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"THIS IS A PRIMARY OBLIGATING DOCUMENT THAT IS NOT  
PURSUANT TO A HANDBOOK 3 PROJECT AGREEMENT"

U.S. AGENCY FOR  
INTERNATIONAL  
DEVELOPMENT

September 24, 1996

Dr. Guillermo López de Romaña  
Director  
Instituto de Investigación Nutricional  
Av. La Universidad No. 685  
LIMA 12

Subject: Award No. 527-0000-A-00-6420-00

Dear Dr. López de Romaña:

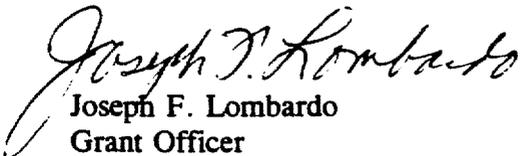
Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the United States Agency for International Development (hereinafter referred to as "USAID" or "Grantor") hereby grants to the Instituto de Investigación Nutricional (hereinafter referred to as IIN or "Recipient"), the sum of \$100,000 to provide support for a study on the benefits to women and their infants of providing Vitamin A supplementation to post-partum women, as described in the Schedule of this award and Attachment 2, entitled "Program Description."

This award is effective and obligation is made as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives during the period beginning with the effective date and ending September 30, 1997. USAID shall not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This award is made to IIN on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment 1, entitled "Schedule"; Attachment 2, entitled "Program Description"; and Attachment 3 entitled "Standard Provisions."

Please sign the original and each copy of this letter to acknowledge your receipt of this award, and return the original and all but one copy to the Grant Officer.

Sincerely,

  
Joseph F. Lombardo  
Grant Officer

Attachments:

1. Schedule
2. Program Description
3. Standard Provisions
4. Special Provision entitled "Rights in Data"
5. Special Provision "Relocation of U.S. Business ..."
6. IIN Proposal

Acknowledged: Instituto de Investigación Nutricional

By:



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Title:

*Director Interino*

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Date:

*Sept 24, 1996*

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## ACCOUNTING AND APPROPRIATION DATA

## A. GENERAL

1. Total Estimated Amount: \$100,000
2. Total Obligated Amount: \$100,000
3. Cost-Sharing Percentage  
(Non-Federal):
4. Project No.: 527-0000
5. USAID Project Officer: Susan Brems  
HPN, USAID/Peru  
Larrabure y Unanue 110  
Lima, Peru

## B. SPECIFIC

1. PIO/T Number: 527-0000-60058
2. Appropriation: 726-71021
3. Allotment:
4. BPC: LDV6-96-25527-CG13
5. PIO/T Obl. Amount: \$100,000

## SCHEDULE

### A. PURPOSE OF AGREEMENT

The purpose of this Agreement is to provide support for the program described in Attachment 2 of this Agreement, entitled "Program Description."

### B. PERIOD OF AGREEMENT

The effective date of this Agreement is the date of the Cover Letter, and the estimated completion date is September 30, 1997.

### C. AMOUNT OF AWARD AND PAYMENT

1. USAID hereby obligates the amount of \$100,000 for purposes of this Agreement.
2. Payment shall be made to the Recipient in accordance with procedures set forth in Attachment 3 - Optional Standard Provisions No. 1 entitled "Payment - Periodic Advance."

### D. AWARD BUDGET

The following is the Award Budget, including local-cost financing items, if authorized. Revisions to this budget shall be made in accordance with the Standard Provision of the Award entitled "Revision of Grant Budget," and, if applicable, Cost Sharing M hng.

## FINANCIAL PLAN

### GRANT BUDGET

ITEM	US\$	IIN CONTRIBUTION	TOTAL
<b>Personnel</b>			
Professional staff	19,000		19,000
Technical staff	29,700		29,700
<b>Sub-total</b>	<b>48,700</b>	<b>17,000</b>	<b>65,700</b>
<b>Operating Costs</b>			
Field and office supplies	3,000		3,000
Medicines for sick infants	500		500
Sample supplies	1,600		1,600
Printing costs	600		600
Gasoline or petrol	5,000		5,000
Laboratory tests/supplies	21,433		21,433
Data analysis costs	500		500
<b>Sub-total</b>	<b>32,633</b>		<b>32,633</b>
<b>Administrative Assistance</b>			
Personnel Administration (\$300 per month)	3,600		3,600
Financial Administration (\$300 per month)	3,600		3,600
Logistic Support (Local & Foreign Purchases, Custom Clearance Costs)	667	3,000	3,667
Transportation (\$.90 per mile)	6,000		6,000
Communications	1,000		1,000
Office space	1,800		1,800
<b>Sub-total</b>	<b>16,667</b>	<b>3,000</b>	<b>19,667</b>
<b>Transportation</b>			
Vehicle, Maintenance, Gasoline, etc.		5,000	5,000
<b>Other Direct Costs</b>			
Dihydroretinol for MRDR	2,000		2,000
<b>Total</b>	<b>100,000</b>	<b>25,000</b>	<b>125,000</b>

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E. SUBSTANTIAL INVOLVEMENT UNDERSTANDINGS

It is understood and agreed that USAID will be substantially involved during performance of this Award. The USAID Project Officer identified in the Cover Letter of this Award shall provide the following:

- (1) Approval of an annual workplan.

