

PDFAI 198

CONTRACT AMENDMENT

MEMORANDUM

Date: September 5, 1978

TO : Distribution

FROM : ^{AID/SD} CM/SOD, Donald B. Dickie

SUBJECT: Contract No. AID/pha-C-1146 between A.I.D.
and The Johns Hopkins University

This transmits one copy of a Negotiated Indirect Cost Rate Agreement dated July 6, 1978. This Agreement is also Amendment No. 4 to the subject Contract.

The purpose of this Amendment is to establish final and/or provisional indirect cost rates.

If additional copies are required, please contact CM/SOD/OSC.

DISTRIBUTION:

- CM/SD/SUP, Mrs. B. Lewis
- CM/SD/SUP, Mr. G. Nell
- SER/FM, Mr. W. McKeel
- AAG/W, Mr. B. Abshire (2 copies)

Contracting Officer, CM/ COD/PE, Mr. G. Gold

Project Manager, DS/POP, Mr. J. Shelton

USAID/

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

NEGOTIATED INDIRECT COST RATE AGREEMENT

Date: July 6, 1978

SUBJECT: Indirect Cost Rates for Use in Cost Reimbursement Type Agreements With the Agency for International Development (AID)

REFERENCE: DHEW Negotiation Agreement dated April 5, 1978

INSTITUTION The Johns Hopkins University
" Baltimore
OTHER Maryland 21218

PART I - NEGOTIATED INDIRECT COST RATES (%):

Type	Effective Period		Research Rates		Educational Service Agreement Rates	
	From	Thru	On-Campus	Off-Campus	On-Campus	Off-Campus
Predetermined	7-1-77	6-30-78	48	24	27	14
Predetermined	7-1-78	6-30-79	51	28	27	14
Provisional	7-1-79	Until Amended	51	28	27	14

Acceptance of the rate(s) agreed to herein is predicated upon the conditions: (1) that no costs other than those incurred by the grantee/contractor were included in its indirect cost rate proposal and that such costs are legal obligations of the grantee/contractor, (2) that the same costs that have been treated as indirect costs have not been claimed as direct costs, (3) that similar types of costs have been accorded consistent treatment, and (4) that the information provided by the grantee/contractor which was used as the basis for acceptance of the rate(s) agreed to herein is not subsequently found to be materially incomplete or inaccurate.

Base of Application

Total direct cost less items of equipment \$1,000 and over, major subcontracts \$10,000 and over, alterations and renovations \$5,000 and over and patient care costs. Beginning July 1, 1978, charges for the University operated scientific computer are also excluded from the overhead base.

SEE PART III FOR APPLICATION OF THESE RATES TO AID AGREEMENTS.

X
3

PART II - ITEMS NORMALLY TREATED AS DIRECT COSTS:

PART III - SPECIAL TERMS AND CONDITIONS:

Pursuant to § 7-3.705 of the Agency For International Development Procurement Regulations (AIDPR), the negotiated indirect cost rates set forth in Part I of this Agreement are incorporated into AID Agreements shown below. This Agreement shall not change any monetary ceiling, obligation, or specific cost allowance or disallowance provided for in the Contracts or Grants listed below or any other Agreement between the parties.

<u>Contract No.</u>	<u>Amend. No.</u>	<u>Project No.</u>	<u>Applicable Rate</u>
AID/csd-2944	9	931-17-560-530	Research Off-Campus
AID/csd-2956	43	931-11-570-916	Research & ESA On & Off-Campus
AID/csd-3627	21	931-17-580-548	Research & ESA On & Off-Campus
AID/pha-C-1146	4	932-11-570-629	Research On-Campus
AID/ta-C-1450	1	931-1157	Research On and Off-Campus
AID/ta-G-1463	2	931-1015	ESA On-Campus
ID /1a-C-1233	1	532-0040	ESA On and Off-Campus
AID/ta-C-1312	6	931-17-510-249	Research On and Off-Campus

ACCEPTED: The Johns Hopkins University

BY Richard E. Hufnail
 Richard E. Hufnail
 PRINTED OR TYPED NAME
 Director of Sponsored Projects
 TITLE

Donald Dickie
 Donald Dickie
 CONTRACTING OFFICER
 Overhead and Special Costs Branch
 Services Operations Division
 Office of Contract Management
 Agency for International Development

DATE: 7/27/78

DISTRIBUTION:	<u>CM/ROD</u>	<u>CM/COD</u>
	AFR	AN
	NE	X PE
X	LA	OTR
	ASIA	
		<u>CM/SOD</u>
		X PDC

OTHER

X	AAG/W		
X	CM/SD/SUP		<input type="checkbox"/> DD
X	SER/FM/PAD	X TA/N	X DS/POP
X	LA/DR	X NES/TECH	

4

CONTRACT/GRANT/COOPERATIVE AGREEMENT DATA SHEET

SER/CM/SD/SUP Action Monitor

SER/CM/SD/SUP Ac Office

INSTRUCTIONS: AID/W - Complete 4 copies of the form. Original SER/CM/SD/SUP Statistical Section Copy; Copy 2 SER/CM/SD/SUP Administrative Copy 3 Contracting Officer's Copy; Copy 4 SER/CM/SD/SUP Admin. (Suspense) Copy.
Missions - Complete 2 copies of the form. Original SER/CM/SD/SUP Statistical Section Copy, and Copy 2 will be retained in the Mission File.

PART IA.

Contractor/Grantee Name

Johns Hopkins Univ.

PIO/T Number <u>N/A</u>	Appropriation Number <u>N/A</u>	Allotment Number <u>N/A</u>	Project Number <u>932-0629</u>
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Project Title

Amount of this PIO/T <u>0</u>	Project Manager's Name and Office Symbol	Contractor's D-U-M-S Num
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Negotiator's Typed Name Signature Date

Cari Gaskins

Contract/Grant Officer's Typed Name Signature Date

Jerry Gold

PART IB.

Contract/Grant Number <u>pna - c - 1146</u>	Type Order	Order Number	Amendment/Modification Number: <u>4</u>	Date PIO/T Received by CM or Mission Contract Office
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PART II.

Effective Date of Document <u>1/8/80</u>	Signature Date of Document <u>1/8/80</u>	Estimated Completion Date	Contract/Grant funded through (date)
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Host Country Institution (University contract ONLY)	Campus Coordinator (University contract ONLY)	Amount Obligated/Deobligated/Subobligated by this Action <u>\$ 65,794.74</u>	Cumulative Obligation through Action <u>\$ 434,205.21</u>
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PART III.

Description of Contract/Grant: Please 'X' ONLY ONE item under each heading. IF OTHER, please specify. (Complete both pages 1 and 2). NOTE: Not completed for Amendment or Modification Actions.

M03 - TYPE ACTION

- 0. Contract/Grant/Cooperative Agreement
- 1. Task Order (BOA)*
- 2. Work Order (IOC)*
- 3. Delivery Order (Requirements)*
- 4. Purchase Order

*If 1, 2, or 3 have an 'X', complete M12 ONLY.

M04 - CONTRACT/GRANT TYPE

- 0. NOA, (BOA, BMA, etc.)
- 1. Fixed Price (Specify: FFP, FPRD, FPEPA, FPI) _____
- 2. Cost Reimbursement (Specify: CR, CPEF, CS, CPAF, CPI) _____
- 3. Cooperative Agreement
- 4. Grant - General Support*
- 5. Grant - Specific Support*
- 6. Grant - 211(D)*
- 7. Do Not Use
- 8. IQCs
- 9. Host Country Contract/Grant*

*Complete ONLY through M51.

M05 - SELECTION PROCEDURES

- A. Formally advertised (IFB) (AIDPR 7-2.4 & FPR 1-2.4)
- B. Negotiated Price Competition, General Procedure (RFP) (AIDPR 7-4.56)
- C. A & E (AIDPR 7-4.10)
- D. Fed. Inst. and/or Int'l Research (AIDPR 7-4.57)
- E. Collaborative Assistance (AIDPR 7-4.58)
- F. Predominant Capability (AIDPR 7-3.101-50(b)(3))

- G. Unsolicited Proposal (AIDPR 7-3.101-50(b)(6))
- H. Procurement to be Performed by the Contractor in Person (AIDPR 7-3.101-50(b)(1))
- I. Sole Source (AIDPR 7-3.101-50(b)(4))
- J. Impairment of Foreign Policy Objectives (AIDPR 7-3.101-50(b)(7))
- K. 8(a) Selection (FPR 1-1.713-1)
- L. Grant (Handbook 13)
- M. Do Not Use
- N. Cooperative Agreement (Handbook 13)
- O. Small Business Set-Aside (FPR 1-1.706-8)
- P. Overseas Procuring Activities (AIDPR 7-3.101-50(b)(2))

M06 - TYPE SERVICE

- A. Training of Participants
- B. Technical Assistance (Program, Project related except A & E Services)
- C. A & E Services
- D. Construction
- E. Research
- F. Technical Services to AID (other than training; usually operating expense)
- G. Training Service for AID
- H. Equipment, Materials, Supplies, Commodities
- I. Translation Service

M07 - TYPE CONTRACTOR/GRANTEE

- A. Firm - All profit-making firms (other than A & E)
- B. A & E Firms

- C. Individual (Non-personal service)
- D. Individual (Personal Service)
- E. University/Other Educational Institution (other than Ed or PVO)
- F. Non-Profit Organization, Institution, or Association (other than Ed or PVO)
- G. Private Voluntary Organization (PVO)
- H. International Agricultural Research Institution
- I. Public International Organizations (Agencies, ICRC World Bank, etc. (HB 13, Chapter 5))

M08 - TYPE AWARD

- A. SB Set-Aside - Awarded to Non-Minority
- B. SB Set-Aside - Awarded to Minority
- C. SB Not Set-Aside - Awarded to Non-Minority
- D. SB Not Set-Aside - Awarded to Minority
- E. 8(a) SBA Awarded to Non-Minority Owned, Veterans, etc.)
- F. 8(a) SBA Awarded to Minority
- G. Personal Service Contract - Non-Minority
- H. Personal Service Contract - Minority
- I. Individual Non-Personal Service Contract - Non-Minority
- J. Individual Non-Personal Service Contract - Minority
- K. Not Small Business (Univ., Non-Profit Firms) Non-Minority
- L. Not Small Business (Univ., Non-Profit Firms) Minority
- M. U.S. Government

(Continued)

5

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

JAN 17 1980

1. AMENDMENT/MODIFICATION NO. 4	2. EFFECTIVE DATE See #19	3. REQUISITION/PURCHASE REQUEST NO. 3277208	4. PROJECT NO. (If applicable) 932-0629
5. ISSUED BY PE Branch Central Operations Division Office of Contract Management Agency for International Development Washington, D.C. 20523		6. Technical Office CODE CG	

7. CONTRACTOR NAME AND ADDRESS CODE FACILITY CODE Johns Hopkins University Baltimore, Maryland 21218 <small>(Street, city, county, state, and ZIP Code)</small>	8. AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See block 9) MODIFICATION OF CONTRACT/ORDER NO. <u>AID/pha-C-1146</u> DATED <u>9/30/76</u> (See block 11)
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9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers is extended, is not extended.

Orders must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment, (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA, (If required)

Appropriation No. : 424-36-099-00-23-83
 Allotment No. : 72-11X1024 Deobligated: \$65,794.74

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) This Change Order is issued pursuant to _____
 The Changes set forth in block 12 are made to the above numbered contract/order.

(b) The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) This Supplemental Agreement is entered into pursuant to authority of the Foreign Assistance Act of 1961, as amended,
 It modifies the above numbered contract as set forth in block 12 and Executive Order No. 12163.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

A. COVER PAGE

Delete the Total Estimated Contract Cost of \$988,906" and delete the amount Obligated of "\$500,000". Insert in lieu thereof, the amount "\$434,205.26."

B. ARTICLE IV - ESTIMATED CONTRACT COST AND FINANCING

Delete in its entirety and substitute in lieu thereof:

"The total cost to the Government and obligated amount of this contract is \$434,205.26".

C. ARTICLE V - BUDGET

Delete in its entirety.

except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect

<input type="checkbox"/> CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT	<input checked="" type="checkbox"/> CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 8 COPIES TO ISSUING OFFICE
4. NAME OF CONTRACTOR/OFFEROR Johns Hopkins University Richard E. Hufnail. <small>(Signature of person authorized to sign)</small>	17. UNITED STATES OF AMERICA Agency for International Development BY <u>Gerald P. Gold</u> <small>(Signature of Contracting Officer)</small>
3. NAME AND TITLE OF SIGNER (Type or print) Richard E. Hufnail, Director Sponsored Projects	16. DATE SIGNED 1/3/80
	18. NAME OF CONTRACTING OFFICER (Type or print) Gerald P. Gold
	19. DATE SIGNED 10 JAN 1980

JUN 5 1978
 Neg. J. Lewis
 PM. V. Shelton DS/POP/R

STANDARD FORM 30, JULY 1966
 GENERAL SERVICES ADMINISTRATION
 FED. REG. (41 CFR) 1-10.10

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 2
 1 2

1. AMENDMENT/MODIFICATION NO. **3**

2. EFFECTIVE DATE **See #19**

3. REQUISITION/PURCHASE REQUEST NO. **932-0629-3277208**

4. PROJECT NO. (If applicable) **932-0629**

5. ISSUED BY **PE Branch** CODE _____
Central Operations Division
Office of Contract Management
Agency for International Development
Washington, D.C. 20523

6. Technical Office **Office of Population** CODE _____
DS/POP/R
Washington, D.C. 20523

ORIGINAL

7. CONTRACTOR NAME AND ADDRESS CODE _____ FACILITY CODE _____

The Johns Hopkins University
Baltimore, Maryland 21218

(Street, city, county, state, and ZIP Code)

8. AMENDMENT OF SOLICITATION NO. _____ DATED _____ (See block 9)

MODIFICATION OF CONTRACT/ORDER NO. **AID/pha-C-1146**

DATED **9/30/76** (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers is extended, is not extended. Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment, (b) By acknowledging receipt of this amendment on each copy of the offer submitted, or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) This Change Order is issued pursuant to _____
 The Changes set forth in block 12 are made to the above numbered contract/order.

