PD-AAR-336

AGENCY FOR INTERNATIONAL DEVELOPMENT

PROJECT DATA SHEET

1. TRANSACTION CODE: A (A = Add, C = Change, D = Delete) — Amendment Number: ISA 40185

DOCUMENT CODE: 3

2. COUNTRY/ENTITY: Worldwide

3. PROJECT NUMBER: 936 - 5940

4. BUREAU/OFFICE: ST/Health 00086.

5. PROJECT TITLE (maximum 40 characters): Pediatric Chronic Diarrheal Disease Research Training

6. PROJECT ASSISTANCE COMPLETION DATE (PACD): MM 12 DD 31 YY 88

7. ESTIMATED DATE OF OBLIGATION (Under 'B.' below, enter 1, 2, 3, or 4)
A. Initial FY 84 B. Quarter C. Final FY 87

8. COSTS ($000 OR EQUIVALENT $1 =)

A. FUNDING SOURCE	FIRST FY B. FX	C. L/C	D. Total	LIFE OF PROJECT E. FX	F. L/C	G. Total
AID Appropriated Total						
(Grant) HF	( )	( )	(1,000)	( )	( )	(3,000)
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
TOTALS			1,000			3,000

9. SCHEDULE OF AID FUNDING ($000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE 1. Grant	2. Loan	D. OBLIGATIONS TO DATE 1. Grant	2. Loan	E. AMOUNT APPROVED THIS ACTION 1. Grant	2. Loan	F. LIFE OF PROJECT 1. Grant	2. Loan
(1)						3,000		3,000	
(2)									
(3)									
(4)									
TOTALS						3,000		3,000	

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 480 characters)

To improve the treatment of chronic diarrheas in LDC children.

14. SCHEDULED EVALUATIONS
Interim MM YY MM YY Final MM 9 YY 8 6

15. SOURCE/ORIGIN OF GOODS AND SERVICES
☐ 000 ☐ 941 ☐ Local ☐ Other (Specify) 935

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a ____ page PP Amendment.)

17. APPROVED BY
Signature: [signature]
Title: Director, Office of Health
Date Signed: MM 02 DD 24 YY 84

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

AID 1330-4 (8-79)

PROJECT AUTHORIZATION

Country/Entity: Worldwide

Project Title:
Pediatric Chronic Diarrheal
Disease Research Training

Project No.: 936-5940

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961 as amended, I hereby authorize grant funding of $3,000,000 for a new project, Pediatric Chronic Diarrheal Disease Research Training, 936-5940.

2. Agreements with implementing agencies and groups shall be subject to the following terms and conditions together with any other terms and conditions which A.I.D. may deem appropriate.

Source and Origin of Goods and Services

a. Each developing country where training and other assistance takes place under this project shall be deemed to be a cooperating country for the purpose of permitting local cost financing.

b. Goods and services, except for ocean shipping, financed by A.I.D. under the project shall have their source and origin in the cooperating country or in the United States except as A.I.D. may otherwise agree in writing. 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.

N. C. Brady
Bureau for Science and Technology

Date 3/22/84

Clearances:
ST/H:G. Curlin Date: 2/24/84
ST/HP:J. Sar Date: 3/4/84
ST/PO:G. Eaton Date: 2/27/84

UNITED STATES INTERNATIONAL DEVELOPMENT COOPERATION AGENCY
AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

MAR 16 1984

ACTION MEMORANDUM FOR THE SENIOR ASSISTANT ADMINISTRATOR FOR SCIENCE AND TECHNOLOGY

FROM: S&T/HP, James Sarn

SUBJECT: Approval of a New Project, Pediatric Chronic Diarrheal Disease Research Training, 936-5940

Problem: Your approval is required to authorize a new project, Pediatric Chronic Diarrheal Disease Research Training, and a grant to the Children's Hospital of Buffalo to establish an International Center of Infant Nutrition and Gastrointestinal Diseases for Training, Intervention, and Research in Developing Countries.

Discussion: The Office of Health of the Bureau for Science and Technology has received an unsolicited proposal from the Children's Hospital of Buffalo to establish an Internatonal Center of Infant Nutrition and Gastrointestinal Diseases to support training, research, and intervention programs focused on chronic pediatric diarrheal disease. The main objectives of the program are the following:

(1) to determine the factors that lead an infant with acute diarrhea to develop chronic diarrhea;

(2) to provide information to and train personnel from four Research Centers in LDCs in the diagnosis and treatment of chronic pediatric diarrheal disease;

(3) to disseminate information about the treatment of chronic pediatric diarrhea through long- and short-term training, workshops, and international meetings; and

(4) to establish country-specific treatment programs based on the nature of the diarrheal disease problem and the availability of LDC financial and human resources.

Diarrheal disease is one of the major killers of infants and young children in LDCs. AID's programs treat acute diarrhea, through oral rehydration therapy and related programs, are moving ahead rapidly; but research on and treatment of chronic diarrhea must receive commensurate attention. The proposed program will link the research and training activities of a U.S. institution with the program of selected LDC research agencies and will, furthermore, link the research interests of these LDC research groups one with another.

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In short, the outcome of this grant is likely to be both a substantive advance in our understanding of the nature and treatment of chronic pediatric diarrhea, and an institutionalization of international research and training efforts through the establishment and/or upgrading of research centers associated with the International Center in Buffalo. The grant will be instituted through a cooperative agreement with the Center. We have just received a letter from Dr. Lebenthal of the Center stating the intent of the institution to absorb all overhead costs as part of their cost sharing contribution. This means that all resources provided by AID can be applied to the direct program costs

Congressional interest in this proposal has been high, and the Administrator has been invited to join Congressman Kemp at the inauguration of the International Center on March 5, 1984, in Buffalo. In view of the strong political interest in this activity and the general eagerness to get it launched quickly, we are requesting approval to waive normal Sector Council review and solicitation of field comments on the proposal. Because of this departure from standard review procedures, we have asked PPC, GC, and LEG to clear off on this memorandum prior to your approval of the project. The congressional notification was sent to the Hill yesterday and the fifteen day waiting period prior to obligation will end on March 9.

