AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT DATA SHEET

1. TRANSACTION CODE
   A = Add
   C = Change
   D = Delete

2. COUNTRY/ENTITY
   WORLDWIDE

3. PROJECT NUMBER
   936-5952

4. BUREAU/OFFICE
   S&T/Health

5. PROJECT ASSISTANCE COMPLETION DATE (PACD)
   MM, DD, YY
   10/30/91

6. PROJECT TITLE (maximum 40 characters)
   Applied Diarrheal Disease Research

7. ESTIMATED DATE OF OBLIGATION
   A. Initial FY 1985
   B. Quarter
   C. Final FY 1990

8. COSTS ($000 or equivalent $1 = )
   A. AID Appropriated Total
   (Grant) S&T 575
   (Loan) (Grant) Other
   Other
   TOTAL $12,500

9. SCHEDULE OF AID FUNDING ($000)
   A. APPROPRIATION
   B. PRIMARY PURPOSE CODE
   C. PRIMARY TECH. CODE
   D. OBLIGATIONS TO DATE
   E. AMOUNT APPROVED THIS ACTION
   F. LIFE OF PROJECT
   (1) U 513 590
   (2)
   (3)
   (4)
   TOTALS

10. SECONDARY TECHNICAL CODES (maximum 6 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 450 characters)
   To support country-specific applied research to adapt new and improved technologies for the control and prevention of diarrheal diseases in particular country settings.

14. SCHEDULED EVALUATIONS
   Interim 09/87 09/90
   Final

15. SOURCE/ORIGIN OF GOODS AND SERVICES
   A. Provider
   B. Type

16. AMENDMENTS/NATURE OF CHANGE PROPOSED

17. APPROVED BY
   Signature
   Title
   Date Signed

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

AID 13504 (8-79)
Project Authorization

Name of Country: Interregional       Project Title: Applied Diarrheal Disease Research

Project Number: 936-5952

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the "Applied Diarrheal Disease Research Project" involving centrally funded planned obligations not to exceed $9.5 million in grant funds over a six year period from the date of authorization, subject to the availability of funds in accordance with the A.I.D. OYB/allotment process, to help in financing foreign exchange and local currency costs for the project. This project may also include such additional funding as may be made available for this purpose by Regional Bureaus and A.I.D. Missions.

2. The project will apply the findings from state-of-the-art diarrheal disease research (DDR) to diarrheal disease control programs in LDCs by supporting country specific applied research. The project will assist in the design and implementation of applied research activities with technical assistance, a competitive small grants programs, and modest institutional support for small scale research centers.

3. The agreement(s) which may be negotiated and executed by the officer(s) to whom such authority is delegated in accordance with A.I.D. regulations and Delegations of Authority shall be subject to the following terms and conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

4. Source and Origin of Commodities, Nationality of Services
   a. Commodities financed by A.I.D. under the project shall have their source and origin in the cooperating country* or the United States except as A.I.D. may otherwise agree in writing. Except for ocean shipping, the suppliers of commodities or services shall have the cooperating country or the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

* Each country where research, training, technical, or other assistance takes place under the project shall be deemed to be a cooperating country for the purpose of permitting local cost financing of goods and services for the activity being conducted in such country.
b. Ocean shipping financed by A.I.D. under the project shall, except as A.I.D. may otherwise agree in writing, be financed only on flag vessels of the United States.
ACTION MEMORANDUM FOR THE AGENCY DIRECTOR FOR HEALTH AND POPULATION

FROM:  S&T/H, Ann Van Dusen

SUBJECT: New Applied Diarrheal Disease Research Project

Action: To authorize a new six year project, Applied Diarrheal Disease Research (936-5952), at an estimated total cost not to exceed $9.5 million.

Discussion: Oral rehydration therapy (ORT) for controlling mortality due to diarrheal disease is one of a select group of primary health care interventions that AID is promoting. AID is currently one of the largest donors to ORT programs worldwide. The current ORS formulation, however, is but a single intervention in the campaign against this massive world problem. New oral rehydration solutions promise more rapid absorption of electrolytes, and longer shelf life. Oral rehydration solutions are also being developed that promise to reduce the effects of malnutrition during episodes. On the side of prevention of diarrhea new campaigns to promote changes in health behaviors have implication for many health sector and nutrition goals. Several new vaccines supported by AID also promise to reduce the incidence of diarrheal disease. In order to ensure that national diarrheal disease control programs will be able to profit from these new technological and scientific advances, A.I.D. must now launch a parallel effort to develop the techniques and personnel that will be needed to adapt these advances to the needs of particular countries and programs.

To accomplish this, the project will complement A.I.D.'s contributions to research activities at the International Center for Diarrheal Diseases Research, Bangladesh and the Diarrheal Diseases Control Program of the World Health Organization by supporting a competitive grants research program, focusing on problem-solving research in on-going programs of diarrheal disease control, by focusing on strengthening LDC institutions to conduct diarrheal diseases research in a small number of high infant mortality rate (IMR) nations and by providing technical assistance to conduct research and improve institutional capabilities.

