

PDWAP 945

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

11/30 30 1989

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 16

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development has amended the subject Cooperative Agreement to provide an additional seventeen thousand two hundred one dollars (\$17,201) for the continued support of a program directed toward fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is hereby increased from \$51,689,668 to \$51,706,869. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives.

The subject Agreement is amended as follows:

Under Attachment 1, Schedule, make the changes listed below:

A. Article II - Funds Obligated, Payment, and Total Estimated Cost:

Delete Paragraph A - Funds Obligated, in its entirety and insert in lieu thereof:

"The amount obligated by this Agreement is \$51,706,869. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1990."

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$51,689,668" and insert in lieu thereof "\$51,706,869".

FHI
DPE-0537-A-00-4047-00
Amendment No. 16
Page 2

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge receipt and acceptance of Amendment No. 16. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Stephen A. Jean
Agreement Officer
Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY:  _____

TYPED NAME: Robert W. Hughes

TITLE: Controller

DATE: September 19, 1989

FHI
DPE-0537-A-00-4047-00
Amendment No. 16
Page 3

FISCAL DATA

Appropriation No.:	72-1191021.4
Budget Plan Code:	DDPA-89-13600-JG11
Allotment No.:	944-36-099-00-81-91
PIO/T No.:	9361528
Amount Obligated:	\$17,201
Funding Source:	S&T/POP
Total Estimated Cost:	\$63,400,000
Total Obligation this Action:	\$17,201
Cumulative Obligation:	\$51,706,869
Duns No.:	06-718-0786
IRS Employer ID No.:	23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C. 20623

JUL 26 1989

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 15

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development has amended the subject Cooperative Agreement to provide an additional eight hundred seventy one thousand dollars (\$871,000) for the continued support of a program directed toward fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is hereby increased from \$50,818,668 to \$51,689,668. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives.

The subject Agreement is amended as follows:

Under Attachment 1, Schedule, make the changes listed below:

A. Article II - Funds Obligated, Payment, and Total Estimated Cost:

Delete Paragraph A - Funds Obligated, in its entirety and insert in lieu thereof:

"The amount obligated by this Agreement is \$51,689,668. It is anticipated that this amount will support Recipient performance of the Program Description through August 30, 1990."

B. Article VI - Financial Plan

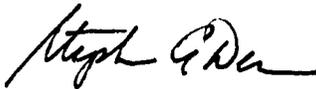
In the first sentence of the paragraph preceding the budget table, delete the amount of "\$50,818,668" and insert in lieu thereof "\$51,689,668".

FHI
DPE-0537-A-00-4047-00
Amendment No. 15
Page 2

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge receipt and acceptance of Amendment No. 15. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Stephen A. Dean
Agreement Officer
Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: Malcolm Potts

TYPED NAME: Dr. Malcolm Potts

TITLE: President

DATE: August 14, 1989

FISCAL DATA

Appropriation No.:	72-11X1021.4
Budget Plan Code:	LDPX-89-25521-KG13
PIO/T No.:	521-0189-3-90029 A1
Amount Obligated:	\$171,000
Funding Source:	USAID/HAITI
Appropriation No.:	72-1191021.4
Budget Plan Code:	DDPA-89-13600-KG11
Allotment No.:	944-36-099-00-81-91
PIO/T No.:	936-3041-3-9361119 A1
Amount Obligated:	\$700,000
Funding Source:	S&T/POP
Total Estimated Cost:	\$63,400,000
Total Obligation this Action:	\$871,000
Cumulative Obligation:	\$51,689,668
Duns No.:	06-718-0786
IRS Employer ID No.:	23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

III. 26 1989

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 14

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development has amended the subject Cooperative Agreement to provide an additional one hundred eight thousand five hundred seventy dollars (\$108,570) for the continued support of a program directed toward fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is hereby increased from \$50,710,098 to \$50,818,668. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives.

The subject Agreement is amended as follows:

Under Attachment 1, Schedule, make the changes listed below:

A. Article II - Funds Obligated, Payment, and Total Estimated Cost:

Delete Paragraph A - Funds Obligated, in its entirety and insert in lieu thereof:

"The amount obligated by this Agreement is \$50,818,668. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1990."

