

10-172-354

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT DATA SHEET

1. TRANSACTION CODE

A = Add  
 C = Change  
 D = Delete

Amendment Number

DOCUMENT CODE

3

2. COUNTRY/ENTITY

S&T/INTERREGIONAL

3. PROJECT NUMBER

931-0453.17

4. BUREAU/OFFICE

S&T/H/CD

10

5. PROJECT TITLE (maximum 40 characters)

MALARIA IMMUNOLOGY - AGOURON

6. PROJECT ASSISTANCE COMPLETION DATE (FACD)

MM DD YY  
 0 9 3 0 8 9

7. ESTIMATED DATE OF OBLIGATION

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

A. Initial FY  84 B. Quarter  3 C. Final FY  89

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 | 1,095    |        | 1,095    | 6,583           |        | 6,583    |
| (Grant)                | (1,095)  | ( )    | (1,095)  | (6,583)         | ( )    | (6,583)  |
| (Loan)                 | ( )      | ( )    | ( )      | ( )             | ( )    | ( )      |
| Other U.S. 1           |          |        |          |                 |        |          |
| Other U.S. 2           |          |        |          |                 |        |          |
| Host Country           |          |        |          |                 |        |          |
| Other Donor(s)         |          |        |          |                 |        |          |
| <b>TOTALS</b>          | 1,095    |        | 1,095    | 6,583           |        | 6,583    |

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) S&T/H        | 540                     | 542                   |         | 2,630                  |         | 6,583                          |         | 6,583              |         |
| (2)              |                         |                       |         |                        |         |                                |         |                    |         |
| (3)              |                         |                       |         |                        |         |                                |         |                    |         |
| (4)              |                         |                       |         |                        |         |                                |         |                    |         |
| <b>TOTALS</b>    |                         |                       |         | 2,630                  |         | 6,583                          |         | 6,583              |         |

10. SECONDARY TECHNICAL CODES (maximum 5 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 identify, isolate, and begin chemical characterization of some of the macromolecular components of the asexual erythrocytic forms of human parasites which can be used to induce immunity in primates.

14. SCHEDULED EVALUATIONS

Interim MM YY MM YY Final MM YY

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

Signature: *Ann Van Dusen*

Title: Ann Van Dusen  
 Dep. Dir., Office of Health

Date Signed

MM DD YY  
 06 12 87

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

MM DD YY

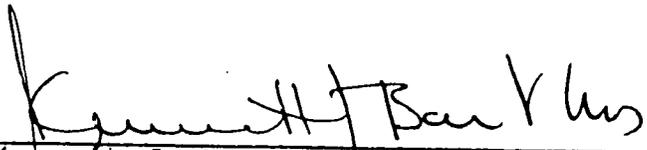
PROJECT AUTHORIZATION AMENDMENT NO. 1

Name of Country: Worldwide  
Project Title: Malaria Immunity and Vaccination  
Project number: 931-0453.17 (Agouron Institute:  
Contract No.

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 April 5, 1984. That authorization is hereby amended as follows:

Increase the life-of-project funding from \$3,266,000 to \$6,582,088 in grant funds over a five-year period from the date of authorization. The Project Assistance Completion Date will be September 30, 1989.

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

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

6/12/87  
(Date)

Clearances:

S&T/H, GStandrod 925 Date 6/16/87  
S&T/PO, GGower [Signature] Date 6/17/87  
GC/CP, STisa (DRAFT) Date 6/17/87  
S&T/H, JHeiby [Signature] Date 6/11/87  
4403t

100H17

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D C 20523

JUN 12 1987

ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH

FROM: S&T/H, Ann Van Dusen



SUBJECT: Increased Funding Authority for Project 931-0453.17, Malaria Immunity and Vaccination - Research: Agouron Institute, Entitled: Antigens to Human Malarial Parasites

Problem: Your approval is required to extend the Life of Project period and to increase the Life of Project funding for project 931-0453.17, Malaria Immunity and Vaccination Research, Agouron Institute (Robert T. Reese). The life of project period would be extended from FY 87 to FY 89. The Project Agreement Completion Date would be extended to September 30, 1989. The life of project funding would be increased by \$3,316,088 for a new LOP of \$6,582,088. Of this, \$1,622,495 will be obligated in FY 87.