(b) The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12

(c) This Supplemental Agreement is entered into pursuant to authority of the Foreign Assistance Act of 1961, as amended,
 It modifies the above numbered contract as set forth in block 12 and Executive Order No. 11223.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

1. On page 2 of the Negotiated Indirect Cost Rate Agreement dated August 3, 1977, opposite the Contract No. AID/pha-C-1146, delete "1" and substitute in lieu thereof, the number "2".

2. Article IV - Estimated Contract Cost and Financing - Paragraph A - Delete the date shown as "April 30, 1978" and substitute in lieu thereof, the date "September 30, 1978".

3. Article V - Budget - Delete in its entirety and substitute in lieu thereof, the following:

Except as provided here in, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13. CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN **7** COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR **The Johns Hopkins University**

BY **Richard E. Hufnail** (Signature of person authorized to sign)

17. UNITED STATES OF AMERICA Agency for International Development

BY **Gerald P. Gold** (Signature of Contracting Officer)

15. NAME AND TITLE OF SIGNER (Type in print)
Richard E. Hufnail, Director Sponsored Projects

16. DATE SIGNED
5/4/78

18. NAME OF CONTRACTING OFFICER (Type in print)
Gerald P. Gold

19. DATE SIGNED
MAY 18 1978

"Article V - Budget

Within the total estimated cost of this contract the Contractor may adjust line item amounts, as may be reasonable necessary for the performance of this contract, except that the obligated amount under the contract may not be exceeded.

BUDGET

	<u>Fr: 10/1/76</u> <u>To: 9/30/77</u>	<u>Fr: 10/1/77</u> <u>To: 9/30/78</u>	<u>Fr: 10/1/78</u> <u>To: 9/30/79</u>	<u>Total</u>
Salaries	\$ 84,750	\$ 97,270	\$ 55,740	\$237,760
Fringe Benefits	12,091	15,462	9,198	36,751
Travel & Transportation	1,076	2,224	8,500	11,800
Equipment, Materials and Supplies*	44,606	17,389	8,500	70,495
Other Direct Costs	7,648	5,560	2,128	15,336
Subcontracts	-0-	85,137	361,966	447,103
Overhead	<u>58,872</u>	<u>67,915</u>	<u>42,874</u>	<u>169,661</u>
	<u>\$209,043</u>	<u>\$290,957</u>	<u>\$488,906</u>	<u>\$988,906</u>

*Written approval of the AID Contracting Officer is required prior to procurement of the liquid scintillation Counter. See Clause 16 of the General Provisions."

11 AUG 1977

Mrs. Booker

MEMORANDUM

ORIGINAL

Date: August 10, 1977

TO : Distribution

FROM : CM/SOD, ^{RESD.} Donald B. Dickie

SUBJECT: Contract No. AID/pha-C-1146 between A.I.D. and The Johns Hopkins University

This transmits one copy of a Negotiated Indirect Cost Rate Agreement dated August 3, 1977. This Agreement is also Amendment No. 12 to the subject Contract.

The purpose of this Amendment is to establish final and/or provisional indirect cost rates.

If additional copies are required, please contact CM/SOD/OSC.

DISTRIBUTION:

- CM/SD/SUP, Mrs. G. Booker
- CM/SD/SUP, Mrs. E. Amis
- CM/SD/SUP, Mr. G. Nell
- SER/FM, Mr. W. McKeel
- AG/AUD, Mr. B. Abshire (2 copies)

Contracting Officer, CM/ COD/PHA , Mr. G. Gold

Project Manager, PHA/POP, Mrs. M. Dobrovir

USAID/ _____

ORIGINAL

NEGOTIATED INDIRECT COST RATE AGREEMENT

Date: August 3, 1977

SUBJECT: Indirect Cost Rates for Use in Cost Reimbursement Type Agreements With the Agency for International Development (AID)

REFERENCE: DHEW Negotiation Agreement dated March 7, 1977

INSTITUTION: The Johns Hopkins University
or Baltimore
OTHER: Maryland 21218

PART I - NEGOTIATED INDIRECT COST RATES (%):

Type	Effective Period From	Thru	Overhead Rates (%)			
			Research Agreement (%)		ESA Agreement (%)	
			On-Campus	Off-Campus	On-Campus	Off-Campus
Predetermined	7-1-76	6-30-77	51.00	31.00		
Predetermined	7-1-77	6-30-78	48.00	24.00		
Provisional	7-1-78	Until Amended	48.00	24.00	27.00	14.00

Acceptance of the rate(s) agreed to herein is predicated upon the conditions: (1) that no costs other than those incurred by the grantee/contractor were included in its indirect cost rate proposal and that such costs are legal obligations of the grantee/contractor, (2) that the same costs that have been treated as indirect costs have not been claimed as direct costs, (3) that similar types of costs have been accorded consistent treatment, and (4) that the information provided by the grantee/contractor which was used as the basis for acceptance of the rate(s) agreed to herein is not subsequently found to be materially incomplete or inaccurate.

Base of Application.

Total direct costs less items of equipment \$1,000 and over, major subcontracts \$10,000 and over, alterations and renovations \$5,000 and over, and hospitalization and other fees related to patient care.

SEE PART III FOR APPLICATION OF THESE RATES TO AID AGREEMENTS.

PART II - ITEMS NORMALLY TREATED AS DIRECT COSTS: Fringe Benefits applicable to direct salaries and wages are treated as direct costs. Application of the following rates are based on salaries and wages including all paid absences.

Predetermined 7-1-76 to 6-30-77	15.00%	- Staff Employees
Predetermined 7-1-76 to 6-30-77	5.95%	- Post Graduate Students
Provisional 7-1-77 to 6-30-78	16.00%	- Staff Employees
Provisional 7-1-77 to 6-30-78	5.90%	- Post Graduates

PART III - SPECIAL TERMS AND CONDITIONS:

Pursuant to § 7-3.705 of the Agency For International Development Procurement Regulations (AIDPR), the negotiated indirect cost rates set forth in Part I of this Agreement are incorporated into AID Agreements shown below. This Agreement shall not change any monetary ceiling, obligation, or specific cost allowance or disallowance provided for in the Contracts or Grants listed below or any other Agreement between the parties.

<u>Contract/Grant No.</u>	<u>Amendment No.</u>	<u>Project Number</u>	<u>Note</u>
✓ Contract AID/pha-C-1146	1	932-11-570-629	a/
Contract AID/ta-C-1312	2	931-17-510-249	b/
Contract AID/ta-C-1362	1	931-11-998-001	a/
Grant AID/otr-G-1496	1	None	a/
Grant AID/otr-G-1511	1	None	a/
Contract AID/csd-2832	9	931-11-570-894	b/
Contract AID/csd-3627	19	932-17-580-548	c/

Notes: a/ Research Rates - On-Site only apply.

b/ Research Rates - On and Off apply.

c/ Both Research and ESA - On and Off apply.

ACCEPTED: The Johns Hopkins University

BY Richard E. Hufnail
RICHARD E. HUFNAIL

PRINTED OR TYPED NAME
Director of Sponsored
Research Administration

TITLE
8/5/77
DATE

Donald B. Dickie

Donald B. Dickie
CONTRACTING OFFICER
Overhead and Special Costs Branch
Special Operations Division
Office of Contract Management
Agency for International Development

DISTRIBUTION:	<u>CM/ROD</u>		<u>CM/COD</u>
	AFR	X	TAB
	NF	X	PHA
	LA	X	OTR
	ASIA		ITA

	<u>OTHER</u>
X	AG/AUD
X	CM/SD/SUP
X	SER/FM/ PAD
X	PHA/POP/R X TA/H
X	PHA/PVC/PDA X PHA/POP/M

WHD

1. AMENDMENT/ MODIFICATION NO. 1	2. EFFECTIVE DATE See # 19	3. REQUISITION/PURCHASE REQUEST NO. 932-0629-3277208	4. PROJECT NO. (If applicable) 932-0629
5. ISSUED BY PHA Branch Central Operations Division Office of Contract Management Agency for International Development Washington, D.C. 20523		6. ADMINISTERED BY (If other than block 5) ORIGINAL PHA/POP/R <i>Jrg - M Laffock</i> <i>D Lewis</i>	
7. CONTRACTOR NAME AND ADDRESS (Street, city, county, state, and ZIP Code) The Johns Hopkins University Baltimore, Maryland 21218		8. AMENDMENT OF SOLICITATION NO. <input type="checkbox"/> DATED _____ (See block 9) <input checked="" type="checkbox"/> MODIFICATION OF CONTRACT/ORDER NO. AID/pha-C-1146 DATED 9-30-76 (See block 11)	

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers is extended, is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:

(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)

Appropriation Symbol: 72-11X1024 Amount Obligated: \$250,000
Allotment Symbol: 424-32-099-00-23-71

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS

(a) This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.

(b) The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.

(c) This Supplemental Agreement is entered into pursuant to authority of the Foreign Assistance Act of 1961, as amended, and Executive Order No. 11223.
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

1. Cover Page

a. Total Estimated Contract Cost - Delete the amount obligated shown as "\$250,000" and substitute in lieu thereof the amount "\$500,000".

b. Delete the paragraph which reads "This Contract consists of this Cover Page" in its entirety and substitute in lieu thereof the following:

"This Contract consists of this Cover Page, the Table of Contents, the Schedule, the General Provisions (Form AID 1420-23C,) dated 7-1-76,

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13. <input type="checkbox"/> CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT		<input checked="" type="checkbox"/> CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 7 COPIES TO ISSUING OFFICE	
14. NAME OF CONTRACTOR/OFFEROR BY <i>Richard E. Hufnail</i> (Signature of person authorized to sign)	17. UNITED STATES OF AMERICA BY <i>Gerald P. Gold</i> (Signature of Contracting Officer)	15. NAME AND TITLE OF SIGNER (Type or print) Richard E. Hufnail, Director Sponsored Research Administration	19. DATE SIGNED 6/29/77
16. DATE SIGNED 6/29/77	18. NAME OF CONTRACTING OFFICER (Type or print) GERALD P. GOLD	19. DATE SIGNED JUN 30 1977	

Additional General Provisions (Form 1420-23D), dated 7-1-76 and an Appendix "A" (Operational Plan)."

2. Table of Contents - Delete the paragraph which reads "The General Provisions applicable" in its entirety and substitute in lieu thereof the following:

"The General Provisions applicable to this contract consists of Form AID 1420-23C entitled 'General Provisions - Cost Reimbursement Contract With An Educational Institution', dated 7-1-76, which includes provisions 1 through 46 and Form AID 1420-23D entitled 'Additional General Provisions - Cost Reimbursement Contract With An Educational Institution', dated 7-1-76, which includes provisions 1 through 18. These provisions apply as of the effective date of this amendment.

3. Article IV - Estimated Contract Cost and Financing - Delete in its entirety and substitute in lieu thereof the following:

"Article IV - Estimated Contract Cost and Financing

The Contractor shall be reimbursed for the costs incurred by it in performing services hereunder in accordance with the applicable provisions of the Schedule and the General Provisions, subject to the following limitation made in respect thereto:

A. Total AID dollar funds available for payment and allotted to this Contract for the period October 1, 1976 through April 30, 1978. See the clause of the General Provisions entitled "Limitation of Funds" and the

FUNDAL OBLIGATED

Approp. No.	11X1024
Allot. No.	424-32-099-00-23-71
Obj. No.	3277208
Amount	250,000.00
Proj. No.	932-0629

By JH Date 7/7/77

Article of the Schedule entitled "Budget", if applicable. \$500,000

B. Estimated additional funds which may be provided, if funds are available. See the clause of the General Provisions entitled "Limitation of Funds" and the Article of the Schedule entitled "Budget". Said amount is an overall estimate only and shall be negotiated when the funds are made available.

\$488,906

Total Estimated Contract Costs

\$988,906"

NOTE: It is estimated that the aforesaid amounts shall be sufficient to complete the work required hereunder as set forth in the Schedule Article entitled "Statement of Work":

4. Article VII - Alterations In Contract

a. Under Paragraph A, add the following new General Provision

"8. GP No. 46 - Privacy Act (Attachment H)"

b. Delete Paragraphs "B", "C", "D", "E", "F".

c. Add a new Paragraph "B" as follows:

"B. Additional General Provision No. 9 - Travel Expenses

(Sept. 1975).

1. In the title, delete the date 'Sept. 1975' and substitute in lieu thereof the date 'December 1976'.

2. Under Paragraph (i) entitled 'Emergency and Irregular Travel and Transportation', delete subparagraph (1)(i) in its entirety and substitute in lieu thereof the following:

(ii) Death or serious illness or injury of a member of the immediate family of the employee or spouse. 'Serious illness or injury' and 'immediate family' are defined in accordance with Section 699.5 of the Uniform State/AID/USIA Regulations, as in effect on the date of such travel."

3. Delete Paragraph (1) entitled "Use of U.S. Flag Carriers" in its entirety and substitute in lieu thereof the following:

"(1) Preference for U.S. Flag Air Carriers

(a) Publ L. 93-623 requires that all Federal agencies and Government contractors and subcontractors will use U.S. flag air carriers for international air transportation of personnel (and their personal effects) or property to the extent service by such carriers is available. It further provides that the Comptroller General of the United States shall disallow any expenditure from appropriated funds for international air transportation on other than a U.S. flag carrier in the absence of satisfactory proof of the necessity therefor.

(b) The contractor agrees to utilize U.S. flag carriers for international air transportation of personnel (and their personal effects) or property to the extent service by such carriers is available.