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$50,710,098" and insert in lieu thereof "\$50,818,668".

7

FHI
DPE-0537-A-00-4047-00
Amendment No. 14
Page 2

Under Attachment 2, Program Description, add the attached Honduras Supplemental Program Description.

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge receipt and acceptance of Amendment No. 14. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Stephen A. Dean
Agreement Officer
Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: Malcolm Potts

TYPED NAME: Dr. Malcolm Potts

TITLE: President

DATE: August 7, 1989

8

FHI
DPE-0537-A-00-4047-00
Amendment No. 14
Page 3

FISCAL DATA

Appropriation No.:	72-1181021
Budget Plan Code:	LDCA-88-25522-KG13
PIO/T No.:	522-0216-3-80271
Amount Obligated:	\$94,000
Funding Source:	Honduras
Appropriation No.:	72-1191021
Budget Plan Code:	LDCA-89-25522-KG13
PIO/T No.:	522-0216-3-90195
Amount Obligated:	\$14,570
Funding Source:	Honduras
Total Estimated Cost:	\$63,400,000
Total Obligation this Action:	\$108,570
Cumulative Obligation:	\$50,818,668
Duns No.:	06-718-0786
IRS Employer ID No.:	23-741-3005

HONDURASSUPPLEMENTAL PROGRAM DESCRIPTIONBackground

In 1987 Family Health International was contracted to provide technical assistance to the Ministry of Health to conduct a National Epidemiology and Family Health Survey. 10,441 women ages 15-44 were interviewed about their reproductive health and their children's health. Using these results, infant mortality rates were calculated both directly and indirectly. Infant mortality has decreased steadily over the past 20 years by more than 50%. Survey results show that the infant mortality rate (IMR) for 1985 was about 61 per 1000 live births based on the indirect method of calculation which uses number of children ever born and number surviving. The 1987 survey instrument utilized a complete birth history and also specifically included the number and survival status of live born children who do not live with their mother. The survey has provided USAID/Honduras with information regarding contraceptive usage as well as information of the status of other child survival interventions supported under our health project.

A follow up survey is planned and its principal objective is to measure infant mortality prospectively. During the 1987 survey, about 2750 women who either were pregnant or had a child less than a year old at the time of interview were identified. These women will be reinterviewed to determine pregnancy outcome and infant survival status. Mortality rates will be compared with those found in the 1987 survey using both direct and indirect methods, and a more definitive rate will be available.

Implementation Plan

General: The recipient will assist the MOH in conducting the follow up survey and assist to:

1. Train interviewers and supervisors.
2. Train MOH Science and Technology personnel in usage of data entry and data editing software package.
3. Design SPSS program to run frequencies and crosstabs on all questions in follow up survey. Run frequencies and analyze the results.
4. Calculate infant mortality and contraceptive prevalence and compare current rates with those obtained in 1987. Data on other health practices such as breastfeeding, introduction of weaning foods, immunizations, growth monitoring and care during illness will also be analyzed.
5. Prepare reports with results from survey.

REPORTS

FHI will prepare draft reports or memos with preliminary results as data is analyzed.

A final report will be presented to USAID/Honduras by September 30, 1989.

ADDITIONAL PROGRAM ACTIVITIES

1. Evaluate Honduras breastfeeding promotion campaign (PROALMA I and II).
2. Analyze national breastfeeding trends (from 1981, 1984 and 1987 national surveys) and breastfeeding on a micro level using survey carried out by PROALMA.
3. Mortality analysis with MOH staff and representatives from CELADE (Centro Latinoamericano de Demografia).

AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D.C. 20523

MAR - 1 1989

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 13

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development has amended the subject Cooperative Agreement to provide an additional seven million four hundred twenty-five thousand dollars (\$7,425,000) for the continued support of a program directed toward fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is hereby increased from \$43,285,098 to \$50,710,098. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1990.

The subject Agreement is amended as follows:

Under Attachment 1, Schedule, make the changes listed below:

A. Article II - Funds Obligated, Payment, and Total Estimated Cost:

Delete Paragraph A - Funds Obligated in its entirety and insert in lieu thereof:

"The amount obligated by this Agreement is \$50,710,098. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1990."

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$43,285,098" and insert in lieu thereof "\$50,710,098".

