

AP-ABF-376  
81024

1. Initial Starting Date (Mo., Day, Yr.) <b>September 25, 1984</b>	<b>PASA PARTICIPATING AGENCY SERVICE AGREEMENT BETWEEN THE AGENCY FOR INTERNATIONAL DEVELOPMENT AND Department of Health and Human Services Office of International Health</b>	6. <input checked="" type="checkbox"/> PASA ORIGINAL <input type="checkbox"/> PASA AMENDMENT
2. Projected Completion Date (Mo., Day, Yr.) <b>September 30, 1988</b>		7. PASA Number <b>BST-5947-P-HI-4265-00</b>
3. Category <input checked="" type="checkbox"/> TDY <input type="checkbox"/> ASSIGNED		8. Country/AID/W Office <b>Worldwide</b>
4. Duration of Funding <input checked="" type="checkbox"/> CURRENT YEAR <input checked="" type="checkbox"/> FORWARD FUNDING	5. Project Number and Title <b>936-5947 Vaccine Development and Health Research</b>	9. Type <input checked="" type="checkbox"/> GRANT <input type="checkbox"/> LOAN <input type="checkbox"/> COUNTRY FINANCED
		10. Year <b>FY 19 84/85</b>

11. FUNDING			
A. CITATIONS	(1) Appropriation Number <b>72-1141021.8</b>	(2) Allotment Number <b>448-36-099-00-20-41 DDAA-84-13600-CC11</b>	(3) PIO/T/Obligation Number <b>936-5947-2-3641673 &amp; A</b>
B. FOR PARTICIPATING AGENCY	(1) Initial or Current <b>\$429,573</b>	(2) Change (+ or -)	(3) New Total <b>\$429,573</b>
C. RETAINED FOR AID DIRECT DISBURSEMENT	(1) Initial or Current	(2) Change (+ or -)	(3) New Total
D. TOTAL AMOUNT OBLIGATED (Blocks B + C)	(1) Initial or Current <b>\$429,573</b>	(2) Change (+ or -)	(3) New Total <b>\$429,573</b> *
E. PRINCIPAL COST COMPONENTS OF (Block B)	(1) Salaries, Differential and Benefits	(2) Transportation Including Per Diem	(3) Miscellaneous
		(4) Overhead	

12. Statement of Purpose

I. Summary

The purpose of this agreement between A.I.D. and the Department of Health and Human Services, Office of International Health, is to fund the development of new and improved vaccines for use in LDC primary health care programs.

Funding period September 25, 1984 through January 31, 1986.

A budget which should include attribution of funds by each activity approved under this agreement, i.e. by each protocol, technical assistance mission, training assignment, and data collection effort, will be provided within 60 days.

\*Partial funding-to include additional funds on subsequent amendments if necessary or required.

13. GOVERNING PROVISIONS: Pursuant to the General Agreement dated March 3, 1966 between AID and the Department of Health and Human Services the Agency named above agrees to provide the services outlined in Block 12 amplified as needed by Appendix A, unless otherwise authorized by AID, all services shall be of U.S. origin. Any appendices attached hereto are considered part of this PASA.

14. Signatures

NAME <u>[Signature]</u>	NAME <u>Ellen R. Wills, Acting</u>
TITLE/OFFICE <u>Surgeon General &amp; Director, Office of International Health</u>	TITLE/OFFICE <u>CHIEF, INTERNAT'L &amp; INTERAGENCY BRANCH CONTRACT MANAGEMENT, AID</u>
DATE <u>OASH 11/11/84</u>	DATE <u>September 26, 1984</u>

15. Appendices <input checked="" type="checkbox"/> APPENDIX A - SCOPE OF WORK <input checked="" type="checkbox"/> APPENDIX B - BUDGET PLAN - General <input checked="" type="checkbox"/> APPENDIX C - USE OF AID PERSONNEL/FACILITIES <input checked="" type="checkbox"/> APPENDIX D - SUBCONTRACTING <input checked="" type="checkbox"/> OTHER/REFERENCE <u>Appendix E - Billings</u> <input checked="" type="checkbox"/> Appendix F - Special Provisions	16. Negotiating Officers AID: CM/SOD/IIA - <u>Helen I. Alexander</u> AGENCY: <u>DHHS/OIH: J. Rutkoski</u>
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<p>APPENDIX A SCOPE OF WORK PAGE <u>2</u> OF <u>5</u></p>	<p>PARTICIPATING AGENCY SERVICE AGREEMENT BETWEEN THE AGENCY FOR INTERNATIONAL DEVELOPMENT AND Department of Health and Human Services Office of International Health</p>	<p><input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> AMEND NO. _____ PASA NO. BST-5947-P-HI-4265-00 FISCAL YEAR 1984/85/86</p>
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IV. Implementation

