

PROJECT DATA SHEET

1. TRANSACTION CODE

A - Add  
 C - Change  
 D - Delete

PD-ABC-122

Amendment Number

2

DOCUMENT CODE

3

2. COUNTRY/ENTITY

WORLDWIDE

3. PROJECT NUMBER

936-5979

4. BUREAU/OFFICE

5. PROJECT TITLE (maximum 40 characters)

S&T/Health

Malaria Vaccine Research and Development

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)

MM DD YY  
 09 30 94

7. ESTIMATED DATE OF OBLIGATION

(Under "B" below, enter 1, 2, 3, or 4)

A. Fiscal FY 90 B. Quarter 2

C. Fiscal FY 91

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

A. FUNDING SOURCE	FIRST FY 90			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	6,550		6,550	15,100		15,100
(Grant) S&T/Health	( 6,550 )	( )	( 6,550 )	( 15,100 )	( )	( 15,100 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S. 1						
Other U.S. 2						
Host Country						
Other Donor(s)						
<b>TOTALS</b>	6,550		6,550	15,100		15,100

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		6,550		8,550		15,100	
(2)									
(3)									
(4)									
(5)									
(6)									
<b>TOTAL</b>				6,550		8,550		15,100	

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code	B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

The project will support A.I.D.'s world-wide efforts in Malaria Control which are part of the Agency objectives in health and child survival.

14. SCHEDULED EVALUATIONS

Location MM YY MM YY Fiscal MM YY  
 02 92 11 11 02 94

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000  941  Local  Other (Specify) 935

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

The purpose of this amendment is to increase the total life of the project funding from \$6,550,000 to \$15,100,000.

17. APPROVED BY

Signature: *Ann Van Dusen*

Title: Ann Van Dusen  
 Acting Agn. Director for Health

Date Signed MM DD YY  
 11 02 90

18. DATE DOCUMENT IN AID/W, OR FOR AMENDMENTS, DATE OF DIST

MM DD YY  
 11 02 90

PROJECT AUTHORIZATION

Amendment No. 2

Project Title: Malaria Vaccine Research and Development Project

Project Number: 936-5979

Name of Country: Interregional

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961 as amended, the Malaria Vaccine Research and Development Project was authorized March 14, 1990 and amended on June 29, 1990. That authorization is hereby amended as follows:

- a) to increase the authorized level of funding by \$8,550,000 to \$15,100,000; and
- b) extend the life of project to 9/30/94.

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

Approved: [Signature]

Disapproved: \_\_\_\_\_

Date: 10/23/90

Clearances:

S&T/H/CD:KMiller	<u>[Signature]</u>	Date	10-16-90
S&T/H/CD:RWrin	<u>[Signature]</u>	Date	10-16-90
S&T/H:GPettigrew	<u>[Signature]</u>	Date	10-16-90
S&T/H:NPielemeier	<u>[Signature]</u>	Date	10-16-90
S&T/PO:DSheldon	<u>[Signature]</u>	Date	10/23/90
GC/CP:STisa	<u>[Signature]</u>	Date	10-22-90
DAA/S&T:BLangmaid	<u>[Signature]</u>	Date	10/24/90

Drafter: S&T/H/MVD:EPeterson:ps:x54654:10/5/90:2897s

Attachment 2  
Program Description

A. Objective

In accordance with the Grantee's proposal no. 90-003 dated July 10, 1989, entitled "Malaria Prevention and Control" Status Review and Alternative Strategies" which in Attachment 1 hereto was incorporated by reference into this Grant, the Grantee will undertake a study of the status of malaria prevention and control efforts worldwide and operational recommendations for future effort in effective prevention and control of the spread of this disease.

B. Grant Activities

The Grantee will appoint a multidisciplinary committee of approximately 12 experts, to meet five times over the first 16 months of the study; commission papers where the state of the science so requires; conduct workshops with associated proceedings; and publish a final report. The final report, based on the commissioned papers and workshop proceedings, will: (1) synthesize the state of the science in each relevant subfield; (2) present alternative strategies, and their relative cost-effectiveness, for the international and national research and action agendas for malaria control and prevention; and (3) recommend the most promising of those alternatives, for the shorter and longer terms.

