

A.I.D. EVALUATION SUMMARY - PART I

64489

- 1. BEFORE FILLING OUT THIS FORM, READ THE ATTACHED INSTRUCTIONS.
- 2. USE LETTER QUALITY TYPE, NOT "DOT MATRIX" TYPE.

IDENTIFICATION DATA					
A. Reporting A.I.D. Unit: Mission or AID/W Office <u>AID/W</u> (ES# _____)		B. Was Evaluation Scheduled in Current FY Annual Evaluation Plan? Yes <input type="checkbox"/> Slipped <input type="checkbox"/> Ad Hoc <input type="checkbox"/> Evaluation Plan Submission Date: FY 88 Q <u>1</u>		C. Evaluation Timing Interim <input checked="" type="checkbox"/> Final <input type="checkbox"/> Ex Post <input type="checkbox"/> Other <input type="checkbox"/>	
D. Activity or Activities Evaluated (List the following information for project(s) or program(s) evaluated; if not applicable, list title and date of the evaluation report.)					
Project No.	Project /Program Title	First PROAG or Equivalent (FY)	Most Recent PACD (Mo/Yr)	Planned LOP Cost (000)	Amount Obligated to Date (000)
936-5951	Child Survival Action Program	8.30.85	8-30-90	\$8,500	\$5,312

ACTIONS		
E. Action Decisions Approved By Mission or AID/W Office Director Action(s) Required	Name of Officer Responsible for Action	Date Action to be Completed
1. Appoint CTO	Johnson	10/88
2. Consolidate JHU Management	Mosley	9/89
3. Extend CA	Heiby	6/89
4. Develop budget plans	Seaton	9/88
5. Implement extramural review	Johnson	8/88
(Attach extra sheet if necessary)		

APPROVALS				
F. Date Of Mission Or AID/W Office Review Of Evaluation: _____ (Month) _____ (Day) _____ (Year)				
G. Approvals of Evaluation Summary And Action Decisions:				
Name (Typed)	Project/Program Officer	Representative of Borrower/Grantee	Evaluation Officer	Mission or AID/W Office Director
	James Heiby	Paul Seaton	Genease Pettigrew	Kenneth Bart
Signature		Paul Seaton		
Date	6/27/89		6-26-89	18-22-89

**ABSTRACT**

H. Evaluation Abstract (Do not exceed the space provided)

The five-year Cooperative Agreement for Child Survival was signed in 1985 in response to a Congressional earmark. Activities were organized under three "working groups" (evaluation, immunizations, and Vitamin A) chaired by faculty members. A fourth area of activity is the Child Survival Fellows Program, managed separately.

The ceiling for the overall agreement was set at \$4,700,000. At the time of this evaluation \$4,119,329 have been obligated, of which \$364,329 represent mission and Bureau buy-ins.

The Institute for International Programs has become an established entity at the SHPH. The evaluation, immunization and vitamin A activities have technical merit and are relevant and useful to A.I.D.'s child survival programs. Some excellent studies and programs have been carried out. The Child Survival Fellows program is imaginative and conceptually sound, and represents a desirable long-term initiative on the part of A.I.D.

Recommendations for improvement are as follows:

- S&T/H should simplify its management of the project and provide clearer guidance concerning roles and responsibilities, program planning and budgeting;
- JHU/IIP needs to streamline and improve its management structure and provide better program and financial reporting to A.I.D.;
- The immunization activities should be given to disseminating the findings of the research projects, particularly those of the evaluation working group;
- Priority should be given to completing the Vitamin A activities which have particular merit.
- The Child Survival Fellows Program should be continued. The follow-on project should have adequate central funding and very clearly established objectives so as to ensure broad participation of U.S. institutions.

The team recommends that S&T/H hold off raising the ceiling of the Cooperative Agreement and/or extending the PACD until certain elements of an improvement management system are in place. However, the team takes note of new management at the IIP which has already begun to coordinate SHPH departmental resources and to respond more effectively to the requirements of the Cooperative Agreement.

**COSTS**

**I. Evaluation Costs**

1. Evaluation Team		Contract Number OR TDY Person Days	Contract Cost OR TDY Cost (U.S. \$)	Source of Funds
Name	Affiliation			
Barbara Turner, Director William Bicknell, M.D.	AID/ANE/TR Boston University	20	\$10,000	ST/H
2. Mission/Office Professional Staff Person-Days (Estimate) <u>5</u>		3. Borrower/Grantee Professional Staff Person-Days (Estimate) <u>20</u>		

## A.I.D. EVALUATION SUMMARY - PART II

### SUMMARY

J. Summary of Evaluation Findings, Conclusions and Recommendations (Try not to exceed the three (3) pages provided)

Address the following items:

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>● Purpose of evaluation and methodology used</li> <li>● Purpose of activity(ies) evaluated</li> <li>● Findings and conclusions (relate to questions)</li> </ul> | <ul style="list-style-type: none"> <li>● Principal recommendations</li> <li>● Lessons learned</li> </ul> |
|--|--|

Mission or Office:

AID/W

Date This Summary Prepared:

2/10/89

Title And Date Of Full Evaluation Report:

Mid-Project Evaluation Johns Hopkins  
Institute for International Programs 7-5-88

#### EVALUATION FORMAT AND PURPOSE

This Cooperative Grant Agreement was evaluated retrospectively through review of files, project documents and financial records, and by personal interviews. The objectives of the evaluation were:

1. To determine the technical appropriations and effectiveness of the various project components under the agreement as child survival activities;
2. To assist the AID and JHU administrative management of the program;
3. To provide useful information based on experience under the program for upgrading technical and administrative management and assisting with shaping future directions of these activities.

#### OVERVIEW OF FINDINGS AND RECOMMENDATIONS STRENGTHS

1. The program activities in the evaluation, immunization and vitamin A areas are relevant to the AID Child Survival priorities and, without question, have technical merit.
2. The Child Survival Fellows program is imaginative and has the potential to make a significant contribution to the development of a new cadre of well qualified professionals committed to International Health.
3. The Cooperative Agreement (CA) Institute for International Programs (IIP) has been a central factor in assisting the IIP to get established and functioning at the SHPH.
4. The CA through the IIP has been very effective in getting the time and attention of some of the SHPH's best professionals focused on Child Survival issues. The CA has offered opportunities for graduate students to become attracted to Child Survival research. It has also enabled the SHPH to leverage other resources for activities developed under the CA.
5. The areas chosen for emphasis within the broad parameters of the CA (immunization, vitamin A, evaluation and Fellows) link the strengths of the SHPH to a number of A.I.D. Child Survival priorities.

#### ISSUES

1. A.I.D.'s intent appears to have been to fund a set of activities limited by time and money. The SHPH appears to have implemented the CA as if it were the first phase of an assured long-term institutional support activity rather than for a finite set of activities limited by money and time.
2. The CA describes a set of activities far beyond the capacity of the budget. The annual work plans were intended to prioritize and refine those objectives and their budgetary implications. Unfortunately, this has generally not been the case.
3. Although it is clear that a number of excellent studies and programs have been carried out to date under the CA, the evaluation team was struck by management weaknesses in CA administration at the IIP and S&T/H. These weaknesses should not be viewed as the fault of any one person or either institution. Rather they are the product of such factors as:
  - a. A program that was implemented because of a congressional earmark that circumvented more traditional program development.
  - b. An S&T/H overall program and management work load that severely stretches and perhaps occasionally exceeds the available professional and support staff capacity.

## S U M M A R Y (Continued)

- c. A new organization at the SHPH - the IIP - with a new and evolving mission, new leadership and administrative capacity.
- d. A university environment where professional and academic interests may occasionally outweigh management concerns.

### RECOMMENDATIONS MANAGEMENT

1. A.I.D. should designate a single, knowledgeable, responsible Cognizant Technical Officer (CTO) in S&T/H who has the time, responsibility and authority to act for A.I.D.
2. A single person with faculty rank, administrative skills and time should be designated as project director. This person should have the authority and responsibility within the terms of the CA to allocate funds within and between all CA activities, establish procedures for the working groups, resolve conflicts, assure proper technical oversight before sub-project activities are submitted to A.I.D., and be ultimately responsible to the Dean of the SHPH. This is not a full time position but will require 30% to 50% time (time on the CA may decrease as the procedures are put in place and the CA winds down).
3. At IIP a full-time or near full-time project manager should carry responsibility for day-to-day operations. The project director and project manager should be assisted by a project staff of no more than three full-time equivalent administrative support positions. This management unit should provide all necessary administrative support for all activities carried out in the four program areas (evaluation, vaccines, Vitamin A and Fellows).

