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AGENCY FOR INTERNATIONAL DEVELOPMENT

UNITED STATES AID MISSION TO PERU

C/O AMERICAN EMBASSY

LIMA, 1 PERU

CABLE: USAID/LIMA

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PD-APY-389
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June 17, 1986

Mr. Carlos R. Fitts
Administrative Director
Instituto de Investigación Nutricional
Av. La Universidad s/n
La Molina

Subject: IIN - Use of Bioelectrical Impedance to Measure Malnutrition and Dehydration. Project No. 936-5542

Dear Mr. Fitts:

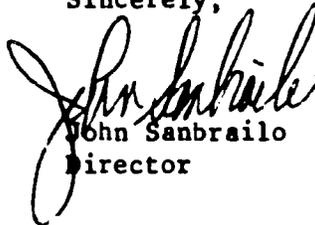
Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the Agency for International Development (hereinafter referred to as AID, or "Grantor") hereby grants to the Instituto de Investigación Nutricional (hereinafter referred to as "IIN" or "Grantee") the amount of US\$49,996 (the "Grant") to carry out a research project entitled "A Novel Method Using Bioelectrical Impedance to Measure Malnutrition and Acute Dehydration in Hospitalized Children," as described in Attachment 1, the Schedule of this Grant, and Attachment 2, entitled Program Description.

This Grant is effective, and obligation is made, as of the date of this letter and shall apply to commitments made by the Grantee in furtherance of program objectives during the period beginning with the effective date of the Grant and ending on December 31, 1987.

The Grant is made to IIN on condition that the funds will be administered in accordance with the terms and conditions set forth in Attachment 1, the Schedule, Attachment 2, Program Description, Attachment 3, Mandatory Standard Provisions and Attachment 4, Optional Standard Provisions which have been agreed to by your organization.

Please sign all six (6) copies of this Agreement to acknowledge your acceptance of the Grant and of the conditions herein established. Five copies should be returned to AID.

Sincerely,


John Sanbrailo
Director

ACKNOWLEDGED:

Instituto de Investigación Nutricional

By


Mr. Carlos R. Fitts

Title: Administrative Director

Date:

JUNE, 25, 1986

Attachments:

1. Schedule
2. Program Description
3. Mandatory Standard Provisions
4. Optional Standard Provisions

Fiscal Data:

Appropriation: 72-1161021-6

Budget Plan Code: DDAA-86-10600-DG11 (646-36-099-00-19-61)

Project No.: 936-5542

Obligation No.: 6361368

Total Estimated Amount: \$49,996

Total Obligated Amount: \$49,996

Funding Source: AID/Washington

SCHEDULE

A. Purpose of the Grant

The purpose of this Grant is to provide support for a research activity to be carried out by the Instituto de Investigación Nutricional (IIN) in collaboration with the Universidad Peruana Cayetano Heredia (UPCH) and Johns Hopkins University (JHU). The activity, entitled "A Novel Method Using Bioelectrical Impedance to Measure Malnutrition and Acute Dehydration in Hospitalized Children," will attempt to validate bioelectrical impedance as a measure of total body water (TBW) in children, through which, (1) hydrational state and (2) caloric reserve in the form of total body fat can be determined. This is a preliminary one year study testing the hypothesis and developing a predictive equation. The validation of the equation would be undertaken in field and clinical trials by means of a separate project. See Attachment 2 for a more complete project description.

B. The Grantee

The recipient institution for the Grant is IIN. The Principal Investigators are Dr. Jaime Freundt-Thurne, Director of Clinical Studies, IIN, and Dr. Eduardo Salazar-Lindo, Director of the Oral Rehydration Unit, UPCH.

C. Period of the Grant

The effective date of this Grant is the day of its signature. The expiration date of this Grant is December 31, 1987.

D. Approved Project Proposal

The Approved Project Proposal consists of the original proposal submitted on August 9, 1985 by Dr. Jaime Freundt-Thurne, as revised by AID/SCI's letter with Provisos dated January 21, 1986 and Dr. Freundt-Thurne's response of March 19, 1986. Originally, the proposal described a two year project. As revised, it is a one year project. The approved Grant Budget appears in Section G below based on the attachment to Dr. Freundt-Thurne's March 19th letter.

E. Amount of Grant and Payment

1. AID hereby obligates the amount of \$49,996 for carrying out the purposes of this grant. This represents the maximum total contribution of AID to the project. The Grantee assumes the responsibility to secure any additional resources that might be required to complete project objectives.