(c) In the event that the contractor selects a carrier other than a U.S. flag air carrier for international air transportation, he will include a certification on vouchers involving such transportation which is essentially as follows:

CERTIFICATION OF UNAVAILABILITY OF U.S. FLAG CARRIERS

I hereby certify that transportation service for personnel (and their personal effects) or property by certified air carrier was unavailable for the following reasons: (state reasons).

(d) The terms used in this clause have the following meanings:

(1) "International air transportation means transportation of persons (and their personal effects) or property by air between a place in the United States and a place outside thereof or between two places both of which are outside the United States.

(2) "U.S. flag air carrier" means one of a class of air carriers holding a certificate of public convenience and necessity issued by the Civil Aeronautics Board, approved by the President, authorizing operations between the United States and/or its territories and one or more foreign countries.

(3) The term "United States" includes the fifty states, Commonwealth of Puerto Rico, possessions of the United States, and the District of Columbia."

(e) The contractor shall include the substance of this clause, including this paragraph (3), in each subcontract or purchase hereunder which may involve air transportation.

d. Add a new Paragraph "C" as follows:

"C. Additional General Provision No. 10 - Transportation and Storage Expenses (Sept. 1974)

1. In the title, delete the date "(Sept. 1974)" and substitute in lieu thereof the date "(December 1976)".

2. Delete Paragraph (d) in its entirety and substitute in lieu thereof the following:

"(d) International Ocean Transportation

(1) All international ocean transportation of persons and things which is to be reimbursed in U.S. dollars under this contract shall be by U.S. flag vessels to the extent they are available.

(i) Transportation of things. Where U.S. flag vessels are not available, or their use would result in a significant delay, the Contractor may obtain a release from this requirement from the Transportation Support Division, Office of Commodity Management, Agency for International Development, Washington, D.C. 20523, or the Mission Director, as appropriate, giving the basis for the request.

(ii) Transportation of Persons. Where U.S. flag vessels are not available, or their use would result in a significant delay, the Contractor may obtain a release from this requirement from the Contracting Officer or the Mission Director, as appropriate.

(2) Transportation of foreign-made vehicles. Reimbursement of the costs of transporting a foreign (non U.S.) made motor vehicle will be made in accordance with the provisions of the Uniform State/AID/USIA Foreign

Service Travel Regulations, as from time to time amended.

(3) Reduced rates on U.S. flag carriers. Reduced rates on United States flag carriers are in effect for shipments of household goods and personal effects of AID contract personnel. These reduced rates are available provided the shipper states on the bill of lading that the cargo is "Personal Property - not for resale - payment of freight charges is at U.S. Government (AID) expense and any special or diplomatic discounts accorded this type cargo are applicable." The Contractor will not be reimbursed for shipments of household goods or personal effects in amount in excess of the reduced rates available in accordance with the foregoing".

e. Renumber Paragraph "G" to read Paragraph "D".

f. In the new Paragraph "D", delete the number "16" wherever it appears and substitute in lieu thereof the number "15".

GENERAL PROVISIONS

Cost Reimbursement Contract With An Educational Institution

INDEX OF CLAUSES

1. Definitions
2. Approvals
3. Biographical Data
4. Personnel Compensation
5. Leave and Holidays
6. Travel Expenses
7. Allowable Cost and Payment
8. Negotiated Overhead Rates
9. Limitation of Funds
10. Examination of Records by Comptroller
General
11. Audit
12. Reports
13. Research Activities and the Use of Graduate Students
14. Training of Foreign Country Nationals
15. Source Requirements of Procurement of Equipment, Vehicles, Materials, Supplies, and Services
16. Subcontracts
17. Government Property
18. Material Change in Conditions
19. Disputes
20. Termination for Convenience of the Government
21. Rights in Data and Publication
22. Authorization and Consent
23. Notice and Assistance Regarding Patent and Copyright Infringement
24. Insurance—Liability to Third Persons
25. Assignment of Claims
26. Inspection
27. Equal Opportunity
28. Utilization of Small Business Concerns
29. Utilization of Labor Surplus Area Concerns
30. Convict Labor
31. Officials Not to Benefit
32. Covenant Against Contingent Fees
33. Language, Weights, and Measures
34. Utilization of Minority Business Enterprises
35. Listing of Employment Openings
36. Payment of Interest on Contractors' Claims
37. Employment of the Handicapped
38. Notices

1. DEFINITIONS (JAN. 1975)

(a) "Administrator" shall mean the Administrator or the Deputy Administrator of the Agency for International Development.

(b) "AID" shall mean the Agency for International Development.

(c) "Campus Coordinator" shall mean the representative of the Contractor at the Contractor's home institution, who shall be responsible for coordinating the activities carried out under the Contract.

(d) "Consultant" shall mean any especially well-qualified person who is engaged on a temporary or intermittent basis and who is not an officer or employee of the Contractor.

(e) "Contracting Officer" shall mean the person executing this Contract on behalf of the United States Government and any other Government employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this Contract, the authorized

representative of a Contracting Officer acting within the limits of his authority.

(f) "Contractor" shall mean the educational institution providing services hereunder.

(g) "Contractor Employee" shall mean an employee of the Contractor assigned to work under this Contract.

(h) "Economy Class" air travel (also known as jet-economy, air-coach, tourist-class, etc.) shall mean a class of air travel which is less than first-class.

(i) "Federal Procurement Regulations (FPR)," when referred to herein, shall include AID Procurement Regulations (AIDPR).

(j) "Government" shall mean the United States Government.

2. APPROVALS (JUNE 1973)

All approvals made under the Contract by the Contracting Officer, or Mission Director, shall be in writing and obtained by the Contractor

ADDITIONAL GENERAL PROVISIONS

COST REIMBURSEMENT CONTRACT WITH AN EDUCATIONAL INSTITUTION

(Additional General Provisions for an Overseas Cost Reimbursement Contract with an Educational Institution are also attached, and except for the clauses omitted as specified on the preceding page, such Additional General Provisions are incorporated in this Contract.)

INDEX OF CLAUSES

1. Definitions
2. Contractor-Mission Relationships
3. Personnel
4. Personnel Compensation
5. Orientation and Language Training
6. Leave and Holidays
7. Post Privileges
8. Differential and Allowances
9. Travel Expenses
10. Transportation and Storage Expenses
11. Inspection Trips by Contractor's Officers and Executives
12. Notice of Changes in Regulations
13. Conversion of United States Dollars to Local Currency
14. Facilities and Services to be Arranged by AID
15. Title to and Care of Property
16. Marking
17. Insurance-Workmen's Compensation, Private Automobile, Marine and Air Cargo (Overseas)

1. DEFINITIONS (JUNE 1973)

(a) "Campus Personnel" shall mean representatives of the Contractor performing services under the Contract at the Contractor's home institution and shall include the Campus Coordinator

(b) "Contractor's Chief of Party" shall mean the representative of the Contractor in the cooperating country who shall be responsible for supervision of the performance of all duties undertaken by the Contractor in the cooperating country.

(c) "Cooperating Country or Countries" shall mean a foreign country in which there is an AID assistance program or activity administered by AID in which services are to be rendered hereunder

(d) "Cooperating Country National" shall mean an individual who is a citizen or resident of the cooperating country.

(e) "Cooperating Government" shall mean the government of the cooperating country.

(f) "Dependents" shall mean:

(1) Spouse;

(2) Children (including step and adopted children) who are unmarried and under 21 years of age or, regardless of age, are incapable of self-support;

(3) Parents (including step and legally adoptive parents), of the employee or of the spouse, when such parents are at least 51 percent dependent on the employee for support;

(4) Sisters and brothers (including step or adoptive sisters or brothers) of the employee,

or of the spouse, when such sisters and brothers are at least 51 percent dependent on the employee for support, unmarried and under 21 years of age, or, regardless of age, are incapable of self-support.

(g) "Local Currency" shall mean the currency of the cooperating country.

(h) "Mission" shall mean the United States AID Mission to, or principal AID office in, the cooperating country.

(i) "Mission Director" shall mean the principal officer in the Mission in the cooperating country or his designated representative.

(j) "Participants" shall mean nationals of the cooperating country brought to the United States or to third countries for training.

(k) "Regular Employee" shall mean a Contractor employee appointed to serve one year or more in the cooperating country.

(l) "Resident" shall mean an individual who has been physically present for 3 consecutive years, substantially uninterrupted, in a country.

(m) "Short-Term Employee" shall mean a Contractor employee appointed to serve less than one year in the cooperating country.

(n) "Third Country National" shall mean an individual who is neither a U.S. citizen, U.S. resident, or a cooperating country national.

(o) "Traveler" shall mean the Contractor's regular employees, dependents of the Contractor's regular employees, the Contractor's short-term employees, consultants, campus coordinator, or other professional personnel on its staff, prospective regular or short-term em-

General Provision No. 46

(This clause shall be included in every solicitation and resulting contract, and in every contract awarded without a solicitation, when the statement of work requires the design, development, or operation of a system of records on individuals to accomplish an agency function).

PRIVACY ACT

(a) The Contractor agrees:

(1) To comply with the Privacy Act of 1974 and the rules and regulations issued pursuant to the Act in the design, development, or operation of any system of records on individuals in order to accomplish an agency function when the contract specifically identifies (i) the system or systems of records and (ii) the work to be performed by the contractor in terms of any one or combination of the following: (A) design, (B) development, or (C) operation;

(2) To include the solicitation notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation when the statement of work in the proposed subcontract requires the design, development, or operation, of a system of records on individuals to accomplish an agency function:

PRIVACY ACT NOTIFICATION

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 U.S.C.552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

(3) To include this clause, including this paragraph (3) in all subcontracts awarded pursuant to this contract which requires the design, development, or operation of such a system of records.

(b) In the event of violations of the Act, a civil action may be brought against the agency involved where the violation concerns the design, development, or operation of a system of records on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency where the violation concerns the operation of a system of records on individuals to accomplish an agency function. For purposes of the Act when the contract is for the operation of a system of records on individuals to accomplish an agency function, the contractor and any employee of the contractor is considered to be an employee of the agency.

(c) The terms used in this clause have the following meanings:

(1) "Operation of a system of records" means performance of any of the activities associated with maintaining the system of records including the collection, use, and dissemination of records.

(2) "Record" means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education, financial transaction, medical history, and criminal or employment history and that contains his name or the identifying number, symbol, or other identifying particular assigned to the individual, such a finger or voice print or a photograph.

(3) "System of records" on individuals means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

CONTRACT

Section IA.

Proprietor/Grantee

Name: Johns Hopkins U.

Section IB.

Contract/Grant Number:

AID/PHA-C-1146

Section II.

Description of Contract/Grant: PLEASE CIRCLE ONLY ONE ITEM UNDER EACH HEADING: IF OTHER, PLEASE SPECIFY. (Complete both pages 1 and 2) (Not to be completed for Amendment or Modification Actions)

MD4 - CONTRACT/GRANT TYPE

- 0. NDA, (BOA, BMA, etc.)
- 1. Fixed Price (Specify: FPP, FPE, FPEA, FPI)
- 2. Cost Reimbursement (Specify: CPTT, CS, CPAT, CPIT)
- 3. Cooperative Agreement
- 4. Grant - General Support
- 5. Grant - Specific Support
- 6. Grant - 211(d)
- 7. Do not Use
- 8. IQCs
- 9. Host Country Contract/Grant } Complete only through M51.

MD5 - SELECTION PROCEDURES

- A. Formally advertised (IFB) (AIDPR 7-2.4) & (FPR 1-2.4)
- B. Negotiated Price Competition, General Procedure (RFP) (AIDPR 7-4.56)
- C. A & E (AIDPR 7-4.10)
- D. Ed. Inst and/or Intl Research (AIDPR 7-4.57)
- E. Collaborative Assistance (AIDPR 7-4.58)
- F. Predominant Capability (AIDPR 7-3.101-50(b)(3))
- G. Unsolicited Proposal (AIDPR 7-3.101-50(b)(6))
- H. Procurement to be Performed by the Contractor in Person (AIDPR 7-3.101-50(b)(1))
- I. Sole Source (AIDPR 7-3.101-50(b)(4))
- J. Impairment of Foreign Policy Objectives (AIDPR 7-3.101-50(b)(7))
- K. S(a) Selection (FPR 1-1.713-1)
- L. Grant (Handbook 13)
- M. Do Not Use
- N. Cooperative Agreement (Handbook 13)
- O. Small Business Set-Aside (FPR 1-1.706-8)
- P. Overseas Procuring Activities (AIDPR 7-3.101-50(b)(2))

MD6 - TYPE SERVICE

- A. Training of Participants
- B. Tech Assistance (Program, Project related except A & E Services)
- C. A & E Services
- D. Construction
- E. Research
- F. Tech Services to AID (other than training) (usually operating expense)
- G. Training Service for AID
- H. Equipment, Materials, Supplies, Commodities
- I. Translation Service

MD7 - TYPE CONTRACTOR/GRANTEE

- A. Firm - All profit-making firms (other than A & E)
- B. A & E Firms
- C. Individual (Non-personal service)
- D. Individual (Personal Service)
- E. Univ/other Ed Institutions
- F. Non-Profit Organ., Institutions (other than Ed or PVO)
- G. Private Voluntary Organisation (PVO)
- H. International Agri. Research Organisation
- I. Public International Organisations (UN Agencies, ICRC World Bank, etc.) (Handbook 13, Chapter 5)

MD8 - TYPE AWARD

- A. SB Set-Aside - Awarded to Non-Minority
- B. SB Set-Aside - Awarded to Minority
- C. SB Not Set-Aside - Awarded to Non-Minority
- D. SB Not Set-Aside - Awarded to Minority
- E. S(a) SMA Awarded to Non-Minority (Women-Owned, Veterans, etc.)
- F. S(a) SMA Awarded to Minority
- G. Personal Service Contract - Non-Minority
- H. Personal Service Contract - Minority
- I. Individual Non-Personal Service Contract - Non-Minority
- J. Individual Non-Personal Service Contract - Minority
- K. Not Small Business (Univ., Non-Profit, Large firms) Non-Minority
- L. Not Small Business (Univ., Non-Profit, Large firms) Minority
- M. U. S. Government