### BUDGET AND IMPLEMENTATION

1. If A.I.D. chooses to support through the CA completion of selected ongoing activities (e.g. Indonesia Vitamin A study and probably the Philippines tier 3 study), this will require extending the project completion date, increasing the funding ceiling and providing additional funds. (n.b. The team wants to emphasize that it feels the Vitamin A study has worldwide policy relevance and once technical issues have been resolved, recommends that the study be carried out in a timely manner.) Prior to doing this, a careful and comprehensive inventory of all projects underway should be rapidly completed and tight, realistic expenditure plans developed for each activity. These activities also need to be related to the capacity of the management support unit.
2. Mission buy-ins to date (\$64,329) have been substantial and anticipated buy-ins are anticipated to greatly exceed this, perhaps approximating 50% of total funds awarded to date. Care should be taken to assure that existing and anticipated buy-ins fall within the overall program, time and financial framework of the CA.
3. As consideration is now being given to modifications in the CA, it is essential there be clarity with regard to expenditures, obligations, unobligated funds, projects completed, projects underway, projects approved but not begun, etc. The IIC needs to develop a comprehensive project tracking system including program descriptions, annual budgets, issues, and implementation schedules, both financial and programmatic.
4. EXTRAMURAL SCIENTIFIC REVIEW OF PROPOSED WORKING GROUP ACTIVITIES SHOULD BE REQUIRED

1. Finding reviewers, working with them and feeding their results back to SHPH faculty is a time consuming and technically demanding task. It is not clear that in-house staff resources are now or in the foreseeable future will be sufficient to coordinate and direct this type of extramural review. This issue doubtless extends beyond this CA and illustrates the problems of diverse and competing agendas faced by S&T/H.

### SUBPROJECTS CHILD SURVIVAL FELLOWS PROGRAM

The concept behind the Fellows Program - Providing a financial and program incentive for health professionals to gain substantial long-term overseas experience and opt for a career in International Health - is sound and from a public policy perspective is emblematic of a very desirable long term A.I.D. initiative. The evaluation team emphasizes that the concept of the Fellows Program has great merit. It is unlikely that other funding agencies will assume a comparable responsibility for strengthening-

the cadre of U.S. health professionals committed to international health. Subject to the resolution of policy issues raised in the evaluation, we urge A.I.D. to continue the program.

#### IMMUNIZATION

The team recommends that the activities underway in the vaccine area should be completed. New activities in this area that A.I.D. may wish to support should be incorporated into the overall S&T/H vaccine research program through a vehicle more sensitive to the needs of vaccine development and testing such as the S&T/H agreement with HHS/OIH.

#### VITAMIN A

The CA activities in Vitamin A are very relevant to current A.I.D. priorities. The impression cytology findings were timely and useful. The state of the art paper is widely regarded as a significant contribution. The Vitamin A morbidity study scheduled to begin soon in Indonesia is the centerpiece of the activities of this working group and has the potential to make a major impact on Vitamin A program decisions. The Vitamin A morbidity study now planned for Indonesia has near immediate important policy relevance for A.I.D. and the larger international health community. Prior to final approval of the Indonesia Vitamin A study, the research protocol should be submitted by A.I.D. to selected independent expert reviewers. In the review process particular attention should be paid to assuring rigorous attention to epidemiological detail.

#### EVALUATION

The activities of this working group are very consonant with the mission of A.I.D. and the current Child Survival program priorities. They are an excellent example of the type of activity that should be centrally funded. It is most appropriate that this research has focused on the tier 3 level evaluations.

In addition to completing activities underway in the evaluation area, S&T/H with the IIP should consider ways to disseminate findings, methods and information generated by evaluation projects not only to the academic community but also to individuals and agencies responsible for the planning, management and evaluation of international health programs worldwide. Although findings are only now becoming available, plans for dissemination are weak.

ATTACHMENTS

K. Attachments (List attachments submitted with this Evaluation Summary; always attach copy of full evaluation report, even if one was submitted earlier, attach studies, surveys, etc., from "on-going" evaluation, if relevant to the evaluation report.)

COMMENTS

L. Comments By Mission, AID/W Office and Borrower/Grantee On Full Report

S&T/H find the report insightful and is in the process of implementing the recommendations

~~64491~~

7

64491

JOHNS HOPKINS UNIVERSITY  
SCHOOL OF HYGIENE & PUBLIC HEALTH  
INSTITUTE FOR INTERNATIONAL PROGRAMS

MID-PROJECT EVALUATION

July 5, 1988  
Final Report

Cooperative Agreement  
DPE-5951-A-00-5051-00

Prepared By

Barbara Turner, M.P.H.  
Director  
Asia/Near East Office of Technical Resources  
Agency for International Development

&

William J. Bicknell, M.D., M.P.H.  
Professor of Public Health  
Boston University

7

JOHNS HOPKINS UNIVERSITY  
SCHOOL OF HYGIENE & PUBLIC HEALTH

INSTITUTE FOR INTERNATIONAL PROGRAMS

MID-PROJECT EVALUATION

Cooperative Agreement  
DPE-5951-A-00-5051-00  
Final Report, July 5, 1988

TABLE OF CONTENTS

I - THE EVALUATION TEAM -----	1
II - OVERVIEW -----	1
III - THE FUNDING VEHICLE -----	4
IV - FINDINGS AND RECOMMENDATIONS -----	5
A - Overvue -----	5
B - Management -----	6
C - Fellows Program -----	10
D - Vitamin A -----	12
E - Immunizations -----	13
F - Evaluation -----	13
V - CONCLUSION -----	14
VI - APPENDICES	
1 - Scope of Work	
2 - Immunization Working Group Review by Dr. William Jordan Jr.	
3 - Vitamin A Protocol Comments by Dr. Larry C. Clark	
4 - Institute for International Programs Organization chart	
5 - Advisory Council	
6 - Immunization Working Group	
7 - Evaluation Working Group	
8 - Vitamin A Working Group	
9 - International Child Survival Fellowship Program Advisory Committee	
10 - Projects completed, underway and pending	

## I - THE EVALUATION TEAM

This mid-project evaluation was carried out by Ms. Barbara Turner (team leader) Director, Asia/Near East Office of Technical Resources, Agency for International Development (A.I.D.), and Dr. William Bicknell, Professor of Public Health and Director of the Office of Special Projects, Boston University. The charge to the team is outlined in the Scope of Work (appendix 1). The team interpreted its charge to mean it would limit itself to a mid-project overview of project activities and would not conduct a detailed scientific and technical review of each activity.

The team was augmented by Dr. William Jordan Jr., formerly Director, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases. Dr. Jordan contributed to the review of immunization activities (appendix 2). Dr. Larry Clark, Assistant Professor of Epidemiology at the University of Arizona School of Medicine was provided with project background materials on Vitamin A and provided most helpful input by telephone and in writing to the team ( appendix 3).

The team has reviewed project documents supplied by Johns Hopkins University (J.H.U.) and A.I.D., met with numerous J.H.U. faculty, staff and fellows in group and individual sessions and interviewed selected A.I.D. central and mission staff.

The Bureau of Science and Technology/Health Staff particularly Dr. Pamela Johnson, Ms. Veronica Elliott and Ms. Julia Terry provided much needed input, support and perspective. The Johns Hopkins faculty and staff, exemplified but by no means limited to Dr. Mosely, Dr. Black and Mr. Seaton, organized an excellent, intensive and informative set of briefings over 1 1/2 days for the team in Baltimore.

## II - OVERVIEW

The Johns Hopkins University School of Hygiene and Public Health (SHPH) Institute for International Programs (IIP) Cooperative Agreement Number DPE-5951-A-00-5051-00 (CA) began August 30, 1985 in response to a Congressional earmark with a ceiling of \$4,706,000 for a 5 year period ending August 29, 1990. Initial funding was for \$1,156,000 from Science and Technology/Health (S&T/H) central funds which have been augmented to date by \$2,599,000 additional Bureau of Science and Technology funds (Health, Child Survival and Nutrition) and \$364,329 buy-ins by missions and regional bureaus for a total obligation of \$4,119,329.

The SHPH, the IIP's parent, is a long established, preeminent school with an annual operating budget of \$90,000,000, endowment income of \$1,500,000, 900 students (20% non-U.S.) and nearly 300 full-time faculty in 11 departments (Biochemistry, Biophysics, Biostatistics, Environmental Health Sciences, Epidemiology, Health Policy and Management, Immunology and Infectious Diseases, International Health, Maternal and Child Health, Mental Hygiene and Population Dynamics).

The IIP is a new entity within the SHPH and is intended to facilitate the Schools ability to coordinate its departmental resources particularly in response to the needs of the international donor community.

The current programs of the IIP are:

- 1 - Cooperative Agreement for Child Survival (CA), \$4,706,000
- 2 - Private Voluntary Organization Child Survival Support, \$1,040,000
- 3 - Joint Memorandum of Understanding J.H.U./Charles Drew, \$399,000
- 4 - Hubert H. Humphrey North-South Fellowship Program, U.S.I.A., \$9,000\*
- 5 - India Network, Ford Foundation, \$300,000

\*Tuition funds are not included in this figure.