FHI
DPE-0537-A-00-4047-00
Amendment No. 13
Page 2 of 3

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge receipt and acceptance of Amendment No. 13. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Stephen A. Dean
Agreement Officer
Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: 

TYPED NAME: Robert W. Hughes

TITLE: Controller

DATE: March 13, 1989

FHI
DPE-0537-A-00-4047-00
Amendment No. 13
Page 3 of 3

FISCAL DATA

Appropriation No.: 72-1191021.4
Budget Plan Code: DDPA-89-13600-KG11
Allotment No.: 944-36-099-00-81-91
PIO/T No.: 9361119
Amount Obligated: \$7,350,000
Funding Source: S&T/POP

Appropriation No.: 72-1191021.4
Budget Plan Code: LDPA-89-25521-KG13
PIO/T No.: 521-0189-3-90029
Amount Obligated: \$75,000
Funding Source: USAID/Haiti

Total Estimated Cost: \$63,400,000
Total Obligation this Action: \$7,425,000
Cumulative Obligation: \$50,710,098
Duns No.: 06-718-0786
IRS Employer ID No.: 23-741-3005

FUNDS AVAILABLE
Gloria Craig
MAR 02 1989
o/c 4190
Program Acctg Fin Division
Office of Financial Management

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

SEP 29 1988

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 12

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional five hundred sixty thousand dollars (\$560,000) in continued support for a program directed towards fostering the development, introduction, assessment, and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$43,285,098. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1989.

This subject Agreement is hereby further amended as follows:

Under Attachment 1, Schedule, make the following changes:

A. Under Article II - Funds Obligated, Payment, and Total Estimated Cost:

- a. delete paragraph "A. Funds obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$43,285,098. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1989."

BEST AVAILABLE DOCUMENT

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$42,725,098" and insert in lieu thereof "\$43,285,098".

Except as expressly herein amended, all other terms and conditions of the subject Cooperative agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,

Joyce E. Frame

Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL
BY: *Robert W. Hughes*

TYPED NAME: Robert W. Hughes

TITLE: Controller

DATE: October 12, 1988

BEST AVAILABLE DOCUMENT

16

FISCAL DATA

Appropriation No. 72-1181021.4
Budget Plan Code: DDPA-88-13600-KG11
Allotment 844-36-099-00-81-81
PIO/T No.: 8361185-A2
Amount Obligated: \$435,000
Funding Source: USAID/W

Appropriation No. 72-1181021.7
Budget Plan Code: DDCA-88-13600-KG11
Allotment 847-36-099-00-20-81
PIO/T No.: 8361615
Amount Obligated: \$50,000 *Child Survival*
Funding Source: USAID/W

Appropriation No. 72-11X1021.4
Budget Plan Code: LDPX-88-25521-KG13
Allotment N/A
PIO/T No.: 521-0189-3-80038
Amount Obligated: \$75,000
Funding Source: USAID/HAITI

Total Estimated Cost: \$63,400,000
Total Obligation This Action: \$560,000
Cumulative Obligation: \$43,285,098
Duns No.: 06-718-0786
IRD Employer ID No.: 23-741-3005

FUNDS AVAILABLE
Gloria Craig
SEP 30 1988
0/64190
Programs and Division
Office of Financial Management

17

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

AUG 24 1988

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 11

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional two million five hundred seventy five thousand seven hundred and ninety seven dollars (\$2,575,797) in continued support for a program directed towards fostering the development, introduction, assessment, and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$42,725,098. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1989.

This subject Agreement is hereby further amended as follows:

Under Attachment 1, Schedule, make the following changes:

- A. Under Article II - Funds Obligated, Payment, and Total Estimated Cost:
- a. delete paragraph "A. Funds obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$42,725,098. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1989."

CC: EWIKER
~~LEWIS~~
JA LEWIS
POTTS

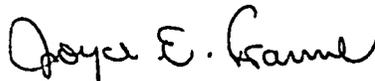
B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$40,149,301" and insert in lieu thereof "\$42,725,098".