It is expected that the cumulative products of the study will both provide the foundation for AID activities in the field of malaria and, more broadly, offer guidance for a larger audience of policy-makers working in this area of tropical disease.

MALARIA VACCINE DEVELOPMENT

INSTITUTION PRINCIPAL FY - 91

Project 936-5979

UH	IZUTSU	552,000
CASE	AIKAWA	250,000
NIH/UMD	LEVINE	400,000
PAHO	ARAMBULO	90,000
NYU	NUSSENZWEIG	1,043,000
BRIH	HOLLINGDALE	395,000
CDC (KENYA)	CAMPBELL	168,000
CDC (ATLANTA)	CAMPBELL	193,000
GEORGETOWN	TAYLOR	275,000
UMD	THOMAS	159,828
UMD	LEVINE	304,413
AGOURON	STANLEY	204,000
ARC	MUSILLO	591,275
MONKS-RFP		938,142
NIH/DRG (RFA-REV)		55,000
BATTELLE	WELLER	1,766,858
DISCOV		300,000
DESIGN/TEST		664,484
CDC-TAACS	MILLER	135,000
AAAS FLD		65,000
S U B T O T A L		8,550,000

\*\$50,000 PROVIDED BY NIH IN FYs 90 & 91

<b>AGENCY FOR INTERNATIONAL DEVELOPMENT</b> <b>PROJECT DATA SHEET</b>	<b>1. TRANSACTION CODE</b> <input type="checkbox"/> A = Add <input type="checkbox"/> C = Change <input type="checkbox"/> D = Delete <span style="font-size: 2em; border: 1px solid black; padding: 2px;">A</span>	<b>Amendment Number</b> <u>1</u>	<b>DOCUMENT CODE</b> <u>3</u>
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<b>2. COUNTRY/ENTITY</b> WORLDWIDE	<b>3. PROJECT NUMBER</b> <u>936-5979</u>
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<b>4. BUREAU/OFFICE</b> S&T/Health	<b>5. PROJECT TITLE (maximum 40 characters)</b> <u>Malaria Vaccine Research and Development</u>
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<b>6. PROJECT ASSISTANCE COMPLETION DATE (FACD)</b> MM DD YY <u>09 30 93</u>	<b>7. ESTIMATED DATE OF OBLIGATION</b> (Under "B" below, enter 1, 2, 3, or 4) A. Initial FY <u>930</u> B. Quarter <input type="checkbox"/> C. Final FY <u>930</u>
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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	6,500		6,500	6,550		6,550
(Grant) S&T/Health	( 6,500 )		( 6,500 )	( 6,550 )		( 6,550 )
(Loan)						
Other U.S.						
1.						
2.						
Host Country						
Other Donor(s)						
<b>TOTALS</b>						

9. SCHEDULE OF AID FUNDING (\$000)									
A. APPRO-PRATION	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					50		6,550
(2)									
(3)									
(4)									
<b>TOTALS</b>							50		6,550

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

<b>13. PROJECT PURPOSE (maximum 480 characters)</b> <div style="border: 1px solid black; padding: 10px; margin-top: 5px;"> <p>The project will support A.I.D.'s world-wide efforts in Malaria Control which are part of the Agency objectives in health and child survival.</p> </div>
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<b>14. SCHEDULED EVALUATIONS</b> Interim: MM YY <u>02 93</u> Final: MM YY <u>02 93</u>	<b>15. SOURCE/ORIGIN OF GOODS AND SERVICES</b> <input type="checkbox"/> 000 <input type="checkbox"/> 941 <input type="checkbox"/> Local <input type="checkbox"/> Other (Specify) <u>935</u>
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<b>16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a _____ page PP Amendment.)</b> The purpose of this amendment is to increase the total life of project funding from \$6,500,000 to \$6,550,000.
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<b>17. APPROVED BY</b>	Signature Title: <u>Ann Van Dusen</u> <u>Acting Agn. Director for Health</u>	<b>18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/WARRANTS, DATE OF DISTRIBUTION</b> Date Signed: MM DD YY <u>          </u>
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PROJECT AUTHORIZATION

Amendment No. 1

Project Title: Malaria Vaccine Research and Development Project  
Project Number: 936-5979  
Name of Country: Interregional