MD11 ADVANCE

- 1. No Advance
- 2. Advance- Non FELC
- 3. Advance- Federal Reserve Letter of Credit

MD13 - Is any travel required outside U. S.? Yes No

M15 - TYPE OWNERSHIP

- 1. American Oriental
- 2. Black American
- 3. American Aleuts or Eskimos
- 4. American Indian
- 5. Hispanic
- 6. Other than 1 thru 5

M37 - AFFIRMATIVE ACTION PLAN ON FILE

Yes No

M38 - AFFIRMATIVE ACTION PLAN ON PREVIOUSLY HELD CONTRACTS

Yes No

M60 - INCREMENTAL FUNDED CONTRACT

Yes No

M61 - CONSULTANT TYPE AWARD

Is the Award for Consulting Type Service to AID? Yes No

M63 - EXTENT OF COMPETITION IN NEGOTIATION

- COMPETITIVE
 - A1. Small Business Total Set-Aside
 - A2. Small Business Partial Set-Aside
 - A3. Labor Surplus Set-Aside
 - A4. Labor Surplus/Small Business Set Aside
 - A9. Other Negotiated Competitive
- NON-COMPETITIVE
 - B1. Buy Indian
 - B2. S(a) Program
 - B3. Follow-on After Competition
 - B9. Other Negotiated Non-Competitive

M65 - TYPE OF BUSINESS

- E1. Source: Non-U. S. and Used Outside U. S. and Possessions
- E2. Source: Non-U. S. and Possessions (Foreign Purchases Used Inside U. S.) (If U. S. Source, A - D)
 - A1. Small Business - Disadvantaged S(a)
 - A2. Small Business - Owned by Minority Group
 - A3. Other Small Business (including individuals)
 - B1. Large Minority Business
 - B2. Other Large Business
- C1. Non-Profit Private Educational Organization
- C2. Non-Profit Hospital
- C3. Non-Profit Research Institution, Foundation, and Laboratories
- C4. Other Non-Profit Institutions
- D1. State/Local Government Educational Institution
- D2. State/Local Government Hospital
- D3. State/Local Government Research Organization
- D4. Other State/Local

M66 - COST ACCOUNTING STANDARDS

Required Not Required

M67 - NUMBER OF BIDDERS OFFERING ITEMS OR SERVICES OF FOREIGN CONTENT

0

M68 - WOMEN OWNED BUSINESS

Yes No

M69 - PERCENT FOREIGN CONTENT OF COMMODITIES AND SERVICES

6

M70 - LABOR SURPLUS AREA (LSA) PREFERENCE (Location of Contractor)

- 1. Labor Surplus Area - No Preference
- 2. Labor Surplus Area - Tie Bid Preference
- 3. Not a Labor Surplus Area Preference Award
- 7. Total Labor Surplus/Small Business Set-Aside Preference
- 8. Total Labor Surplus Set-Aside Preference (P.L. 95-89)

M12 - COUNTRY OF PERFORMANCE

USA (Specify)

UNITED STATES GOVERNMENT

Memorandum

TO : *OOD, PE, G. GOLD*

DATE: *April 24, 1979*

FROM : *CM/SD/SUP, B. Nichols*

SUBJECT: Computer Data Required for COORS and FPDS Systems for those Actions Carried Over into FY-79

Attached is a special revised Contract/Grant/Cooperative Agreement Data Sheet for the basic contract NO. *AD/PHA - C-1146* that was active FY-78 and carried over into FY-79.

Johns Hopkins Univ.
Presently, our new Contract On-Line Reporting System does not contain accurate data on those contracts and grants that were carried over from FY-78 (the old COORS System) to FY-79 and the new COORS System. Therefore, it is necessary for CM/SD/SUP to obtain this data on all "carryover" contracts/grants for the purpose of updating and making more accurate the information in the new data system. Accordingly, it is necessary that you complete this revised data sheet for the above listed basic document and return the completed form to CM/SD/SUP as soon as possible.

Please note that this data sheet is shorter than the usual one. Hopefully, it will not take too much of your time to complete. We have been receiving your completed data control sheets for new FY-79 business. Overall, the data provided has been excellent. We appreciate your efforts in this matter.

Any questions concerning this requirement should be directed to Bill Nichols, Room 778 Pomponio Plaza or at 235-9111.

Attachment: Special Revised Contract/Grant/Cooperative Agreement Data Sheet



6 OCT 1976
Program - M. Johnson
Pha - A. Lewis

COST REIMBURSEMENT CONTRACT WITH AN EDUCATIONAL INSTITUTION

AGENCY FOR INTERNATIONAL DEVELOPMENT NEGOTIATED CONTRACT NO. AID/pha-C-1146

NEGOTIATED PURSUANT TO THE FOREIGN ASSISTANCE ACT OF 1961, AS AMENDED, AND EXECUTIVE ORDER 11223	TOTAL ESTIMATED CONTRACT COST \$988,906 (Obligated \$250,000)
CONTRACT FOR: Prolongation of Lactational Infertility	CONTRACTOR (Name and Address) The Johns Hopkins University
PROJECT NO: 932-11-570-629	NAME ORIGINAL
ISSUING OFFICE (Name and Address) PHA Branch Central Operations Branch Office of Contract Management Agency for International Development Washington, D.C. 20523	STREET ADDRESS Baltimore, Maryland 21218
ADMINISTRATION BY Issuing Office	CITY, STATE, AND ZIP CODE
MAIL VOUCHERS (Original and 3 copies) TO: Agency for International Development Office of Financial Management Washington, D.C. 20523	COGNIZANT SCIENTIFIC, TECHNICAL OFFICE PHA/POP/R
EFFECTIVE DATE 10-1-76	ACCOUNTING AND APPROPRIATION DATA PIO/T NO. <u>932-11-570-629-3217208</u> APPROPRIATION NO. <u>72-11X1024</u> ALLOTMENT NO. <u>424-32-099-00-23-51</u>
	ESTIMATED COMPLETION DATE 9-30-79

The United States of America, hereinafter called the Government, represented by the Contracting Officer executing this Contract, and the Contractor, an educational institution chartered by the State of Maryland with its principal office in Baltimore, agree that the Contractor shall perform all the services set forth in the attached Schedule, for the consideration stated therein. The rights and obligations of the parties to this contract shall be subject to and governed by the Schedule and the General Provisions. To the extent of any inconsistency between the Schedule and the General Provisions and any specifications or other provisions which are made a part of this contract, by reference or otherwise, the Schedule or the General Provisions shall control. To the extent of any inconsistency between the Schedule and the General Provisions, the Schedule shall control.

This Contract consists of this Cover Page, the Table of Contents, and the Schedule consisting of 10 pages, the General Provisions (Form AID 1420-23C), dated 7-1-75 and Additional General Provision (Form 1420-23D), dated 7-1-75, and an Appendix "A" (Operational Plan).

NAME OF CONTRACTOR The Johns Hopkins University	UNITED STATES OF AMERICA AGENCY FOR INTERNATIONAL DEVELOPMENT
BY (Signature of authorized individual) <i>Robert C. Bowie</i>	BY (Signature of Contracting Officer) <i>Gerald P. Gold</i>
TYPED OR PRINTED NAME ROBERT C. BOWIE	TYPED OR PRINTED NAME GERALD P. GOLD
TITLE Vice President for Business Management	CONTRACTING OFFICER
DATE 9/30/76	DATE SEP 30 1976

Schedule

Table of Contents

The Schedule, on pages 1 through 10, consists of this Table of Contents and the following Articles:

Article I	-	Statement of Work
Article II	-	Key Personnel
Article III	-	Period of Contract Services
Article IV	-	Estimated Contract Costs and Financing
Article V	-	Budget
Article VI	-	Negotiated Overhead Rates
Article VII	-	Alterations in Contract
Article VIII	-	Additional Provisions

The General Provisions applicable to this contract consist of form AID 1420-23C entitled "General Provisions-Cost Reimbursement Contract With An Educational Institution", dated 7/1/75, which includes provisions 1 through 45; and form AID 1420-23D entitled "Additional General Provisions-Cost Reimbursement Contract With An Educational Institution", dated 7-1-75, which includes provisions 1 through 18.

FUNDS OBLIGATED

Approp. No. 72- 11 X1024
Allot. No. 124-32-099-00-23-51
Obl. No. 3217208 Obl. Cl. 2590
Amount \$ 250,000.00
Proj. No. 932-11-570-629-73

By M. Hughes FM/CSD Date 9/30/76

Schedule

Article I - Statement Of Work

For a period hereinafter set forth in the Schedule, the Contractor shall render technical advice and assistance as more specifically provided for in Appendix "A", Operational Plan, attached hereto and made a part hereof.

Article II - Key Personnel

A. The Key personnel which the Contractor shall furnish for the performance of this contract are as follows:

Key Personnel: J.E. Tyson, M.D., Principal Investigator

W.H. Mosley, M.D., Co-Investigator

B. The personnel specified above are considered to be essential to the work being performed hereunder. Prior to making any change in the key personnel, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. The listing of key personnel may, with the consent of the contracting parties, be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

C. (1) The Contractor shall obtain AID's approval to change the principal investigator or project leader, or to continue the research work during a continuous period in excess of three months without the participation of the approved principal investigator or project leader.

(2) The Contractor shall consult with AID if the principal investigator plans to, or becomes aware that he will, devote substantially less effort to the work than anticipated in the Operational Plan. If AID determines that the reduction of effort would be so substantial as to impair the successful prosecution of the research, AID may request a change of principal investigator, terminate the research effort or make any other appropriate modification of the research agreement.

Article III - Period of Contract Services

The effective date of this Contract is October 1, 1976 and the estimated completion date is September 30, 1979.

Article IV - Estimated Contract Cost and Financing

The Contractor shall be reimbursed for the costs incurred by it in performing services hereunder in accordance with the applicable provisions of the Schedule and the General Provisions, subject to the following limitation made in respect thereto:

A. Total AID dollar funds available for payment and allotted to this Contract for the period October 1, 1976 through July 31, 1977. See the clause of the General Provisions entitled "Limitation of Funds" and the Article of the Schedule entitled "Budget", if applicable.

\$250,000

B. Estimated additional funds which may be provided, if funds are available. See the clause of the General Provisions entitled "Limitation of Funds" and the Article of the Schedule entitled "Budget". Said amount is an overall estimate only and shall be negotiated when the funds are made available.

\$738,906

Total Estimated Contract Costs

\$988,906

28

NOTE: It is estimated that the aforesaid amounts shall be sufficient to complete the work required hereunder as set forth in the Schedule Article entitled "Statement of Work":

Article V - Budget

Within the total estimated cost of this contract the Contractor may adjust line item amounts, as may be reasonable necessary for the performance of this contract, except that the obligated amount under the contract may not be exceeded.

	<u>BUDGET</u>			<u>Total</u>
	Fr: <u>10/1/76</u> To: <u>9/30/77</u>	Fr: <u>10/1/77</u> To: <u>9/30/78</u>	Fr: <u>10/1/78</u> To: <u>9/30/79</u>	
Salaries	\$ 92,800	\$ 87,700	\$ 55,740	\$236,240
Fringe Benefits	13,925	14,909	9,476	38,310
Travel and Transportation	1,800	6,000	8,500	16,300
Equipment, Materials and Supplies *	59,500	14,500	8,500	82,500
Other Direct Costs	7,250	1,250	1,850	10,350
Subcontracts	128,481	150,000	150,000	428,481
Overhead	<u>70,785</u>	<u>63,066</u>	<u>42,874</u>	<u>176,725</u>
	<u>\$374,541</u>	<u>\$337,425</u>	<u>\$276,940</u>	<u>\$988,906</u>

*Written approval of the AID Contracting Officer is required prior to procurement of the liquid scintillation Counter. See Clause 16 of the General Provisions.

29

Article VI - Negotiated Overhead Rates

A. Establishment of Predetermined Indirect Cost Rates

Pursuant to the provisions of the clause of the General Provisions of this Contract entitled "Negotiated Overhead Rates - Predetermined", a rate or rates shall be established for each of the Contractor's accounting periods during the term of the Contract. The rate for the initial period shall be as set forth below:

	<u>Rate</u>	<u>Base</u>	<u>Period</u>
On Campus	51%	*	Fr: 10/1/76 To: 6/30/77

B. Pending establishment of final overhead rates for the initial period provisional payments on account of allowable indirect costs shall be made on the basis of the following negotiated provisional rates applied to the base which is set forth below:

	<u>Rate</u>	<u>Base</u>	<u>Period</u>
On Campus	51%	*	Fr: 7/1/77 Until Amended

*Total Direct Costs less items of equipment of \$1,000 and over; major subcontracts \$10,000 and over; alterations and renovations \$5,000 and over and hospital and other fees related to patient care.

Article VII - Alterations In Contract

A. Add the following additional General Provisions:

1. GP No. 39 - Minority Business Enterprises Subcontracting Program (Attachment A)
2. GP No. 40 - Small Business Subcontracting Program (Attachment B)
3. GP No. 41 - Employment of the Handicapped (Attachment C)

4. GP No. 42 - Cost Accounting Standards
(Attachment D)
5. GP No. 43 - Patent Rights - Acquisition By The
Government (Attachment E)
6. GP No. 44 - Clean Air and Water
(Attachment F).
7. GP No. 45 - Voluntary Participation
(Attachment G)

B. General Provision No. 7, Allowable Cost and Payment

Delete in its entirety General Provision No. 7, "Allowable Cost and Payment (September 1974)" and insert in lieu thereof General Provision No. 7, "Allowable Cost and Payment (September 1975)" as Attachment H.