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,

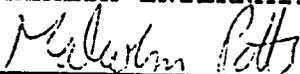


Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: _____



TYPED NAME: Malcolm Potts

TITLE: President

DATE: September 15, 1988

FUNDS AVAILABLE
Glenn Craig
AUG 30 1988
o/c 4190
Program Accounting Division
Office of Financial Management

FISCAL DATA

Appropriation No. 72-1181021.4
Budget Plan Code: DDPA-88-13600-KG11
Allotment 844-36-099-00-81-81
PIO/T No.: 8361185-A1
Amount Obligated: \$1,751,000
Funding Source: USAID/W

Appropriation No. 72-117/81037
Budget Plan Code: QES7-87-27263-KG13
Allotment N/A
PIO/T No.: 263-0144-3-70146
Amount Obligated: \$138,341
Funding Source: USAID/EGYPT

Appropriation No. 72-1171021
Budget Plan Code: GDPA-87-21615-KG13
PIO/T No.: 615-0232-3-70071
Amount Obligated: \$464,791
Funding Source: USAID/KENYA

Appropriation No. 72-1161021
Budget Plan Code: GDAA-86-21615-BG13
PIO/T No.: 615-0232-3-60099
Amount Obligated: \$221,665
Funding Source: USAID/KENYA

Amount Obligated: \$63,400,000
Cumulative Obligation: \$42,725,098
Obligation this Action: \$ 2,575,797
Duns No.: 06-718-0789
IRD Employer ID No.: 23-741-3005

25

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D. C. 20523

JUN 22 1988

MAY 27 1988

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

RECEIVED
JUN 10 1988

Subject: Cooperative Agreement No. DPE-0537-A-00-4047-00
Amendment No. 10

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional eight million four hundred fifteen thousand one hundred and thirty one dollars (\$8,415,131) in continued support for a program directed towards fostering the development, introduction, assessment, and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$40,149,301. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1989.

The subject Agreement is also amended to insert language reflecting the transfer of non-expendable property from Contract No. DPE-0537-C-00-1028 to the subject Cooperative Agreement.

This subject Agreement is hereby further amended as follows:

Under Attachment 1, Schedule, make the following changes:

A. Under Article II - Funds Obligated, Payment, and Total Estimated Cost:

- a. delete paragraph "A. Funds obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$40,149,301. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1989."

21

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$31,734,170" and insert in lieu thereof "\$40,149,301".

C. Article VIII - Special Provisions

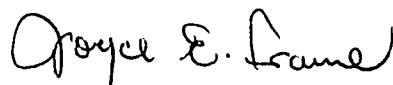
Insert a new paragraph "H" as follows:
"H. Equipment and Supplies

One voltage converter computer power, [model #FC-60-10000-60-50] (non-expendable property) acquired under DPE-0537-C-0-1028 and in inventory shall be transferred and used in the performance of this Cooperative Agreement".

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

DPE-0537-A-00-4047-00
FHI
Amendment No. 10
Page 3.

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: *Robert W. Hughes*

TYPED NAME: Robert W. Hughes

TITLE: Controller

DATE: June 13, 1988

Fiscal Data

PIO/T No.: 8361185
Appropriation No.: 72-1181021.4
Allotment No.: 844-36-099-00-81-81
Budget Plan Code: DDPA-88-13600-KG11
Project No.: 936-3041
Amount: \$6,900,000
Funding Source: USAID/Washington

PIO/T No.: 263-0144-3-60114
Appropriation No.: 72-1161037
Project No.: 263-0144
Budget Plan Code: QESA-86-27263-KG13
Amount: \$156,000
Funding Source: USAID/Egypt

PIO/T No.: 263-0144-3-70062
Appropriation No.: 72-117/81037
Budget Plan Code: QES7-27263-KG13
Project No.: 263-0144
Amount: \$1,323,667
Funding Source: USAID/Egypt

PIO/T No.: 263-0144-3-70062-A1
Appropriation No.: 72-117/81037
Budget Plan Code: QES7-87-27263-KG13
Project No.: 263-0144
Amount: -\$14,536
Funding Source: Egypt

FUNDS AVAILABLE

Glenie Craig

JUN 03 1988

o/c 4190

Program Acctg Fin Division
Office of Financial Management

DPE-0537-A-00-4047-00
Amendment No. 10
FHI
Page 4.

