DATE OF OBLIGATION (Under 'B.' below, enter 1, 2, 3, or 4) A. Initial FY 84 B. Quarter 4 C. Final FY 88		

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	600		600	1749		1749
(Grant)	(600)	()	(600)	(1749)	()	(1749)
(Loan)	()	()	()	()	()	()
Other U.S.						
1.						
2.						
Host Country						
Other Donor(s)						
TOTALS	600		600	1749		1749

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)	540	542		750		999		1749	
(2)									
(3)									
(4)									
TOTALS				750		999		1749	

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)

This project will develop, monitor and coordinate all bio-chemical data base for all primates with the A.I.D. malaria vaccine program.

14. SCHEDULED EVALUATIONS	15. SOURCE/ORIGIN OF GOODS AND SERVICES
Interim MM YY MM YY Final MM YY	<input 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)

To expand the non-human primate data system to include Iquitos, Peru (in Spanish) and to add squirrel monkeys to data set developed already for owl monkeys.

17. APPROVED BY	Signature	18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION
	Title	
	Kenneth J. Bart, M.D. Agency Director for Health	MM DD YY 01 14 87

PROJECT AUTHORIZATION AMENDMENT NO. 1

Name of Country: Worldwide
Project Title: Malaria Immunity and Vaccination
Project Number: 931-0453.42 (Battelle Pacific Northwest Laboratories) Contract Number DPE-04563-A-00-4076-00

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 July 13, 1984. That authorization is hereby amended as follows:

Increase the life-of-project funding from \$750,000 to \$1,749,245 in grant funds over a seven-year period. The life of project period is extended to August 29, 1991.

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

Clearances:

S&T/H/CD, JHAustin	<u>JH Austin</u>	date	<u>19 Oct 87</u>
S&T/H, GPettigrew		date	
S&T/H, AVanDusen	<u>AVD</u>	date	<u>5/22/87</u>
GC/CP, STisa	<u>DEMET</u>	date	<u>5/15/87</u>
S&T/PO, GGower	<u>Km for</u>	date	<u>5/24/87</u>

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

5/14/87
(Date)

S&T/H/CD: JH Austin tns:3/4/87:3463t:X5-8934
Revised: CMiller/JHeiby: tns:4/28/87:5/13/87
JH

12'

AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C. 20523

MAY 22 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 931-0453.42 -
Malaria Immunity and Vaccination - Research, Battelle
Pacific Northwest Laboratories

Problem: Your approval is required to extend the Life of Project period and to increase the Life of Project funding for project 931-0453.42, Malaria Immunity and Vaccination Research, Battelle Pacific Northwest Laboratories.

Discussion: Based upon the research progress outlined at the A.I.D. Malaria Vaccine Network Coordination Meeting (Urbana, May 5-8, 1986), the researchers at Battelle Pacific Northwest Laboratories have submitted a two-year acceleration request. The acceleration plan includes: (1) an significant increase in the number of animal files for the advanced non-human primate trials for P. falciparum red blood cell candidate vaccines; (2) the inclusion of up to 600 squirrel monkeys for the advanced testing of P. vivax anti-sporozoite prototype vaccines and potentially anti-RBC products for P. falciparum, P. vivax, P. ovale, and P. malariae which has not previously been included in the data base but now will be required by USFDA guidance; (3) the integration of primate malaria studies for homologous challenge of either owl or squirrel monkeys with P. fragile, P. inui, P. cynomolgi, and/or P. knowlesi, again, not previously included in the data management set; and (4) the full integration of the 20 part RBC stage protocol data into the overall data base for the FDA.

The expansion/acceleration plan presented by the researchers at Battelle Pacific Northwest Laboratories is a very logical, step by step program to quickly develop the appropriate data management system required to assist the Agency's malaria vaccine program through the vast review and approval process required by FDA before human studies can begin. A four-year extension has been recommended by A.I.D. to bring this project into a timeframe in concert with the Animal Facility contract.

Recommendation: That you: (1) approve the extension of the Life of Project period by four years to August 29, 1991 for an overall 7-year Life of Project; and (2) approve \$999,245 increase, of which \$269,000 will be obligated in FY 87, in the Life of Project funding from \$750,000 to a new level of \$1,749,245 by signing the amended project authorization attached.

Attachments:

1. PAF amendment
2. Battelle Labs request
3. External Review, Sept 18-19, 1986
4. Bi-annual Report

- 31

Clearances:

S&T/H, GPettigrew	<u><i>Ja Jor for</i></u>	Date	<u><i>3/15/87</i></u>
GC/CP, STisa	<u><i>DEFT</i></u>	Date	<u><i>5/19/87</i></u>
S&T/PO, GGower	<u><i>La for</i></u>	Date	<u><i>5/26/87</i></u>

S&T/H/CD: *J. Erickson* tns:3/4/87:3463t:X5-8934
Revised: CMiller/JHeiby:tns:4/28/87:5/13/87

yes