Activities 1 - 3 are A.I.D. funded. Other A.I.D. funded activities at the SHPH do not fall within the umbrella of the IIP.

The Chair of the Population Dynamics Department, Dr. W. Henry Mosely, is the Director of the IIP and the Project Director for the CA. The Chair of the Department of International Health, Dr. Robert E. Black serves as Associate Director of the IIP and Associate Project Director (n.b. The Department of International Health is reported to have grown from 6 to 41 full-time faculty in the last several years).

The Deputy Director of the IIP, Mr. Paul Seaton, serves as the overall project manager for the CA. The CA organization closely parallels the organization of the IIP and is the largest activity within the IIP. (appendix 4 - organizational chart)

The IIP/CA has an overall advisory group (appendix 5) chaired by Dr. D. A. Henderson, Dean of the SHPH. Three active working groups and the International Child Survival Fellowship Advisory Committee oversee the funded areas of program activity:

Evaluation - Coordinator: Dr. Ronald H. Gray  
 Immunization - Coordinator: Dr. Neal A. Halsey  
 Vitamin A - Coordinator: Dr. Kenneth H. Brown  
 International Child Survival Fellowship Program: Dr. Stella A. J. Goings

The Social Science working group, coordinated by Dr. Peter A. Berman, and Dr. Carl Kendall has not been funded under the CA. (appendices 6, 7, 8 & 9 list the membership of the working groups).

Expenditures and obligations through March 31, 1988 by program area and management support are shown in Table I.

TABLE I  
 EXPENDITURE SUMMARY  
 (3/31/88 - estimated)

	Expenditures		Total	Percent
	Vouchered	Unvouchered		
Evaluation	\$682,089	\$28,567	\$710,656	21%
Immunization	\$460,550	\$41,330	\$501,880	15%
Vitamin A	\$252,257	\$11,050	\$263,307	8%
Fellows	\$1,044,253	\$114,920	\$1,159,173	35%
Management	\$672,337	\$29,016	\$701,353	21%
<b>Total</b>	<b>\$3,111,486</b>	<b>\$224,883</b>	<b>\$3,336,369</b>	<b>100%</b>
Funds Awarded			\$4,272,000	
Balance Remaining			\$935,631	

A summary of CA funded activities is shown in Table II.

TABLE II  
PROGRAM ACTIVITY SUMMARY  
ACTIVITIES<sup>1</sup>

	COMPLETED	UNDERWAY	APPROVED <sup>2</sup>	Total
Evaluation	3	8	0	11
Immunization	1	2	0	3
Vitamin A	3	1	1 pending	4
Fellows	1	14	1	16
Miscellaneous <sup>3</sup>	5			5
Total	13	25	1	39

1 See Appendix 10 for details

2 USAID approved, funded (in whole or part) but not begun

3 Seminars for USAID staff given in Rosslyn

The IIP reports the following:

- If the CA were to be terminated immediately expenditures and obligations would total \$4.9 million.
- Funds expended and obligated plus what is required to complete approved projects approximates \$5.9 million.
- In order to complete approved projects, initiate and carry to completion the Vitamin A study and the Philippines tier-3 activity funds along the following lines will be required:

Complete approved projects	\$5,900,000
Vitamin A Indonesia*	\$725,000
Philippines tier-3*	\$335,000
 Total estimated cost	 \$6,960,000

It should be noted that none of the activities marked with an \*, if approved by A.I.D., can be completed by August 29, 1990.

Further detail on the Fellows Program is shown in Table III.

TABLE III  
FELLOWS SUMMARY  
Placement

	Overseas*	Domestic	Total
USAID Placement	1	4	5
USAID Choice**	1	0	1
IIP Choice	8	2	10
Career Choice			
New Career	3	0	3
Same Career	7	6	13
Citizenship			
US	8	5	13
Non-US***	2	1	3
Overseas Site			
Asia/Near East	3 *		
LA/Caribbean		5	
Africa			2 *

\*includes placement of Kenyan and Indian nationals in their respective home countries

\*\*person chosen by mission for PVO placement, not an IIP choice

\*\*\*2 of 3 are green card holders.

### III - THE FUNDING VEHICLE

As the majority of the teams findings and recommendations are in the areas of project management and relate to the funding vehicle, it is important that there is a clear understanding of what a Cooperative Agreement is and how it differs from a grant and a contract.

According to the A.I.D. Handbook, a grant or cooperative agreement is "in the nature of a gift in support of an agreed upon purpose." A cooperative agreement is used when a grant would be appropriate except that a substantial involvement is anticipated between A.I.D. and the recipient at mutually agreed upon points during the activity. A cooperative agreement therefore, should begin with a clear statement of the purpose and objectives of the activity and a clear agreement on the points at which A.I.D. involvement will be required. The types and frequency of approvals and reporting should be mutually agreed upon in the cooperative agreement or in some letter exchange subsequent to the agreement. Recommendations for the nature of A.I.D. involvement, approvals and reporting are contained in the sections IV-A. and IV-B.

#### IV - FINDINGS AND RECOMMENDATIONS

##### A - Overview

###### Strengths:

- 1 - The program activities in the evaluation, immunization and vitamin A areas are relevant to the A.I.D. Child Survival priorities and, without question, have technical merit.
- 2 - The Child Survival Fellows program is imaginative and has the potential to make a significant contribution to the development of a new cadre of well qualified professionals committed to International Health.
- 3 - The CA has been a central factor in assisting the IIP to get established and functioning at the SHPH.
- 4 - The CA through the IIP has been very effective in getting the time and attention of some of the SHPH best professionals focused on Child Survival issues. The CA has offered opportunities for graduate students to become attracted to Child Survival research. It has also enabled the SHPH to leverage other resources for activities developed under the CA.
- 5 - The areas chosen for emphasis within the broad parameters of the CA (immunization, vitamin A, evaluation and Fellows) link the strengths of the SHPH to a number of A.I.D. Child Survival priorities.

###### Concerns:

- 6 - A.I.D.'s intent appears to have been to fund a set of activities limited by time and money. The SHPH appears to have implemented the CA as if it were the first phase of an assured long-term institutional support activity rather than for a finite set of activities limited by money and time.
- 7 - The CA describes a set of activities far beyond the capacity of the budget. The annual work plans were intended to prioritize and refine those objectives and their budgetary implications. Unfortunately, this has generally not been the case.
- 8 - Although it is clear that a number of excellent studies and programs have been carried out to date under the CA, the evaluation team was struck by management weaknesses in CA administration at the IIP and S&T/H. These weaknesses should not be viewed as the fault of any one person or either institution. Rather they are the product of such factors as:
  - A program that was implemented because of a congressional earmark that circumvented more traditional program development.
  - An S&T/H overall program and management work load that severely stretches and perhaps occasionally exceeds the available professional and support staff capacity.
  - A new organization at the SHPH - the IIP - with a new and evolving mission, new leadership and administrative capacity.
  - A university environment where professional and academic interests may occasionally outweigh management concerns.

Fundamentally, there is lack of clarity within S&T/H and the IIP with regard to who is responsible for what, what is the approved scope of work and level of effort, what the parties expect of each

other, how they should communicate and what even basic terminology means. A situation such as this can only lead to lost time, increased work, frayed tempers and sub-optimal use of human and financial resources.

The evaluation team chooses not to list examples of the management problem as we feel this may tend to focus on the past when the focus should be forward looking and directed toward making changes that are in the best interests of everyone.

9 - As consideration is now being given to modifications in the CA it is essential there be clarity with regard to expenditures, obligations, unobligated funds, projects completed, projects underway, projects approved but not begun, etc. Therefore we recommend that S&T/H require the IIP to submit the following as a cohesive internally consistent package prior to any consideration of amendments to the CA:

a - A program budget (an example of one possible format is shown in table IV) within the budget framework of funds awarded to date (\$4,272,000).

b - A one paragraph summary of each project supported activity completed to date, its outputs and a cost estimate (we recognize costing completed projects may be impossible and therefore emphasize estimate).

c - A one to three paragraph summary of all ongoing approved CA activities that includes:

i - A realistic timetable for completion.

ii - A realistic line item budget. The budget should include direct costs associated with the activity but not the time of the CA management and administrative support staff. If buy-ins are part of the funding the amount and source of buy-ins to date and anticipated should be shown.

iii - A summary of uncertainties that may result in delay in competing the activity.

iv - A brief statement as to the significance of the activity and how results will be disseminated.

d - A realistic budget estimate of funds required for CA management to support the completion of the remaining activities and a summary of how staff time will be focused.

It should be noted that A.I.D. did request a number of these items in March and several are already in preparation by the IIP.

10 - Prior to amending either the funding ceiling or the end-of-project date, a plan for improved management should be agreed to by J.H.U. and A.I.D. (see recommendations below).

