

PROJECT DATA SHEET

1. TRANSACTION COD.

A = Add  
 C = Change  
 D = Delete

PD-ABN-978  
 Amendment Number  
 1

DOCUMENT CODE  
 3

COUNTRY/ENTITY

Worldwide

3. PROJECT NUMBER

936-5968

PD-ABN-978

BUREAU/OFFICE

Office of Health

5. PROJECT TITLE (maximum 40 characters)

Technologies for Child Health  
 (HEALTHTECH)

PD-ABN-979

PROJECT ASSISTANCE COMPLETION DATE (PACD)

MM DD YY  
 01/4/31/97

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

93711

A. Initial FY 87

B. Quarter

C. Final FY 94

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				\$14,100		\$14,100
(Grant)	(\$1,125)	( )	( )	\$14,100	( )	( )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S.	1.					
	2.					
Host Country						
Other Donor(s) Add-ons				2,100		2,100
<b>TOTALS</b>				16,200		\$16,200

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	510	590		2,361		8,100		10,100	
2) CS	510	590		1,000				4,000	
3)									
4)									
<b>TOTALS</b>				3,361		8,100		14,100	

10. SECONDARY TECHNICAL CODES (maximum 8 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)

To develop, test and introduce new child survival technologies and infectious research diagnostics for use in primary health care in in communities of the developing world.

14. SCHEDULED EVALUATIONS

Interim MM YY 01/9/91 Final MM YY 02/9/97

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 PP Amendment.)

06/92

This amendment extends the PACD from 3/31/91 to 4/30/97; increases the LOP funding from \$6,000,000 to \$14,100,000; consolidates the activities of projects 936-5968, HEALTHTECH and 936-5935, DIATECH; approves a new cooperative agreement with the Program for Appropriate Technology in Health (PATH).

17. APPROVED BY

Signature

Roxanne Van Dusen

Title

Roxanne Van Dusen  
 Acting Agency Director for Health

Date Signed

MM DD YY  
 01/06/97

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

MM DD YY

PROJECT AUTHORIZATION AMENDMENT NUMBER 1

Name of Country: Worldwide  
Project Title: Technologies for Child  
Health: HEALTHTECH  
Project Number: 936-5968

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, the Technologies for Child Health: HEALTHTECH project was authorized on April 8, 1987.

That authorization is hereby amended as follows:

- a) increase the life-of-project (LOP) funding by \$8,100,000, from \$6,000,000 to \$14,100,000,
- b) increase the authorized centrally-funded LOP from \$6,000,000 to \$14,100,000 from the Health and Child Survival Accounts.
- c) change the PACD from 3/31/91 to 4/30/97.
- d) Funds authorized under Section 104 (c)(1) and Section 104 (c)(2) may be used without regard to previously authorized dollar limits for each appropriation so long as the total authorization of \$14,100,000 for the project is not exceeded.
- e) In addition to the amount authorized above, an estimated \$2,000,000 may be contributed to the project by Missions, Regional Bureaus, and other offices of A.I.D. Funding may be provided from the Economic Support Fund (ESF) or the Development Fund for Africa (DFA), as well as the accounts authorized for S&T funding under this project.
- f) The revised purpose is to develop, test, and introduce new child survival technologies and infectious disease diagnostics for use in primary health care in communities of the developing world.

2. The authorization cited above remains in force except as hereby amended.

3. In accordance with Handbook 13, 2B.3.d, it is hereby certified that the proposed grant to the Program for Appropriate Technology in Health (PATH) is a follow-on assistance award intended to continue or further develop an existing assistance relationship.

*Ann Van Dusen*

Ann Van Dusen  
Acting Agency Director for Health

*June 5 1990*  
Date

Clearances:

S&T/H, N. Pielemeier *LS* date *6/1/90*  
S&T/H, G. Pettigrew *GP* date *5/31/90*  
S&T/PO, D. Sheldon *DS* date *6/5/90*  
GC/CP, S. Tisa Rene Matalon date 5/29/90

Drafter: S&T/H/AR:CGonzmart:x54427:4832j:5/24/90

Agency for International Development  
Washington, D.C. 20523

MAY 30 1990

ACTION MEMORANDUM FOR THE ACTING AGENCY DIRECTOR FOR HEALTH

FROM: S&T/H/AR, Pamela Johnson 

SUBJECT: Authorization for the Technologies for Child  
Health: HealthTech Project (936-5968)

**PROBLEM:** Your approval is requested to amend the authorization for the Technologies for Child Health: HealthTech project (HEALTHTECH) 936-5968. You are requested to approve:

- 1) extending the project completion date for a period of six additional years to 4/30/97;
- 2) increasing the estimated life of project (LOP) funding level from \$6,000,000 to \$14,100,000;
- 3) consolidating the activities of the HEALTHTECH project and the Diagnostic Technology for Community Health: DIATECH project (936-5935); and,
- 4) a non-competitive award of a new cooperative agreement for an unsolicited proposal with the Program for Appropriate Technology in Health (PATH), a nonprofit non-government organization.