C. General Provisions No. 8, Negotiated Overhead Rates

(a) Delete the title "Negotiated Overhead Rates (Nov. 1973)" and insert in lieu thereof "Negotiated Overhead rates (September 1975)".

(b) From paragraph "i(c)" of the General Provision delete the parenthetical "(Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Educational Institutions)" and insert in lieu thereof "(Grants and Contracts with Educational Institutions)".

(c) Delete paragraph "ii(c)" in its entirety and substitute in lieu thereof the following:

"(c) Allowability of costs and acceptability of cost allocation methods shall be determined in accordance with the provisions of Subpart 1-15.3 (Grants and Contracts with Educational Institutions) of the Federal Procurement Regulations as in effect on the date of this contract".

D. General Provision No. 14, Training of Foreign Country Nationals

1. From the title delete the date "(Nov. 1973)" and insert in lieu thereof "(September 1975)".
2. From paragraph "(a)(4)" of the General Provision delete the phrase "manual orders" and insert in lieu thereof "Handbook".

E. Additional General Provision No. 3, Personnel

1. From the title delete the date "(Nov. 1973)" and insert in lieu thereof "(September 1975)".
2. Delete in its entirety paragraph "(d)(3)" of the Additional General Provision and insert in lieu thereof:

"(d)(3) The Contractor is encouraged to establish its own policy of pre- and post- tour medical examinations. As a contribution, AID shall reimburse the Contractor for physical examinations authorized in paragraphs (d) (1) and (2) of this section as follows:

(1) For the employee and dependents
12 years of age and over: not to
exceed \$85 for the physical examination
plus reimbursement of charges for immunizations.

(11) For dependents under 12 years of age:
Not to exceed \$25 for each child plus
reimbursement of charges for immunizations."

F. Additional General Provision No. 4, Personnel Compensation

Delete the subhead and paragraph "(a)" and substitute in lieu thereof:
"Personnel Compensation (January 1976)

(a) Overseas recruitment incentive.

(1) Contractor employees serving overseas under this

contract who do not qualify, request, and receive an exemption for overseas, income provided under Section 911 of the U.S. Internal Revenue Code (26 U.S.C. 911) are eligible to receive an overseas recruitment incentive, provided that the average incentive for all such employees does not exceed 10 percent of the initial base annual salary of all employees eligible for the incentive under this contract.

(2) The overseas recruitment incentive is payable under one of the following alternative methods:

(1) As a lump-sum amount after the eligible employee has completed his tour of duty in the Cooperating Country under this contract, and has furnished to the Contractor a Certification that he does not qualify, and will not apply for an exemption from overseas income as provided by 26 U.S.C. 911 (Contractor shall retain such Certifications for post-audit); or

(11) At the option of the Contractor, the overseas recruitment incentive may be paid in increments during an employee's tour of duty; provided however, that payments made by the Contractor to employees who become eligible for an exemption from overseas income as provided by 26 U.S.C. 911, which payments were reimbursed by AID under this contract, shall be refunded to AID; and provided further, that neither the Contractor's (nor the Subcontractor's) inability to collect refunds from ineligible employees shall be used as a basis to excuse subsequent refunds by the Contractor to AID.

(3) If the overseas recruitment incentive causes the employee's salary to exceed the FSR-1 level, Contracting Officer approval must be obtained."

G. Additional General Provision No. 16 - Title to and Care of Property -

Delete Additional General Provision No. 16 in its entirety.

ARTICLE VIII - Additional Provisions

A. Abortion Related Activities (Sept. 1975)

No funds made available under this grant/contract will be used for the following family planning and population assistance activities:

- 1) procurement or distribution of equipment provided for the purpose of inducing abortions as a method of family planning;
- 2) information, education, training or communication programs that seek to promote abortion as a method of family planning;
- 3) payments to women in less developed countries to have abortions as a method of family planning;
- 4) payments to persons to perform abortions or to solicit persons to undergo abortions.

The Contractor/Grantee shall insert a clause containing all of the above provisions, including this paragraph, in all subordinate agreements, subgrants, subcontracts or purchase orders hereunder.

B. Utilization of Excess and Near Excess Foreign Currencies

Full utilization of excess and near excess foreign currencies in an objective of the U.S. Government. The Contractor should obtain its supply of certain foreign currencies which have been determined by the U.S. Treasury Department to be excess to its needs from the U.S. Government—either through local accommodation exchanges or through the Treasury Department in Washington, D.C.

Travel to, through, or from certain countries shall, at AID's option, be funded from U.S.-owned foreign currency. When AID intends to exercise this option, it will so advise the Contractor after receipt of the Contractor's notice of intent to travel required under this contract. AID will issue a Government Transportation Request (GTR) which the Contractor may exchange for tickets, or AID will issue the tickets directly.

Per Diem (subsistence) expense of the Contractor in certain countries shall, at AID's option, be funded from U.S. -owned foreign currency. If such is to be the case, AID will so advise the Contractor after receipt of the Contractor's notice of intent to travel to those countries, or the employees of the Contractor will be so notified upon contact with the USAID Mission when first arriving in such a country.

The use of said U.S.-owned currencies will constitute a dollar charge to this contract.

Contractors who do not qualify, request, and receive an exemption for overseas, income provided under Section 911 of the U.S. Internal Revenue Code (26 U.S.C. 911) are eligible to receive an overseas recruitment incentive, provided that the average incentive for all such employees does not exceed 10 percent of the initial base annual salary of all employees eligible for the incentive under this contract.

(2) The overseas recruitment incentive is payable under one of the following alternative methods:

(1) As a lump-sum amount after the eligible employee has completed his tour of duty in the Cooperating Country under this contract, and has furnished to the Contractor a Certification that he

does not qualify, and will not apply for an exemption from overseas income as provided by 26 U.S.C. 911 (Contractor shall retain such Certifications for post-audit); or

(ii) At the option of the Contractor, the overseas recruitment incentive may be paid in increments during an employee's tour of duty; provided however, that payments made by the Contractor to employees who become eligible for an exemption from overseas income as provided by 26 U.S.C. 911, which payments were reimbursed by AID under this contract, shall be refunded to AID; and provided further, that neither the Contractor's (nor the Subcontractor's) inability to collect refunds from ineligible employees shall be used as a basis to excuse subsequent refunds by the Contractor to AID.

C. Special Provision Regarding Additional General Provision No. 3

In accordance with paragraph (a-1) of Additional General Provision No. 3 whereunder the contractor may not send individuals outside the United States to perform work under the contract without the prior written approval of the Contracting Officer, the Contracting Officer does, hereby, provide said approval for those individuals required to travel outside the United States; provided, however, that concurrence with the assignment of any and all said individuals outside the United States is obtained, in writing, from the cognizant technical office of AID prior to their assignment abroad.

After approval of the proposed international travel, the Contractor shall provide the cognizant USAID Mission advance notification, with a copy to the cognizant technical officer, of the arrival date and flight identifications of AID financed travellers.

Operational Plan

I. Objective and Purposes

A. The overall objective of this project is to develop an improved means of fertility control for use during the postpartum and lactational period.

B. The purposes of this study shall be to:

1. Determine the efficacy of oral TRH in extending the period of postpartum amenorrhea through the enhancement of breast-feeding; and
2. Determine the effect of TRH on maternal thyroid function and on milk production.

II. Specific Objectives

Specifically, the Contractor, under the direction and leadership of a Principal Investigator, shall conduct a three year research program to examine the effects of oral TRH in lactating mothers in order to accomplish the following:

1. Identify suckling as the principal mechanism via a neuro reflex in conferring infertility on puerperal women;
2. Develop a new radioimmunoassay for thyrotropin releasing hormone in human plasma and human milk;
3. Test the influence of TRH on plasma TSH and T_4 in women receiving TRH at different dosage levels;
4. Evaluate the elevation in plasma prolactin brought about by repeated suckling and to assess ovarian steroid production in women who are

in full lactation;

5. Standardize all laboratory procedures in preparation for application to field trails; and

6. After baseline and standardization studies in Baltimore, evaluate the safety and efficacy of oral TRH in rural Bangladesh as a means of enhancing lactation and prolonging infertility.

III. Work Plan

In order to accomplish the objectives listed in Items I and II above, the Contractor shall follow the Work Plan as set forth in Phases I through III below:

Phase I - A: Baltimore Studies

All studies shall be performed in healthy, human, female volunteers who have had all the procedures and goals of this study explained to them in detail. All will have signed informal consents and the proposed study has received the approval of the Joint Committee on Clinical Investigation of the Johns Hopkins Medical Institutions. The women shall have completed a normal term gestation and will be desirous of breastfeeding their infant. Where possible, several studies can be performed simultaneously on different groups of women. The most ideal group of women to be used in this study will be those from the Baltimore-Washington chapter of the LaLeche League. Preliminary contact with this Society has indicated that the women would be willing to engage in this study provided an appropriate honorarium is provided. Since not only hPRL but LH secretion changes markedly between the

first and the 90th postpartum days, it is chosen to evaluate patients during this period of time.

1. Development of an Assay for Thyrotropin Releasing Hormone (TRH)

A sensitive radioimmunoassay for TRH shall be developed to measure the concentration of this tripeptide in the peripheral plasma of women and in breast milk obtained from women receiving oral TRH.

The assay shall be developed using purified TRH. One mg of TRH will be carefully mixed with Freund's adjuvant and injected at specific intervals into selected sites of the skin of guinea pigs and rabbits. It is anticipated that as many as 15 animals will be required from each species in order to be sure to develop an antibody in at least one animal.

Immunizations shall be performed at weekly intervals for the first month, at biweekly intervals for the second month, and at monthly intervals for two months, after which each animal will be bled and serial dilutions of extracted plasma fractions will be tested against iodinated TRH tracer. The purpose of this shall be to identify the specificity and antigenicity of any antibody found and to determine the binding affinity of these antibodies for iodinated TRH.

Since TRH is a rather fragile molecule, new methods shall be devised for iodinating TRH. At first, the traditional methods of Greenwood and Hunter shall be employed followed by the use of the lactoperoxidase method. It is anticipated that assay development will require at least 8-10

months and testing of appropriate cross-reacting substances will also be necessary. Such substances shall include other pituitary polypeptides such as LH, FSH, TSH, and the releasing hormone LH-RH.

After testing is complete, the assay shall then be employed in the measurement of TRH on maternal plasma and milk samples obtained during the course of this study. The plasma shall be treated in a manner similar to that used for all immunoassays; however, milk samples may have to be dealt with differently due to the high fat content known to be present in human milk. It is anticipated that a different assay system will have to be developed.

2. Baseline Studies of the Gonadal, Thyroid, and Lactational Hormones in Lactating Women

Twenty nursing mothers shall be studied on three separate occasions during the first three postpartum months. Studies shall be performed during the third, seventh, and eleventh postpartum weeks. Each woman shall be placed at rest in a hospital bed and shall be accommodated with a crib to be used for her infant. Blood shall be obtained at periodic intervals from a venous catheter to an antecubital vein attached to a heparin lock. This system has been shown to be effective in providing for frequent blood sampling.

Two basal blood samples shall be drawn five minutes apart, after which the women shall breastfeed their children for at least 30 minutes. Each nipple shall ideally be stimulated for 15 minutes. Blood samples shall then be obtained at 5, 10, 15, and 30 minutes. The same procedure shall be

repeated during a second and third feeding on the same day, approximately four hours apart. Thus, the influence of nipple stimulation on prolactin, gonadotropins and TSH secretion shall be measured on three occasions in one day, and this will be repeated twice more during the first 90 post-partum days. It is the intent to remove as much of the variation associated with nipple stimulation as possible.

Plasma samples shall be separated and stored at -20° C until analyzed for changes in plasma hPRL, hGH, LH, FSH, and TSH. To assess the effect of nursing on thyroid function more fully, plasma TSH shall be measured on basal, 15 and 30 minute plasma samples, while plasma T_4 shall be measured on the basal samples obtained prior to each feeding. The purpose is to attempt to identify any subtle change in T_4 which would occur 3-4 hours after any increase in TSH. It is assumed that by measuring the T_4 concentration at the beginning of the second and third feeding on any one day, it would be possible to see any change brought about by a rise in TSH observed during the first morning feed. The plasma samples from these studies shall subsequently be assayed for TRH when that assay is available from Work Area 1, above.

Milk samples shall be obtained from each woman prior to and at the end of each nursing event. The milk shall be assayed for TRH and TSH. These latter studies are designed to standardize the TRH assay before its use in field trials under Phase II.

At the conclusion of these studies, the data shall be analyzed for the changes in hPRL and gonadotropins which occur in response to nipple stimulation. Furthermore, it should go far to identify any significant change in the secretion of these hormones which may influence ovarian function.

3. Baseline Studies of the Interrelationship between TSH, LH, and Prolactin in Lactating and Non-lactating Women

A question has been raised regarding the effect of the nursing interval and duration of nursing on basal hPRL levels. Considerable individual variation in basal prolactin levels exist between nursing women as well as between nursing and non-nursing women. Therefore, attempts must be made to correlate basal TSH and hPRL levels in nursing and bottle feeding mothers. This study shall be performed as follows:

Twenty nursing and five bottle feeding mothers shall be evaluated. The studies shall be performed after the 14th postpartum day to allow for stabilization of the basal plasma hPRL level.

Breastfeeding mothers shall be asked to record the frequency and duration of each feeding interval. Blood samples shall be drawn on each woman in the basal state twice a week for four weeks. The levels of plasma hPRL and gonadotropins as well as TSH shall be compared to those obtained on bottle feeding women studied during a similar time frame. In addition, coefficients of correlation shall be constructed between the cumulative mean hPRL level of nursing mothers and the cumulative mean duration of nursing time per day.

These data should more clearly identify the relationship between the nursing interval and the hPRL-LH secretory profile.