Discussion: Recent advances in molecular biology and biochemistry have opened new horizons for vaccine development. Merozoite immunity represents one of the major avenues of the Agency's malaria vaccine research program. The characterization of merozoite surface antigens and identification of potential blocking proteins within the P. falciparum system, represent promising areas of investigation for the development of polyvalent erythrocytic stage malaria vaccines. The investigation of a wide range of surface antigens, and characterization of their role in merozoite penetration will add to our knowledge of merozoite invasion and general malaria immunity. Furthermore, the exploration of a number of antigens and their potential for combination, could lead to the development of a highly "immunogenic" vaccine product. Eight proteins have been associated with the surface of merozoites, the Agouron group has studied cDNA clones which encode for all but one of these molecules. The potential for the identification of protective, merozoite-blocking antigens which elicit a robust antibody response is strong, given the diversity of antigens being explored within the Agouron Institute, and recent collaborative efforts with the CDC concerning the analysis of immunogenicity in the Aotus model.

The attached proposal, reviewers' comments, correspondence, and site visit reviews indicate strong peer confidence in the work of Dr. Reese and his group. Throughout the tenure of this extension, A.I.D. will closely monitor the direction and results of Dr. Reese's efforts and their direct relationship to the development of suitable malaria vaccine prototypes.

#### Non-Competitive Procurement

The proposal for extension submitted by Dr. Reese indicates a change in the site for the conduct of the proposed research from the Scripps Clinic and Research Foundation, San Diego, California, to the Agouron Institute, LaJolla California. The proposal for extension has been approved by an A.I.D. external panel of experts (see attachments). The proposal extension meets the same requirements for Non-Competitive Procurement as those enunciated in the memorandum of April 5, 1984. The conduct of a market search for this procurement would require disclosure of details of specific, isolated candidate antigens which are fundamental to the research program and are proprietary. These biochemical agents are exclusively available through the Agouron group headed by Dr. Reese. Thus, justification of a non-competitive procurement for the extension of this contract is appropriate and the Administrators Determination, dated December 20, 1987, will be revised to include the Agouron Institute.

For your information and reference, the original Project Data Sheet (March 28, 1984), Project Authorization (April 4, 1984), Action Memorandum (March 26, 1984), and original Justifications for Non-Competitive Procurement (March 26, 1984, April 5, 1984) are attached.

Recommendation: That you: (1) approve the extension of the Life of Project period by two years from FY 88 to FY 89 for an overall 5-year Life of Project; (2) approve \$3,316,088 increase in the Life of Project funding from \$3,266,000 to a new level of \$6,582,088 by signing the amended project authorization attached; and (3) sign the Justification for Non-Competitive Procurement and Justification for Unsolicited Proposal. All other terms and conditions of the project remain unchanged.

. H'

Attachments:

1. PAF Amendment
2. Pertinent Correspondence
3. Agouron Request for Extension
4. Reviewers' Comments
5. Site Visit Report (9/86)
6. Project Evaluation Summary
7. Project Data Sheet (3/28/84)
8. Project Authorization (4/5/84)
9. Action Memorandum (3/26/84)
10. Non-Competitive Justification (3/26/84)
11. Non-Competitive Justification (4/5/84)
12. Justifications for Unsolicited Proposal
13. Justification for Non-Competitive Procurement

*JH*

jh/vkb/4403t/5/26/87

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AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

June 3, 1987

MEMORANDUM

TO: SER/OP/W/HP, Joyce Frame

FROM: S&T/H, Kenneth J. Bart, M.D. *KJBart*

SUBJECT: Justification for Non-Competitive Procurement under  
Project No. 931-0453.17, Agouron Institute.