Recommendation: That you waive Sector Council and field mission review of this proposal by signing below; and that you approve a three-year $3 million program of research and training at the International Center of Infant Nutrition and Gastrointestinal Diseases of the Children's Hospital of Buffalo by signing the attached project authorization.

Approved T R Brady

Disapproved

Date 3/21/84

Attachments:
1. Project Authorization
2. Project Data Sheet
3. Lebenthal/Curlin ltr, Feb. 22
4. Unsol. Prop., Feb. 3

S&T/PO, G.Eaton [signature] Date 2/27/84
GC, Howard Fry [signature] Date 2/28/84
LEG, K.Kammerer [signature] Date 2/28/84
AA/PC (Act.) R.Derham [signature] Date 3/2/84

S&T/H:AVanDusen:gt:2/13/84:X58926:Destler,2/24/84:0928u

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Journal of Pediatric Gastroenterology and Nutrition

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Emanuel Lebenthal, M.D.
Children's Hospital of Buffalo
219 Bryant Street
Buffalo, New York 14222
Telephone 716-883-3155

ASSOCIATE EDITOR
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An International Journal of Clinical, Experimental, and Developmental Investigations

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John B. Watkins / *Philadelphia, Pennsylvania*
Myron Winick / *New York, New York*
Vernon Young / *Cambridge, Massachusetts*
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SELECTED REVIEWS
William F. Balistreri / *Cincinnati, Ohio*

BOOK REVIEWS
John N. Udall / *Boston, Massachusetts*

February 22, 1984

George Curlin, M.D.
Director, Office of Health
Bureau for Science and Technology
Agency for International Development
Washington DC 20523

Dear Dr. Curlin:

Re: Budget for the International Center of Infant Nutrition and Gastrointestinal Diseases at the Children's Hospital of Buffalo

We received your letter of February 7, 1984 in which you acknowledged that our proposal for the establishment of an International Center of Infant Nutrition and Gastro-intestinal Diseases at the Children's Hospital of Buffalo is acceptable from the technical point of view with only minor changes. However, you asked that we resubmit the budget since it did not include the indirect costs (overhead), and to omit the note contained in paragraph 5 on page 23.

Enclosed you will find the final budget for the three years of the award to be exactly $3million as was agreed upon. The Administration and all the parties involved in the building of the International Institute have discussed at length how to cover the overhead expenses for the first three years of the award amounting to $774,560, calculated at 35.8% of personnel costs as recognized by the NIH. This amount is included in the budget but only for reference. After long deliberations, the following options were recognized:

(1) To reduce the actual amount of the grant by the 35.8% designated for the indirect costs and overhead.
(2) To renegotiate the overhead with A.I.D.
(3) To reduce the number of trainees and possible Associate Research Centers.
(4) To take the painful route of cost-sharing and finding the resources in Western New York for the overhead costs.

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1/84

It was finally decided that the indirect cost of $774,560 will be cost-shared by the Children's Hospital of Buffalo with a provision for an amendment in the future when additional funding can be recognized. I am very thankful to the Board of Trustees and the Administration of the hospital who made a tremendous effort so that every dollar in the grant will be available for actual expenses.

The budget is forecasted to exceed funds in certain defined categories; as actual experience occurs, realignment of amounts among categories may be necessary. As this occurs you will be advised of such changes for your approval.

I am enclosing the final budget for the project proposal with the signatures of the authorized institutional officials, namely, Mr. John Jefferies, President of the hospital, and Mr. Paul Sweet, Vice President for Finance.

I am looking forward to the ceremony of the signing of the agreement between the Agency for International Development and the Children's Hospital of Buffalo on March 5, 1984 when Mr. Peter MacPherson will be present for the official signing of this important endeavor, together with Congressman Jack Kemp, and officials of the hospital and university.

I look forward to finalizing this important agreement. We are indebted to the Agency in general and to you in particular for the trust placed on us to fulfill this unprecedented project to look into the determinants that are affecting acute diarrhea to develop into chronic diarrhea and to the demise of five million children a year worldwide.

With best personal regards.

Sincerely,

Emanuel Lebenthal, M.D.
Professor of Pediatrics
Chief, Division of Gastroenterology
and Nutrition

cc: Congressman Jack Kemp
Mr. Peter MacPherson
Mr. John Jefferies
Mr. Paul Sweet
Dr. John Naughton
Dr. Elliot Ellis

EL:dr
Enc:

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The
Children's Hospital
of Buffalo
founded 1892

219 Bryant Street, Buffalo, New York 14222
716 878-7285

Office of the President

February 22, 1984

George Curlin, M.D.
Director, Office of Health
Bureau for Science and Technology
Agency for International Development
Washington, D.C. 20523

Dear Dr. Curlin:

We are delighted by becoming the recipient of funds from your Agency to conduct a program entitled "International Center of Infant Nutrition and Gastrointestinal Diseases at The Children's Hospital of Buffalo", in an effort to reduce pediatric diarrheal diseases.

The enclosed budget of $1 million per year for a period of three years represents projections of direct costs that would be experienced in conducting such a program. As has been discussed, a significant component of the budget, the indirect costs, has been omitted. This amount is exhibited on the summary page and represents what the National Institute of Health would have reimbursed the Hospital. It is understood we will receive only direct cost reimbursement at this time, but encourage your Agency to devise a way to see if we could be reimbursed for overhead at some future date.

Again, we are encouraged by the Agency's association with our Hospital and look forward to working with you in the future.

Sincerely,

John R. Jefferies
President

Paul W. Sweet
Vice President - Finance

JRJ:PWS:ld

Enc.

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BOOK REVIEWS
John N. Udall / *Boston, Massachusetts*

February 3, 19[illegible]

Dr. George Curlin
Director, Office of Health
Bureau for Science and Technology
Agency for International Development
Washington, D.C. 20523

Dear George:

Re: International Center of Infant Nutrition and Gastro-intestinal Diseases at the Children's Hospital of Buffalo

In response to your letter of January 27, and the many discussions and deliberations with AID representatives and their independent technical experts, we are enclosing the fourth edition of our proposal. The enclosed final proposal is directed and limited to research and training programs which coincides with the mandate and strategy of AID.