**DISCUSSION:** One of A.I.D.'s primary health strategy goals is the improvement of child survival through the use of effective and affordable technologies. These technologies must be appropriately designed to meet the challenges posed by disease problems and the delivery of health services in the developing world. HEALTHTECH was authorized in 1987 to develop a mechanism for promotion of the development, testing, introduction, and where possible the local manufacture of primary health care child survival technologies for use in developing and advancing countries. The activity has been successful in developing several innovative technologies, including four injection technologies, five adjunct technologies for immunization/vaccination, five maternal care technologies, three newborn care technologies, and three health care technologies. Complete technology transfer of production capability has been accomplished for one technology in two countries and for another technology in one country. A recent evaluation found that the HEALTHTECH project has made valuable contributions to A.I.D., and recommended extension of the project for at least a five year span for new technology development (PES attached).

DIATECH was authorized through 1992. The principal implementing mechanism is a five year cooperative agreement which commenced in 1985 and is scheduled to terminate in September, 1990. The project was designed to adapt existing or emerging biotechnologies to advance A.I.D.'s health sector strategy for promoting child survival, and to provide a method through which to develop and transfer simple, cost-effective diagnostic technologies. A total of 42 diagnostic technologies have been at least partially or fully developed by DIATECH.

The final evaluation of the project recommended that DIATECH be given high priority, that the activity be continued, and that A.I.D. coordinate and integrate the focus of DIATECH with other program priorities and activities within S&T/H. The final evaluation identified six diagnostic technologies that can be developed and transferred to developing countries in a relatively short time period, and recommended these technologies for accelerated development (PES attached).

Both DIATECH and HEALTHTECH are implemented through respective cooperative agreements between A.I.D. and the Program for Appropriate Technology in Health (PATH), a nonprofit, non-governmental organization based in Seattle, Washington. PATH's purpose is to improve the availability, acceptance and use of health products and technologies in developing countries. PATH seeks to identify new health technologies and to improve existing ones by adapting them to the culture and conditions in which they are to be used.

UNSOLICITED PROPOSAL: S&T/H has received an unsolicited proposal from PATH to continue and consolidate activities which are currently being undertaken through the HEALTHTECH and DIATECH cooperative agreements.

PATH proposes to implement an activity which supports the A.I.D. child survival program through the identification, development and introduction of primary health care technologies in less developed countries during a period of five years. The proposal requests \$10,381,000 from S&T/H to support core activity costs and anticipates \$1,980,000 from A.I.D. add-ons. PATH will seek an additional \$5,260,000 in prospective cofunding for the activity through parallel agreements with other donors and foundations, and various parts of A.I.D. The proposal consolidates the HEALTHTECH and DIATECH projects.

An estimated \$250,000 will be required to fund evaluations and audits, and for contingency and inflationary costs not already included in the unsolicited proposal. Currently, approximately \$3,400,000 of centrally appropriated funds has been obligated in the HealthTech project. The LOP is \$6,000,000, and an additional \$8,100,000 is required in centrally funded authorization for a total of \$14,100,000.

5

The activity incorporates several strategies and approaches for supporting the child survival program through the identification, development and introduction of primary health care technologies and infectious disease diagnostics in less developed countries. The proposed activity will build upon the experiences, resources and accomplishments of the current HEALTHTECH cooperative agreement, and will use proven mechanisms developed under HEALTHTECH and DIATECH to identify, screen and process new technologies. The activity will continue to advance child and maternal health technologies and priority infectious disease diagnostics which are in the development and production pipelines.

The proposal outlines plans for an expanded scope of work. It describes 15 primary care technologies which are in the development pipeline and are proposed for advancement during the first eighteen months of the activity; identifies another 37 technologies that are currently in the early stages of selection and screening; and, incorporates a new component to promote the rapid development of six high priority infectious disease diagnostic technologies which have been advanced through the DIATECH project.

PATH indicates that if the proposal achieves full core funding for the five year period, it will:

- investigate no less than 60 perceived needs or new technologies;
- undertake feasibility studies on at least 25 of these technologies;
- develop field tests for at least 20 products;
- advance and introduce at least 13 products; and,
- transfer manufacturing capability for at least six technologies to developing world manufacturers three of which are infectious disease diagnostics.

In addition, the proposal offers to provide select technology services to USAID missions and A.I.D. bureaus in support of the proposed activity. These services are designed to support mission-assisted health product development at the local level, and range from needs assessments to product introduction and distribution activities.