A cooperating agency (C.A.) will be selected competitively to serve as the principal technical resource for diarrheal disease control research activities funded by AID, and assist AID in identifying, monitoring, implementing and reviewing project activities. The C.A. will rely on an expert Technical Advisory Group (TAG) which will assist A.I.D. in establishing project priorities; developing new activities; reviewing proposals;
providing technical assistance; and evaluating projects. Three broad areas have been outlined above: technical assistance, research, and institutional support.

Thirty-five AID Missions have responded favorably to the development of this project.

S&T anticipates funding this project at approximately $9.5 million over a 6 year period. An additional $3 million is expected to be made available from Regional Bureau and Mission funds over the life of project.

Recommendation: That you approve this project and sign the attached authorization. The require Advice of Program Change has been prepared and is in the clearance process. This project was approved by the Health Sector Council on April 4, 1985.

Attachment: a/s

Clearances:
ST/H, W. Oglesby 7/29/85 Date 7/29/85
ST/T/PO, G. Eaton 9/23/85 Date 9/23/85

S&T/CKendall:3/22/85:2319t:235-9649
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Attachments:

Logframe
Budget
List of African Institutions and Scientists
<table>
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<tr>
<th>Abbreviation</th>
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<tr>
<td>ADDR</td>
<td>Applied Diarrheal Disease Research</td>
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<tr>
<td>DDC</td>
<td>Diarrheal Disease Control</td>
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<td>DDR</td>
<td>Diarrheal Disease Research</td>
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<td>CDD</td>
<td>Diarrhoeal Diseases Control Programme</td>
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<td>C.A.</td>
<td>Cooperating Agency</td>
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<td>ICDDR,B</td>
<td>International Centre for Diarrhoeal Diseases Research, Bangladesh</td>
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<tr>
<td>ORS</td>
<td>Oral Rehydration Solution</td>
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<tr>
<td>ORT</td>
<td>Oral Rehydration Therapy</td>
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<tr>
<td>TAG</td>
<td>Technical Advisory Group</td>
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<td>WHO</td>
<td>World Health Organization</td>
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2339u
1. Summary

The Bureau for Science and Technology proposes a new six-year project, Applied Diarrheal Disease Research (ADDR), 936-5952, at an estimated cost of $12.5 million.

This project is designed to adapt and apply the findings from state-of-the-art diarrheal disease research (DDR) to LDC diarrheal disease control (DDC) programs through country-specific applied diarrheal diseases research. This project will assist in the design and implementation of such research with technical assistance, a competitive small grants program, and modest institutional support for small-scale research centers.

The large number of diarrheal diseases constitute a continuing threat to the well-being of children throughout the world. These diseases cause an estimated 5 million deaths and one billion episodes of disease each year. Oral rehydration therapy, a treatment that is safe and effective for use by mothers in the home and which has been heavily supported by A.I.D., has already made significant inroads in preventing deaths due to acute dehydrating diarrheas.

New knowledge of diarrheal disease agents, their transmission, and advances in immunology and vaccine development suggest that it is possible to prevent many episodes of diarrheal disease and bring about a further drastic reduction in morbidity and mortality. Promising additional innovations are:

- improved oral rehydration solutions
- active feeding during diarrheal episodes
- the use of media to change the treatment of diarrhea in the home and clinic
- the discovery of the role of micronutrients such as vitamin A in preventing diarrheal disease mortality
- the discovery of the relationship between measles and diarrheal disease.

These are examples of potential new approaches to improving treatment that need field testing and promotion. Our experience with ORT and other improvements in disease prevention and treatment suggests that for such innovative practices to be effectively and rapidly transferred to developing countries, there needs to be country specific
applied research. Such research can serve a number of important purposes. These include making the local medical community aware of the utility and feasibility of a new health approach in the specific country; the discovery of required modifications in approach or practice to meet local conditions; requirements for logistical support; personnel training or informational materials; and identification of necessary or promising areas for further research. Many of the innovations to be promoted are the result of A.I.D. investment in basic and applied research at the International Center for Diarrheal Diseases Research, Bangladesh (ICDDR,B) and the Diarrheal Diseases Control Program of the World Health Organization (WHO/CDD). In order to ensure that national diarrheal disease control programs will be able to profit from these new technological and scientific advances, A.I.D. must now launch a parallel effort to develop the techniques and personnel that will be needed to adapt these advances to the needs of particular countries and programs.

The project will draw upon the technical resources of a cooperating agency (C.A.) with special expertise in research, training, and technical assistance in diarrheal disease control programs, and upon an expert Technical Advisory Group. The C.A. will participate in, oversee and monitor a complex program of research, disseminate the findings of research, and provide general technical assistance. It is essential that the C.A. not only have technical expertise in the area of diarrheal disease control programs, but also have demonstrated experience in research implementation and management in LDC's. Such experience is essential to maximize the efficiency and effectiveness of the project, to insure that important linkages between project activities are developed and maintained, and to ensure that research and program support activities are coordinated with other organizations funding and conducting similar activities. A Technical Advisory Group (TAG) will be established to provide advice to the C.A. and project manager. It will assist in establishing priorities, developing new activities, reviewing proposals and evaluating project activities.

Some activities in support of the overall project goal and purpose such as, for example, surveys, training, and operations research may be carried out through collaboration with existing technical resources established under current A.I.D. contracts and agreements.