The training program will have short-term (6 months) and long-term (2 year) components at the International Institute as well as workshops and other continuing educational activities in LDC. It is hoped that the concept of apprenticeship during the training program together with the close association to AID missions in LDC will be a major factor in building the infrastructure for the associate research centers in LDC. International symposia and publications will be utilized to disseminate the knowledge worldwide.

We believe that the commitment of AID to help children with chronic diarrhea in LDC's is a natural outcome of the support of acute diarrhea with oral rehydration solution. The research programs will specifically be addressed to the problem of chronic diarrhea and will direct our efforts to improve methods of intervention in the LDC. We hope that this humane endeavor will eventually allow us to substantially decrease morbidity and mortality in the LDC via appropriate, inexpensive, and locally available therapies.

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Best Available Document

We are awaiting the final signing of the agreement, announcement and commencement of the Institute so that we may contact and visit the AID missions according to the established AID priorities to begin the selection process of the associate research centers, key mentors, and trainees.

Thank you for your continued support and cooperation.

Sincerely yours,

Emanuel Lebenthal, M.D.
Professor of Pediatrics
Chief, Division of Gastroenterology
and Nutrition

EL:smm
Enclosure

cc Congressman Jack Kemp
Mr. Peter MacPherson
Dr. N.C. Brady
James Sarn, M.D.
Mr. Leonard Yaeger
Mr. John Jefferies
Dean John Naughton
Dr. Elliot Ellis

A PROPOSAL FOR THE ESTABLISHMENT OF

AN INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

AT

THE CHILDREN'S HOSPITAL OF BUFFALO

FOR

TRAINING, INTERVENTION, AND RESEARCH

IN

THE DEVELOPING COUNTRIES

Director: Emanuel Lebenthal, M.D.
Professor of Pediatrics
State University of New York at Buffalo
Chief, Division of Gastroenterology
and Nutrition
The Children's Hospital of Buffalo
Buffalo, New York

INTRODUCTION

A survey conducted by the Programme for Control of Diarrhoeal Diseases (WHO, CDD, 8/83) has indicated that in 1980 nearly one billion episodes of acute diarrhea occurred in children under five years of age in the less developed countries (LDC). A significant number of these episodes results in serious retardation of growth and development of the affected children. In those children where diarrhea persists, complications may develop and they may ultimately die. It was estimated that five million children under five years of age died in 1980 from intractable diarrhea.

In the majority of cases, the etiology of the diarrheal morbidity and mortality is not identified. Irrespective of the cause, a variety of bacteria, viruses and parasites have been shown to precipitate the onset of intractable diarrhea. When associated with malnutrition due to previous episodes of diarrhea, excessive morbidity and mortality have been recorded.

Environmental factors, including poor sanitation, contaminated water supply, improper waste disposal, inadequate food processing, storage and handling, and underlying poor nutrition have been considered to be the initiating and perpetuating factors of infantile chronic diarrhea. The complexity of the problem has only recently emerged. In considering the major physiologic mechanisms of intractable diarrhea of infancy, we have formulated a working concept by compiling several factors that have been identified to be crucial. Based on our own study, in the majority of cases the final common pathway of intractable diarrhea of infancy is that of prolonged small intestinal mucosal injury. The mucosal injury is caused, intensified and

perpetuated by the associated factors; namely, protein energy malnutrition, deficient enteric hormones, increased absorption of native foreign protein, ineffective villous repair, bacterial overgrowth, infection, and malabsorption of nutrients.

The research thrust of the institute and Associate Research Centers (ARC) in the LDCs is to analyze these multiple factors such as nutritional status, recurrent infections, gastric acidity, motility of the gut, exocrine pancreatic and biliary function, small intestinal absorptive, secretory and reabsorptive capacity, small intestinal immunity and colonic salvage. The emphasis is to integrate studies of gastrointestinal pathophysiology, nutritional status and patient management, and the possible impact of these factors on the development of chronic diarrhea and its consequences. The aim is to provide a better understanding of the interacting events that promote the progression from acute to chronic diarrhea in infants and young children, so that an efficient therapeutic approach to the management and nutritional rehabilitation of these infants may be designed. Thus a decrease in the morbidity and mortality from this disease is expected from such an undertaking.

RATIONALE

We have recently witnessed a significant improvement in the treatment of acute diarrhea in LDCs but little progress in the treatment of chronic diarrhea. An urgent need for research and training of health care professionals in the diagnosis and treatment of chronic diarrhea became apparent after visits to LDCs like Peru, Indonesia, Thailand, Brazil, etc. There is very little known about why five million children under five years of age will develop chronic diarrhea and die. General statements are made in

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regard to the patient's poor nutritional status and recurrent infections, but much must yet be learned about the functional and progressive changes in the digestive tract of infants during acute and recurrent episodes. By meticulous and prospective studies, we will be able to assess various changes in different stages during the deterioration of their gastrointestinal functions. Recognizing the stage and extent of gastrointestinal function failure, therapeutic intervention will be formulated. We believe that through carefully planned and executed animal and clinical research, we will find the optimal time and method for nutritional interventions that are both cheap and available for children in the LDC.

WORKING HYPOTHSIS

The unifying working hypothesis of this proposal is as follows. Persistent small intestinal mucosal injury, associated with an initial infectious insult, is the initiating and perpetuating factor for the transformation of acute diarrhea into chronic diarrhea. The factors which are responsible for perpetuation of mucosal injury may be both exogenous and endogenous and remain to be fully explained.

Small intestinal mucosal injury that occurs early in life can establish a vicious cycle of events which in turn perpetuate the injury. Routine infant feedings often are not tolerated by infants with mucosal injury due to disaccharidase deficiencies, and at times due to intolerance of specific dietary protein. Partial or total malabsorption of nutrients, secondary acquired immune deficiency, and the inherent diminished capability of the infantile mucosa to regenerate, each contribute to this cycle. Reduced gastrointestinal hormones, which mediate secretion of acid, pepsin, pancreatic

enzymes and bile salts are also important in failure to digest and absorb dietary nutrients. Diminished nonspecific host defenses are also altered by these events.