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961 as amended, the Malaria Vaccine Research and Development Project was authorized March 14, 1990. That authorization is hereby amended to increase the authorized level of funding by \$50,000 to \$6,550,000

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

Approved: Roxann A. Burdsey

Disapproved: \_\_\_\_\_

Date: June 28 1990

Clearances:

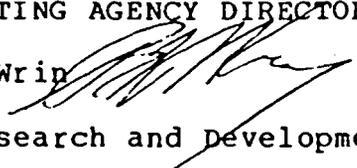
S&T/H/MVD: CDiggs CDiggs Date 29 May 90  
S&T/H/MVD: RWrin RWRin Date 29 May 90  
S&T/H: GPettigrew GP Date 5/29/90  
S&T/H: NPielemeier NP Date 5/30/90  
S&T/PO: DSheldon DSheldon Date 6/25/90  
GC/CP: STisa R. Matson for ST Date 6/21/90

Drafter: S&T/H/MVD: EPeter EPeter son: ps: x54654: 5/24/90: 2550s

Agency for International Development  
Washington, D.C. 20523

JUN 7 1990

ACTION MEMORANDUM FOR THE ACTING AGENCY DIRECTOR FOR HEALTH

FROM: S&T/H/MVD, Robert Wrip 

SUBJECT: Malaria Vaccine Research and Development Project  
(936-5979)

Problem: Your approval is requested to increase the funding authorization of the Malaria Vaccine Research and Development (MVRD) project to \$6,550,000 in accordance with Section 104 of the Foreign Assistance Act of 1961, as amended.

Discussion: The Agency for International Development has negotiated a grant with the Pan American Health Organization to evaluate natural populations and establish the geographic distribution of the different sub-species of monkeys in Latin America which are being used in malaria research. The National Institutes of Health (NIH) has offered to contribute \$100,000, \$50,000 each in FY 90 and FY 91, as part of this non-human primate research and conservation effort. These funds are to be transferred from NIH to the Office of Health budget through an interagency agreement. The MVR&D authorization ceiling of \$6,500,000 for malaria vaccine research in FY 90 was established prior to NIH's recent confirmation of its intention to make these funds available.

Because the increase of \$50,000 for FY 90 is less than 10% of the present project authorization of \$6,500,000, a congressional notification is not required.

Recommendation: That you sign the attached project authorization amendment which authorizes an additional \$50,000 for the Malaria Vaccine Research and Development project.

Attachment: a/s

1

A

Agency for International Development  
Washington, D.C. 20523

ACTION MEMORANDUM FOR THE ASSISTANT ADMINISTRATOR,  
BUREAU FOR SCIENCE AND TECHNOLOGY

FROM: Acting Agency Director for Health, Ann Van Dusen *Ann Van Dusen*

SUBJECT: Malaria Vaccine Research and Development Project  
(936-5979)

PROBLEM: Your approval is requested to authorize the Malaria Vaccine Research and Development Project for an additional one year period and authorize a new funding ceiling of \$15,100,000 of which \$8.55 million is FY 91 central funds from the Health Account.

DISCUSSION: On March 14, 1990 the Malaria Vaccine Research and Development Project was authorized for a three-year period centrally funded at the level of \$6.55 million in FY 90. (An additional \$2 million was obligated in FY 90 under project #931-0453.) The design of the activities funded in FY 90 was specifically crafted to be consistent with the recommendations contained in the review of the Malaria Immunity and Vaccine Research project (931-0453) by the General Accounting Office (GAO). The A.I.D. Office of Health has addressed all the concerns raised in the GAO report. The GAO has recently given notice that it considers the response adequate and has closed its recommendations.

Also in compliance with the GAO report, the agency in cooperation with the National Institutes of Health and the Department of Defense (NIH and DOD) initiated a major study, "Malaria Prevention and Control: Status Review and Alternative Strategies." This study, being undertaken by the Institute of Medicine (IOM) of the National Academy of Sciences, is scheduled to be completed in July 1991 with preliminary drafts available on a selected basis by April.