F. REPORTING

1. Financial Reporting

- a. Financial reporting requirements shall be in accordance with the Optional Standard Provision of this award entitled Payment - Periodic Advance, as shown in Attachment 3.

2. Performance Monitoring and Planning Reports

- a. Reports. The Recipient shall submit an original and one copy of brief quarterly program performance reports, which coincide with the financial reporting periods, to the USAID Project Officer specified in the Cover Letter of this Award. In addition, one copy shall be submitted to USAID/CDIE/D, Washington, D.C. 20523-1802. These reports shall be submitted within 30 days following the end of the reporting period.

- b. Paying Office. The paying office of this award is:

Office of the Controller  
USAID/Peru  
Larrabure y Unanue 110  
Lima 1, Peru

- c. Final Report. Within 30 days following the estimated completion date of this Award, the Recipient shall submit five (5) copies of a final report in English and Spanish to the USAID Project Officer specified in the Cover Letter of this Award. In addition, one copy shall be submitted to USAID/CDIE, Washington, D.C. 20523-1802. It will cover the entire period of the Award.

- d. Special Reports. Between the required program performance reporting dates, events may occur that have significant impact on the program. In such instances, IIN shall inform the appropriate USAID/Peru Project Officer.

#### G. FINANCIAL REVIEWS

In lieu of an audit, financial analysts from the USAID Controller's Office will conduct periodic financial reviews of the Agreement.

#### H. CLOSE-OUT PROCEDURES

This sections prescribes uniform close-out procedures for this Award.

1. The following definitions shall apply for the purpose of this section:
  - a. Close-out: The close-out of a grant is the process by which USAID determines that all applicable administrative requirements and all required work of the Grant have been completed by the Recipient and USAID.
  - b. Date of Completion: The date of completion is the date on which all work under the Grant is completed or the date of the award document, or any supplement or amendment thereto, on which sponsorship ends.
  - c. Disallowed Costs: Disallowed costs are those charges to a Grant that USAID or its representative determines to be unallowable in accordance with the applicable Federal cost principles or other conditions contained in the Grant.
2. USAID close-out procedures include the following requirements:
  - a. Upon request, USAID shall make prompt payments to a Recipient for allowable reimbursable costs under the Agreement being closed out.
  - b. The Recipient shall immediately fund any balance or unobligated (unencumbered) cash that USAID has advanced or paid and that is not authorized to be retained by the Recipient for use in other Agreements.

- c. In the event a final report has not been performed prior to the close-out of the Grant, USAID shall retain the right to recover an appropriate amount after fully considering the recommendations on questioned costs resulting from the financial reviews.

I. SPECIAL PROVISIONS

1. As set forth in Attachment 3, all Mandatory Standard Provisions for Non-U.S. Non-Governmental Grantees apply to this Grant. Applicable Optional Standard Provisions are indicated on the Checklist.
2. To assist in the implementation of this agreement, USAID from time to time will issue implementation letters furnishing additional information on requirements regarding matters stated in this Award. Such letters shall not modify the terms of the Award.
3. The USAID Project Officer is authorized to issue all approval documents which can clearly and reasonably be considered within the terms of this Award as written.
4. The "Rights in Data" and the "Relocation of U.S. Business" provisions, attached, form part of this Award.

## Program Description

### I. Background

Vitamin A deficiency represents a serious public health problem to populations living in many developing countries -- especially among infants and children. A significant reduction in infant and child mortality, primarily in deaths associated with diarrheal diseases, has been documented after supplementation with high doses of vitamin A given every four to six months in children six to 59 months of age.<sup>1</sup> Vitamin A is also known to protect against the risk of death from other childhood diseases such as measles and respiratory infections.<sup>2</sup>

One of the strategies to reduce the level of vitamin A deficiency in Peru is to provide a high dose (200,000 IU of retinol) of vitamin A to women in their postpartum period. There is no information in Peru on the possible benefits that this strategy offers to the infants of these women. One study of this kind has been done, but it was done in a country where xerophthalmia is endemic, and where characteristics of the subject population differ from those in Peru. Peru has evidence of a moderate level of vitamin A deficiency, documented only by low intake of vitamin A in the diet of the vulnerable population and evidence of subclinical deficiency in populations studied. There is a need to document if the strategy of high dose supplementation of vitamin A for lactating women will be effective in improving the vitamin A status of the women and their infants, before a cost-benefit analysis can be done to evaluate the need of a public health intervention in Peru.