OBJECTIVES

To test this proposal, we have outlined the methods by which we will evaluate the relative importance of various endogenous factors in the perpetuation of mucosal injury. In addition, we will formulate therapeutic approaches, modelled after those successfully used at the Children's Hospital of Buffalo and modified for suitability to large-scale clinical trials in selected centers. The results from our research efforts and state-of-art knowledge will be disseminated by workshops, meetings, lectures and publications, and will allow more focused therapeutic endeavors for increased cost-effectiveness and reduced morbidity and mortality in these centers.

The main objectives are to elaborate the determinants and alterations in the gastrointestinal function and their causative factors that lead an infant with acute diarrhea to develop chronic diarrhea; to train personnel from the ARCs; to develop international cooperation for high-level long and short-term training, workshops, and international meetings for dissemination of the state-of-the-art achievements in the field; to give training and disseminate information in the field to health professionals through the ARCs; and to establish treatment modalities tailored to a given center according to available LDC resources.

SITE JUSTIFICATION

The community of Western New York and the Children's Hospital have pledged $750,000 for the renovation of 11,000 sq.ft. of space at the hospital for the establishment of the Institute. The availability of the extensive inpatient and outpatient services and intensive care treatment at the Children's Hospital for prematures and compromised infants will enhance the clinical training of the LDC physicians' from the ARCs.

In the last eight years the Children's Hospital of Buffalo has been concerned with chronic diarrhea of infancy. Our extensive experience and success with 87 infants with this disease, none of whom died, have been instrumental in formulating the working hypothesis that prolonged small intestinal mucosal injury is the most important event that can affect the outcome of an infant with persistent diarrhea.

The division performed approximately 1,500 intestinal biopsies which were analyzed from biochemical, morphological, immunological and infectious aspects, as well as conducting more than 300 pancreatic exocrine function tests and numerous other sophisticated techniques, including esophageal and rectal manometry, endoscopies, colonoscopies, gastric acid output and nearly all of the available diagnost methods in clinical gastroenterology.

More than 20 clinical and research papers have been published by our division during 1983 and 19 fellows and visiting scientists have been trained in the last eight years. We conducted three International Symposia on Infant Nutrition and Gastrointestinal Disease, and a recent International Symposium on

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Chronic Diarrhea in Children that culminated in a textbook of approximately 600 pages (in press) We have organized three national meetings on the state-of-the-art of gastrointestinal disease and nutrition in infancy. In addition, three textbooks and a journal supplement were published from our division which also serves as the editorial board for an international JOURNAL OF PEDIATRIC GASTROENTEROLOGY AND NUTRITION.

In 1983 we have seen 1,800 outpatients and had 600 admissions to our service. The magnitude of the clinical services, laboratories, and research, and foremost the teaching and academic endeavors, provides the foundation for the establishment of the Institute. In addition, during the last few years Dr. Lebenthal has made many trips to LDCs to assess first-hand the unique and devastating problems in chronic diarrhea that they are faced with.

CRITERIA FOR THE SELECTION OF ASSOCIATE RESEARCH CENTERS

(1) Countries will be selected in consultation with A.I.D. and in accordance with its priorities.

(2) An ARC within the country will be selected in consultation with the local A.I.D. mission.

(3) Trainees and their mentors will be selected from the leading academic institute in the said country. Only candidates with appropriate background who have completed their pediatric training and have a long-term commitment to academic and public health goals will be considered.

(4) Candidate trainees must be qualified to participate fully in clinical training and take responsibility during their apprenticeship at the Institute.

NUMBER AND ORIGIN OF TRAINEES

We propose to have at least one key mentor from each ARC for short-term training as well as at least three long-term trainees from that ARC. Two key mentors, one from each ARC, will be trained for six months in each of the three years. Each center will also send one long-term trainee in the first year for two years in Buffalo; a second trainee will come in the second and third years; a third trainee will come in the third and fourth years. In this way the program will have in the first year in Buffalo 2 mentors and 4 long-term trainees; in the second and each subsequent year, 2 mentors and 8 long-term trainees will be in the program.

Each long-term trainee will spend two years in Buffalo and a third year with the key mentor in the ARC in their LDC.

TRAINING

Two training programs, a short-term and a long-term program, will be tailored to the key mentors and trainees respectively. Ancillary programs such as workshops and regular site visits by representatives from the Institute to the several ARC will also be available. The aim of the training will be to prepare clinical researchers: (1) to become leaders and authorities in specific issues related to chronic diarrhea in children; (2) to be the main educators and promoters of up-to-date therapeutic intervention in chronic diarrhea, particularly in their LDC; and (3) to conduct coordinated investigations on specific aspects of chronic diarrhea. The physicians will not be trained as general pediatric gastroenterologists but they will be trained to provide answers to one of the foremost problems in the LDCs.

The training will be mostly an apprenticeship plus a limited core curriculum. We will provide the trainees with all the ongoing weekly activities in our division and hospital, namely Grand Rounds, patient discussions, x-ray conference, pathology conference, research seminars, Journal Club, and working sessions given by members of the Institute, faculty, associated consultants and visiting professors. Taking into consideration the needs of some trainees from the LDC, the following limited core curriculum will also be available, in which the trainee will actively participate in preparing and presenting a seminar in one or more of the following topics under the supervision of a tutor:

(a) physiology and pathophysiology of the GI tract

(b) development of the GI tract

(c) clinical nutrition including nutritional requirements in normal and abnormal states, and nutritional assessment

(d) enteric infections

(e) other infections such as measles of relevance to diarrheal disease

(f) microbiology relevant to proposed research

(g) assessment of immunologic competence

(h) biostatistics and research design

(i) laboratory techniques

Short-term training: A program of six months duration designed for key mentors from the designated ARC. The main objectives will be: to familiarize the key mentors with our research methodologies; to gain first-hand experience with analytical procedures for diagnosis and the development of research protocols; to be acquainted with the standards of working at the Institute for quality control, specimen retrieval and handling; to acquaint the mentors with professional and academic meetings as well as bedside discussions, conference sessions, and rounds. Each key mentor is expected to formulate a written protocol, with elements of research and intervention, designed specifically to suit his or her ARC at the end of the six-month period. The selection of the key mentors will be based on their previous interest in acute and chronic diarrhea, and academic achievements.