PIO/T No.:	521-0206-3-80012
Appropriation No.:	72-1181021.7
Budget Plan Code:	LDCA-88-25521-KG13
Project No.:	521-0206
Amount:	\$50,000
Funding Source:	USAID/Haiti
Amount Obligated:	\$8,415,131
Cumulative Obligation:	\$40,149,301
Duns No.:	06-718-0789
IRD Employer ID No.:	23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

DEC 21 1987

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Amendment No. DPE-0537-A-00-4047
Amendment No. 09

Dear Dr. Potts:

Pursuant the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject agreement to provide additional incremental funding in the amount of \$20,000 for your efforts in Honduras. This additional funding is in continued support for a program directed towards fostering the development, introduction, assessment, and evaluation of fertility control technologies.

The cumulative obligation under this agreement is now \$31,734,170. Funds are obligated on the date of this letter and shall apply to commitments made by the recipient in furtherance of the program objectives through May 30, 1988.

The Cooperative Agreement is hereby further amended as follows:

A. Cover Letter

1. Delete the cumulative obligation amount "\$31,714,170" in the first paragraph and insert in lieu thereof "\$31,734,170".

B. Article VI - Financial Plan

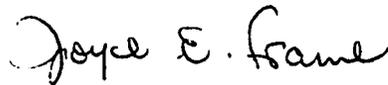
In the first sentence of the paragraph preceding the budget table, delete the amount of "\$31,714,170" and insert in lieu thereof "31,734,170"

75

Except as expressly herein amended, all other terms and conditions of this Cooperative Agreement remain the same.

Please acknowledge your understanding and acceptance of this Amendment by signing the original and all copies in the space provided below. Retain one copy for your files and return the original and remaining copies to this office.

Sincerely,



Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED

FAMILY HEALTH INTERNATIONAL

BY: Malcolm Potts

TYPED NAME: Malcolm Potts

TITLE: President

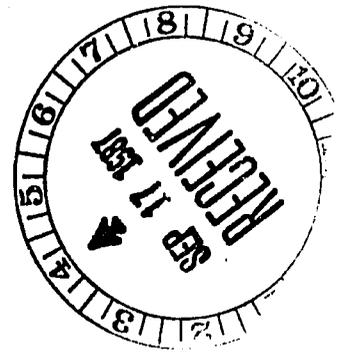
DATE: December 29, 1987

FISCAL DATA

Appropriation No.	72 - 1171021
Budget Plan Code:	LDPA-87-25522-KG13
PIO/T:	522-9104-3-70161
Obligation Amount:	\$20,000
Cumulative Obligation	\$31,734,170
Agreement Amount	\$63,400,000
Duns:	06-718-0786
Technical Office:	S&T/POP
Funding Source	USAID HONDURAS

24

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523



AUG 28 1987

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement DPE-0537-A-00-4047-00
Amendment No. 8

Dear Mr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional one million eight hundred seventeen thousand three hundred dollars (\$1,817,300) in continued support for a program directed towards fostering the development, introduction, assessment, and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$31,714,170. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1988.

The subject Agreement is also amended to insert language reflecting the transfer of all residential non-expendable property from Contract No. PHA-C-1172 to the subject Cooperative Agreement.

The subject Agreement is hereby further amended as follows:

A. Article II - Funds Obligated, Payment, and Total Estimated Cost

Under paragraph A, delete the amount of "\$29,896,870" and insert in lieu thereof "\$31,714,170".

B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of \$29,896,870" and insert in lieu thereof \$31,714,170".

C. Article VIII - Special Provisions

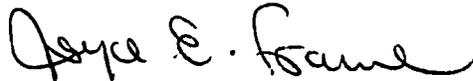
Insert section "H. Equipment and Supplies

All residential non-expendable property acquired under AID/PHA-C-1172 and in inventory shall be transferred and used in the performance of this Cooperative Agreement".