2. BACKGROUND

Diarrheal disease—1,100,000,000 episodes (in the world excluding China) causing an estimated 5,000,000 infant deaths
each year -- is one of the world's greatest scourges. Diarrheal disease has many other more indirect but significant consequences. For days and weeks after a diarrheal episode, due both to the disease process and in some cases the treatment itself, absorption of nutrients can be affected. Malnutrition predisposes a child to diarrhea, and diarrhea in turn creates malnutrition, creating a cycle that often results in death. Even when dehydration due to diarrhea doesn't cause death, the nutritional consequences of diarrheal disease have been amply demonstrated. Much of the stunting that characterizes children's growth in LDC's can be attributed to diarrheal disease. Much of this lost growth may never be regained.

High mortality due to diarrheal disease may inhibit family planning when parents believe they must have many children to guarantee that some will survive to adulthood. High morbidity overwhelms clinic and scarce hospital staff and resources. Paradoxically, high morbidity and mortality also undermine faith in medicine and national health systems, and LDC parents often feel pressed to use all locally available (including bogus and unhealthy) health systems and self-treatment.

The cost of treatment of diarrheal diseases is high—in time and financial resources—for a disease that is estimated to strike each child under 5 years in LDC's an average of three times a year. In most LDC's diarrheal disease is either the first or second most frequently treated disease in clinics and hospitals. It is clear that research to identify effective preventive strategies and more cost-effective approaches to treatment is a high priority for A.I.D.

Finally, inappropriate therapies for diarrhea abound. Folk remedies such as lead oxide purgatives are highly toxic and can kill children outright. Antibiotics may be more benign, but they are ineffective for most agents of diarrhea and their use accelerates the development of resistant strains of pathogens such as the new multiple-resistant strains of Shigella throughout the world.

A.I.D.-sponsored research has already played a crucial role in the development of oral rehydration therapy (ORT) through support for the International Center for Diarrheal Disease Research, Bangladesh (ICDDR,B). The current success of oral rehydration therapy is built on twenty years of biomedical, health services and medical social science research. The outcome of this effort has been a cost-effective, easily deliverable diarrheal disease treatment—oral rehydration therapy—that has been successful in lowering infant mortality due to common causes of acute diarrheal disease.
Oral rehydration therapy is based on the mixing and administration in the home, clinic or hospital of a special solution that restores the body's balance of electrolytes. Because of the availability of a low cost, easily deliverable remedy for dehydration, diarrheal disease control was selected by Walsh and Warren in 1980 as one of a special set of selective primary health care programs. These selected approaches to improving health promise to reach a population of children never before touched by cosmopolitan health care systems or water and sanitation programs. This promise has only been partially fulfilled. The massive extension of coverage needed to reach all the episodes of diarrheal disease has forced extensive and ongoing rethinking of existing delivery, monitoring, supervision, and health education and promotion strategies.

The current ORT formulation, moreover, is but a single intervention in the campaign against this massive world problem. New oral rehydration solutions promise more rapid absorption of electrolytes, and longer shelf life. Oral rehydration solutions are also being developed that promise to reduce the effects of malnutrition during episodes. On the side of prevention of diarrhea new campaigns to promote changes in health behaviors have implication for many health sector and nutrition goals. Several new vaccines supported by AID also promise to reduce the incidence of diarrheal disease. The technology of delivery, however, has not kept pace with these technologies. Current Expanded Program on Immunizations (EPI) coverage - one of the most successful of the selective primary health care programs - is 25% of children less than five years of age. Research is required to develop effective diarrheal disease control programs both curative and preventive in scope which can reach the largely untreated and neediest portion of the population that does not now have access to health care. ORT alone, especially when applied through inefficient delivery systems, will fall short of what can be done in diarrheal disease control. Applied research focused on the problems of actual delivery of diarrheal disease control programs is urgently needed. Much more work, for instance, needs to be done on improving health education and promoting health behavior change, on evaluation, and on program planning and supervision.

Health services delivery for diarrheal disease control is inadequate in many countries because empirically oriented problem-solving management approaches are not used. This approach requires scientists and program managers to adapt programs to local needs. The research grant program will encourage LDC health workers to focus on improving the design and management of diarrheal disease control programs.
Technical assistance will be provided to upgrade the capabilities of selected institutions where it can be shown that modest investments are likely to have a major impact on the ability of the institution to conduct program-oriented research. Where a major strengthening activity is warranted, the mission or regional bureau will be expected to "buy-in" to the program.

Support for research into diarrheal disease is found in A.I.D.'s Health, Nutrition and Co-Financing Policy Papers. A.I.D.'s Health Policy Paper emphasizes increasing biomedical and health delivery research to control mortality and morbidity from diarrhea.

3. PROJECT DESCRIPTION

3.1. Project Goal and Purpose

Goal- The goal of this project is to improve the health status of populations in LDC's through reducing mortality and morbidity in small children due to diarrheal disease.

Purpose- The purpose of the project is to support country-specific applied research to adapt new and improved technologies for the control and prevention of diarrheal diseases to particular country settings.