Long-term training: The concept of an apprenticeship is especially important in the research training phase. A segment from the ongoing projects in gastrointestinal disease and function begun on an animal model will be conceived and assigned according to the needs of the trainee's ARC during the key mentors' time in Buffalo, and keeping in mind the research and intervention objectives of the particular LDC for many years to come. Selection will be similar to that for short-term training except for a weighted consideration for potential rather than for prior academic achievement. In addition, each long-term trainee will be nominated and approved by their key mentor. The training will be based on a research project that will be undertaken from the beginning of his or her training. The project will be carefully formulated to cover an area that the trainee is expected to continue, following his or her return to the ARC. For the sake of simplicity and training purposes, an animal model will be employed. In this way he or she will be acquainted with the necessary background, research design, methods, data collection, their interpretation, and biostatistical analysis. The trainee will learn in the process, the other issues involved in research, conceivably in greater depth than the key mentors.

We have found from our accumulative experience that such a training is superior to any other form of teaching. For this to succeed, a minimum of two years is required to bring the research project to a reasonable completion and to allow its refinement and continuation in a clinical model at the ARC. This not only will serve as a process for evaluation of the trainee but also provide a sense of accomplishment for each individual. In addition, the trainee will be involved in the execution and performance of intestinal

biopsies, pancreozymin and secretin tests, and other relevant tests. He or she will also see patients and will be required to do case presentations, answer management problems and be involved in direct patient care with supervision. At the end of the training period, each trainee is expected to submit a specific protocol entirely on his own but based on the designated research protocol as provided by his or her mentor who had attended the short-term program.

Workshops will be planned on an annual basis. Topics will deal with multiple factors in the gastrointestinal tract that are involved in the development of chronic diarrhea and problems related to research and recent advances in this field. At the moment we are designing an International Symposium on infant nutrition and gastrointestinal disease to be held in the fourth week of August, 1985 that will include 700 researchers and clinicians from around the world with presentations by 70 world authorities. As has been our usual practice in the past, we will encourage the ARCs to participate actively in the international workshops and to submit chapters based on their experience and background, to enhance the knowledge and the international recognition of the ARCs. We have always encouraged our trainees to write a treatise on their specific area of interest.

Teaching in the ARC: It is expected that the key mentors and the trainees will organize meetings and disseminate knowledge to physicians in their own country in the form of workshops, seminars, and field demonstrations which will be a part of the research and intervention protocols. These meetings will also foster and enhance local intervention strategies

together with the counsel and approval of the A.I.D. missions in that country. Staff of the Institute will make periodic visits in order to continue the strong association between the Institute and the ARC and will try to attract other world authorities to organize meetings in the specific center in order to enhance its teaching capacity and credibility.

International Scholars as Visiting Professors at the Institute: We will promote and invite those who are specifically interested in infant nutrition and gastrointestinal disease to spend four weeks of lectureship as well as analysis of research at the Institute. Dr. Lebenthal has a long list of personal acquaintances who would like to participate in this endeavor.

Communications and Publications: The trainees in the LDCs will be encouraged to serve as the principal authors in the research they are involved in, as well as coauthors in the research endeavors of the Institute in which they will be peripherally involved. The Institute will provide and encourage the dissemination of data and will look upon it as an indicator of the success and accomplishment of the ARC. Furthermore, the ARCs will be called upon to contribute their insight and experience in specific issues related to the gastrointestinal tract and will be asked to write state-of-the-art, medical progress reports, and chapters in books and proceedings of meetings organized or sponsored by the Institute.

Future Role as Leaders: The key mentor will have the responsibility of developing a teaching center in the LDC, and of the organization of local meetings with the help of the Institute and local A.I.D. mission. He will design the protocol for his ARC and decide on the priorities of the research in his center according to his agreement with the Institute and the approval of the local mission for continuing support. The implementation of the protocol will occur with the help of the trainees.

RESEARCH

The research activities of the Institute will be based on the projected outline of the research subjects that are planned for the Division of Pediatric Gastroenterology and Nutrition with particular emphasis on those projects that are relevant and suitable for training purposes. The main concept during the apprenticeship of the trainee is to assign each trainee to a research project in an animal model related to the given studies that will be done on a clinical level after his or her return to the ARC. During our subsequent acquaintance and interaction with the directors of the missions in various target countries, one of the priorities is to develop a mechanism of local support according to the availability of funds and goals of the missions in the LDCs. The role of the Institute is to coordinate the research efforts at the different ARCs and at the same time conduct sophisticated studies for the ARC after developing the logistics for specimen retrieval and shipment. This will serve also as a mechanism for quality control of studies that are done at the ARCs. The objective of this portion of the present proposal is specifically to evaluate the probable factors that result in the transformation of acute diarrhea into chronic diarrhea and ultimately to the demise of the child. In this respect we will expose the key mentors and

the trainees to specific aspects of the problem and the techniques involved in research so that the ARC will be able to conduct a specific research protocol within an overall framework. Although several fundamental techniques for basic data collection will be presented and taught to the key mentors and trainees, each ARC will develop a comprehensive protocol for laboratory and research analysis. For example, the ARC involved in gastric function will do gastric emptying rates, and gastric secretory functional tests with characterization of stimulated output in gastric aspirates, including determinations of pensinogen, acid, and perhaps also of intrinsic factor, etc. Another center will be concerned with exocrine pancreatic function and do specific tests, direct and indirect, that are involved in the assessment of pancreatic function such as pancreozymin-secretin tests, determinations of amylase, lipase, trypsin, chymotrypsin, etc.

Ethical Considerations

All the research to be suggested will be reviewed and modified for approval by the Institutional Review Board of the Children's Hospital of Buffalo as well as by the Ethical Committee of the respective ARC according to guidelines at the NIH and WHO including modification for literate and semiliterate persons. Great emphasis will be placed on the research that has a direct bearing on intervention. To some extent, the children who will be involved in the study will be subjected to reverse discrimination since they will have the privilege of receiving better treatment than their peers.