## B - Management

1 - Given the limited time remaining to complete CA activities, it is now essential that S&T/H and IIP agree on the definition and use of key terms such as approved, funded, expended, obligated and unobligated. An early task of both parties should be to list and define key terms and the "process" of specific clearances within the IIP and within A.I.D. that must be in place prior to initiation of a sub-project activity. These definitions and agreements as to process should be shared by IIP with all working groups.

2 - At present, at least five persons in S&T are actively involved in the day-to-day management of the CA. This is not working well. A.I.D. should designate a single, knowledgeable, responsible cognizant technical officer (CTO) in S&T/H who has the time, responsibility and authority to act for A.I.D.

3 - Three levels of management by S&T/H are possible:

a-detailed oversight, review and approval of all activities on a near day-to-day basis.

b-a quarterly review and approval of the program and budget including a travel plan with day-to-day involvement limited to essential coordination within the agency and particularly with field missions.

c-an annual review and approval of program and budget with quarterly submissions of travel plans for review and approval. This essentially converts the CA into a grant and J.H.U. becomes fully responsible, in an audit sense, for program performance.

Level a is unworkable and inappropriate.

Level b is desirable if, and only if, a staff member with the time, skill and knowledge is realistically available who occupies a position that allows the requisite assumption of full CTO authority and responsibility. Estimated level of effort - 1 to 2 days/week heavily clustered around the quarterly reporting periods.

Level c is the minimum acceptable level of Agency oversight. Estimated level of effort - 0.5 days/week.

In determining the management approach to be taken by S&T/H, it is essential that a very hard-nosed and realistic assessment be made regarding staff capacity, S&T/H priorities and the many other competing demands for scarce S&T/H staff time.

Although the CA specifies only minimal annual reporting, under Section VIII of the CA there is clear authority to request and obtain such information as the agency may feel is needed. Further, when the CA is about to be opened to amend funding ceilings and dates it is a propitious moment to also amend reporting requirements consistent with a revised S&T/H and IIP CA management plan. This should include as a minimum the program and budget status information recommended in IV.A.9a, b, c, d.

4 - The IIP CA administrative structure is cumbersome and communication problems appear to be substantial. At present there are functionally three not quite coequal project directors and 2 of these persons and others from within the IIP are in frequent contact with S&T/H over CA management issues. A single person with faculty rank, administrative skills and time should be designated as project director. This person should have the authority and responsibility within the terms of the CA to allocate funds within and between all CA activities, establish procedures for the working groups, resolve conflicts, assure proper technical oversight before sub-project activities are submitted to A.I.D., and be ultimately responsible to the Dean of the SHPH. This is not a full-time position but will require 30% to 50% time (time on the CA may decrease as the procedures are put in place and the CA winds down).

At IIP a full-time or near full-time project manager should carry the brunt of responsibility for day to day operations. The project director and project manager should be assisted by a project staff of no more than three full-time equivalent administrative support positions. This management unit should provide all necessary administrative support for all activities carried out in the four program areas (evaluation, vaccines, Vitamin A and Fellows). When overload situations occur, they can be

handled by overtime and the occasional use of temporary personnel.

5 - Working group coordinators and all faculty responsible for carrying out specific projects should have a clear quantitative understanding of the funds available to them and how they may be used. This is most important at this time so that Working Groups can be assured there is either sufficient time and money to complete subproject activities or to make needed adjustments now.

6 - Assuming that A.I.D. opts for a management intensity along the lines of level b (item IV.B.b3 above) then certain guidelines should be established. For example:

- Discrete new projects within the CA whose direct costs are less than \$50,000 do not require A.I.D. approval. However, they must be described in a quarterly report prior to their being initiated. If in-country contact is a part of such a project IIP is responsible for obtaining written mission concurrence for the overall activity before commencing same. Travel must still be approved but will be done on the basis of a quarterly travel plan.

- Projects costing between \$50,000 and \$100,000 require presentation to A.I.D. on a case by case basis. This will be most easily done within the context of the quarterly reporting process. However, time constraints may dictate presentation between reports. In any case all such projects must be included in the quarterly reporting process. If A.I.D. does not respond in writing in 4 work weeks the project is deemed approved. Travel and mission contact as above.

- Projects costing over \$100,000 must have the formal written approval of A.I.D..

- At any time A.I.D. reserves the right to suspend or terminate a specific CA activity. However, this right should only be exercised for good cause such as serious political objections to a project, political unrest or other sensitivity that in the judgment of A.I.D. requires suspension or termination.

Whatever guidelines are chosen by A.I.D., the essential point is they must be clear, understood by both parties and workable. This places a burden on S&T/H to develop management guidelines that are crafted to reflect the existing realities of an already seriously over burdened staff within S&T/H.

7 - S&T/H, in consultation with the contracting office, may wish to initiate an improved management process by sending the SHPH a comprehensive management letter that spells out the following:

- What must be done prior to any consideration of a change in funding ceiling (e.g. recommendations IV.A.9a, b, c, d. & IV.B.4).

- Defines the decision rules for extending the time for those few CA activities that cannot be completed by August 29, 1990. Requires IIP to identify any activities in this category and propose a specific plan for completion (e.g. amend activity and/or extend project completion date, delete activity, etc.).

- Defines IIP program and budget reporting requirements to S&T/H.

- Defines the content of the package that must be submitted to S&T/H for activities requiring requiring additional time and/or money (IV.B.10).

- Specifies and clearly defines the S&T/H project management choice (e.g. IV.B.3b or c or some defined variant, such as IV.B.6).

8 - Extramural scientific review of proposed working group activities should be required. This is basic to good science. However, the means of accomplishing such reviews may pose a policy and management dilemma for A.I.D. Finding reviewers, working with them and feeding their results back to SHPH faculty is a time consuming and technically demanding task. It is not clear that in-house staff resources are now or in the foreseeable future will be sufficient to coordinate and direct this type of extramural review. This issue doubtless extends beyond this CA and illustrates the problem of diverse and competing agendas faced by S&T/H.

A partial answer to this problem for this CA is to establish in the CA the conditions for extramural review that must be met by all or designated classes of activity. For example:

- Require the SHPH to identify non-J.H.U. reviewers and submit for approval to S&T/H the names and credentials of proposed reviewers as well as the charge to the proposed reviewers.
- After approval (or no A.I.D. comment in 2 work weeks constitutes approval) the review process commences.
- Reviewer's comments are sent simultaneously to S&T/H and IIP.
- IIP must respond to the reviewers comments in a single document that accepts or rejects each comment. If rejected the reason must be stated and if accepted note made as to how the proposed activity will be modified.
- If no A.I.D. comment in 2 work weeks, this again constitutes approval and the activity may begin.

Should a process along these lines be desirable to A.I.D., funds will be needed to support the costs of extramural review.

A.I.D. would still reserve the right to further review any activity as should be done in the case of the upcoming Vitamin A study in Indonesia.

9 - The team recommends that the CA evolve along several different lines:

- S&T/H should reaffirm that it sees the CA as a time limited vehicle.
- Contracting limitations on new activities should be explicit and clear to S&T/H and the IIP.
- Buy-ins should be carefully defined as to program content, time required and cost. Each buy-in should fall within the overall time, program and financial limits of the CA.
- Should A.I.D. wish to continue or expand support for vaccine development, consideration should be given to transferring such a meritorious activity to a vehicle more consonant with the needs of vaccine development such as the Office for International Health, Department of Health & Human Services PASA. (Please see further discussion in Section E and appendix 2.)
- Other activities such as the Fellows Program and the resource center require special consideration. Suggestions for approaching these activities are given below. (Sections C & F)
- The IIP and the working groups should be aware that they are free and encouraged to

submit unsolicited proposals outside the framework of the CA for the support of new or continuing activities.

10 - If A.I.D. chooses to support through the CA completion of selected ongoing activities (e.g. Indonesia Vitamin A study and probably the Philippines tier 3 study), this will require extending the project completion date, increasing the funding ceiling and providing additional funds. (n.b. The team wants to emphasize that it feels the Vitamin A study has worldwide policy relevance and, once technical issues have been resolved, recommends that the study be carried out in a timely manner.)

Prior to doing this a careful and comprehensive inventory of all projects underway should be rapidly completed and tight, realistic expenditure plans developed for each activity. These activities also need to be related to the capacity of the management support unit.

11 - Mission buy-ins to date (\$364,329) have been substantial and anticipated buy-ins are anticipated to greatly exceed this, perhaps approximating 50% of total funds awarded to date. Care should be taken to assure that existing and anticipated buy-ins fall within the overall program, time and financial framework of the CA.

12 - If S&T/H raises the CA ceiling and provides additional funds, care should be taken to avoid the program development problems associated with the funding to date. Specifically:

- Additional funds should be awarded for mutually agreed upon activities that are well-defined as to content, cost and time before funding. In this regard, particular attention should be given to the Vitamin A study and the Philippines tier-3 evaluation as both require more time and money than is possible within the current CA.
- The management of new funds and new activities should be subsumed within the overall CA management (see earlier recommendations in this section).