In the initial Project Authorization Action Memorandum, the Office of Health committed itself to presenting annual requests for project authorization until the IOM study is received and its recommendations considered in relation to our malaria prevention and control strategy. These one year incremental authorizations (of which this is expected to be the last) allow research to continue while retaining the flexibility of changing programmatic direction in the near term upon completion of the IOM study.

The action which you are now being asked to take is consistent with last year's action memorandum which indicated that until the IOM study has been completed and A.I.D. has responded to its recommendations, you will be presented with an action memorandum and PAF amendment authorizing an additional year of funding and extending the PACD for one year in order to maintain a three-year expenditure period for the funds being authorized.

The A.I.D. assistance will provide continuing funds for research on vaccines for three stages of the malaria parasite, as well as development and service functions which will include vaccine testing in primates and humans, primate care, peer review assistance, and management assistance, as well as miscellaneous costs. All continuing activities that made up the original Malaria Immunity and Vaccine Research Project, #931-0453, and the current Malaria Vaccine Research and Development Project, #936-5979, are included, completing the consolidation that was started during FY 90.

EVALUATION: The IOM study is an opportunity to examine the Malaria Vaccine Research and Development project in the context of the entire spectrum of possible anti-malarial programs. A major program evaluation is planned to coincide with the completion of the IOM study.

FUNDING: \$8,500,000 in Health funds are expected to be available in the FY 91 OYB for S&T Health for this activity. An additional \$50,000 is anticipated to be transferred into the health account as the second installment of the \$100,000 contribution by the National Institutes by Health (NIH) for the Pan American Health Organization as part of NIH's non-human primate research and conservation effort. These funds are to be transferred from NIH to the Office of Health's budget through an interagency agreement. Thus the total FY 91 funding will be \$8,550,000

This Authorization is \$50,000 greater than the level for the project indicated in the FY 91 Congressional Presentation. Since the increase is less than 10 percent, a congressional notification is not required. The attached list identifies the planned and proposed projects for FY 91 funding.

PROVISIONS AND DETERMINATIONS: All applicable laws and NIH guidelines concerning research, particularly the use of laboratory animals and the protection of human subjects, will be observed.

SECTOR COUNCIL REVIEW: The Health Sector Council has reviewed several versions of the concept paper for a follow-on activity to the Malaria Immunity and Vaccine Research project and recommended that only incrementally funded activity be authorized until the IOM study is completed and its findings can be reflected in a revised malaria vaccine development strategy.

RECOMMENDATION: That you sign the attached project authorization which authorizes the Malaria Vaccine Research and Development project (936-5979) for an additional one year period and authorizes \$8.55 million in FY 1991 central funds from the Health account.

Attachments:

1. Project Authorization Amendment No. 2.
2. IOM Study SOW.
3. FY 91 Budget for planned and proposed activities.
4. Project Authorization.
5. Project Authorization Amendment No. 1.

Clearances:

S&T/H/MVD:CDiggs	<u>SI</u>	Date	<u>5/29/90</u>
S&T/H/MVD:RWrin	<u>SI</u>	Date	<u>5/29/90</u>
S&T/H:GPettigrew	<u>SI</u>	Date	<u>5/29/90</u>
S&T/H:NPielemeier	<u>SI</u>	Date	<u>5/29/90</u>
GC/CP:STisa K. Matalon for		Date	<u>6/21/90</u>
S&T/PO:DSheldon	<u>SI</u>	Date	<u>05/24/90</u>

Drafter: S&T/H/MVD:EPeterson:ps:x54654:5/24/90:2550g

Clearances:

S&T/H/MVD:CDiggs	<u>B1</u>	Date	<u>5/24/90</u>
S&T/H/MVD:RWrin	<u>121</u>	Date	<u>5/23/90</u>
S&T/H:GPettigrew	<u>B1</u>	Date	<u>5/26/90</u>
S&T/H:NPielemeier	<u>151</u>	Date	<u>5/23/90</u>
GC/CP:STisa	<u>K. Matalon for</u>	Date	<u>6/21/90</u>
S&T/PO:DSheldon		Date	