I. Existing research projects related to chronic diarrhea and malnutrition.

A. Clinical studies

1. Evaluation of various corn syrup starches (polymers of glucose) as an alternative carbohydrate source in formulas for premature and compromised

infants including those of chronic diarrhea. This includes both short-term and long-term tolerance studies.

2. Evaluation of intravenous alimentation as a treatment modality both for nutritional support and bowel rest in patients with mucosal injury and chronic diarrhea.

3. Characterization of the control mechanism of gastric emptying rate by food components as a means of controlling food entry into the small bowel to facilitate absorption in patients with compromised small intestinal function.

4. Evaluation and establishment of pancreatic functional parameters in patients with chronic diarrhea.

5. Evaluation and establishment of small intestinal functional parameters in patients with chronic diarrhea.

6. Evaluation of cell dynamics, mitotic rate, mitotic index, crypt/villous ratio, lamina propria infiltration in chronic diarrhea.

7. Evaluation of immunocompetence of patients with chronic diarrhea specifically of the immunoglobulin levels in the gastrointestinal lumen.

8. Evaluation of specific serum antibodies as markers for mucosal injury.

9. Body composition in chronic diarrhea--measurements with CT scan, anthropometry and urinary creatinine.

B. Animal studies

1. The effect of malnutrition on small intestinal and pancreatic digestive enzymes.

2. Reversibility of gastrointestinal digestive enzyme changes in malnourished rats following nutritional rehabilitation.

3. Absence of enteral feeding, such as acute fasting, and its effect on pancreatic and small intestinal digestive enzymes.

4. Evaluation of cell dynamic in the small intestinal mucosa following malnutrition and nutritional rehabilitation.

5. In vitro cell preparation for the evaluation of pancreatic and intestinal functions following malnutrition and other physiological disturbances.

6. Interaction between virus and enterocyte receptors and its effect on host nutrition and enzymatic markers.

II. Projected expansion and modification of existing research efforts.

A. Research at Buffalo

1. To initiate gastric functional evaluations in a clinical setting as a routine procedure in the evaluation of patients with chronic diarrhea.

2. To expand the search for specific serum antibodies as markers for mucosal injury.

3. To develop animal models with experimentally induced mucosal injury for use in the evaluation of alterations in their gastrointestinal functions. This can be achieved by feeding specific lectins or a high osmolar solution such as 20% mannitol for a defined period. The length and extent of mucosal injury can be controlled and its regeneration structurally and biochemically will be followed.

4. To adapt our routinely used in vitro isolated cell systems, specifically isolated intestinal cells, to evaluate their functions such that it can be carried out in a simple laboratory setting.

5. To further investigate the abnormality in cell dynamics by measuring cellular activities in biopsy samples of diarrheal and control subjects using techniques already available in our laboratories.

6. Effect of meal composition and source of gastric emptying in chronic diarrhea and malnutrition.

B. Research at ARCs

Depending on the capability and the available personnel of the individual centers, the fellows, following a brief across-the-board training will be assigned a project specialized in a particular area. Selection of the specific area will be governed by the previously agreed on project to be carried out in the candidate's ARC. The following areas are identified at present:

1. Evaluation of pancreatic function.

2. Evaluation of gastric function.

3. Evaluation of intestinal function.

4. Evaluation of immunological function specifically related to the gastrointestinal tract.

A clinical project will be designed within the identified category.

One or more centers will also be involved in the evaluation of various local and readily available products as feasible substitutes for components of a special formula for enteral nutritional support in chronic diarrhea.

Intervention

The intervention strategies will be aimed primarily to the treatment of chronic diarrhea, but we will exclude the studies related to acute diarrhea since there are many other good centers researching this area, and hopefully association with these established centers will enhance our capacity to study chronic diarrhea. We will implement, in different periods of the development of chronic diarrhea, several programs of treatment and long-term followup to determine at the ARC the best locally available treatment that will be practical and workable in the specific LDC.

Evaluation of the Activities of the Institute: In the third year of activities, the Institute will have fulfilled the following aspects:

1. Indicated and demonstrated that four ARCs have been established and are functioning in the designated countries with the key mentor and trainees.

2. During the period of training of key mentors, specific protocols for operations, research teaching and intervention will be designed for their respective ARC.

3. The Insitute will have successfully trained four key mentors and four trainees and initial studies conducted by trainees on animal models related to chronic diarrhea will have been completed during their time in Buffalo.

4. A field study will have started in each ARC.

5. Local symposia will have been organized to provide the teaching and state-of-the-art knowledge to the health professionals in the respective LDC.

6. An International Symposium on Chronic Diarrhea and Gastrointestinal Disease, directed by the Institute faculty and consultants, will have been organized.

Upon fulfillment of these aspects, the grant will be extended for another period of three years and at the sixth year of the program the achievements detailed above should have been doubled with the additional requirements that:

1. Each ARC should have finalized at least one comprehensive study as was assigned to them.

2. A proceedings in regard to the state-of-the-art on infant nutrition and gastrointestinal disease should have been published.

3. Indications from the public health sector in the LDC that the programs have had an impact on infant morbidity and mortality in regard to chronic diarrhea.