This PASA between A.I.D. and the PHS defines the overall project activities. Specific technical activities of the project are to be performed by Agencies of the PHS according to the directions and terms of sub-agreements between the Office of International Health and the PHS units, such as NIAID and the Centers for Disease Control (CDC). The subagreements, which will be written with the consultation and approval of A.I.D., will provide a mechanism for allocation of funds to the appropriate PHS Agency for specific activities. The PASA Agency may also sub-contract with non-PHS Agencies or with private sector and educational institutions for specific technical activities.

V. SCOPE OF WORK:

A. Program Management: The PASA Agency will provide a senior, full-time professional as the PHS Project Coordinator to develop an implementation strategy, to serve as the principal contact with the Office of Health, Bureau for Science and Technology, to prepare and submit to A.I.D. recommendations for specific activities to be carried out under the PASA, to organize scientific panels to evaluate the merits of individual research protocols submitted for funding under the PASA, and to prepare semi-annual reports on the progress of the overall PASA.

B. Program Strategy: Within the initial 120 days, the PASA Agency will submit for A.I.D. approval an overall strategy for selecting vaccines to be supported under this PASA. This strategy is to summarize the status of current R&D on vaccines that appear highly relevant for LDC primary health programs; to identify the criteria for selecting vaccines for support under this program, to describe the mechanisms that will be used to implement the various activities funded under this program, and to nominate the candidate for program manager.

C. Research and Development: The PASA Agency is authorized to enter into sub-agreements to implement research protocols for the following two vaccines before finalizing the program strategy for other vaccines:

- a. Field trials of a rhesus monkey rotavirus vaccine developed by scientists of the Laboratory of Infectious Diseases of NIAID.
- b. Field trials of a human diploid-grown attenuated measles virus vaccine to be administered by both subcutaneous and aerosolized routes.

These protocols are to contain, in addition to the usual scientific content, documentation identifying principal investigators, participating LDC institutions, budget, schedule, compliance with investigational new drug regulations and human subject procedures, and concurrence of participating host-government technical institutions.

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D. Technical Assistance: In addition to technical assistance for project management and research directly related to development and testing specific vaccines, technical assistance in support of the general purpose of the PASA is authorized up to ten percent of the accrued obligations. Generally, this assistance will be to help LDC officials to define the needs and opportunities for adapting, testing, and applying new vaccines for primary health care programs; to provide laboratory, clinical, immunological and epidemiological support to LDC institutions for safety and efficacy and field testing new and improved vaccines; and to support the collection of country data relevant to the implementation of this program.

E. Training: Training of LDC scientists and technicians will be short-term and limited primarily to acquisition of specific technical skills needed to support the field trials and data collection supported under this PASA.

VI. Liaison and Guidance. The PASA Agency carries out this vaccine development program under the policy guidance of A.I.D. A.I.D. must approve the program strategy, concur in individual activities recommended for funding under the program strategy, have the right to make suggestions for changes in activities recommended for funding, and approve all travel. Copies of all correspondence sent to overseas A.I.D. Missions must be cleared by the A.I.D. project manager or his designee. A.I.D. is responsible for securing host country clearances for project work sponsored by the PASA.

VII. Reports: The PASA Agency will submit semi-annual substantive and quarterly financial reports to the A.I.D. Project Officer. The substantive reports are due 30 days after the reporting periods ending March 31 and September 30 of each year. The reports should include all travel and research activities for the previous six-month period. In addition, the report due after September 30 of each year should contain an action plan for the following 12-month period and an assessment of accomplishments against the previous year's action plan.

The PASA Agency shall submit three copies of all reports listed as being a product of the PASA (administrative, progress, final, and technical reports, etc.) to the Documentation Coordinator, PPC/DIU, A.I.D., Washington, D.C. 20523, or his designee. Such reports shall include a title page showing the title of the report, project title as set forth in this agreement and the PASA agreement number. One copy of each report shall be clearly typed or printed on white paper so that it may be photographed to produce a micro-film master. Technical Reports shall be accompanied by an author-prepared abstract.