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: Malcolm Potts

TYPED NAME: Malcolm Potts

TITLE: President

DATE: 9/8/87



FISCAL DATA

PIO/T No.	:	7361150 A2	
Appropriation No.	:	72-1171021.4	
Allotment No.	:	744-36-099-00-81-71	
Budget Plan Code	:	DDPA-87-13600-KG11	
Project No.	:	936-3041	
Amount	:	\$385,000	
Funding Source	:	USAID/Washington	<i>includes PPC NIH transfer</i>
PIO/T No.	:	7361528	
Appropriation No.	:	72-1171021.8	
Allotment No.	:	748-36-099-00-20-71	
Budget Plan Code	:	DDHA-87-13600-KG11	
Amount	:	\$150,000	
Funding Source	:	USAID/Washington	<i>ST/ Health</i>
PIO/T No.	:	624-0929-3-70017	
Appropriation No.	:	72-11X1012 A730020	
Budget Plan Code	:	GSHX-87-21624-KG14	
Project No.	:	625-0929.24	
Amount	:	\$26,000	
Funding Source	:	USAID/Sahel	
PIO/T No.	:	624-0510-3-70019	
Appropriation No.	:	72-1171021 A730022	
Budget Plan Code	:	GDHA-87-2162X-KG62	
Project No.	:	698-0510.24	
Amount	:	\$44,500	
Funding Source	:	USAID/CCWA	
PIO/T No.	:	263-0144-3-30137	
Appropriation No.	:	72-11M1037	
Budget Plan Code	:	NESA-83-23263-KG13	
Project No.	:	263-0144	
Amount	:	\$136,270	
Funding Source	:	USAID/Egypt	
PIO/No.	:	386-0485-3-70062	
Appropriation No.	:	72-1171021	
Budget Plan Code	:	QDPA-87-27386-KG13	
Project No.	:	986-0485	
Amount	:	\$400,000	
Funding Source	:	USAID/India	

DPE-0537-A-00-4047-00
Amendment No. 8
Page 4 of 4

PIO/T No.	:	521-0124-3-70047
Appropriation No.	:	72-1171021.4
Budget Plan Code:	:	LDPA-87-25521-KG13
Project No.	:	521-0124
Amount	:	\$465,000
Funding Source	:	USAID/Haiti
PIO/T No.	:	519-0181-3-70038
Appropriation No.	:	72-1171021
Budget Plan Code	:	LDPA-87-25519-KG13
Project No.	:	519-0181
Amount	:	\$145,530
Funding Source	:	USAID/EI Salvador
PIO/T No.	:	398-0048-3-7632021
Appropriation No.	:	72-1171021.4
Budget Plan Code	:	QDPA-87-37398-KG12
Project No.	:	398-0048
Amount	:	\$65,000
Funding Source	:	USAID/Pakistan (Regional)
Allotment No	:	744-63-398-60-69-71
Amount Obligated	:	\$ 1,817,300
Cumulative Obligation	:	\$31,714,170
DUNS No.	:	06-718-0789
IRD Employer ID No.	:	23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

MAY 15 1987

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement DPE-0537-A-00-4047-07

Dear Mr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional \$534,096 in continued support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$29,896,870. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1988.

The subject Agreement is hereby further amended as follows:

A. Article II - Funds Obligated, Payment and Total Estimated Cost

Under paragraph A, delete the amount of "\$29,362,774" and insert in lieu thereof "\$29,896,870".

B. Article VI - Financial Plan

1. In the first sentence of the paragraph preceding the budget table, delete the amount of "\$29,362,744" and insert in lieu thereof "\$29,896,870".

2. After the budget table insert the following sentence:

"All expenditures of funds provided herein shall be reported by funding source."

C. Article VIII - Special Provisions

1. Delete the words "Agreement Officer" in the third sentence of paragraph E and insert in lieu thereof "A.I.D. CTO".
2. Add new paragraph H as follows:

"H. Authorized Geographic Code

The authorized geographic code for source and origin of commodities purchased by the Recipient under this Agreement is 935."

D. Article IX - Standard Provisions

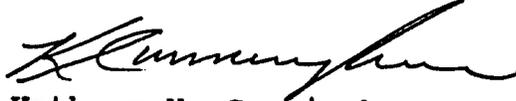
Delete paragraph E in its entirety and insert in lieu thereof the following:

"Standard Provision No. 22 entitled 'Subordinate Agreements' is hereby amended to require only A.I.D. CTO approval of all subordinate agreements to implement subprojects. Approval of the Grant Officer will be required only at the request of the CTO."

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies to this office.