Drafter:S&T/H/MVD:EPeterson:ps:x54654:5/24/90:2550g

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT DATA SHEET

1. TRANSACTION CODE

A = Add  
 C = Change  
 D = Delete

Amendment Number

DOCUMENT CODE

3

2. COUNTRY/ENTITY  
 WORLDWIDE

3. PROJECT NUMBER

936-5979

4. BUREAU/OFFICE  
 S&T/Health

5. PROJECT TITLE (maximum 40 characters)

Malaria Vaccine Research and Development

6. PROJECT ASSISTANCE COMPLETION DATE (FACD)

MM DD YY  
 09 30 93

7. ESTIMATED DATE OF OBLIGATION  
 (Under "B" below, enter 1, 2, 3, or 4)

A. Initial FY  90 B. Quarter  3 C. Final FY  90

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	6,500		6,500	6,500		6,500
(Grant)	( 6,500 )	( )	( 6,500 )	( 6,500 )	( )	( 6,500 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
<b>TOTALS</b>	6,500		6,500	6,500		6,500

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				6,500		6,500	
(2)									
(3)									
(4)									
<b>TOTALS</b>						6,500		6,500	

10. SECONDARY TECHNICAL CODES (maximum 5 codes of 3 positions each)

11. SECONDARY PURPOSE COD.

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code

B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

The project will support A.I.D.'s world-wide efforts in Malaria Control which are part of the Agency's objectives in health and child survival.

14. SCHEDULED EVALUATIONS

15. SOURCE/ORIGIN OF GOODS AND SERVICES

Interim MM YY Final MM YY  
 02 91 02 93

000  941  Local  Other (Specify) 935

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

17. APPROVED BY

Signature: Nancy R. Pielmeier  
 Title: Ann Van Dusen  
 Acting Agn. Director for Health

Date Signed MM DD YY  
 03 09 93

18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION

MM DD YY

## PROJECT AUTHORIZATION

Name of Country: Interregional  
Project Title: Malaria Vaccine Research and  
Development Project  
Project Number: 936-5979

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961 as amended, I hereby authorize the Malaria Vaccine Research and Development project for three years involving centrally funded planned obligations for FY 1990 of \$6.5 million subject to the availability of funds in accordance with the A.I.D. OYB/allotment process.

2. The project will support A.I.D.'s world-wide efforts in Malaria Control which are part of the Agency's objectives in health and child survival.

3. In keeping with a GAO recommendation, further funding of this project will be reviewed annually, with funds provided by amendment, until the Institute of Medicine completes its evaluation of malaria control, providing the basis for creating a strategy to underpin a long term project.

4. 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.

5. 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 (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 or services for the activity being conducted in such country. Such

activities may be undertaken in any country included in A.I.D. Geographic Code 935). 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.

APPROVED: *Barbara J. [Signature]*

DISAPPROVED: \_\_\_\_\_

DATE: MAR 14 1990

Clearances:  
S&T/H/MVD:CDiggs *CDiggs* Date 9 mn 90  
S&T/H/MVC:RWrin *RWRin* Date 9/22/90  
S&T/H:GPettigrew *GP* Date 3/9/90  
S&T/H:NPielemeier *NP* Date \_\_\_\_\_  
S&T/PO:DSheldon *DS* Date 2/13/90  
GC/CP:STisa *R. Matalon EP* Date 3/6/90

Drafter: S&T/H/MVD, EPeterson: ps: 2/22/90: 2193s

MAR 9 1990

ACTION MEMORANDUM FOR THE ACTING ASSISTANT ADMINISTRATOR BUREAU  
FOR SCIENCE AND TECHNOLOGY

FROM: Acting Agency Director for Health, Ann Van Dusen *MVP for*

SUBJECT: Malaria Vaccine Research and Development Project  
(936-5979)

**Problem:** Your approval is requested to authorize the Malaria Vaccine Research and Development project for a three year period and authorize \$6.5 million of FY 90 central funds from the Health account. Funding for this project will be authorized only on an annual basis. The Malaria Vaccine Research and Development (MVRD) project continues the work performed under the Malaria Immunity and Vaccine Research project (931-0453).

**Discussion:** During the past year, at the request of the US Congress, the General Accounting Office (GAO) conducted a review of the Malaria Vaccine Research project (931-0453) which resulted in the recommendation that A.I.D. not make any long term funding commitments until management deficiencies are corrected and the results of a major evaluation of malaria control and options by the Institute of Medicine (IOM) are completed.