3.2. Project Activities

Globally based laboratory science and donor centralized health planning have developed new technologies for diarrheal disease prevention and treatment. But these findings need to be tested and modified in situ through country-specific applied research. To accomplish this, the project will complement A.I.D.'s contributions to research activities at ICDDR,B* and WHO/CDD** by supporting a competitive grants research program, focusing on problem-solving research in on-going programs of

*ICDDR,B: The ICDDR,B has been the locus of biomedical research into the causes, therapy and preventive approaches to cholera and other diarrheal diseases since the early 1960s. Initially named the Cholera Research Laboratory, ICDDR,B has largely been a bilateral U.S. - Bangladesh enterprise. Work has focused on identifying the causes of diarrhea, understanding the epidemiologic patterns of cholera and other diarrheas, testing vaccines for cholera, understanding the pathophysiology of diarrheas, and developing appropriate therapeutic interventions.

**WHO/CDD: The WHO Diarrheal Diseases Control (CDD) program was founded in 1978 to meet the mandate of the Thirty-First World Health Assembly to mount a concerted attack on diarrheal diseases.
diarrheal disease control and by focusing on strengthening LDC institutions to conduct diarrheal diseases research in a small number of high infant mortality rate (IMR) nations. It is anticipated that with the limited resources available to S&T for institutional support activities, such activities will be limited except where Missions are interested in "buy-ins". A cooperating agency (C.A.) will be selected competitively to serve as the principal technical resource for Diarrheal Disease Control Research activities funded by AID, and assist AID/W in concurrence with local Missions in identifying, monitoring, implementing and reviewing project activities. The C.A. will rely on an expert Technical Advisory Group (TAG) which will assist A.I.D. in establishing project priorities; developing new activities; reviewing proposals; providing technical assistance; and evaluating projects. Three broad areas have been outlined above: technical assistance, research, and institutional support.

3.2.1. Technical Assistance

Developing countries and developing country scientists need a variety of technical assistance in order to (a) examine the implications of new diarrheal disease control programs and the delivery of services through new channels, (b) make program and policy decisions and incorporate these and other decisions resulting from research into national programs.

The project will provide short term technical assistance in response to host country governments and private and public agencies, organizations and programs with Mission concurrence. This will be in addition to the more specific technical assistance required to implement the research activities described elsewhere in the project paper.

Examples of requests which might be met include, but are not limited to:

Requests from host country governments to carry out needs assessments, estimate demand, and design diarrheal disease research (DDR) components.

Requests from host country governments and USAIDs to review and assist in the modification of proposals for demonstration projects or research activities.

Requests from host country governments, USAIDS, or other agencies and programs to undertake technical reviews of current DDR activities.

In response to AID/W or Mission requests, the project will collaborate with grantees who have programs in ORT and DDR. The C.A. will maintain a roster of expert consultants who are capable of providing technical assistance for all types of DDR programs.
3.2.2. Research Grant Program

Research activities will be financed by the project in two ways: a) directed research activities; b) grants to LDC research institutions in response to their proposals.

The bulk of the project's research resources will be utilized for grants to LDC research institutions in response to their proposals. With Mission concurrence the C.A. will advise the LDC DDR community of the availability of grants and the areas of particular research interest. Proposals will be reviewed and judged by the TAG. Grants will be made by the C.A. after approval by the TAG and the project manager. The C.A. will administer the grant and assure that all financial and reporting requirements are met. Final reports from each grantee will be reviewed by the TAG. Grants will normally not exceed $100,000 per year and will be for a fixed duration not exceeding the life of this project. For small grants (under $10,000) where urgency precludes prior TAG review, the project manager may authorize the C.A. to make a small grant, and simultaneously submit the proposal to the TAG.

Research Areas

The resources of the project will be focused on a small set of problems defined below.

A) Improving the Delivery and Cost-effectiveness of Diarrheal Disease Control Programs. Reaching beyond the clinic to areas currently underserved may require use of new delivery systems for health care, such as the private commercial sector, or the local school. These programs require the development of new financing strategies, new community participation programs, new training materials, new monitoring systems and problem-solving research. Each of the new extension of coverage programs, such as Expanded Program on Immunizations, and Diarrheal Diseases Control, creates special needs. One such need for Diarrheal Disease Control is delivering oral therapy to households. Although a number of approaches have been tried they need to be carefully monitored and evaluated. The Applied Diarrheal Disease Research Project (ADDR) would
support innovative efforts to implement and evaluate these programs, paying special attention to cost-effectiveness.

B) Improving the use of oral therapy in the home. Delivering oral therapy to the home, either from a clinic or a village health worker, only addresses part of the diarrheal disease problem. Although few studies have addressed this issue, they demonstrate that when oral therapy is mixed and administered in the home, too little is used. Other problems, such as preservation of the solution for many days, mixing with too little water, and adulterating the solution with other ingredients undoubtedly exist. The possibilities for abuse of a wide-spread therapy such as ORT is high, but little is currently being done to identify and correct this abuse. Studies need to be conducted to observe the use of ORT in the home, and to improve health educational efforts to promote the correct mixing and administration of oral rehydration therapy.