### II. Study Description

The IIN is one of three centers of a World Health Organization multicenter study that is evaluating the risks and benefits of providing vitamin A supplements. In this study, women and their infants are randomized to receive either vitamin A supplementation (a one time high dose for the woman and subsequent supplements to her infant at the time of the normal immunization schedule) or placebos. This study, which is evaluating the effect of this intervention on the vitamin A status of women and their infants, and the incidence and prevalence of diarrheal and respiratory diseases in the infants and the effects on growth of the infant, was not designed to be able to provide information on the benefits to the infants of providing vitamin A only to the mother.

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<sup>1</sup>Fawzi, W.W., Chalmers, T.C., Herrera, G., Mosteller, F., *Vitamin A Supplementation and Child Mortality: A Meta-analysis*. JAMA, 1993.

<sup>2</sup> Sanghvi, Tina G., *Vital Nutrients, Vitamin A Field Support Project*, International Science and Technology Institute.

To take advantage of the infrastructure and expertise already in place for the aforementioned study, the IIN will add to the WHO study a group of 200 women who will receive either a high dose of vitamin A in the postpartum period or a placebo. This will broaden the original study to provide the additional information on the effect of a vitamin A supplement given to the woman on her infant. The infants will receive no supplementation at the time of immunizations, but will be tested for the level of retinol in their serum at pre-determined intervals. The breastmilk and serum of the women participants will be tested for retinol levels at six months after delivery.

### III. Study Purpose

The overall purpose of this study is to test the following hypotheses:

1. Six months after giving birth, the breastmilk of women who receive a supplement of 200,000 IU of vitamin A 18 to 28 days postpartum will contain higher levels of retinol than women receiving placebo.
2. The vitamin A status as measured by MRDR and serum retinol at six months of age will be higher in those infants whose mothers receive postpartum retinol compared with those who receive placebo.

### IV. Objectives

#### A. Primary Objectives

- 1) To evaluate the effect of one dose of 200,000 IU of vitamin A given to women 14 to 28 days postpartum on the vitamin A status of their infants at six months of age;
- 2) To evaluate the effect of one dose of 200,000 IU of vitamin A given to women 14 to 28 days postpartum on the vitamin A level in serum and breastmilk, at pre-determined intervals.

#### B. Secondary Objectives

- 1) To evaluate the correlation between serum retinol levels and breastmilk retinol levels in lactating women;

ATTACHMENT 2

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- 2) To evaluate the effect of one dose of 200,000 IU of vitamin A given to women in the period of 14 to 28 days postpartum on the vitamin A status of their infants at six months of age.

V. Activities

General activities to be supported under this Cooperative Agreement will include:

- 1) Enrollment of 200 women in the post-partum period and administration of a single dose of 200,000 IU of retinol or placebo.
- 2) Provision of placebo capsules to infants from women enrolled in the program at the time of receiving their polio and DPT (diphtheria, pertussis and tetanus) immunization.
- 3) Collection of breastmilk and serum samples from women at baseline and six months after delivery and measurement of the retinol levels.

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MANDATORY AND OPTIONAL STANDARD PROVISIONS

The following Mandatory and Optional Standard Provisions for Non-U.S. Non-Governmental Grantees in effect as of the effective date of this Award are incorporated herein by reference with full force and effect as though fully set forth herein:

- |     |   |                 |
|-----|---|-----------------|
| 1.  | Allowable Costs   | (June 1993)     |
| 2.  | Accounting, Audit, and Records                          | (March 1994)    |
| 3.  | Refunds   | (June 1993)     |
| 4.  | Revision of Grant Budget                                | (June 1993)     |
| 5.  | Termination and Suspension                              | (June 1993)     |
| 6.  | Disputes  | (June 1993)     |
| 7.  | Ineligible Countries                                    | (May 1986)      |
| 8.  | Debarment, Suspension, and Other Responsibility Matters | (March 1989)    |
| 9.  | U.S. Officials not to Benefit                           | (November 1985) |
| 10. | Nonliability  | (November 1985) |
| 11. | Amendment   | (November 1985) |
| 12. | Notices   | (November 1985) |
| 13. | Metric System of Measurement                            | (August 1992)   |

B. Optional Standard Provisions

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|-----|--|-------------|
| 1.  | Payment - Period Advance                     | (June 1993) |
| 4.  | Ocean Shipment of Goods                      | (June 1993) |
| 5.  | Procurement of Goods and Services            | (June 1993) |
| 6.  | AID Eligibility Rules for Goods and Services | (June 1993) |
| 8.  | Local Cost Financing                         | (June 1993) |
| 17. | Title To and Use of Property (Grantee Title) | (May 1986)  |
| 20. | Cost Sharing (Matching)                      | (June 1993) |

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