2. Payment shall be made to the Grantee in accordance with procedures set forth in Attachment 4 - Optional Standard Provision No. 1 entitled "Payment-Periodic Advance" and in accordance with Section G, Financial Plan. Payment shall be made on a quarterly basis.

F. Required Accounting Records

Grantee hereby agrees to establish a separate banking account and to keep separate accounting records for the funds received under this Grant in accordance with, and as required by, Optional Standard Provisions, 1-(a) of Attachment 4.

G. Financial Plan

Following is the Grant Budget. It includes local cost financed items, as authorized, as well foreign exchange cost items. Procurement of goods and services is limited (see Grant Budget), but shall be implemented in accordance with Optional Standard Provision No. 5, 6 and 8 of Attachment No. 4. Contributions of IIN and UPCH are also described.

Revisions to the Grant Budget shall be made in accordance with Mandatory Standard Provision No. 4 (see Attachment No. 3) entitled, "Revision of Grant Budget." Transfers among AID financed categories in the Grant Budget in excess of 15% shall require the written approval of AID.

Grant Budget

(in U.S. Dollars)

	<u>AID</u>	<u>IIN/UPCH Contribution</u>
1. Compensation (incl. allowances)	\$38,539	
a. Co-Principal Investigators (2)	5,072	
b. Investigators (4)	7,667	
c. Johns Hopkins Investigators (2)	21,600 *	
d. Nurse	2,400	
e. Micro/Para Technician (1)	1,800	
2. Patient Care Costs		\$13,600
3. Equipment and Supplies	650	9,000
a. U.S. Purchase (incl. shipping)	400 *	
b. Local Purchase	250	
4. Data Entry and Analysis	1,500	
5. Isotype Analysis (U. of Chicago) (incl. Intl. Travel Cost)	4,600 *	
6. International Travel (UPCH)	500 *	
7. Miscellaneous Administrative Costs	3,747	
a. IIN	1,475	
b. UPCH	2,272	
8. Contingency	460	
GRAND TOTALS	<u>\$49,996</u> =====	<u>\$22,600</u> =====

SUMMARY:

AID Contribution	\$49,996 (69%)
IIN/UPCH Contribution	22,600 (31%)
TOTAL PROJECT	<u>\$72,596 (100%)</u> =====

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- Notes:
1. See Approved Project Proposal, specifically the one year budgets in the Freundt-Thurne/Asher letter of 3/19/86, for more detail on specific types of personnel included in (1) above and percentage of work time to be provided project.
 2. Starred (*) figures above represent U.S. Dollar costs, totalling \$27,100. All other figures represent local cost items, totalling \$22,896.
 3. U.S. Purchase items (3-a above) represent diagnostic supplies to be procured and shipped with assistance of Johns Hopkins University.
 4. Details on IIN/UPCH contribution filed in USAID project file.

H. Reporting and Evaluation

1. Interim progress reports are required from the Principal Investigator, Dr. Jaime Freundt-Thurne of IIN no later than December 31, 1986 and June 30, 1987. By December 31, 1987, a final report is to be submitted. These reports shall be given to the Chief of the Health and Nutrition Division, USAID/Lima, who shall be the AID Project Manager. Five (5) copies of each report are to be provided, three (3) of which will be transmitted to AID/SCI for distribution in AID/Washington to the AID/SCI files, the AID Reference Center and the technical backstop officer. These reports may be submitted in the Spanish language if accompanied by an adequate English language summary.

2. The purpose of the interim progress report is to keep the AID Project Manager and AID/SCI informed that the research is proceeding in accordance with this Grant Agreement and to document any changes in the research plan or in key dates or benchmarks. In reporting on revisions in plans or dates, the report should request any administrative changes which may be required in the project. Emphasis should be placed in the report on announcing any substantive scientific developments as they occur.

3. The Final Report, when prepared by the Principal Investigator, should be submitted by the Grantee to the USAID Project Manager for transmittal to AID/SCI. It should be submitted prior to December 31, 1987. It shall be in sufficiently detailed presentation to substantiate research findings and to permit a scientific evaluation of the research. The Principal Investigator is encouraged to share the draft report with the AID Project Manager for comment prior to final submission.

4. Quarterly financial reports, setting forth the amounts of funds received, spent and liquidated in accordance with the Grant Budget and its budget categories, shall be submitted by the Grantee to the AID Project Manager in five (5) copies, three of which shall be forwarded promptly to AID/SCI.