C) Dietary management of diarrheal cases. Oral therapy deals with dehydration deaths alone. As the program improves, the nutritional consequences of diarrheal disease become increasingly important. There has long been an awareness of an association between infections and nutritional status. As early as 1968 a temporal relationship was observed between episodes of infections – including diarrhea – and growth faltering. The exact relationship of this phenomena, however, is not well known. Among the factors affecting growth faltering are feeding patterns, prior nutritional status, specific etiologies of diarrheal disease, and anorexia. Feeding patterns affect the incidence of diarrheal disease, and poor nutritional status appears to predispose to greater nutritional consequences following an attack of diarrhea. Few studies of growth-faltering have identified agents, but Black has identified enteropathogenic E. coli and Shigella spp as the major pathogens causing growth faltering in Bangladesh. Growth faltering may also be due to anorexia accompanying episodes or the withholding of food by parents. Dietary intake appears to drop during acute infection, by as much as 40% below pre-morbic levels, although the role this drop plays in growth-faltering is unclear. In addition, new interventions, such as rice-based ORS promise great benefits for child diets, but additional research is needed before these interventions can be widely promoted.

D) Breastfeeding. Breastfeeding, whether exclusive or partial, appears to offer protection to children up to one year of age. It is estimated that breast-feeding promotion may reduce diarrhea mortality by 24-27% among infants aged 0-5 months, and by 8-9% in older children. A number of areas of
ignorance remain, however. Studies need to determine the level of protection against diarrhea mortality afforded by partial or exclusive breastfeeding, as well as studies of severity and feeding mode. These studies also need to be etiology-specific in order to clarify the differences between level of protection against different pathogens. More information is also needed on the design, effectiveness, and cost of breastfeeding promotion in developing countries.

E) Health Behavior. Epidemiological studies emphasize that human behavior patterns exert a major influence on the incidence and transmission of acute diarrheal diseases in children and on the nature and consequences of their sequelae. Programs have been designed to change these behavior patterns, but they have achieved only limited success. Programs that failed were often those planned in such a way that they could not be operated within the cultural and economic framework of the community. To improve these programs research needs to be conducted to provide:

- Basic information about the interrelationships between individual and household behavior patterns of defecation, water use, food preparation, child hygiene, infant feeding patterns and the risk of developing diarrheal diseases, including studies of positive deviance in those families who escape diarrheal disease. These studies need to include observation as well as self-report design elements.

- Studies of traditional beliefs and practices related to the treatment and cause of diarrheal disease especially health seeking behaviors for diarrheal disease and differential assessment of outcomes.

- Observational studies of the use of ORS in the home.

- Studies of the influence of seasonal employment demands and other socioeconomic factors on diarrheal diseases.

F) Personal Hygiene Education Programs. One of the most studied interventions in the area of personal hygiene is hand-washing. Several studies in Bangladesh, the USA and Guatemala have documented reductions in diarrhea incidence rates of between 14% and 48%. The ICDDR,B has also demonstrated that handwashing can play a significant role in reducing diarrhea due to shigella. However, little is known on the impact of other hygiene education programs on specific types of diarrheas or on their impact on mortality. Information is lacking on the optimal design of such programs,
on their costs, and on their dependence on pre-existing levels of sanitary facilities. Research is necessary to fill the current gaps in understanding and to clarify the operational aspects of these programmes. In general, methods used to improve the impact of and evaluate health education programs need to be improved.

G) Monitoring and Supervision. Extension of coverage programs that reach the household raise special problems for supervisory and monitoring functions. Most routine health information systems begin at the lowest fixed facility level, reporting episodes treated and medicines disbursed. This routine health information system in Honduras, for example, reports only 9% of diarrheal episodes and is inadequate for diarrheal disease control programs. Sentinel health information systems, which identify a few select health posts, increase the regional level of supervision and monitoring, and provide additional staff for community monitoring, have been suggested but not yet implemented. The project would support the development and evaluation of a sentinel surveillance system.

3.2.3. Institutional Support

In conjunction with the LDC research grants, the project will assess the institutional capacity of the proposer. Where necessary, support may be given for staff salaries, small equipment purchases and/or logistical support. This support is needed since developing country public health specialists currently have little local support for research. The few available University posts that provide limited salaries to researchers either support basic bench science or are overwhelmingly politicized. Ministry of Health posts support administrative and management activities, not research. International research programs, such as WHO/CDD's do not provide principal investigator salaries or capital for equipment purchases. Those programs, such as the World Bank's which provide capital for construction and equipment purchases often do not support research. The project proposes salary support to public health scientists, and funding for capital equipment purchases to conduct research. Additional support would be provided through extensive technical assistance in country. Such assistance might include on-the-job training in laboratory techniques or use of microcomputer application packages.

Institutional support is recommended by many authorities. REDSO/WCA cabled:
REDSO/WCA has previously stated that the problems are great in Africa, resources meagre but interest high. We request consideration of a D.D. [diarrheal diseases] research center (like Dacca) for Africa with accompanying training, research, research support and management capability.

A number of national institutions, with small additional support will be able to initiate and support the research activities mentioned here. Because of Regional and Mission encouragement of institutional support activities it is anticipated that increased funding will be made available from these sources (see 7.3).

Attachment 4 is a list of African research institutions which will be reviewed for support. The TAG will assist the C.A. and A.I.D. to identify the research institutions and scholars who will warrant support. Key institutions are the Faculte de Medecine et de Pharmacie, Dakar, Senegal and the Faculte de Medecine, Universite de Kinshasa, Kinshasa, Zaire. Institutional support efforts will be closely coordinated with CCCD staff on-site in Africa. Dr. Melinda Moore, Regional CDC Medical Epidemiologist has agreed to work closely with ADDR in Zaire. Other institutions which may be supported include The International Nutrition Institute of Central America and Panama, (INCAP), Cayetano Heredia University, Lima, Peru, and Mahidol University, Bangkok, Thailand.