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VIII. Evaluation: Within six months of the conclusion of the first 24 months of PASA activity, technical experts from the Research Advisory Committee of A.I.D., professionals from the Directorate of Health and Population, and from non-U.S. Government organizations will assess project progress against the stated technical goals of the project and will recommend changes to A.I.D. Within three months of the conclusion of the 60th month of PASA activity a terminal evaluation of the PASA will be conducted by non-A.I.D. health and biomedical research professionals. Specific plans for the mid-term and terminal evaluations will be developed by the PASA Agency and submitted to the A.I.D. Project Manager for approval.

IX. Special Conditions:

- a) A.I.D. must review and approve all research sub-projects to be implemented under the PASA.
- b) A.I.D. must have a complete list of PHS staff and their specific identities to be included in the "key personnel" clause of the PASA. Key personnel will include the PHS Project Coordinator, those directly responsible for field trials, and those responsible for each individual vaccine sub-project whether in a PHS Agency or in an organization contracted through the PHS.
- c) All equipment purchased under this PASA must remain the property of A.I.D. until such time that A.I.D. releases title in writing.
- d) All cables sent to overseas A.I.D. missions must be cleared by the A.I.D. Project Manager or his designee.
- e) The PHS will take all necessary steps to secure approval for testing vaccines in humans in the U.S. and in LDC settings including exemptions to investigate new drugs (IND) and approval of institutional review boards which oversee compliance with regulations governing human subject research.

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X. Travel

All travel, foreign and domestic, must be cleared in writing in advance by the A.I.D. project manager or his designee.

All travel arrangements will be handled by the Participating Agency, including tickets, and/or advances.

XI. Sub-contracting

DHHS/OIH is hereby authorized to sub-contract as appropriate to support the best research and development on the selected vaccines, under its own contracting authority and in accordance with AID Handbook 12, pages 1-21, 1c7, paragraph (a) through (f).

## APPENDIX B

GENERAL BUDGET

Overall Vaccine Development Activities		\$179,368
Technical Assistance		130,668
Project Management	106,668	
Other Professional TA	24,000	
Travel		40,000
Domestic	7,000	
International	33,000	
Other vaccine development activities		8,700
Studies to Adapt and Test Vaccines		245,260
Measles		145,260
Rotavirus		100,000
Total Direct Costs		424,628
Indirect Costs		59,474
Technical Assistance		19,600
Project Management	16,000	
Other Professional TA	3,600	
Other Vaccine Development Activities		1,300
Measles Studies		23,574
Rotavirus Studies		15,000
Total Costs		484,102

APPENDIX C

"Use of AID Facilities and/or Personnel

- a. Participating agencies, their employees, and consultants are prohibited from using AID facilities (such as office space or equipment) and AID clerical/technical personnel in the performance of services specified in a Resources Support Service Agreement (RSSA) or Participating Agency Service Agreement (PASA), unless the use of such personnel and/or facilities is/are specifically authorized in the RSSA/PASA agreement.
  
- b. If at any time it is determined that the participating agency has used AID facilities or personnel without authorization in the RSSA or PASA, then the amount payable under the RSSA or PASA agreement shall be reduced by an amount equal to the value of the AID facilities or personnel used by the participating agency as determined by the AID Agreement Officer."

APPENDIX D

"Subcontracting"

- a. As used herein, the term "subcontracting" includes purchase orders.
- b. Subcontracting by the participating agency with AID funds must be specifically authorized in the PASA or RSSA involved or, separately requested in writing and approved by the AID Agreements officer prior to negotiations. Accordingly, participating agencies are required to clearly indicate in their budget submission to AID for a particular PASA or RSSA the extent of anticipated subcontracting. Where such subcontracting arises during performance an amended budget and amendment to the PASA or RSSA to cover subcontracting may be necessary prior to entering into a subcontract. All subcontracting under PASA and RSSA agreements using AID funds is subject to the provisions on contracting as stated in AID Handbook 12, 1C7. a. through f. pages 1-21 and 1-21a.
- c. AID authorized subcontracting shall be undertaken using the participating agency's own contracting authority and its own contracting regulations. Such authority shall be cited in the subcontract. When subcontracts are negotiated, the circumstances permitting negotiation shall also be cited. AID may, when it is in the best interest of the Government, authorize a participating agency to subcontract with an individual for personal services abroad under a subcontract in which the participating agency may, absent its own authority to contract for personal services, cite Section 636(a) (3) of the Foreign Assistance Act of 1961, as amended (FAA). In such event, the circumstance permitting negotiation is 41 U.S.C. 252(c)(15). Where the FAA is used as authority, the participating agency shall also use applicable AID contracting regulations."