4. Baseline and Safety Studies of Gonadal, Thyroid, and Lactational Hormones in Lactating Women Receiving Oral TRH

Having characterized a profile of normal basal and postnursing hPRL, hLH, hFSH, and TSH secretion, the same ten nursing mothers shall receive TRH 10 mg twice daily for seven days. Thus, each woman previously studied shall receive oral TRH during the 4th, 8th, and 12th postpartum weeks. Such treatment shall be adequate to provoke a significant increase in the circulating concentration of hPRL. On the final day of each week of therapy, the patient shall undergo the same testing as described in Work Area 3 above. As before, plasma hormone concentrations shall be measured in addition to plasma T₄.

These results shall be compared to those of normally lactating women who did not receive oral TRH.

5. Baseline Studies of Milk Production, Composition and Volume

Since oral TRH will influence the production and composition of human milk indirectly through its effect on prolactin secretion, it is important to determine the effects of oral TRH ingestion on the composition and volume of human milk.

As a baseline, milk volume shall be determined in a group of five lactating women by pumping the breasts thoroughly at 3-4 hour intervals for

a 24 hour period. These studies shall be performed in the Clinical Investigation Unit of the Johns Hopkins Hospital. The milk shall be weighed and the volume measured. After careful mixing, a sample shall be obtained for analysis of fat, protein and lactose content. The remaining milk shall then be administered to the child via bottle. This analysis shall be performed at one month, three months, and six months following delivery so as to determine the normal variation in human milk composition and volume in women who are in full lactation.

6. Influence of Oral TRH on Ovulation and Milk Production

Thirty women shall be asked to participate in a study where oral TRH shall be administered twice a day for a minimum of six months. This study shall again be started after the 30th postpartum day so as to exclude all possible variations related to the gradual fall in plasma hPRL which normally occurs following delivery. Fifteen women shall receive 10 mg of oral TRH twice daily while the second group shall receive 15 mg of oral TRH twice daily. Blood samples shall be obtained biweekly for the determination of the hormones previously mentioned in addition to plasma estrogen and plasma progesterone. Should vaginal bleeding occur in any volunteer, an endometrial biopsy shall be performed to establish the presence or absence of histologic changes indicating ovulation.

Five women from either the 10 mg or the 15 mg oral TRH group shall be asked to provide milk samples via breast pump for a 24 hour period at the end of the first or the fourth week of oral TRH therapy. Composition of

such milk shall be compared to that obtained from five control women.

7. Study of the Association Between Lactational Failure and Prolactin Levels

Approximately 20 percent of breastfeeding women abandon the method due to a failure of milk supply. No research results are available on the exact etiology of this disorder. Therefore, it is assumed that this condition may contribute to an earlier resumption of cyclic postovulatory bleeding in such women even though they continue to attempt to breastfeed their infants.

This study is designed to evaluate the condition. It shall establish whether a deficiency in hPRL secretion is associated with nursing in women who experience lactational failure. It shall assess the frequency and the duration of the nursing stimulus and its subsequent effect on the development of lactational insufficiency. Third, it shall attempt to demonstrate that lactational insufficiency will lead to a more rapid restoration of ovulatory menstrual function and that this restoration occurs much sooner than in women who have never breastfed at all.

Women who claim to have a decreasing milk supply in spite of an adequate nursing interval shall be entered into the study. None shall be accepted before the 30th postpartum day or after the 6th postpartum month.

Basal plasma hPRL, LH, FSH, estrogen, progesterone and TSH shall be measured in the basal state on two occasions 15 minutes apart. Hormonal responses to suckling will then be measured in plasma obtained at five

minute intervals during a 30 minute nursing event. The tests shall then be repeated at the next feeding approximately four hours later.

Milk samples shall be obtained prior to and at the end of each nursing test and shall be subsequently analyzed for the fat, protein, and lactose content. Each woman shall receive oral TRH, 10 mg twice daily for five days. The endocrine response to oral TRH is usually prompt and predictable and consists of a rise in the basal hPRL concentration with a marked increase in milk production.

Basal hPRL, TSH, and gonadotropins will be measured daily during the test period. When available, TRH shall also be measured in peripheral plasma and maternal milk. The postnursing hPRL and TSH responses shall be measured during the fifth day or oral TRH therapy during a 30 minute nursing interval and the results of this study compared with those obtained in the same woman prior to therapy.

Milk samples shall be obtained twice daily before and during therapy to be analyzed for fat, protein and carbohydrate.

8. Study of the Relationship Between Prolactin and LH Secretion

The purpose of this study is to identify what relationship exists between the secretion of gonadotropins and hPRL and whether this secretion severely interferes with the ability of the gonadotroph to respond to cyclic stimulation and thereby bring about ovulation.

Six women between the 30th and the 90th postpartum day shall be asked to volunteer for a 12 hour study. Each shall be maintained in the Clinical Research Unit with provisions made for the care of her child. After insertion of a venous catheter into an antecubital vein, a heparin lock shall

be attached and, thereafter, 15 minute samples of blood shall be obtained for 12 hours. The women will be asked to feed their infants at will, during which time blood sampling shall be advanced to five minute intervals. The women shall be allowed to eat ad libitum and be allowed to tend their infants' needs as they see fit.

Plasma so obtained shall be analyzed for hPRL and gonadotropins. Areas under the curve for prolactin and gonadotropins shall be calculated and the values obtained for LH shall be compared to those previously reported by Yen et al for normally cycling women. The purpose of this study is to confirm preliminary results which indicate that the episodic secretion of LH is distinct from the normal pulsatile secretion of LH and that this episodic secretion is directly related to changes in the secretion of prolactin.

Phase I-B: Limited Field Studies in Bangladesh

To ensure physiologic differences (relating to size, endemic disease, nutrition, etc.) of Bengali women do not limit transferability of safety and efficacy studies carried out in Baltimore, a limited trial of effects of oral TRH will be carried out in Bangladesh. It is expected this study will duplicate, with appropriate modifications, the studies carried out in Baltimore described in I-A, 3, and 4 and, if possible, I-A, 5 and 6.

Prior to initiating this phase of activity, a detailed protocol for work shall be submitted to the AID technical monitor for review and approval.

Phase I-C: Epidemiological Study of Potential Demographic Impact of Lactational Infertility

The contractor shall subcontract to obtain an independently derived estimation of the potential demographic impact of the proposed method, using a variety of assumptions concerning levels of effectiveness and practice. This study should include a thorough review of the empirical data relating to the extent of lactation and its fertility impact in various settings and among women of various nutritional status.

Phase II: Matlab Field Study

This study shall be conducted in Matlab Thana, a rural area of Bangladesh, in coordination with the Cholera Research Laboratory. Although the exact study design must be submitted to AID and the Research Advisory Committee for review and approval prior to initiating work, it is expected that the study will be carried out along the following lines:

About 400 women (200 treated, and 200 controls) will be entered into this study and encouraged to participate for one year. Controls and treatment groups shall be matched in order to reduce biases associated with age, parity, sex of child, and socio-economic status.

Two different postpartum groups shall be studied. Within each postpartum study group, there shall be 100 women receiving oral TRH twice daily, and 100 controls receiving a lactose capsule twice daily.

Two hundred women with infants 15-18 months of age shall be studied with the primary intent of examining extensions of the period of amenorrhea by use of oral TRH based on menstrual status histories obtained by local female field workers (dais) and another group of women 6-9 months postpartum will be studied.

At monthly intervals, the field workers shall deliver oral TRH pills or the placebo capsules and collect old packages in order to estimate consumption of the pills. They shall also obtain anthropometric measurements (length and weight for infants, weight for mothers), measure pulse rates, ask women about their current menstrual status, interview women about their breastfeeding patterns (full or partial), and about supplementary foods given to the infants. In order to assure that oral TRH does not cause nutritional deterioration in the mothers, weight changes shall be plotted for each woman.

Monitoring for hyperthyroidism shall be done on all patients through monthly pulse rate measurements and simple histories taken according to an objective format by trained field assistants. A sample of study participants and any volunteers suspected of having a hyperthyroid state will undergo more extensive screening for thyroid abnormalities.

Full informed consent shall be obtained from all women volunteering to participate in the study.

III. Accomplishments

Phase I-A, Baltimore Studies; I-B, Limited Field Studies in Bangladesh; and I-C, Epidemiology Study; should be completed within the first 12 to 15 months of the program. Prior to initiation of Phase I-B, written approval of the AID technical monitor is required. Toward the end of this time period, the Phase I studies will be reviewed and protocols for Phase II studies will be finalized and submitted to the Research Advisory Committee and to the AID technical monitor for approval prior to their initiation.

IV. Reporting Requirements

1. In addition to the Reports Requirements of General Provision No. 16, the Contractor shall submit semi-annual research reports prepared as specified in Attachment E "Guidelines for Preparation of Research Annual Report", dated January 20, 1972, (except as modified herein) with a report summary in the specified format and expanded narrative, and submitted to the Technical Officer PHA/POP/R, AID, Washington, D.C., 20523, in ten copies on or about October 15 and April 15, covering the work from April 1, through September 30, and October 1 through March 31, respectively.

2. The Semi-Annual Progress Reports, as required in Paragraph (a) of General Provision No. 16, shall provide the following additional information:

a. An accounting of all personnel including consultants utilized under the contract during the reporting period as follows:

- i. Name of the person
- ii. Title of position

- iii. Effort in person-months or fraction thereof
 - iv. Salary for this period
 - v. Consultant by name, hours, or days worked as appropriate and fee paid
 - vi. In the case of new personnel, the date brought on board
- b. The total amount paid for (1) salaries, (2) fringe benefit, (3) overhead, and (4) other fees which are based on salaries paid.

3. The substantive final report shall be submitted in fifteen (15) copies in lieu of the three (3) copies required in General Provision No. 16 (c).

4. Toward the completion of Phases I-A, I-B, and I-C, the Contractor shall prepare a summary report and shall finalize protocols for Phase II studies for review and approval by the AID Technical Officer and the Research Advisory Committee prior to their initiation.

V. Additional Requirements

1. The Contractor shall obtain, with the exception of professional personnel to be identified by name in this contract, prior written approval of the AID Technical Monitor on the selection of all professional personnel and consultants who work on this project, with or without compensation.

2. The contractor shall obtain the written approval of the Contracting Officer before entering into any subcontracts, service agreements or collaborative relationships with institutions or individuals, not on the staff of this project, for any work performed under this contract. The contractor shall ascertain beforehand that such institutions or individuals

are not being compensated by AID for the same services through other contracts or grants.

3. Each subcontract shall include a key personnel clause.

4. The contractor shall assure that appropriate provisions are included in subcontracts or other collaborative arrangements so that the data, rights, and results of any work performed under this contract are in the public domain, insofar as possible.

5. The contractor shall afford the AID Technical Monitor the opportunity to review and provide comments on any proposed publication, prior to its publication, which pertains to work developed in connection with this contract in accordance with the general provisions.

6. The contractor is required to disclose to the Contracting Officer in the approved format any patentable inventions developed in the performance of this contract.

7. Written authorization from the AID Technical Monitor shall be required prior to all foreign travel under this contract.

8. Within the total estimated cost, with exception of salaries, the contractor may adjust line item amounts in the budget as reasonably necessary for the performance of the contract.

9. The estimated budget for the first 12 months of services, shall include the procurement of a Liquid Scintillation Counter. Written approval from the AID contract office is required prior to this procurement in order

to assure beforehand that similar or otherwise suitable U.S. Government-owned equipment cannot be made available to this program.

10. The contractor shall maintain liaison with FDA to assure, insofar as possible, that all requirements of FDA are taken into consideration in the design of experiments. The contractor will be responsible for assuring that the necessary INDs are obtained to support the clinical studies.

11. The contractor will assure that all clinical studies performed under this contract by the contractor, subcontractors or other collaborating individuals meet the requirements set forth below:

I. AID Policy for Protection of the Individual as a Research Subject

a. Safeguarding the rights and welfare of human subjects involved in research supported by AID is the responsibility of the institution to which support is awarded. It is the policy of AID that no work shall be initiated under a grant, award, or contract for the support of research involving human subjects unless the research is given initial and continuing review and approval by an appropriate committee of the applicant institution. This review shall assure that (a) the rights and welfare of the individuals involved are adequately protected, (b) the methods used to obtain informed consent are adequate and appropriate, and (c) the risks and potential medical benefits of the investigation are assessed.

b.. The institution must provide written assurance to AID that it will abide by this policy for all research involving human subjects

supported by AID. This assurance shall consist of a written statement of compliance with the requirements regarding initial and continuing review of research involving human subjects and a description of the institution review committee structure, its review procedures, and the facilities and personnel available to protect the health and safety of human subjects. In addition to providing the assurance, the institution must also certify to AID for each proposal involving human subjects that its committee has reviewed and approved the proposed research before any work may be initiated.

c. Since the welfare of the subject is a matter of concern to AID as well as to the institution, AID advisory groups, consultants, and staff may independently review all research involving human subjects, and prohibit research which presents unacceptable hazards. This provision, however, shall not derogate in any manner from the responsibility of the institution set forth herein.

d. All of the above provisions apply to any research involving human subjects conducted outside of the United States, and in addition such overseas research will conform to legal and other requirements governing human research in the country where it is conducted.

e. In addition to the procedures set forth above, studies with unmarketed drugs will be carried out in compliance with provisions applicable to such studies in the country where such studies are conducted. In the United States, the regulations of the Food and Drug Administration

will be followed and evidence of such compliance provided to AID.

f. Guidance on procedures to safeguard human subjects involved in research is found in the Provisions of Part 46 and Title 45 of the Code of Federal Regulations as published in 39 Federal Register 18914 on May 30, 1974. Compliance with these procedures except as modified as above is required.