PROPOSAL REVIEW PROCESS: The proposal was favorably reviewed for technical merit by Central and Regional Bureau HPN staffs, S&T/H internal reviewers, an external peer review panel, and by the Health Sector Council (HSC). Discussions during the HSC meeting noted that the HEALTHTECH and DIATECH activities were a natural combination and

that consolidating them would help relieve S&T/H's overall management burden. The five external reviewers evaluated the proposal on the basis of technical criteria, including relevance of proposed scope of work to S&T/H mission and goals, appropriateness of the proposed budget to the scope of work, relevant qualifications of proposed key personnel, adequacy of proposed activity time schedules, PATH's previous experience in doing similar work in research, product development and field testing, and the organization's demonstrated experience in promoting technology transfer to developing countries. In addition to the above technical criteria, the external reviewers assessed the proposal on the basis of business and end-of-project status criteria. Based on the reviewers' comments on PATH's original proposal for S&T/H funding at the level of \$13,523,308, we identified a number of cost savings, and PATH has reduced its request to \$10,381,000.

EVALUATION AND AUDIT PLANS: The activity will be closely monitored and evaluated on a continuing basis by S&T/H. Formal evaluations will include S&T/H project reviews, management reviews, and interim and final evaluations. The project and management reviews will be done by S&T/H/AR at 12 month intervals following the signing of the final agreement between A.I.D. and PATH. Other substantive reports which will be requested from PATH include annual work plans, quarterly progress reports, annual reports and a final report. Performance norms will closely follow those which are used in the product development business. PATH indicates it will follow criteria which as been recommended by Booz, Allan, and Hamilton, Inc in related industry publications.

It is anticipated that the quarterly and annual reports will review strategy issues and progress in attaining milestones, and will include all financial information required by A.I.D. The interim evaluation will be done at the estimated mid-point of the activity following the signing of the final agreement. The final evaluation will be accomplished at the conclusion of the activity.

A financial review of the project by a non-Federal independent accounting firm will be accomplished at the mid-point and during the final year of the project. All evaluations, reviews and audits will be funded separately from the assistance award.

IMPLEMENTATION PLAN: The proposed activity will be accomplished on the basis of annual work plans that will be approved by S&T/H prior to implementation. The activity will incorporate program performance reporting to S&T/H, and an internal evaluation process that will compare and evaluate outputs and accomplishments at regular intervals in relation to the specific objectives that are identified in the proposal and in the individual work plans.

IMPLEMENTATION ISSUES: The proposal submitted by PATH consolidates two separate activities which are currently accomplished through discrete cooperative agreements with A.I.D. In order to merge these activities, continue the progress which has been achieved under the agreements, and avoid a lapse in funding, the proposed award will need to be effective no later than 1 July, 1990.

OTHER CONCERNS: PATH has recently established a Human Subjects Protection Committee that functions as the organization's Institutional Review Board (IRB) for research involving human subjects in accordance with HHS regulations. It is anticipated that PATH will implement and maintain policy and management controls to meet FDA regulatory requirements for the manufacture, marketing and distribution of medical devices, and will employ procedures for assuring the safety and effectiveness of in vitro diagnostic products.

Guidance has been provided from the Office of the General Counsel (GC) on legal issues relating to the compliance of the proposed activity with U.S. law. These relate to the appropriateness of PATH's policies and practices on licensing and protecting the public interest, the development of adequate oversight procedures, and the proper use of potential revenues.

GC has recommended measures to address these issues that will allow this grant application to go forward. The specific guidance which has been received from GC will be incorporated in the prospective Project Implementation Order/Technical Assistance - PIO/T (See attachment).

JUSTIFICATION TO CONGRESS: An Advice of Program Change is being prepared.

AUTHORIZATION AUTHORITY: A concept paper was approved by the AA/S&T on 2/2/90 (Attached). You are authorized, under Delegation of Authority 133 as amended, to amend project authorizations provided that the amendment (a) does not result in a total LOP cost in excess of \$20 million, (b) does not present significant policy issues, and (c) does not require waivers that may only be approved by the Administrator. The Authorization Amendment No. 1 is attached.

RECOMMENDATION:

1) That you approve extending the project completion date to 4/30/97;

APPROVE: R. Alan Doser

DISAPPROVE: \_\_\_\_\_

DATE: June 1 1990

2) That you approve increasing the LOP funding level to \$14,100,000;

APPROVE: R A Van Dusen

DISAPPROVE: \_\_\_\_\_

DATE: June 1 1990

3) That you approve consolidating the activities of the HEALTHTECH and DIATECH projects;

APPROVE: R A Van Dusen

DISAPPROVE: \_\_\_\_\_

DATE: June 1 1990

4) That you approve a new cooperative agreement with a life of funding of \$10,381,000 from central S&T Health and Child Survival Accounts. An additional \$1,980,000 may be provided through Mission and Central and Regional Bureau funding of additional activities.

APPROVE: R A Van Dusen

DISAPPROVE: \_\_\_\_\_

DATE: June 1 1990

Attachments:

1. Project Authorization Amendment No. 1
2. Justification for Non-Competition Procurement
3. HEALTHTECH Logframe
4. A.I.D. Evaluation Summary - HEALTHTECH
5. A.I.D. Evaluation Summary - DIATECH
6. Project Budget
7. Memorandum from the Office of the General Counsel
8. Action Memorandum for the Acting Assistant Administrator Bureau for Science and Technology