#### C - Fellows Program

1 - The concept behind the Fellows Program - providing a financial and program incentive for health professionals to gain substantial long-term overseas experience and opt for a career in International Health - is sound and from a public policy perspective is emblematic of a very desirable long term A.I.D. initiative.

2 - The Fellows Program staff have amassed considerable and valuable experience in determining placements, selecting fellows and providing ongoing support. The overseas assignments offer a longer term development of international health skills. 10 of the 16 fellows have been assigned overseas. However, only 3 of 16 fellows can be considered persons attracted to international health who otherwise might have opted for a different career path.

3 - Carefully selected and structured placements of fellows in A.I.D. or other donor agencies could have real professional development merit. However, the 5 A.I.D. agency placements to date appear to have been agency initiated with the fellows carrying out routine staff functions.

4 - The financial support available to fellows makes it extremely attractive to potential fellows. The possibility for more senior SHPH faculty to use the fellows to their advantage cannot be ignored. The limited number of fellow slots makes selection very difficult. If, as the Fellows director states, it is a national program, providing equitable access to students from other universities and other agencies must be assured.

5 - Notwithstanding the long-term future of the program, the awarding of a fellowship should assure funding for the full period of award even if problems develop with the intended overseas assignment. For the remainder of the CA the funds for fellows should be clearly separate from the funds for evaluation, vitamin A and vaccines. This will limit competition for resources between the Fellows Program and the qualitatively very different activities developed by the three working groups.

6 - Any new fellows selected for placement, if they are to complete their term of service within the framework of this CA, must have a substantially shorter overseas placement and be placed almost immediately. As additional funds are considered for this purpose, careful attention should be given to the management and planning concerns raised in section IV-B as well as the program and policy concerns in this section.

7 - The evaluation team emphasizes that the concept of the Fellows Program has great merit. It is unlikely that other funding agencies will assume a comparable responsibility for strengthening the cadre of U.S. health professionals committed to international health. Subject to the resolution of policy issues outlined below, we urge A.I.D. to continue the program. However, we emphasize S & T/H faces some difficult policy issues as it grapples with whether or not and, if so, how to continue the Fellows Program.

- If A.I.D. is to continue the Fellows Program it must be for at least 5 and preferably 10 years. This is exactly the kind of program that will be destroyed by on again, off again support.

- Some co-funding beginning in 2 to 3 years may be possible. However, this will not be easy to achieve and it is not realistic for A.I.D. to assume a fellowship program can become substantially or probably even partially self-sustaining. This implies a long-term A.I.D. central funding commitment.

- A program such as this is inappropriate to use as a vehicle to provide staff in Washington or at A.I.D. missions. The numerous other contracts, inter-agency agreements and IPA arrangements are far more appropriate for this purpose. In addition, it will not be long before someone placed in A.I.D. raises a fairness or salary discrimination issue.

- Using the Fellows Program to support foreign nationals to work in either their home country or in the US appears both unneeded and unjustified. Other US government programs and programs of other donors are intended to meet this need. Among other things, this use of fellowship funds diverts an already limited resource away from the intended beneficiaries - U.S. nationals who may be attracted to a career in international health. In this context, it would be appropriate to consider defining the precise meaning of US national with the assistance of the Office of the General Counsel.

- In any long-term follow-on fellows type program, the conditions of participation for mission buy-ins must be clearly specified to assure that buy-ins, on a case-by-case basis, do not distort the intent of the program.

- Consideration should be given to allowing mission buy-ins only if each buy-in for every fellow is matched by central funds.

- 12 to 24 month developing country placements should be a part of every fellowship. Domestic placements, though appealing to individuals and agencies, generally do not relate to the intent or make the best use of the Fellows Program.

- The relationship of a fellow to faculty research under the CA has been well linked in a number of cases. However, this need not be a pre-requisite for a successful fellowship.
- There is serious doubt that funding this program on a non-competitive basis directly to the IIP can ever handle the equity of access issues. The expanded advisory board is a small, but hardly sufficient, step toward improving this situation.
- Even if the current CA is extended, S&T/H must start now to develop a follow-on Fellows Program if it is to be ready when this portion of the CA terminates in 1990.

8 - A long-term fellows program must have a clear and easily understood set of objectives that serve several purposes:

- Give consistent long-term direction to those responsible for implementing the fellows program.
- Allow A.I.D. to easily justify long-term support for purposes of acquiring budgetary resources, answering the inevitable complaints of other universities, PVOs and firms that would like to administer such a program and to answer congressional inquiries.
- Clearly set the parameters for eligibility (e.g. master's level, pre-doctoral, post-doctoral; the mix of service and management vs. research assignments; new career vs. mid-career).
- Establish broad criteria for field placements and institutional back-up required to support fellows in the field.
- Establish criteria for internal and external evaluation.

9 - S&T/H should, if it decides long term support is merited, look for ways to preserve the IIP Fellows Program staff expertise and experience within an organizational framework that assures equity of access to potential fellows nominated by other universities, other agencies or to those who apply directly.

This could be done by establishing very clear criteria (e.g. IV.C.7) and competing the procurement. In the case of university responses, including university consortia, they would have to show very explicitly how they would meet the equity standard.

Another mechanism that should be considered is funding such a program through an agency more broadly representative of the international health community. The National Council for International Health, The Association of Schools of Public Health and the American Public Health Association are possible candidates.

A competition would allow A.I.D. to evaluate diverse responses and make a long term choice. If it is possible under the procurement regulations, the burden on potential bidders could be reduced by requesting a short concept paper or pre-bid that would form the basis for establishing a short list of invited bidders to submit full proposals.

#### D - Vitamin A

The CA activities in Vitamin A are very relevant to current A.I.D. priorities. The impression cytology findings were timely and useful. The state of the art paper is widely regarded as a significant contribution. The Vitamin A morbidity study scheduled to begin soon in Indonesia is the centerpiece of the activities of this working group and has the potential to make a major impact on Vitamin A program decisions.

1 - The Vitamin A morbidity study now planned for Indonesia has near immediate, important policy relevance for A.I.D. and the larger international health community. Specific to this activity, if it is to go forward, the end date of the cooperative agreement must be amended to allow adequate time to complete the study. Delays and complications are to be expected. Whatever time frame is proposed, we suggest adding six to twelve months as a buffer. Adequate funding is equally important. The final funding awarded for this study should have within it the equivalent of a reserve to cover the costs of delays and changes that cannot be specifically predicted or costed at this time.

2 - The Vitamin A morbidity study scheduled to begin soon in Indonesia may have some potentially serious but correctable design flaws (see appendix 3).

3 - This study stems from the prior work of a current J.H.U. faculty member and may or may not substantiate his findings. The same faculty member is an active participant on the Vitamin A Working Group. Investigators in and outside of J.H.U. may question the study findings, particularly if they support previous J.H.U. work.

4 - This study has the potential to contribute substantially to answering policy relevant questions of world-wide importance regarding the role of Vitamin A supplementation.

5 - Therefore, great care should be taken to assure that all aspects of the study design, implementation and analysis are beyond reproach.

6 - Prior to final approval of the Indonesia Vitamin A study, the research protocol should be submitted by A.I.D. to selected independent expert reviewers. In the review process particular attention should be paid to assuring rigorous attention to epidemiological detail. The readers attention is directed to appendix 3 which details some study design concerns.

#### **E - Immunizations**

1 - Appendix 2 summarizes the review of the vaccine research. Clearly this is an important component of A.I.D.'s Child Survival Program and J.H.U. has strong talent in this area. However, the team questions the appropriateness of the cooperative agreement as a funding vehicle for such research given the erratic nature of funding, competition with the activities of other Working Groups for field mission buy-ins, reliance on convincing individual countries and A.I.D. missions of the relevance of the research to specific country programs, etc. In addition, the IIP working group has not been able to integrate the social science/delivery of service aspects of immunization research with more technologically oriented research.

Therefore, the team recommends that the activities underway in the vaccine area should be completed. New activities in this area that A.I.D. may wish to support should be incorporated into the overall S&T/H vaccine research program through a vehicle more sensitive to the needs of vaccine development and testing such as the S&T/H agreement with HHS/OIH.

#### **F - Evaluation**

1 - The activities of this working group are very consonant with the mission of A.I.D. and the current Child Survival program priorities. They are an excellent example of the type of activity that should be centrally funded. It is most appropriate that this research has focused on the tier 3 level evaluations.

2 - In addition to completing activities underway in the evaluation area, S&T/H with the IIP should consider ways to disseminate findings, methods and information generated by evaluation projects

not only to the academic community but also to individuals and agencies responsible for the planning, management and evaluation of international health programs worldwide. Although findings are only now becoming available, plans for dissemination are weak.