In each institutional support site research protocols will be jointly developed by the local researcher, the C.A., and S&T/H with the approval of the local AID mission. On a case-by-case basis, the resources deemed necessary to assure the successful completion of research will be awarded. These may include staff salaries, small equipment purchases or outfitting of a small microbiology laboratory, assistance for local transportation, and on-site training by a member of the C.A. or TAG.

3.3. OTHER PROJECT ACTIVITIES

In the process of providing general and specific technical assistance, and supporting and conducting research, needs may develop for other types of activities which do not fall discretely under the areas already discussed. When in keeping with the overall project goal and purpose and with the approval of the project manager, project resources may be used to support activities such as:
1. International and national conferences, workshops and symposia

When appropriate the C.A. may organize international and national conferences related to different aspects of DDC, e.g., advances in DDC, designing DDC use-effectiveness or cost-effectiveness studies.

2. Travel and study awards

With Mission and AID/W concurrence consideration will be given to supporting the travel and other costs for program personnel, investigators, policy makers and administrators, and other workers to visit DDR programs, attend conferences and meetings, etc., for the purpose of acquiring information that will directly benefit the traveller's institution.

3. Analysis of existing data

The project can support primary and secondary analyses of of existing data such as survey data, service statistics, use-effectiveness data, etc., collected from other projects. Frequently it is difficult to find a mechanism to support such analyses and potentially valuable information is lost.

4. Publication and distribution of research data

The project can provide funds for the publication and distribution of research findings generated through project activities including community based research where necessary.

4. IMPLEMENTATION

4.1 AID Management

Primary technical and administrative responsibility will rest with the Communicable Disease Division, Office of Health (S&T/H/CD). The AID project manager will provide the C.A. with overall technical guidance and ensure that project implementation is consistent with the design set forth in this PP. The project manager will undertake appropriate coordination with other offices in the Agency such as ST/H/HSD, ST/H/WSD, PPC, the Regional Bureaus, and AID Missions. The project manager will arrange for appropriate mission clearances for proposed activities.
Consistent with the "substantial involvement" concepts underlying a cooperative agreement, the project manager will exercise a variety of functions including:

1. Collaborative involvement in the development of an annual workplan which describes the specific activities to be carried out under the agreement.

2. Approval of all activities carried out under this agreement including strategies, protocols, sub-agreements, information dissemination, consultancies, and international travel.

3. As appropriate, involvement in analysis and publication of findings.

4. Participation in site visits, the Technical Advisory Group (TAG), and evaluations to review program progress and future strategy.

5. Responsibility for recommending, in coordination with other AID officials, the allocation of funds for support of DDR activities under other grants and contracts. Such allocations will be approved by the Director of the Office of Health. Examples of where it may be appropriate to use such mechanisms are for the selection of priorities for research support to ICDDR,B and WHO/CDD, review of progress of these two DDR grants, participation in the diarrheal disease component of health surveys and operations research projects.

4.2 Cooperating Agency (C.A.)

The technical resources of a C.A. will be obtained competitively in accordance with A.I.D. regulations to carry out project activities. Participation of minority organizations as defined in the Gray Amendment will be encouraged to the maximum extent feasible. The C.A. will carry out needs assessments; advise on program priorities; coordinate activities; and conduct, oversee and monitor a complex program of research, training, information development and dissemination, and technical assistance. The C.A. must have in-house expertise and demonstrated competence in research, and in providing technical assistance to developing countries. The C.A. must be able to present a staff and roster of consultants who possess technical expertise in the areas above combined with in-depth knowledge of DDR.
4.2.1. Cooperating Agency Capabilities

The Cooperating Agency must devote staff with capabilities in three principal areas: scientific research in diarrheal diseases; social science research in LDCs; and program administration for grants management and sub-contracting. In addition, logistic, editorial and secretarial support must be available.

4.2.2. Facilities

The C.A. must have the facilities necessary to carry out the program described, e.g. access to a medical research library, computer facilities, meeting rooms, communications and mailing systems, printing facilities, etc. Project funds will not be available for construction, renovation of facilities, etc.

4.3 Process for Establishing Priorities and TAG (Technical Advisory Group)

Given the breadth of activities in this project and the limits on funds available, it will be necessary to establish priorities both between and within lines of work. To assist in the determination and ranking of priorities, a Technical Advisory Group (TAG) will be established by the project manager. The TAG will advise the C.A. and the project manager, assist the C.A. in developing projects (through their knowledge of, and contacts in their field of expertise as it relates to the activities of the project); reviewing proposals at meetings of the TAG and recommending specific amendments/modifications, where appropriate (based on criteria approved by the project manager); monitoring funded projects (by reviewing technical progress reports primarily at TAG meetings); and provide general assistance to the C.A. and project manager as requested.