GENERAL PROVISIONS

Cost Reimbursement Contract With An Educational Institution

INDEX OF CLAUSES

1. Definitions
2. Approvals
3. Biographical Data
4. Personnel Compensation
5. Leave and Holidays
6. Travel Expenses
7. Allowable Cost and Payment
8. Negotiated Overhead Rates
9. Limitation of Funds
10. Examination of Records by Comptroller General
11. Audit
12. Reports
13. Research, Activities and the Use of Graduate Students
14. Training of Foreign Country Nationals
15. Source Requirements of Procurement of Equipment, Vehicles, Materials, Supplies, and Services
16. Subcontracts and Purchase Orders
17. Government Property
18. Material Change in Conditions
19. Disputes
20. Termination for Convenience of the Government
21. Rights in Data and Publication
22. Authorization and Consent
23. Notice and Assistance Regarding Patent and Copyright Infringement
24. Insurance—Liability to Third Persons
25. Assignment of Claims
26. Inspection
27. Equal Opportunity
28. Utilization of Small Business Concerns
29. Utilization of Labor Surplus Area Concerns
30. Convict Labor
31. Officials Not to Benefit
32. Covenant Against Contingent Fees
33. Language, Weights, and Measures
34. Utilization of Minority Business Enterprises
35. Listing of Employment Openings
36. Payment of Interest on Contractors' Claims
37. Employment of the Handicapped
38. Notices

1. DEFINITIONS (JAN. 1975)

(a) "Administrator" shall mean the Administrator or the Deputy Administrator of the Agency for International Development.

(b) "AID" shall mean the Agency for International Development.

(c) "Campus Coordinator" shall mean the representative of the Contractor at the Contractor's home institution, who shall be responsible for coordinating the activities carried out under the Contract.

(d) "Consultant" shall mean any especially well-qualified person who is engaged on a temporary or intermittent basis and who is not an officer or employee of the Contractor.

(e) "Contracting Officer" shall mean the person executing this Contract on behalf of the United States Government and any other Government employee who is a properly designated Contracting Officer; and the term includes, except as otherwise provided in this Contract, the authorized

representative of a Contracting Officer acting within the limits of his authority.

(f) "Contractor" shall mean the educational institution providing services hereunder.

(g) "Contractor Employee" shall mean an employee of the Contractor assigned to work under this Contract.

(h) "Economy Class" air travel (also known as jet-economy, air-coach, tourist-class, etc.) shall mean a class of air travel which is less than first-class.

(i) "Federal Procurement Regulations (FPR)," when referred to herein, shall include AID Procurement Regulations (AIDPR).

(j) "Government" shall mean the United States Government.

2. APPROVALS (JUNE 1973)

All approvals made under the Contract by the Contracting Officer, or Mission Director, shall be in writing and obtained by the Contractor

ADDITIONAL GENERAL PROVISIONS

COST REIMBURSEMENT CONTRACT WITH AN EDUCATIONAL INSTITUTION

(Additional General Provisions for an Overseas Cost Reimbursement Contract with an Educational Institution are also attached, and except for the clauses omitted as specified on the preceding page, such Additional General Provisions are incorporated in this Contract.)

INDEX OF CLAUSES

1. Definitions
2. Contractor-Mission Relationships
3. Personnel
4. Personnel Compensation
5. Orientation and Language Training
6. Leave and Holidays
7. Post Privileges
8. Differential and Allowances
9. Travel Expenses
10. Transportation and Storage Expenses
11. Inspection Trips by Contractor's Officers and Executives
12. Notice of Changes in Regulations
13. Documentation for Mission
14. Conversion of United States Dollars to Local Currency
15. Facilities and Services to be Arranged by AID
16. Title to and Care of Property
17. Marking
18. Insurance-Workmen's Compensation, Private Automobile, Marine and Air Cargo (Overseas)

1. DEFINITIONS (JUNE 1973)

(a) "Campus Personnel" shall mean representatives of the Contractor performing services under the Contract at the Contractor's home institution and shall include the Campus Coordinator.

(b) "Contractor's Chief of Party" shall mean the representative of the Contractor in the cooperating country who shall be responsible for supervision of the performance of all duties undertaken by the Contractor in the cooperating country.

(c) "Cooperating Country or Countries" shall mean a foreign country in which there is an AID assistance program or activity administered by AID in which services are to be rendered hereunder.

(d) "Cooperating Country National" shall mean an individual who is a citizen or resident of the cooperating country.

(e) "Cooperating Government" shall mean the government of the cooperating country.

(f) "Dependents" shall mean:

(1) Spouse;

(2) Children (including step and adopted children) who are unmarried and under 21 years of age or, regardless of age, are incapable of self-support;

(3) Parents (including step and legally adoptive parents), of the employee or of the spouse, when such parents are at least 51 percent dependent on the employee for support;

(4) Sisters and brothers (including step or adoptive sisters or brothers) of the employee,

or of the spouse, when such sisters and brothers are at least 51 percent dependent on the employee for support, unmarried and under 21 years of age, or, regardless of age, are incapable of self-support.

(g) "Local Currency" shall mean the currency of the cooperating country.

(h) "Mission" shall mean the United States AID Mission to, or principal AID office in, the cooperating country.

(i) "Mission Director" shall mean the principal officer in the Mission in the cooperating country or his designated representative.

(j) "Participants" shall mean nationals of the cooperating country brought to the United States or to third countries for training.

(k) "Regular Employee" shall mean a Contractor employee appointed to serve one year or more in the cooperating country.

(l) "Resident" shall mean an individual who has been physically present for 3 consecutive years, substantially uninterrupted, in a country.

(m) "Short-Term Employee" shall mean a Contractor employee appointed to serve less than one year in the cooperating country.

(n) "Third Country National" shall mean an individual who is neither a U.S. citizen, U.S. resident, or a cooperating country national.

(o) "Traveler" shall mean the Contractor's regular employees, dependents of the Contractor's regular employees, the Contractor's short-term employees, consultants, campus coordinator, or other professional personnel on its staff, prospective regular or short-term em-

General Provision No. 39

MINORITY BUSINESS ENTERPRISES SUBCONTRACTING PROGRAM (FPR 1-1.1310.2)

(a) The Contractor agrees to establish and conduct a program which will enable minority business enterprises (as defined in the clause entitled "Utilization of Minority Business Enterprises") to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall -

(1) Designate a liaison officer who will administer the Contractor's minority business enterprises program.

(2) Provide adequate and timely consideration of the potentialities of known minority business enterprises in all "make-or-buy" decisions.

(3) Assure that known minority business enterprises will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of minority business enterprises.

(4) Maintain records showing (i) procedures which have been adopted to comply with the policies set forth in this clause, including the establishment of a source list of minority business enterprises, (ii) awards to minority business enterprises on the source list, and (iii) specific efforts to identify and award contracts to minority business enterprises.

(5) Include the Utilization of Minority Business Enterprises clause in subcontracts which offer substantial minority business enterprises subcontracting opportunities.

(6) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's minority business enterprises procedures and practices that the Contracting Officer may from time to time conduct.

(7) Submit periodic reports of subcontracting to known minority business enterprises with respect to the records referred to in subparagraph (4), above, in such form and manner and at such time (not more often than quarterly) as the Contracting Officer may prescribe.

(b) The Contractor further agrees to insert in any subcontract hereunder which may exceed \$500,000, provisions which shall conform substantially to the language of this clause, including this paragraph (b), and to notify the Contracting Officer of the names of such subcontractors.

General Provision No. 40

SMALL BUSINESS SUBCONTRACTING PROGRAM (FPRI-1.710-3(b))

(a) The Contractor agrees to establish and conduct a small business subcontracting program which will enable small business concerns to be considered fairly as subcontractors and suppliers under this contract. In this connection, the Contractor shall-

(1) Designate a liaison officer who will (i) maintain liaison with the Government on small business matters, (ii) supervise compliance with the Utilization of Small Business Concerns clause, and (iii) administer the Contractors "Small Business Subcontracting Program."

(2) Provide adequate and timely consideration of the potentialities of small business concerns in all "make-or-by" decisions.

(3) Assure that small business concerns will have an equitable opportunity to compete for subcontracts, particularly by arranging solicitations, time for the preparation of bids, quantities, specifications, and delivery schedules so as to facilitate the participation of small business concerns. Where the Contractor's lists of potential small business subcontractors are excessively long, reasonable effort shall be made to give all such small business concerns an opportunity to compete over a period of time.

(4) Maintain records showing (i) whether each prospective subcontractor is a small business concern, (ii) procedures which have been adopted to comply with the policies set forth in this clause, and (iii) with respect to the letting of any subcontract (including purchase orders) exceeding \$10,000, information substantially as follows:

- (A) Whether the award went to large or small business.
- (B) Whether less than three or more than two small business firms were solicited.
- (C) The reason for nonsolicitation of small business if such was the case.
- (D) The reason for small business failure to receive the award if such was the case when small business was solicited.

The records maintained in accordance with (iii) above may be in such form as the Contractor may determine, and the information shall be summarized quarterly and submitted by the purchasing department of each individual plant or division to the Contractor's cognizant small business liaison officer. Such quarterly summaries will be considered to be management records only and need not be submitted routinely to the Government; however, records maintained pursuant to this clause will be kept available for review by the Government until the expiration of 1 year after the award of this contract, or for such longer period as may be required by other clause of this contract or by applicable law or regulation.

(5) Notify the Contracting Officer before soliciting bids or quotations on any subcontract (including purchase orders) in excess of \$10,000 if (i) no small business concern is to be solicited, and (ii) the Contracting Officer's consent to the subcontract (or ratification) is required by a "Subcontracts" clause in this contract. Such notice will state the Contractor's reasons for nonsolicitation of small business concerns, and will be given as early in the procurement cycle as possible so that the Contracting Officer may give SBA timely notice to permit SBA a reasonable period to suggest potentially qualified small business concerns through the Contracting Officer. In no case will the procurement action be held up when to do so would, in the Contractor's judgment, delay performance under the contract.

(6) Include the Utilization of Small Business Concerns clause in subcontracts which offer substantial small business subcontracting opportunities.

(7) Cooperate with the Contracting Officer in any studies and surveys of the Contractor's subcontracting procedures and practices that the Contracting Officer may from time to time conduct.

(8) Submit quarterly reports of subcontracting to small business concerns on either Optional Form 61, Small Business Subcontracting Program Quarterly Report of Participating Large Company on Subcontract Commitments to Small Business Concerns, or such other form as may be specified in the contract. Except as otherwise provided in this contract, the reporting requirements of this subparagraph (8) do not apply to small business contractors, small business subcontractors, educational and nonprofit institutions, and contractors or subcontractors for standard commercial items.

(b) A "small business concern" is a concern that meets the pertinent criteria established by the Small Business Administration and set forth in section 1-1.701 of the Federal Procurement Regulations.

(c) The Contractor agrees that, in the event he fails to comply with his contractual obligations concerning the small business subcontracting program, this contract may be terminated, in whole or in part, for default.

(d) The Contractor further agrees to insert, in any subcontract hereunder which may exceed \$500,000 and which contains the Utilization of Small Business Concerns clause, provisions which shall conform substantially to the language of this clause, including this paragraph (d), and to notify the Contracting Officer of the names of such subcontractors.

GENERAL PROVISION 41

EMPLOYMENT OF THE HANDICAPPED (MAY 1976)

(Applicable to all contracts or purchase orders of \$2,500 or more).

(a) The Contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The Contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physical or mental handicap in all employment practices such as the following: employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training including apprenticeship.

(b) The Contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Rehabilitation Act of 1973 as amended.

(c) In the event of the Contractor's noncompliance with the requirements of this clause, actions for non-compliance may be taken in accordance with the rules, regulations and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The Contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Di-

rector, Office of Federal Contract Compliance Programs, Department of Labor, provided by or through the contracting officer. Such notices shall state the Contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The Contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Act and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The Contractor will include the provisions of this clause in every subcontract or purchase order of \$2,500 or more unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase orders as the Director, Office of Federal Contract Compliance Programs, may direct to enforce such provisions, including action for noncompliance.

COST ACCOUNTING STANDARDS

(a) Unless the Cost Accounting Standards Board, or the General Services Administration in the case of non-defense contracts, has prescribed rules or regulations exempting the Contractor or this Contract from standards, rules, and regulations promulgated pursuant to 50 U.S.C. App. 2168 (P.L. 91-379, August 15, 1970), or other statutory authority, the Contractor, in connection with this Contract shall:

(1) By submission of a Disclosure Statement, disclose in writing his cost accounting practices as required by regulations of the Cost Accounting Standards Board. The required disclosures must be made prior to contract award unless the Contracting Officer provides a written notice to the Contractor authorizing postaward submission in accordance with regulations of the Cost Accounting Standards Board. The practices disclosed for this Contract shall be the same as the practices currently disclosed and applied on all other contracts and subcontracts being performed by the Contractor and which contains this Cost Accounting Standards clause. If the Contractor has notified the Contracting Officer that the Disclosure Statement contains trade secrets and commercial or financial information which is privileged and confidential, the Disclosure Statement will not be released outside of the Government.

(2) Follow consistently the cost accounting practices disclosed pursuant to (1), above, in accumulating and reporting contract performance cost data concerning this Contract. If any change in disclosed practices is made for purposes of any contract or subcontract subject to Cost Accounting Standards Board requirements, the change must be applied prospectively to this Contract, and the Disclosure Statement must be amended accordingly. If the contract price or cost allowance of this Contract is affected by such changes, adjustment shall be made in accordance with subparagraph (a)(4) or (a)(5), below, as appropriate.

(3) Comply with all Cost Accounting Standards in effect on the date of award of this Contract or if the Contractor has submitted cost or pricing data, on the date of final agreement on price as shown on the Contractor's signed certificate of current cost or pricing data. The Contractor shall also comply with any Cost Accounting Standard which hereafter becomes applicable to a contract or subcontract of the Contractor. Such compliance shall be required prospectively from the date of applicability to such contract or subcontract.