3 - The resource center begun by the Evaluation Working Project has been the recipient of considerable front-end development. However, development came to a near standstill just as the resource center's potential was about to be tested. S&T/H and IIP should seriously consider:

- finishing the development of this project
- finding a long term home for the center such as the Welch Medical Library or another location within the SHPH that has a long-term commitment to the gathering, cataloging and retrieval of health related information
- define a modest but sufficient operating budget
- consider ways to assure long-term survival of this activity

Funding might come from the CA for completion of development and initial operation and user fees for ongoing support. Alternatively, if the resource center is as valuable as it appears, the IIP and medical library might seek support from other donors. A way to stimulate the development of multi-donor support would be for A.I.D. to agree to match funds from other donors up to a specified dollar limit.

#### V - CONCLUSION

The IIP is an established entity at the SHPH and the CA has played a central role in getting the IIP established. The CA has contributed substantially to the development of a focus of interest at the SHPH on Child Survival activities. The team directs the reader to the full narrative for more detail. However, in brief we recommend:

- Prior to any change in CA funding or project completion date, Immediate strengthening of management and clarification of roles and responsibilities by the SHPH and S&T/H is a priority.
- Selectively augmenting the funding of the CA from central funds and mission buy-ins to complete carefully defined and critical activities.
- We reemphasize the importance of the Vitamin A study and recommend, specific to this study, amending the end-of-project date and providing adequate funding.
- Prior to approving field work, reviewing with care and in close collaboration with the mission the upcoming Indonesia Vitamin A study.
- Planning for a new fellows program with much clearer and more specific objectives and funded in a manner that assures equitable access to participants from all institutions should begin now.
- Any new immunization activities contemplated by A.I.D. should be considered for funding under the auspices of a more appropriate vehicle such as the S&T/H agreement with HHS/OIH. Planning for the funding and management of such activities should begin now.
- In the time remaining in the CA efforts should be made to disseminate results from the evaluation group.

- Reviewing all activities now underway to assure that they can be completed within the framework of available funds and time.

- END -

**VI - APPENDICES**

- 1 - Scope of Work
- 2 - Immunization Working Group Review by Dr. William Jordan Jr.
- 3 - Vitamin A Protocol Comments by Dr. Larry C. Clark
- 4 - Institute for International Programs Organization chart
- 5 - Advisory Council
- 6 - Immunization Working Group
- 7 - Evaluation Working Group
- 8 - Vitamin A Working Group
- 9 - International Child Survival Fellowship Program Advisory Committee
- 10 - Projects completed, underway and pending

MID-TERM EVALUATION  
COOPERATIVE AGREEMENT IN CHILD SURVIVAL  
SCOPE OF WORK FOR EVALUATION TEAM

PURPOSE:

The purpose of the mid-term evaluation is to assess the progress that has been made towards meeting the expectations laid out in the Cooperative Agreement (CA), identify any problems that need attention and make recommendations to USAID about appropriate next steps.

PROCESS:

A team of specialists external to the Office of Health will conduct the evaluation. They will be supported by USAID officials and consultants familiar with the history and current status of the CA. Written materials on the CA will be made available prior to the site visit to JHU. Between two and three days will be spent by the team at JHU holding discussions with faculty and staff of the University. Following this, the team will prepare a draft written report of their findings and recommendations and will conduct a de-briefing at USAID. JHU will be given the opportunity to comment on the team's report before it becomes final.

ISSUES CONCERNED WITH THE RESEARCH COMPONENT:

USAID is particularly interested in the team members' views on a number of issues related to the research component of the CA.

1. To what extent and in what ways will the research activities being undertaken and/or planned contribute to child survival programs?
2. Does the selection of research activities reflect the criteria set out in the Cooperative Agreement? Are the priorities that have been established appropriate? Is the mix of research activities appropriate?
3. What comments do evaluation team members have about specific research protocols?
4. How successful has JHU been in working with research institutions in developing countries?
5. How successful has JHU been in identifying field sites and mounting field research efforts?

25

6. How does the research and the fellows components of the CA interact and what synergy is occurring?
7. What are the team's observations about the Cooperative Agreement as a catalyst for child survival?
8. How successful has JHU been in disseminating the results of the research?

ISSUES CONCERNED WITH THE FELLOWS COMPONENT:

The issues listed below have been identified as being especially pertinent to the Fellows component:

1. To what extent does the Fellows Program meet the larger purpose of USAID's Child Survival Program - to strengthen the delivery, use and effectiveness of child survival technologies and programs?
2. To what extent does the Fellows Program fulfill the training expectations described in the Cooperative Agreement?
3. What is the team's opinion on the calibre of the Fellows, the geographic and functional distribution of their assignments, and the potential that the Fellows will continue to contribute to the field once their fellowships are over?
4. Is there a need to recruit more people into careers that will contribute to child survival? If so, is the Fellows Program a good and cost-effective way to do this?

ISSUES CONCERNED WITH INSTITUTIONAL/ADMINISTRATIVE MATTERS:

The issues under this heading are as follows:

1. Does it seem to the team to be appropriate for JHU to use the funds made available through the CA to establish the IIP? How sustainable is the IIP?
6. How successful has JHU been in attracting other sources of funds (both within and outside USAID) to support child survival activities?
2. How successful has JHU been in establishing IIP as a focal point for coordination of child survival activities within the university?

4. How well does the concept of Working Groups serve the CA? Are the Working Groups appropriately designated, organized and staffed?

3. Are there issues of which USAID should be aware as regards staffing? Is the IIP appropriately staffed? Are staff and faculty appropriately committed to activities under the CA?

4. Are there suggestions that the team would like to make as regards the organizational structure of IIP?

5. Overall, is the CA an appropriate use of USAID child survival funds?

67

Hopkins IIP CSCA  
Immunization Working Group Review

The Immunization Working Group (IWG) is committed to improving the delivery and effectiveness of existing vaccines and to the testing of new vaccines in the developing world. This requires that vaccines produced in the sophisticated laboratories of the developed world be tested at those sites, and under those conditions in the third world where they have the potential of being added to routine immunization programs. This requirement places great demands on the skills of the investigator and her/his collaborating international agencies. Permission must be obtained to conduct studies in a given country and funds must be formed to support the personnel, equipment, travel, laboratory test, etc. needed both at home and abroad. The CSCA between USAID and IIP was designed for this purpose. Each of the partners can claim credit for successes; each must share responsibility for failures. There have been both.

The coordinator of the IWG is Neal A. Halsey, M.D., an acknowledged leader in this field. The 10 other members of the IWG are also outstanding in their respective disciplines of immunology, pediatrics, ect. and many have learned of third world problems first hand. The IWG shares overlapping interests with and can draw on the experience of the NIH funded Center for Vaccine Development at Hopkins and a similar center at the University of Maryland. During a series of meetings, the IWG developed a mechanism for establishing its research priorities, doing so with full knowledge of priorities set by other national (CDC, NIAID) and international (PAHO, WHO) agencies, particularly the WHO EPI Research and Development Group.

The IWG has experienced its share of exasperation and frustration. Polished protocols have fizzled as false starts. For example, over two years were spent designing and planning trials of two different vaccines in India before both A.I.D. and IIP acknowledged that they could not surmount bureaucratic processes in that country. Other proposals failed or were delayed because A.I.D. Washington did not have funds and advised IWG to seek support from A.I.D. missions in the countries in question. The timeliness and effectiveness of this mechanism requires a separate evaluation.

For these and other reasons, the IWG has completed only two projects:

Childhood Survival in Haiti: The Protective Effect of Measles Vaccination. This retrospective study of 1499 children born October 1981 through April 1982 to women residing in Cite Soleil, Haiti, in 1986 showed that 99.17% of infants 9 through 39 months of age given measles vaccine survived as compared to 93.4% not given vaccine. Of particular interest was the demonstration that unvaccinated children born to literate mothers with knowledge of oral rehydration, a birth interval of greater than 24 months, and a high socio-economic status had virtually the same survival rates as vaccinated children. The fact that this observation could be made testifies to the skill with which the study was designed, but raises other questions about the comparability of the groups.

The Case for Routine Hepatitis B Immunization in Infancy for Populations at Increased Risk. This comprehensive review (Pediatr. Inf. Dis J. 6:11-19, 1987) by Drs. Smejo and Halsey will be of great assistance to all those considering this timely question.

Two projects are in progress:

Evaluation of the Effectiveness of Low-Dose Intramuscular and Intradermal Hepatitis B Vaccine in Healthy Neonates. Intradermal administration of HBV vaccine has worked in adults; it is now being tested in children. The amount, and thus the cost, of vaccine needed would be reduced by 90% should this approach be successful. Trials in U.S. infants in Baltimore must, depending on outcome, be followed by trials at selected EPI sites.

A Comparison of Edmonston Zagreb (Yugoslavian) and Schwarz (Merieux) Measles Vaccines in Haitian Infants This is one of several proposed or ongoing trials in Mexico, Zanzibar, Senegal, Togo, Peru, and Turkey. The question is important and it is important that studies be conducted in a number of settings. The ability to effectively immunize children under 9 months of age would represent a major step in the control of measles.