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APPENDIX E

BILLINGS

Billings should be submitted for payment to A.I.D. on Standard Form 1080 or 1081, together with dates of services rendered and a breakdown of accrued expenses. Submissions should be made on a monthly or quarterly basis.

The format of the report accompanying the SF 1080 or 1081 should be substantially as indicated below. Disbursements will not be made without the following identifying information:

DEPARTMENT OR AGENCY  
FINANCIAL STATUS REPORT  
On an Accrual Basis

PASA/RSSA No: \_\_\_\_\_ Period Covered: From: \_\_\_\_\_  
 To: \_\_\_\_\_  
 Project Name: \_\_\_\_\_  
 Project Number: \_\_\_\_\_ PASA/RSSA Agreement Period: From: \_\_\_\_\_  
 To: \_\_\_\_\_  
Fiscal Data: P/O/T Oblig. No. \_\_\_\_\_  
 Appropriation No. \_\_\_\_\_  
 Allotment No. \_\_\_\_\_

<u>Description of Budget Line Items</u>	<u>Current Billing</u>	<u>Cumulative Billing to Date</u>
Salaries		
Benefits		
Travel		
Transportation		
Supplies & Materials		
Other		
Overhead		
<b>Totals</b>	_____	_____
	=====	=====

Cumulative Funds Authorized in PASA/RSSA through  
Amendment Number \_\_\_\_\_

Billings for services rendered under this agreement should be addressed to:

Office of Financial Management  
Agency for International Development  
Washington, D.C. 20523

## APPENDIX F

### 1. IDENTIFICATION, SELECTION AND USE OF CONTRACTORS AND CONSULTANTS

(a) It is the responsibility of the participating agency to identify and select contractors and consultants in accordance with participating agency procedures and, to the maximum extent practicable, under competitive procedures. AID employees are not authorized to suggest or recommend specific individuals or organizations. The participating agency agrees not to solicit suggestions or recommendations of potential contractors or consultants from AID employees. Discussions between AID employees and the participating agency on specific individuals or organizations are permitted only after an individual or organization has been identified as a potential contractor or consultant by the participating agency.

(b) Contractor (nonfederal) employees or consultants performing services under PASA or RSSA agreements shall not participate in policy formulation, budgeting, or supervision of AID personnel.

### 2. LIMITATION ON COMPENSATION OF PARTICIPATING AGENCY PERSONNEL, CONTRACTOR EMPLOYEES, OR CONSULTANTS

(a) Salaries and wages or consultant fees which exceed the maximum level of the Foreign Service Officer Class 1 (FS-1), or the equivalent daily rate, as established in the payment schedule of the uniform State/AID/USIA Regulations, as from time to time amended, must be specifically authorized in advance by the AID Agreement Officer.

(b) Reimbursement will not be made for unauthorized salary and wage, or consultant fee amounts which exceed the maximum FS-1 level.

### 3. RELOCATION WITHIN THE U.S. OF PARTICIPATING AGENCY EMPLOYEES, CONTRACTOR EMPLOYEES, OR CONSULTANTS

(a) Relocation within the United States of participating agency employees, contractor employees, or consultants must be specifically authorized in advance by the AID Agreement Officer.

(b) Relocation allowances for authorized participating agency employees will be reimbursed as provided in the Federal Travel Regulations.

(c) Relocation costs for authorized contractor employees, or consultants will be reimbursed in accordance with Section 31.205-35 of the Federal Acquisition Regulations (FAR).

4. PARTICIPANT TRAINING COSTS

All participant training shall be conducted in accordance with the policies and procedures established in AID Handbook 10 - Participant Training unless otherwise specifically authorized in advance by the AID Agreement Officer.

5. WORKSHOP/CONFERENCE COSTS

Meetings and conferences, including meals, transportation, rental of meeting facilities and other incidental costs are allowable when the primary purposes of the incurrence of the costs is the dissemination of technical information.

6. ENTERTAINMENT COSTS

Costs of amusement, diversion, social activities, and any directly associated costs such as tickets to shows, sports events, meals, lodging, rentals, transportation, and gratuities are not allowable.