(4)(A) Agree to an equitable adjustment (as provided in the Changes clause of this Contract, if any) if the contract cost is affected by a change which, pursuant to (3) above, the Contractor is required to make to his established cost accounting practices whether such practices are covered by a Disclosure Statement or not.

(B) Negotiate with the Contracting Officer to determine the terms and conditions under which a change to either a disclosed cost accounting practice or an established cost accounting practice, other than a change under (4)(A), above, may be made. A change to a practice may be proposed by either the Government or the Contractor, provided, however, that no agreement may be made under this provision that will increase costs paid by the United States.

(5) Agree to an adjustment of the contract price or cost allowance, as appropriate, if he or a subcontractor fails to comply with an applicable Cost Accounting Standards or to follow any practice disclosed pursuant to subparagraphs (a)(1) and (a)(2), above, and such failure results in any increased costs paid by the United States. Such adjustment shall provide for recovery of the increased costs to the United States together with interest thereon computed at the rate determined by the Secretary of the Treasury pursuant to P.L. 92-41, 85 Stat. 97, or 7 per cent per annum whichever is less from the time the payment by the United States was made to the time the adjustment is effected.

(b) If the parties fail to agree whether the Contractor or a subcontractor has complied with an applicable Cost Accounting Standard, rule, or regulation of the Cost Accounting Standards Board and as to any cost adjustment demanded by the United States, such failure to agree shall be a dispute concerning a question of fact within the meaning of the Disputes clause of this Contract.

(c) The Contractor shall permit any authorized representatives of the head of the agency, of the Cost Accounting Standards Board, or of the Comptroller General of the United States to examine and make copies of any documents, papers, or records relating to compliance with the requirements of this clause.

(d) The Contractor shall include in all negotiated subcontracts which he enters into the substance of this clause except paragraph (b), and shall require such inclusion in all other subcontracts of any tier, except that this requirement shall apply only to negotiated subcontracts in excess of \$100,000 where the price negotiated is not based on:

(1) Established catalog or market prices of commercial items sold in substantial quantities to the general public; or

(2) Prices set by law or regulation, and except that the requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to accept the Cost Accounting Standards clause by reason of Para. 331.30(b) of Title 4, Code of Federal Regulations (4 CFR 331.30(b)) or Para. 1-3.1203 (a)(2) of Title 41, Code of Federal Regulations (41 CFR 1-3.1203(a)(2)). However, if this is a contract with an agency which permits subcontractors to appeal final decisions of the Contracting Officer directly to the head of the agency or his duly authorized representative, then the Contractor shall include the substance of paragraph (b) as well.

NOTE: (1) Subcontractors shall be required to submit their Disclosure Statements to the Contractor. However, if a subcontractor has previously submitted his Disclosure Statement a Government Contracting Officer he may satisfy that requirement by certifying to the Contractor the date of such Statement and the address of the Contracting Officer.

(2) In any case where a subcontractor determines that the Disclosure Statement information is privileged and confidential and declines to provide it to his Contractor or higher tier subcontractor, the Contractor may authorize direct submission of that subcontractor's Disclosure Statement to the same Government offices to which the Contractor was required to make submission of his Disclosure Statement. Such authorization shall in no way relieve the Contractor of liability as provided in paragraph (a)(5) of this clause. In view of the foregoing and since the Contract may be subject to adjustment under this clause by reason of any failure to comply with rules, regulations, and standards of the Cost Accounting Standards Board in connection with covered subcontracts, it is expected that the Contractor may wish to include a clause in each such subcontract requiring the subcontractor to appropriately indemnify the Contractor. However, the inclusion of such a clause and the terms thereof are matters the Contractor and the subcontractor, provided that they do not conflict with the duties of the Contractor under its contract with the Government. It is also expected that any subcontractor subject to such indemnification will generally require substantially similar indemnification to be submitted by his subcontractors.

(e) The terms defined in Sec. 331.20 of Part 331 of Title 4, Code of Federal Regulations (4 CFR 331.20) shall have the same meanings herein. As there defined, "negotiated subcontract" means "any subcontract except a firm fixed-price subcontract made by a Contractor or subcontractor after receiving offers from at least two firms not associated with each other or such Contractor or subcontractor, providing (1) the solicitation to all competing firms is identical, (2) price is the only consideration in selecting the subcontractor from among the competing firms solicited, and (3) the lowest offer received in compliance with the solicitation from among those solicited is accepted."

General Provision No. 43

PATENT RIGHTS-ACQUISITION BY THE GOVERNMENT (SHORT FORM) (FPR 1-9.107-6 (a)) (May 1975)

(a) Definitions.

"Subject Invention" means any invention or discovery of the Contractor conceived or first actually reduced to practice in the course of or under this contract, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(b) Invention disclosures and reports. (1)

The Contractor shall furnish the Contracting Officer:

(i) A complete technical disclosure for each Subject Invention, within 6 months after conception or first actual reduction to practice, whichever occurs first in the course of or under the contract, but in any event prior to any on sale, public use, or publication of the invention known to the Contractor. The disclosure shall identify the contract and inventor, and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and to the extent known, the physical, chemical, biological, or electrical characteristics of the invention;

(ii) Interim reports at least every 12 months from the date of the contract listing Subject Inventions for the period and certifying that all Subject Inventions have been disclosed or that there are no such inventions and

(iii) An acceptable final report within 3 months after completion of the contract work, listing all Subject Inventions or certifying that there were no such inventions.

(2) The Contractor agrees that the Government may duplicate and disclose Subject Invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(c) Allocation of principal rights. (1) The Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to each Subject Invention, except to the extent that rights are retained by the Contractor under paragraphs (c)(2) and (d) of this clause.

(2) The Contractor or the employee-inventor with authorization of the Contractor may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (b)(1) of this clause, or not later than 3 months thereafter or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by the Contractor. The information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-6. Each determination of greater rights under this contract shall be subject to the provisions of paragraph (c) "Minimum rights acquired by the Government" of the clause in 41 CFR 1-9.107-5(a), and to the reservations and conditions deemed appropriate by the agency.

(d) Minimum rights to the Contractor.

The Contractor reserves a revocable, non-exclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. Revocation shall be in accordance with the procedure of the clause in 41 CFR 1-9.107-5 (d) (2) and (3).

(e) Employee and Subcontractor agreements.

Unless otherwise authorized in writing by the Contracting Officer, the Contractor shall:

(1) Obtain patent agreements to effectuate the provisions of this clause from all persons who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers.

(2) Insert in each subcontract having experimental, developmental, or research work as one of its purposes provisions making this clause applicable to the Subcontractor and his employees; and

(3) Promptly notify the Contracting Officer of the award of any such subcontract by providing him with a copy of the subcontract and any amendments thereto.

Clean Air and Water Certificate

(Applicable if the bid or offer exceeds \$100,000, or the contracting officer has determined that orders under an indefinite quantity contract in any year will exceed \$100,000, or a facility to be used has been the subject of a conviction under the Clean Air Act (42 U.S.C. 1857c-8(c)(1)) or the Federal Water Pollution Control Act (33 U.S.C. 1319(c)) and is listed by EPA, or is not otherwise exempt.)

The bidder or offeror certifies as follows:

- (a) Any facility to be utilized in the performance of this proposed contract has , has not , been listed on the Environmental Protection Agency List of Violating Facilities.
- (b) He will promptly notify the contracting officer, prior to award, of the receipt of any communication from the Director, Office of Federal Activities, Environmental Protection Agency, indicating that any facility which he proposes to use for the performance of the contract is under consideration to be listed on the EPA List of Violating Facilities.
- (c) He will include substantially this certification, including this paragraph (c), in every nonexempt subcontract.

Signature of Individual Authorized to Sign Offer

Typed Name and Title of Individual Authorized to Sign

Date of Signature

General Provision No. 45

Voluntary Participation

Contractor shall take steps satisfactory to AID to ensure that funds will not be used to coerce any individual to practice methods of family planning inconsistent with such individuals moral, philosophical, or religious beliefs. Further Contractor acknowledges that it will conduct its activities in a manner which safeguards the rights, health, and welfare of all individuals who take part in the Program.

General Provision 7, Cost Reimbursement Contract with an Educational Institution

ALLOWABLE COST AND PAYMENT (SEPTEMBER 1975)

(a) For the performance of this Contract, the Government shall pay to the Contractor the cost thereof (hereinafter referred to as "allowable cost") determined by the Contracting Officer to be allowable in accordance with:

(1) Subpart 1-15.3 of the Federal Procurement Regulations, "Grants and Contracts with Educational Institutions" as in effect on the date of this Contract and

(2) The terms of this Contract.

(b) Dollar payment:

(1) At least once each quarter the Contractor shall submit to the paying office indicated on the Cover Page, a Voucher Form SF-1034 (original) and SF-1034(a) in three copies. Each Voucher shall be identified by the appropriate AID Contract number, properly executed, in the amount of dollar expenditures made during the period covered. The voucher forms shall be supported by:

(i) Original and three copies of a certified fiscal report rendered by the Contractor in a form and manner satisfactory to AID substantially as follows:

Total expenditures

Category	Budget amount	To date	This period (indicate dates)
Salaries and wages:			
On campus-----	\$xxx	\$xxx	\$xxx
Off campus-----	xxx	xxx	xxx
Indirect costs:			
On campus-----	xxx	xxx	xxx
Off campus-----	xxx	xxx	xxx
Consultant fees-----	xxx	xxx	xxx
Allowances-----	xxx	xxx	xxx
Travel and transportation-----	xxx	xxx	xxx
Equipment and materials----	xxx	xxx	xxx
Participant costs-----	xxx	xxx	xxx
Other direct costs-----	xxx	xxx	xxx
Grand total-----	xxx	xxx	xxx

(ii) The fiscal report shall include a certification signed by an authorized representative of the Contractor as follows:

The undersigned hereby certifies: (A) That payment of the sum claimed under the cited Contract is proper and due and that appropriate refund to AID will be made promptly upon request in the event of disallowance of costs not reimbursable under the terms of the contract, and (B) that information on the fiscal report is correct and such detailed supporting information as AID may reasonably require will be furnished promptly to AID on request at the Contractor's home office or base office as appropriate.

By-----
Title-----
Date-----

(iii) Unless otherwise provided in the Contract, a vendor's invoice or photostat covering each transaction for procurement of commodities, supplies, or equipment totaling in excess of \$2,500 appropriately detailed as to quantity, description, and price for each individual item of equipment purchased.

(iv) The bill of lading or airway bill as evidence of shipment by U.S.-flag carrier.

(2) Promptly after receipt of each voucher and statement of dollar cost, the Government shall, except as otherwise provided in this Contract, subject to the provisions of paragraph (d) of this section make payment thereon as approved by the paying office indicated on the Cover Page.

(3) The final voucher shall be submitted by the

Contractor promptly following completion of the work under this Contract, but in no event later than 120 days (or such longer period as the Contracting Officer may in his discretion approve in writing) from the date of such completion. This voucher, clearly identified as final voucher, shall be submitted on Form 1034 (original) and SF-1034(a) in three copies and supported by:

(i) Original and three copies of a certified fiscal report rendered by the Contractor as in paragraphs (b)(1)(i) and (ii) of this section;

(ii) Vendor's invoices as in paragraph (b)(1)(iii) of this section for commodities, supplies, or equipment in excess of \$2,500 procured since the last voucher submission;

(iii) Bill of lading or airway bill as in paragraph (b)(1)(iv) of this section;

(iv) Refund check for the balance of funds (if any remaining on hand and not obligated by the Contractor).

(c) Local currency payment. The Contractor is fully responsible for the proper expenditure and control of local currency, if any, provided under this Contract. Local currency will be provided to the Contractor in accordance with written instructions provided by the Mission Director. The written instructions will also include accounting, vouchering, and reporting procedures. A copy of the instructions shall be provided to the Contractor's Chief of Party and to the Contracting Officer. The costs of bonding personnel responsible for local currency are reimbursable under the Contract.

(d) Until the expiration of three years after final dollar or local currency payment under this Contract, the Contracting Officer may have the vouchers and statements of cost audited. Each payment theretofore made shall be subject to reduction for amounts included in the related voucher which are found by the Contracting Officer, on the basis of such audit, not to constitute allowable cost. Any payment may be reduced for overpayment, or increased for underpayments, on preceding vouchers.

NOTE: When the clause entitled "Audit" (FPR 1-3.814-2(a)) is included in this Contract, this paragraph is self-deleting.

(e) Upon compliance by the Contractor with all the provisions of this Contract, acceptance by the Government of the work and final report, and a satisfactory accounting by the Contractor of all Government-owned property for which the Contractor has custodial responsibility, the Government shall promptly pay to the Contractor any moneys (dollars or local currency) due under the final voucher. The Government will make suitable reduction for any disallowance or indebtedness by the Contractor by applying the proceeds of the voucher first to such deductions and next to any unliquidated balance of advance remaining under the Contract.

(f) The Contractor agrees that all approvals of the Mission Director and the Contracting Officer which are required by the provisions of this Contract shall be preserved and made available as part of the Contractor's records which are required to be preserved and made available by the clauses of this Contract entitled "Examination of Records by the Comptroller General" and "Audit".

(g) The Contractor agrees that any dollar or local currency refunds, rebates, credits, or other amounts (including any interest thereon) accruing to or received by the Contractor or any assignee under this Contract shall be paid by the Contractor to the Government, to the extent that they are properly allocable to cost for which the Contract has been reimbursed by the Government under this Contract. Reasonable expenses incurred by the Contractor for the purpose of securing such refunds, rebates, credits, or other amounts shall be allowable costs hereunder when approved by the Contracting Officer. Prior to final payment under this Contract, the Contractor and each assignee under this Contract whose assignment is in effect at the time of final payment under this Contract shall execute and deliver an assignment and release using AID Forms 1420-40 or 1420-44, as appropriate, as required in AIDPR 7-16.851.