Nine Projects are under development; all have been endorsed by the IWG, all are meritorius. However, there are insufficient funds and time within the CA to complete these. Unfortunately, the CA may not be the most appropriate vehicle for funding immunization research over the long term. The team recommends new vaccine research through JHU be incorporated into the overall S & T research program.

PREPARED BY DR. WILLIAM JORDAN, JR. JUNE 1988

Appendix 3

LETTER RECEIVED FROM DR. CLARK BY ELECTRONIC MAIL  
RE: PROPOSED INDONESIA VITA STUDY PROTOCOL.

June 3, 1988

William Bicknell  
85 Antrim St.  
Cambridge, MA 02139

Dear Bill:

I have briefly reviewed the "Proposal to Assess the Impact of Vitamin A Supplementation on the Reduction of the Incidence and Duration of Episodes of Morbidity among Children Aged 6-60 Months in Indonesia" by Michele R. Forman at your request. While this study is extremely important the protocol needs to be revised to consider an number of important issues prior to its implementation.

The issues which I believe need to be addressed and considered further by the investigators are summarized below in the order by which they appear in the proposal:

1. The specific hypothesis which will be tested need to be explicitly stated and ordered in terms of importance. The statement needs to include the operational definition of the disease states which will be used to calculate incidence rates and duration of illness. Stating that they will investigate "diarrheal and respiratory disease" lacks specificity. The number of potential hypothesis which could be tested in this trial is large enough to destroy the power of the trial when the necessary adjustment for multiple comparisons are made.
2. (page 3) Consideration of confounding in epidemiologic studies is often confusing. The statement of the investigators that the association of VA with morbidity may be due to confounding

with stunting and wasting illustrates a lack of appreciation of the difference between confounding and effect modification, and what factors have a chance association with morbidity and vitamin A status (confounding) and which are in the causal pathway. This difference is important in terms of analytic strategies and the interpretation of the results.

3. (page 4) The discussion of other important covariates is incomplete.
4. (page 5) In a confirmatory study the statistical model which will be tested must be stated explicitly prior to exploration of the data. To state that hypothesis will be tested before and after adjustment seriously weakens the interpretation of the trial.

In a randomized trial adjustment for covariates is not necessary unless the randomization fails, subgroup analysis are to be performed, or there are secondary hypothesis which relate to the covariates in the model. The decisions on subgroup analysis and secondary hypothesis are best made prior to the formal analysis unless they are for exploratory rather than hypothesis testing purposes.

5. (page 5) The inclusion and exclusion of children as they reach a critical age needs further discussion to justify that their is not a cumulative effect of time on study on outcome. Would not enlarging the sample size initially and following all kids for two years be a preferable approach?
6. (page 6) The study site description is inadequate for anyone not familiar with Indonesia.
7. (page 7) The introduction of children into the trial as they move into the study area may introduce a bias as these children are likely to be different from children who are longer term residents of the village.
8. Children with clinical symptoms of vitamin A deficiency who are treated with VA should be randomized into a separate stratum in



order to insure balance and so that valid subgroup analysis can be done with these children.

9. Stratified randomization on age is appropriate, however by using time block randomization, and using a sequential geographic pattern for randomization the need to randomize by distance from the clinic is eliminated. This will simplify any analysis.
10. Randomized time blocks must be divisible by the number of treatment groups therefore units of size 6-9 contain invalid time block sizes. I would consider using smaller time blocks considering the number of strata within which children will be randomized. Will all the time blocks be complete?
11. (page 9) The planned sample size for the trial needs to be determined and explicitly stated, as does the actual power of the study. Will it be 80% or 90%? The desired power of the trial should not be an issue of relative incidence of the outcome of interest. The sample sizes range over ten fold for incidence measures and 3 fold for duration endpoints.
12. The description of the conjunctiva impression cytology is inadequate, out of date, and the references are biased regarding the actual reported usefulness and validity of this technique. The reference on this should be updated and a protocol established which will determine the validity and usefulness of the procedure in identifying marginal vitamin A status.
13. The assessment of VA status does not include an assessment of plasma carotenoid status which is an important determinate of VA status in marginal populations. Characterization of parasitic infections is also a potentially important determinate of VA status and should be included in the protocol, with particular reference to the effect of treatment.
14. The supplementation regimen is not adequately characterized since the actual formulation and composition of the capsule is not described nor is the manufacturer, or its stability in the

23

tropics described. The actual method of child identification, and randomization needs to be described further.

15. The justification for including an active placebo needs further attention. Will children under one receive half the placebo dose ?
16. (page 13) Why not have both conjunctival impressions and blood sera drawn on the same patients in the pilot study?
17. (page 14) What is the estimated time period during which enrollment will be done.
18. More thought should be given to the proposed postponement of the VA regime for sick children since these are the children who may need it the most. It may also complicate the analysis of time to episode of disease and duration of disease.
19. (page 16) What percent of measurement will be rechecked.
20. Quality control issues deserve more considerations and discussion.
21. (page 18) The analysis section should contain the specific models which will be considered include a discussion of adjustments for the multiple comparisons which will be made of all the potential hypothesis that could be investigated in this trial.
22. Consideration should be given to interim and sequential analysis of the data, since if important difference occur it may be possible to report them prior to the end of the 2 year trial.
23. An external safety and monitoring committee should be appointed to advise the trial investigators.
24. Was the issues of routine vaccination of the participants addressed in the protocol? If not this needs to be discussed for obvious reasons including the nature of the hypothesis

being tested.

In summary this study is potentially an extremely important trial which is likely to have great influence on determining the structure of future child survival programs. Adequately addressing the issues raised in this review should help the trial meet its important goal and decrease the potential controversy which may meet the results of this trial.

I know that this is a very brief review but I hope that it can provide you with more information which would assist you in your review of this important program. Please feel free to contact me if you require further clarification on any of the points which I have raised.

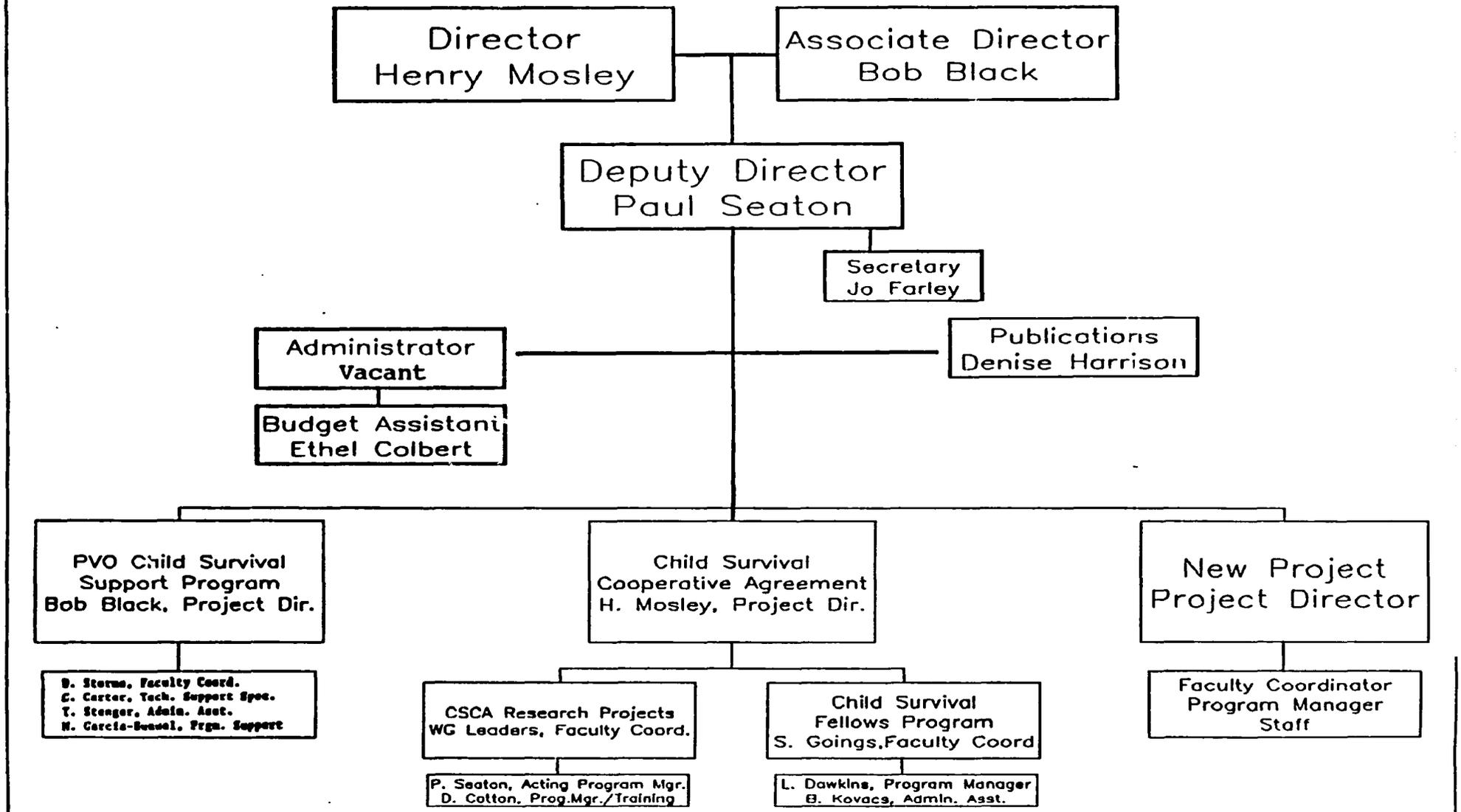
Sincerely yours,

Larry C. Clark, M.P.H., Ph.D.  
Assistant Professor of Epidemiology

37

# Institute for International Programs Organization Chart

MAY 1988



ADVISORY COUNCIL

Donald A. Henderson, MD, MPH  
Dean, School of Hygiene and Public Health  
Hygiene - 1041  
955-3540