The report discusses a number of management weaknesses in the areas of planning procurements, implementation and evaluation. The report also found that A.I.D. has taken steps to correct many of the deficiencies noted during the review. However, the report recommends that "additional actions be taken to improve the planning and implementation of future activities and to insure adequate oversight of project funds." The Agency agrees with the GAO report's principal conclusions and plans to implement all of its recommendations. A coordinated Agency response has been discussed with and submitted to the GAO and the GAO has indicated that they believe the response is appropriate and adequate.

In response to the GAO recommendation of no long term funding commitments, it is proposed that only FY 1990 funding be authorized at this time with the PACD set to allow for a three year period. This is required to permit conventional three-year contracts for research to be undertaken and avoid an interruption of support that could be disastrous to the long-term goal of developing a vaccine.

16

The IOM has been requested to review the malaria research program and provide recommendations for bureau consideration. In the future years, until the IOM study "Malaria Prevention and Control: Status Review and Alternative Strategies" has been completed and A.I.D. has responded to its recommendations, you will be presented with an action memorandum and PAF amendment authorizing an additional year of funding and extending the PACD for one year in order to maintain a three-year expenditure period for the funds being authorized. The action memorandum will state the progress made by the Malaria Program in conforming with the Agency's response to the GAO report and will note progress in the Agency's concerted effort to define its role in and strategy for responding to the malaria problem including an update on the IOM study.

The A.I.D. assistance will provide funds for applied research on vaccine development for three stages of the malaria parasite, as well as development and service functions which will include electron microscopy, entomology, primate testing, management assistance, evaluation, and miscellaneous costs. All existing activities that presently make up the Malaria Vaccine Development Program are to be included under this project. This will allow for easier tracking by A.I.D. management.

Evaluation: The recently initiated IOM study is an opportunity to examine the Malaria Vaccine Research and Development project in the context of the entire spectrum of anti-malarial programs. The results of the study will be taken into consideration in subsequent project design or amendment initiatives.

Funding: \$6,500,000 in health funds are available in the FY-90 OYB for S&T Health. The attached list identifies the planned and proposed projects for FY 90 funding.

Justification to the Congress: The Agency response to the GAO report has been prepared and sent to interested Senators and Congressmen. Also, an Advice of Program Change for this new project has been prepared and sent to Congress.

Clearances: Draft project papers, the GAO report, and the Agency response to the GAO report have been discussed on a number of occasions with all concerned parties.

Provisions and Determinations: All applicable laws and NIH guidelines concerning research, particularly the use of laboratory animals and the protection of human subjects, will be observed.

Sector Council Review: The Health Sector Council has reviewed several versions of the concept paper for a follow-on activity to the Malaria Immunity and Vaccine Research project and recommended that only an incrementally funded activity be authorized until the IOM study is completed and its findings can be reflected in a revised malaria vaccine development strategy.

Recommendation: That you sign the attached project authorization which authorizes the Malaria Vaccine Research and Development project (936-5979) for a three year period involving \$6.5 million in FY 1990 central funds from the Health account.

Attachments

1. Project Authorization
2. GAO Report
3. AID's response to GAO Report
4. IOM Study SOW
5. FY 90 Budget for planned and proposed activities

Clearances:

S&T/H/MVD:CDiggs	<i>CDiggs</i>	Date	<i>7 Mar 90</i>
S&T/H/MVC:RWrin	<i>RWrin</i>	Date	<i>9 Mar 90</i>
S&T/H:GPettigrew	<i>GP</i>	Date	<i>3/9/90</i>
S&T/H:NPielemeier	<i>NP</i>	Date	<i>3/9/90</i>
S&T/PO:DSheldon	<i>DS</i>	Date	<i>3/13/90</i>
GC/CP:STisa	<i>R. Madalan EP</i>	Date	<i>3/6/90</i>

Drafter: S&T/H/MVD, EPeterson: ps:2/22/90:2193s

Draft:2:GPettigrew/AVanDusen:1/23/90

Draft:3:CNoren:1/29/90

Draft:4:CDiggs/RWrin/EPeterson:3/5/90