4. If all these commitments have been fulfilled, then a third period of three years should be granted.

BUDGET

A PROPOSAL FOR THE ESTABLISHMENT OF

AN INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

AT

THE CHILDREN'S HOSPITAL OF BUFFALO

FOR

TRAINING, INTERVENTION, AND RESEARCH

IN

THE DEVELOPING COUNTRIES

INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

EQUIPMENT

	1st Year	2nd Year	3rd Year
Laboratories			
Spectrophotometers (1,6)		$ 30,000	$ 14,800
Gas chromatograph			20,000
High-pressure liquid chromatograph		20,000	
Radionuclide counters	$ 15,000		30,000
Centrifuges (refrigerated)(3)	15,000	15,000	
Balances (4)	2,000	2,000	
PH Meters (4)	1,000	1,000	
Ultracentrifuge & Rotors(L-8 Beckman)(2)		45,000	
Ultralow temperature (-80°C) freezer(5) for specimen storage		6,000	
Automatic pH titrator (7)			15,000
Subtotal	33,000	119,000	79,800
Clinical			
Endoscopes	14,000		14,000
Multichannel records		3,000	
H_2 breath test equipment	8,000		
CCK-Pz Secretin 62 vial each	5,000	5,000	5,000
Subtotal	27,000	8,000	19,000
Office			
Computer and accessories	100,000		
Word processor	16,000		
Copy machine		2,000	
Typewriters	1,000		1,200
Subtotal	117,000	2,000	1,200
Teaching			
Close circuit TV	12,000		
Video recorders	9,000		
Camera w/attachment for endoscope	16,000		
Recording equipment	12,000		
Viewing projectors	4,000		
X-ray boxes		1,000	
Subtotal	53,000	1,000	
TOTALS	$ 230,000	$130,000	100,000

Major pieces of equipment needed to expand the service and research capability and sophistications:

1. Fluorometer - $12,000)
   Thin layer scanning spectrophotometer $5,000) $30,000
   Liquid scintillation counter $ 13,000)

   These instruments will enable the development of new quantitative assay system in better evaluating biochemical parameters involved in digestion and absorption of nutrients.

2. L8 Beckman ultracentrifuge and rotors $45,000

   This instrument enables us to look into many molecular aspects of various disease entities and also helps in the understanding of the numerous intracellular events that occur during development of various cell types of the gastrointestinal tract.

3. Sorvall refrigerated centrifuge with rotors $15,000 x 2 = $30,000

   We have an old ICN centrifuge of this kind in operation in the laborator An additional one is badly needed to cut down the waiting time and a second one would be needed in a few years from now when the ICN gets too old to function.

4. 2 pH meters, 1 analytical balances, 4 stirring tables, 2 incubators, 4 hot plates, $ 6,000

   We have sufficient numbers of this small equipment for our normal functioning at the level of laboratory activities that we are in at present With the expected increase in personnel, additional items will be required to provide adequate service.

5. Ultralow temperature freezer - $ 6,000

   We have one for storage of human small intestinal biopsy specimens and homogenates, samples of duodenal and gastric aspirate, and autopsy samples. Because of the anticipated increase in specimens especially those from the satellite centers, an additional freezer of this type is required to allow for the expansion.

6. Spectrophotometer with UV-viocible capability, plus recording and automatic sampling device = $14,800

   We have two functioning at present; with the increase in laboratory activity, an additional one is required after two or three years in the program.

7. Automatic pH titrator = $15,000

   We have only one at the moment; an additional one would be needed by the or three years time to handle the additional workload anticipated.

Budget Justification

1. The budget is constructed such that in the first year, the main portion of the expense will be the purchase of required equipment while in the following years, more of the expense will be for the salaries of the trainees and teaching faculty and for all applied research.

2. The calculation is a minimum for staff members needed for the Institute and was done according to the teaching needs of 10 trainees from developing countries, the need for joint research with the satellite centers, and the supervision of, and interaction with, the satellite centers.

3. The budget calls for support of the laboratory with 1 Ph.D., 5 research technicians, 1 research nutritionist, 1 research dietitian. The clinical teaching, supervision and liaison with the satellite centers will require more than the number of physicians proposed.

4. The support for the satellite centers will be obtained independently through grants or grant in aids either in the local or international level. The international center will provide all the necessary support and guidance necessary to see this through.

5. The overhead of administering the contract between the Agency for International Development and the Children's Hospital is not specified in the budget. It is expected that it will be commensurate with government practice in similar situations.

TRAVEL

		1ST YEAR	2ND YEAR	3RD YEAR
Trainee	To Buffalo	$ 2,000	$ 2,000	$ 2,000
Trainee	To Buffalo	2,000	2,000	2,000
Trainee	To Buffalo	2,000	2,000	2,000
Trainee	To Buffalo	2,000	2,000	2,000
Key Mentor	To and From Buffalo	4,000	4,000	4,000
Key Mentor	To and From Buffalo	4,000	4,000	4,000
Trainee	Return to associate centers	-----	2,000	2,000
Trainee	Return to associate centers	-----	2,000	2,000
Trainee	Return to associate centers	-----	2,000	2,000
Trainee	Return to associate centers	-----	2,000	2,000
International	Official visit to Associate Center, Visiting Professorships, etc.	19,000	20,000	26,000
	TOTAL:	$ 35,000	$ 44,000	$ 50,000

INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

SUPPLIES	1st Year	2nd Year	3rd Year
Shipping of specimens	$ 10,000	$ 10,000	$ 15,000
Glassware	15,000	10,000	10,000
Office Supplies	15,000	10,000	10,000
Telephone and Telegraph	10,000	10,000	10,000
Maintenance and Repair	30,000	30,000	35,000
Chemicals	10,000	10,000	10,000
Laboratory Supplies	20,000	20,000	20,000
Workshop	10,000	10,000	10,000
Special Tests	15,017	13,247	13,649
	$135,017	$ 123,247	$ 133,649

DIRECT COSTS ONLY

BUDGET CATEGORY TOTALS		1st BUDGET PERIOD (from page 4)	ADDITIONAL YEARS SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL (Salary and fringe benefits.) (Applicant organization only)		599,983	772,753	866,261		
CONSULTANT COSTS						
EQUIPMENT		230,000	130,000	100,000		
SUPPLIES		135,017	123,247	133,649		
TRAVEL	DOMESTIC					
	FOREIGN	35,000	44,000	50,000		
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
CONSORTIUM/ CONTRACTUAL COSTS						
OTHER EXPENSES						
TOTAL DIRECT COSTS		1, 000,000	1,070,000	1,149,910		

TOTAL FOR ENTIRE PROPOSED PROJECT PERIOD *(Also enter on page 1, item 8)* → $ 3,219,910

JUSTIFICATION (Use continuation pages if necessary): Describe the specific functions of the personnel and consultants. If a recurring annual increase in personnel costs is anticipated, give the percentage. For *all* years, justify any costs for which the need may not be obvious, such as equipment, foreign travel, alterations and renovations, and consortium/contractual costs. For any additional years of support requested, justify any significant increases in any category over the first 12 month budget period. In addition, for COMPETING CONTINUATION applications, justify any significant increases over the current level of support.