The TAG will have about 12 members drawn from around the U.S., all of whom should be knowledgeable in diarrheal disease control programs, and meet at least annually. The TAG members will have technical expertise in areas such as:
- Clinical Medicine (1)
- Microbiology (1)
- Vaccine Development (1)
- Epidemiology (2)
- Health Planning and Administration (1)
- Nutrition (1)
- Medical Social Sciences (4), e.g.-
  Health Economics
  Medical Anthropology
  Health Education and Communications
  Medical Geography
- Health Program Evaluation (1)

The TAG may include additional ad hoc members or reviewers when other special expertise is required. The C.A. will provide administrative support to the TAG. Project priorities will be translated into project activities by the C.A. in collaboration with AID/CTO and TAG L: incorporated in the annual workplan.

TAG members will receive per diem during annual meetings and will be reimbursed for travel expenses. They will receive no salary for their services on the TAG during the annual meeting. Proposals may be reviewed by mail throughout the year when urgency does not permit review at an annual meeting.

5. Coordination and Implementation of Project Activities

5.1 Coordination

The C.A. will act as the Agency's main technical resource for diarrheal disease research activities. It will be expected to establish good working relations will all appropriate AID Bureaus, Missions, C.A.s, Contractors, and Grantees. The C.A. will be responsible for collecting program data on other A.I.D.-financed DDR activities to ensure that all DDR which are supported by this project are not duplicative and are complementary to the overall DDR strategy established by the Agency, Missions and detailed in this project paper.

To do this, the C.A. will:

1. Seek approval of other AID health projects, such as PRITECH, when activities conducted within the scope of work of ADDR, such as a field trial, overlap that of these projects.
2. Undertake a thorough review of all DDR activities.

3. Provide regular updated information on DDR activities throughout the world so that host country governments, other donors and family planning organizations are fully informed on the latest technology, results and ongoing activities. This information will be disseminated by appropriate means, such as a regular newsletter. Where there is an overlap, as in the case of breastfeeding research in the Nutrition Improvement of Maternal and Infant Diet Project (931-1010), information dissemination will take place in coordination with such projects.

4. Develop a semi-annual reporting system in conformity with S&T's and participant Mission's established procedures for all AID-financed DDR activities including information from all AID projects/programs, C.A.s, Contractors, Grantees (both centrally and Mission/Bureau funded). The C.A. will analyze this information and prepare reports to AID which (a) list the activities by C.A., Contractor, Mission, etc., with current FY obligations and (b) which provide more detailed information (such as summary or comprehensive descriptions of the activities) as requested by the project manager.

5. Provide technical and material assistance to other AID-financed Contractors, C.A.s, etc. who wish to increase their DDR activities (see section 3.3).

5.2 Development, Management and Implementation of Project Activities

The steps involved in developing, managing and implementing sub-projects and other activities will follow the same general pattern whether these are research, institutional support or technical assistance activities. These steps include assessing current knowledge and needs; identifying capable collaborators, institutions, and consultants; obtaining necessary clearances and approvals; designing, funding, monitoring and evaluating projects; and analyzing, writing up
and disseminating results. A more detailed explanation of these steps is provided below for research and training activities:

5.3 Research

1. Determine and prepare an overview or summary of what is already known about the biomedical, service delivery and health behavioral aspects of DDC and breastfeeding in the developed and developing countries, and identify priority issues for further research. Meetings drawing together experts in relevant disciplines may be required to provide direction for specific research. The C.A. will draw upon published literature and information gathered from consultations with DDR experts and family planning researchers, population professionals, AID Office of Health staff, and others as appropriate.

2. Assess regional and country-specific DDC research needs and resources on a worldwide basis. DDC research needs will be assessed in AID’s priority countries for health assistance in Africa, Asia, Near East and Latin America and the Caribbean. A.I.D officials from the Office of Health, Regional Bureaus and Missions, and DDC experts will be an important source of information about the potential development of DDR projects.

3. Provide technical assistance to host country institutions to (i) design sub-projects, (ii) identify researchers and institutions capable of conducting sub-projects, (iii) implement sub-projects in each of the three research areas in the AID geographic regions as appropriate, (iv) monitor and evaluate research and (v) prepare technical reports and manuscripts and disseminate results of such studies at the national and international level.
6. **Timetable**

1. Authorization  
   March 1985
2. Congressional Notification  
   March 1985
3. PIO/T to SER/CM  
   April 1985
4. RFP announced in CBD  
   April 1985
5. Award of Cooperative Agreement  
   July 1985
6. S&T/H advises Missions of project award and disseminates information regarding recipient and types of assistance available (First solicitation of proposals)  
   July-August 1985
7. Operations begin, start-up activities, first meeting of TAG  
   August - December 1985
8. Development of Annual Work Plan  
   December 1985
   Sept 1985-Feb 1986
10. Technical Assistance  
    January 1986 -
11. Resource Guides first draft  
    August 1986
12. Update of Annual Workplan  
13. Semi-Annual Report -  
    Jan 1986, July 1986, etc
14. Provide quarterly updated reports  
    Jan 1986, Apr 1986, etc
15. External Evaluations  
    Oct-Nov 1987 and 1989
7. **Budget**

The total life of project funding will be $12.5 million over 6 years. The budget reflects an anticipated level of support from Regional Bureaus and USAID's of approximately $3 million for institutional support activities (see 7.3).