John G. Bartlett, MD  
Div. of Infectious Diseases  
JHH/Blalock - 1111  
955-3150

Phyllis T. Piotrow, PhD  
Population Information Program  
Hampton House - 827  
955-8200

Ronald T. Burkman, MD  
JHPIEGO/Dept. of OB/GYN  
Harvey/JHH - 310  
955-2147

B. Frank Polk, MD, MSc  
Dept. of Epidemiology  
Hygiene - 6021  
955-3019

Edward A. Emmett, MBBS, MS  
Dept. of Environ. Hlth. Sci.  
Wyman Park Health Services, Bldg. 6  
338-3501

Moses B. Pounds, PhD  
Dept. of Behav. Sci. & Hlth. Educ.  
Hampton House - 755  
955-2312

Ronald H. Gray, MBBS, MFCM, MSc.  
Dept. of Population Dynamics  
Hygiene - 4503  
955-7818

William A. Reinke, PhD  
Dept. of International Health  
Hygiene - 2509  
955-3928

Rosalyn C. King, Pharm. D., MPH  
Director, Office of International Health  
Charles R. Drew Postgraduate Med. Sch.  
7923 Eastern Avenue, Suite 700  
Silver Spring, MD 20910  
(301) 649-6696

Noel Rose, MD, PhD  
Dept. of Immunology and Inf. Dis.  
Hygiene - 4013  
955-3459

A. Marshal McBean, MD, MSc.  
Dept. of Health Policy and Mgmt.  
Hygiene - 4033  
955-8110

R. Bradley Sack, MD, ScD  
Dept. of International Health  
Hygiene 5509  
955-6931

James F. McCarthy, PhD  
Dept. of Population Dynamics  
Hygiene - 4517  
955-7803

Alfred Sommer, MD, MHS  
Dept. of Ophthalmology  
Wilmer/JHH - 120  
955-6931

Matthew Tayback, ScD  
Dept. of Medicine  
Harvey/JHH - 402  
955-2748

**IMMUNIZATION WORKING GROUP**

**IMMUNIZATION COORDINATOR**

Neal A. Halsey, MD  
Dept. of International Health  
Hygiene - 5515  
955-6964

Joan Aron, PhD  
Dept of Population Dynamics  
Hygiene - 4501  
955-7821

Noel Rose, MD, PhD  
Dept. of Immunol. and Inf. Dis.  
Hygiene - 4013  
955-3459

Robert E. Black, MD, MPH  
Dept. of International Health  
Hygiene - 5939  
955-3934

David Sack, MD  
Dept. of International Health  
Hygiene - 5503  
955-6931

Mary Lou Clements, MD  
Dept. of International Health  
Hampton House - 105  
955-4054

Mathuram Santosham, MD  
Dept. of International Health  
Hygiene - 5503  
955-6931

Karen Midthun, MD  
Dept. International Health  
Hampton House - 105  
955-4362

Mark Steinhoff, MD  
Dept. of International Health  
Hygiene - 5515C  
955-6964

John Modlin, MD  
Dept. of Pediatrics  
JHH/CMSC - 1102A  
955-3271

Timothy Townsend, MD  
Dept. of Pediatrics  
JHH/Brady - 117  
955-8384

Frank Polk, MD, MSc  
Dept. of Epidemiology  
550 Bldg - 701  
955-3019

**14\*Members. IWG**

EVALUATION WORKING GROUP

EVALUATION COORDINATOR

Ronald H. Grav, MBBS, MFCM, MSc.  
Department of Population Dynamics  
Hygiene - 4503  
955-7818

Members

Frank Baker, PhD  
Dept. of Behav. Sci. and Hlt. Educ.  
Hampton House - 755  
955-2312

Kenneth Hill  
Population Dynamics  
Hygiene - 4506  
955-7816

Timothy Baker, MD  
Dept. of International Health  
621 N. Washington St.  
955-3734

W. Henry Mosley, MD, MPH  
Dept. of Population Dynamics  
Hygiene - 4041  
955-3260

Peter A. Berman, PhD  
Dept. of International Health  
Hygiene - 2509  
955-3928

Moses B. Pounds, PhD  
Dept. of Behav. Sci. and Hlt. Educ.  
Hampton House - 755  
955-2312

Robert E. Black, MD, MPH  
Dept. of International Health  
Hygiene - 5039  
955-3934

Debra Schumann, PhD, MPH, MA  
Post Doctoral Fellow  
Hygiene - 2604  
955-7898

Kenneth H. Brown, MD  
Dept. of International Health  
Hygiene - 2014  
955-2786

Gordon S. Smith, MD  
Dept. of Health Policy and Mgmt.  
Hygiene - 4027  
955-7980

Anouch Chahnazarian, PhD  
Dept. of Population Dynamics  
Hygiene - 4503C  
955-7819

Moyses Szklo, MD, PhD  
Dept. of Epidemiology  
Hygiene - 6009  
955-3462

Scott Zeger, PhD  
Dept. of Biostatistics  
Hygiene - 3505  
955-7133

VITAMIN A WORKING GROUP

VITAMIN A COORDINATOR

Kenneth H. Brown, MD  
Dept. of International Health  
Hygiene - 2041  
955-2786

MEMBERS

Robert E. Black, MD, MPH  
Dept. of International Health  
Hygiene - 2041  
955-3934

W. Henry Mosley, MD, MPH  
Dept. of Population Dynamics  
Hygiene - 4041  
955-3260

Michele Forman, PhD  
Dept. of International Health  
Hygiene - 2041  
955-3260

R. Bradley Sack, MD, ScD  
Dept. of International Health  
Hygiene - 5509  
955-6931

Ronald H. Gray, MBBS, MFCM, MSc.  
Dept. of Population Dynamics  
Hygiene - 4503  
955-7818

Alfred Sommer, MD, MHS  
Dept. of Ophthalmology  
JHH/Wilmer - 120  
955-2029

Lawrence Grossman, PhD  
Dept. of Biochemistry  
Hygiene - 8013  
955-3671

James M. Tielsch, PhD  
Dept. of Ophthalmology  
JHH/Wilmer - 120  
955-2029

Neal A. Halsey, MD  
Dept. of International Health  
Hygiene - 5513  
955-6964

Keith West  
Dept. of Ophthalmology  
JHH/Wilmer - 120  
955-2061

INTERNATIONAL CHILD SURVIVAL FELLOWSHIP PROGRAM

ADVISORY COMMITTEE

W. Henry Mosley, MD, MPH  
Dept. of Population Dynamics  
Hygiene - 4041  
955-3260

Robert E. Black, MD, MPH  
Dept. of International Health  
Hygiene - 5039  
955-3934

FACULTY SUPERVISOR

Stella A.J. Goings, MD  
Dept. of International Health  
Hygiene - 5514  
955-6964

PROGRAM MANAGER

Ms. Jo-Anne Dawkins, MHSA  
621 N. Washington St.  
955-1239

ADMINISTRATIVE ASSISTANT

Ms. Brenda Kovacs  
621 N. Washington St.  
955-1239

Appendix 10

A=completed, B=underway, C=pending, 0=not a product

EVALUATION

B Haiti-3  
B Bangladesh 3  
B Philippines 3  
A Oman survey  
B Indonesia Utiliz.  
A Methods Workshop  
B Verbal Autopsy  
A QA  
B Interview Survey  
B Rapid Ethno  
B Resource File\*

\*Suspended

IMMUNIZATION

B Low Dose Hep B in US  
B Zagreb vs. S. Haiti  
0 Low Dose Hep. B article  
A Measles Vac & Child Survival

VITAMIN A

A Conj. cytology  
A State of Art paper  
A Indonesia feasibility  
B Bangladesh Diarrhea  
C Indonesia Morbidity

# Institute for International Programs Organization Chart

November 1987