I request that you negotiate only with the Agouron Institute for the Malaria Vaccine Research in the PAF and PIO/T. The following justifies non-competitive procurement for this unsolicited proposal and FPR 1-4.910 (b) and (c).

1. Need Which This Procurement is Intended to Satisfy:

The latest estimates of the world wide incidence of malaria range, by WHO projection, is at between 300-400 million cases with between 2-4 million deaths due to malaria, primarily malaria caused by Plasmodium falciparum. The Agency's malaria vaccine program is accelerating its pace to develop, test, and market a safe, effective malaria vaccine against the several forms of human malaria. Although significant progress has been made against the mosquito stage (=sporozite) and several prototypes are being tested, much work continues to be done to isolate "protective" antigens from the red blood cell phases (=RBC) of malaria parasites. The main reasons for the difficulties involved in research on RBC parasite forms lies in part with difficulties in "purity" involved with blood-based in-vitro cultures and, as well the fact that during the RBC stages antigens, was specifically identified as an area for program acceleration in the Administrator's recent approval of a greatly expanded malaria vaccine program.

2. Agouron Institute Qualifications to Meet the Need:

The unsolicited research proposal submitted by the Agouron Institute, covers the research area to be addressed to isolate, identify, and chemically characterize the macromolecular components of the asexual erythrocytic forms of human malaria parasites which can be used to induce immunity in primates. The proposal has been reviewed and approved by A.I.D.'s external panel of expert consultants. The panel, which is composed of leading

scientists in the field of malaria immunology, parasite biochemistry, vaccine development in-vitro cultivation and primate biology has endorsed (in accordance with FPR 1-4.909) the scientific methodology, the exceptional experience and qualifications of Dr. Reese and his staff, and the institutional capacity of the Agouron Institute to conduct the proposed scope of work. The panel concluded that Agouron Institute is the only institute in the United States dealing with synthesized peptides form the cDNA library constructed from the poly A+ fraction of the RNA isolated from trophozoite/schizont state Honduras I isolates of Plasmodium falciparum.

3. Prohibition Against Conducting a Market Search for this Procurement per 1-4.911:

Any advertisement to find other sources to meet the objectives of this procurement would require disclosure of the research methodology and experimental design which was proposed by the Agouron Institute, including details of specific isolated candidate protective antigens as well as the genetic engineering plans including the specific insect vectors, insect sites (specially plasmids pUc8, pUc9), and the details of the preparation of the DNA and RNA maps. These components of the research are fundamental to the research program, are extremely proprietary, and cannot be obtained by A.I.D. from any other source than the Agouron Institute. This exclusive availability was confined by the expert review panel mentioned in paragraph 2 above.

Clearance:

S&T/H, A. Van Dusen \_\_\_\_\_ date \_\_\_\_\_  
S&T/PO, G. Gower *[Signature]* \_\_\_\_\_ date 6/10/87

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

June 3, 1987

MEMORANDUM

TO: SER/OP/HP, Joyce Frame

FROM: S&T/H, Kenneth J. Bart, M.D. *KJB*

SUBJECT: Justification for non-competitive procurement of  
unsolicited proposal from the Agouron Institute,  
entitled: "Antigens to Human Malarial Parasites".

The subject research proposal is an unsolicited proposal. The substance of the proposal is not available to the Government without restriction from another source, nor does it resemble any pending competitive solicitation. The substance is sufficiently unique to justify acceptance as an unsolicited proposal.

The project officer certification with reference to A.I.D. PR Notice 78-4 follows:

I certify that neither I nor, to the best of my knowledge and belief, any other A.I.D. employee solicited the proposal or had any prior contact with the proposing institution, other than to convey interest in the field of malaria immunity and vaccination relative to the efforts described in the unsolicited proposal.

*James R. Heiby*  
\_\_\_\_\_  
Dr. James Heiby, Project Manager

I request that you award this contract on a non-competitive basis to the Agouron Institute without consideration of other sources.

cc: S&T/PO, G. Gower *KJB* date 6/17/87  
S&T/H, A. Van Dusen *AVD* date 6/12/87