7.1 The total project resources ($12.5 million) are tentatively allocated among functional areas as follows:

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<th>Functional Area</th>
<th>Percent</th>
<th>All Years ($'000)</th>
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<tr>
<td>Research</td>
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<td>Technical Assistance</td>
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7.2 Illustrative Budget (see Attachment 2)

7.3. **Financial Plan**

Attachment 3 shows planned financing of the project by fiscal year. Financial participation by the S&T Bureau is $9.5 million; financial participation by other Bureaus, Offices and Missions is projected at $3 million over the life of the project. The budget for the six year project is $12.5 million. The large increase in funding in the third and fourth years of the project reflect the lead time necessary for the establishment of contracts, preparation of proposals and scientific review. The C.A. will devote a large portion of its staff time during the first year to the development of relationships with potential LDC research entities and assistance to those organizations in the development of research proposals. The flow of resulting proposals is expected to grow sharply in year 2 with the need for extensive TAG review. The bulk of grant awards will take place in years 3, 4 and 5.
8. Reports

The C.A. shall submit reports as follows:

1. Two reports will be submitted annually consisting of interim activity reports (submitted six months after the project commences and then at 12 month intervals) and annual progress reports (submitted 12 months after the project commences and then at 12 month intervals). All reports shall be submitted to the AID project manager in six copies covering ongoing and completed activities as well as plans for the next six months. The reports should include, but not be limited to, a description of activities, summary of results and accomplishments and problems in the areas of program development and execution.

2. All financial reports and vouchers for payment and reporting of expenditures will conform to standard AID regulations and procedures.

9. Evaluation

It is recognized that formal and informal evaluation is an effective tool for project management. The project will be closely monitored and evaluated on a continuing basis by the project manager with the assistance of the technical staff of the Office of Health. A management review will be conducted by the project manager annually. Major external evaluations are anticipated at the end of the second year and again at the end of the fourth year. These intensive evaluations will use AID staff and independent experts to make a detailed assessment of project organization and development; project management; project output; research; training, and technical assistance procedures; and recommendations for project improvement and future activities. The results of the fourth year evaluation will be used to make decisions on project extension.

10. Conditions and Covenants

Agreements which may be negotiated under this project and executed by the officer(s) to whom such authority is delegated, in accordance with AID regulations and Delegations of Authority, shall be subject to the following terms and conditions together with such other terms and conditions as AID may deem appropriate:
Equal Employment Opportunity

Women and minorities will be recruited to serve in key roles associated with this project’s activities. All applicants will be judged solely upon their professional qualifications.

Subcontracting

The C.A. is required to have substantial institutional and staff experience and expertise in conducting diarrheal disease research and surveys overseas. The C.A. will also need to have in place the administrative infrastructure required to successfully manage a program as large and complex as ADDR. For these reasons, it is clearly inappropriate for ADDR to be considered as a small business set-aside. However, the C.A. may subcontract with domestic or foreign researchers or research organizations for activities relating to project objectives. Whenever possible, preference should be given to the use of small and minority businesses for these contracts. All contracts will be reviewed by the Office of Health.

Source and Origin of Goods and Services

Each country where research, training, technical or other assistance takes place under this project shall be deemed to be a cooperating country for the purpose of permitting local cost financing. The aggregate cost of all goods and services under each subagreement in a cooperating country may be procured in the special free world category (Code 935) up to $750,000 for the purpose of permitting local cost financing.
### Applied Diarrheal Disease Research Project

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List of Potential African Research Institutes

Dr. S.N. Kinoti
Kenyetta National Hospital
Nairobi
Kenya

Dr. B. Koumare
Institut National de Recherche en Sante Publique
Bamako
Mali

Dr. E. Offor
College of Medical Sciences
University of Benin
Benin
Nigeria

Dr. O. Seriki
Department of Pediatrics
University College Hospital
Ibadan
Nigeria

Dr. A.H. Fagbami
College of Medicine
University of Ibadan
Nigeria

Dr. C.O. Oyejide
University College Hospital
Ibadan
Nigeria

Dr. O. Dosunmu-Ogunbi
College of Medicine
University of Lagos
Nigeria

Dr. A.O. Grauge
University of Lagos
Nigeria

Dr. T.C. Okeahialam
University of Nigeria Teaching Hospital
Enugu
Nigeria

Dr. Osisayna and Dr. S. Ola Daniel
University of Sokoto
Nigeria
Dr. I. Diop Mar  
Faculte de Medecine et de Pharmacie  
Dakar  
Senegal

Dr. A.M. Ndiaye  
Organisme de Recherches sur l'Alimentation et la Nutrition Africaines  
Dakar  
Senegal

Dr. F.S. Mhalu  
Muhimbili Medical Centre  
Dar Es Salaam  
Tanzania

Dr. J. Shao  
Muhimbili Medical Centre  
Dar Es Salaam  
Tanzania

Dr. N.I. Ngama  
Clinique de Goma  
Zaire

Dr. Utshu Omanga  
Faculte de Medecine  
Universite de Kinshasa  
Kinshasa  
Zaire

Professor C. Chintu  
Faculty of Medicine  
University of Zambia  
Lusaka  
Zambia

Dr. H.S. Kunene  
Godfrey Huggins School of Medicine  
University of Zimbabwe  
Harare  
Zimbabwe

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