1. Initial $1,000,000 as agreed on for first year.

2. Second and third years reflect mainly merit and inflationary increase for salaries, wages, and supplies.

INTERNATIONAL CENTER FOR INFANT NUTRITION AND GASTROINTESTINAL DISEASES

NAME	POSITION	% HOURS	1ST YEAR Salary	1ST YEAR Fr. Ben.	1ST YEAR Total	2ND YEAR Salary	2ND YEAR Fr. Ben.	2ND YEAR Total	3RD YEAR Salary	3RD YEAR Fr. Ben.	3RD YEAR Total
E. Lebenthal	Exec. Director	70	$56,823	$14,206*	$71,029	$60,801	$15,808	$76,609	$65,057	$17,565	$82,622
Laboratory Operations and Research											
P. C. Lee, Ph.D. (*100% begins 2nd year)	Director	*80	35,406	8,852*	44,258	47,356	12,313	56,669	50,671	13,681	64,352
Steven Brooks	Chief Technician	100	21,807	3,489	25,296	23,333	3,967	27,300	24,966	4,493	29,459
To be appointed	Research Nutritionist	100	20,776	3,324	24,100	22,230	3,779	26,009	23,786	4,281	28,067
To be appointed	Ph.D. Research Associate	100	21,741	3,478	25,219	23,262	4,955	28,217	24,890	4,479	29,369
"	"		----	----	-----	-----	-----	-----	22,000	3,960	25,960
Ok Kim	Research Tech.	100	18,257	2,921	21,178	19,535	3,321	22,856	20,903	3,763	24,666
Bridget Krantz	Research Tech.	100	19,697	3,152	22,849	21,076	3,583	24,659	22,551	4,059	26,610
Sharl Kohut	Research Tech.	100	14,731	2,357	17,088	15,762	2,680	18,442	16,865	3,036	19,901
To be appointed	Research Tech.	100	14,231	2,277	16,508	15,227	2,589	17,816	16,293	2,933	19,226
To be appointed	Research Tech.	100	----------			----------			15,200	2,736	17,936
To be appointed	Research Dietitian	100	15,762	2,522	18,284	16,865	2,867	19,732	18,046	3,248	21,294

* 8/83 Professional Time and Effort

INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

NAME	POSITION	YEAR	1ST YEAR			2ND YEAR			3RD YEAR		
			Salary	Fr. Ben.	Total	Salary	Fr. Ben	Total	Salary	Fr. Ben.	Total
To be appointed	Trainee	1st Year	$18,820	$ 3,011	$ 21,831	$ 20,137	$ 3,423	$ 23,560	$ 21,547	$ 3,878	$ 25,425
To be appointed	Trainee	1st Year	18,820	3,011	21,831	20,137	3,423	23,560	21,547	3,878	25,425
To be appointed	Trainee	1st Year	18,820	3,011	21,831	20,137	3,423	23,560	21,547	3,878	25,425
To be appointed	Trainee	1st Year	18,820	3,011	21,831	20,137	3,423	23,560	21,547	3,878	25,425
To be appointed	Trainee	2nd Year				21,544	3,663	25,207	23,052	4,149	27,201
To be appointed	Trainee	2nd Year				21,544	3,663	25,207	23,052	4,149	27,201
To be appointed	Trainee	2nd Year				21,544	3,663	25,207	23,052	4,149	27,201
To be appointed	Trainee	2nd Year				21,544	3,663	25,207	23,052	4,149	27,201
To be appointed	Key Mentor	6 months	16,000	2,560	18,560	17,120	2,739	19,859	18,318	2,931	21,249
To be appointed	Key Mentor	6 months	16,000	2,560	18,560	17,120	2,739	19,859	18,318	2,931	21,249

INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

NAME	POSITION	% HOURS	1ST YEAR Salary	1ST YEAR Fr. Ben.	1ST YEAR Total	2ND YEAR Salary	2ND YEAR Fr. Ben.	2ND YEAR Total	3RD YEAR Salary	3RD YEAR Fr. Ben.	3RD YEAR Total
Clinical Operations and Research											
T. Rossi, M.D.	Director	70	$42,524	$10,631*	$53,155	$45,500	$11,375	$56,875	$46,686	$12,171	$58,857
Leo Heitlinger, M.D.	Teaching Director	70	32,488	8,122*	40,610	34,762	8,690	43,452	37,195	5,951	43,146
To be appointed	Clinical Research	70	32,488	8,122	40,610	34,762	8,690	43,452	37,195	5,951	43,146

* 8/83 Professional Time and Effort

INTERNATIONAL CENTER OF INFANT NUTRITION AND GASTROINTESTINAL DISEASES

NAME	POSITION	% HOURS	1ST YEAR Salary	1ST YEAR Fr. Ben.	1ST YEAR Total	2ND YEAR Salary	2ND YEAR Fr. Ben.	2ND YEAR Total	3RD YEAR Salary	3RD YEAR Fr. Ben.	3RD YEAR Total
Mary Lou Stein	Secretary	50	$ 7,292	$ 1,167	$ 8,459	$ 7,802	$ 1,326	$ 9,128	$ 8,348	$ 1,503	$ 9,851
Sharon Morelli	Secretary	100	10,933	1,749	12,682	11,698	1,989	13,687	12,517	2,253	14,770
To be appointed	Secretary	100	10,495	1,679	12,174	11,230	1,909	13,139	12,016	2,163	14,179
To be appointed	Secretary	100				11,230	1,909	13,139	12,016	2,163	14,179
To be appointed	Computer Analyst	100	19,000	3,040	22,040	20,330	3,456	23,786	21,753	3,916	25,669
	GRAND TOTAL:		$501,731	$ 98,252	$599,983	$643,725	$129,028	$772,753	$723,986	$142,275	$866,261