5. Project Evaluation will be based on an analysis of the Final Report and other information deemed appropriate by the AID Project Manager. AID/SCI is prepared to assist in the analysis of the Final Report. The Evaluation is to be completed by the AID Project Manager within 90 days after the submission by the Grantee of the Final Report and is to be forwarded promptly to AID/SCI. AID/SCI will thereafter prepare the Project Completion Report, drawing upon the Project Evaluation and all other reports submitted by the Principal Investigator and Grantee.

I. AID/SCI Technical Backstopping

Upon request by USAID/Lima, AID/SCI will arrange for technical backstopping support on technical issues, including assessment of the Interim and Final reports. The AID/SCI Project Monitoring System will keep track of key action dates and remind the Grantee and USAID Project Manager 30 days in advance of when these actions fall due.

J. Special Provisions

The following Optional Standard Provisions (AID 1420-541-85) apply to this Grant: Sections 1, 3, 4, 5, 6, 7, 8, 14, 17 and 20.

PROGRAM DESCRIPTION

A. Purpose of the Grant

This grant provides support for a research activity to be carried out by the Instituto de Investigación Nutricional (IIN) in collaboration with the Universidad Peruana Cayetano Heredia (UPCH) and Johns Hopkins University (JHU). The activity, entitled "A Novel Method Using Bioelectrical Impedance to Measure Malnutrition and Acute Dehydration in Hospitalized Children," will attempt to validate bioelectrical impedance as a measure of total body water (TBW) in children, through which (1) hydrational status and (2) caloric reserve, in the form of total body fat, can be determined. A preliminary study, the project will have the sole end of developing a predictive equation from tests involving about 160 children in the hospitals at UPCH and IIN. The validation of that equation would be the subject of a follow-on study involving extensive field and clinical trials if justified by the preliminary study results.

B. Specific Objectives

This study will test the hypothesis that bioelectrical impedance, by measuring total body water (TBW), can provide: (1) Monitoring of the success or failure of oral rehydration therapy in children with acute diarrhea, including the development of tables for estimating changes in hydrational status and other tables to test a method for making a single point evaluation of the degree of dehydration; and (2) A more precise method of determining body fat than can be measured by other existing methods available in LDCS, thereby providing improved data on caloric reserve and nutritional status in children.

C. Project Implementation and Responsibilities

Both IIN and UPCH now have bioelectrical impedance analyzers. These will provide a safe, non-invasive method of measuring TBW. About 100 children, in-patients at the Oral Rehydration Unit at UPCH, will be involved in the preliminary study, together with 20 in-patient and 40 out-patient children at IIN. From these studies, to be conducted over the course of one year, will come predictive equations for further testing under field as well as clinical conditions.

The project will be administered, and the funds managed, by the Grantee, IIN, with Dr. Jaime Freundt-Thurne as Principal Investigator, assisted at IIN by Dr. Claudio Lanata, Research Director, and two visiting scientists from JHU, Dr. Carla Fjeld and Dr. Robert Gilman. Gilman will provide coordination of the IIN and UPCH studies; Fjeld will supervise the body fat and nutritional status studies and work in conjunction with the University of Chicago to perform the isotope studies. These will provide an independent measure of TBW for comparison with the bioelectrical impedance method.

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At UPOCH, the study's Co-Principal Investigator will be Dr. Eduardo Salazar-Lindo, Director of the Oral Rehydration Unit, assisted by Dr. Raúl León Barúa, Gastroenterologist, and Dr. Miguel Campos, an expert in medical statistical analyses.

As this research effort involves human subjects, included among the Optional Standard Provisions in Attachment No. 4 is Optional Standard Provision No. 14, "Protection of the Individual as a Research Subject." Letters are on file from the participating Peruvian institutions' Research Ethics Committees, approving this project. These letters are also part of the Approved Project Proposal. It is agreed that all research supported by this Grant will comply with the laws and protocols of the Peruvian Ministry of Health and of Johns Hopkins University.

The AID Project Manager for this project will be the Chief of the Health and Nutrition Division of USAID/Perú. She will receive and forward the required reports, make site visits, act in liaison between the research investigators and AID/SCI and prepare and forward the project's Evaluation Report to AID/SCI. AID/SCI will provide, upon request of the AID Project Manager, backstopping support on technical issues, if required, including the assessment of reports, and will prepare the Project Completion Report.