Sincerely,



Kathryn Y. Cunningham
Grant Officer
Chief, A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: Malcom Potts

TYPED NAME: Malcom Potts

TITLE: President

DATE: May 28, 1987

Fiscal Data

PIO/T No.	:	522-9104-3-50592
Appropriation No.	:	72-11M1021
		72-11M1021
		72-1151021
Budget Plan Code	:	LDAA-83-25522-BG61 (\$4,570.09)
		LDAA-84-25522-BG61 (\$ 486.84)
		LDAA-85-25522-BG61 (\$1,543.07)
Project No.	:	522-9104-3-50592
Amount	:	\$6,600
Funding Source	:	USAID/Honduras

PIO/T No.	:	522-9104-60237
Appropriation No.	:	72-1161021
Budget Plan Code	:	LDAA-86-25522-BG13
Project No.	:	522-9104.02
Amount	:	\$4,400
Funding Source	:	USAID/Honduras

PIO/T No. : 263-0144-3-60040
Appropriation No. : 72-1161037
Budget Plan Code : QESA-86-27263-KG13
Project No. : 263-0144
Amount : \$16,000
Funding Source : USAID/Egypt

PIO/T No. : 263-0144-3-60040, A-1
Appropriation No. : 72-1161037
Budget Plan Code : QESA-86-27263-KG13
Project No. : 263-0144
Amount : \$29,769
Funding Source : USAID/Egypt

PIO/T No. : 522-9104-3-60239
Appropriation No. : 72-1161021
Budget Plan Code : LDAA-86-25522-BG13
Project No. : 522-9104.02
Amount : \$55,800
Funding Source : USAID/Honduras

PIO/T No. : 522-9108-3-70062
Appropriation No. : 72-1171021
Budget Plan Code : LDHA-87-25522-KG13
Project No. : 522-9108.06
Amount : \$49,200
Funding Source : USAID/Honduras

PIO/T No. : 263-0144-3-60046
Appropriation No. : 72-1161037
Budget Plan Code : QESA-86-27263-KG13
Project No. : 263-0144
Amount : \$119,046
Funding Source : USAID/Egypt

PIO/T No. : 688-0227-3-60020
Appropriation No. : 72-11X1012
Budget Plan Code : GSHX-86-21688-KG13
Project No. : 688-0227
Amount : \$24,000
Funding Source : USAID/Mali

PIO/T No. : 263-0144-3-30099, A-1
Appropriation No. : 72-11M1037
Budget Plan Code : NESA-83-23263-KG13
Project No. : 263-0144
Amount : \$229,281
Funding Source : USAID/Egypt

Amount Obligated : \$ 534,096
Cumulative Obligation: \$29,896,870
DUNS No. : 06-718-0786
IRS Employer ID No. : 23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523



Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement DPE-0537-A-00-4047-06
Amendment No. 6

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development hereby amends the subject Cooperative Agreement to provide an additional \$7,000,000 in continued support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies.

The cumulative obligation under this Agreement is now \$29,362,744. This obligation is effective as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives through September 30, 1988.

The subject Agreement is hereby further amended as follows:

A. Article II - Funds Obligated, Payment and Total Estimated Cost

Under paragraph A, delete the amount of "\$22,362,774" and the date "31 December 1987" and insert in lieu thereof "\$29,362,774" and "30 September 1988" respectively.

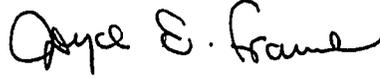
B. Article VI - Financial Plan

In the first sentence of the paragraph preceding the budget table, delete the amount of "\$22,362,774" and insert in lieu thereof "\$29,362,774".

Except as expressly herein amended, all other terms and conditions of the subject Cooperative Agreement remain unchanged.

Please sign all copies of this letter to acknowledge your receipt and acceptance of this amendment. Retain one copy for your files and return the original and all remaining copies, including all those stamped "Funds Available", to this office.

Sincerely,



Joyce E. Frame
Grant Officer
Chief, Health & Population Branch
A.I.D./W Projects Division
Office of Procurement

ACKNOWLEDGED:

FAMILY HEALTH INTERNATIONAL

BY: Malcolm Potts

TYPED NAME: Malcolm Potts

TITLE: President

DATE: April 17, 1987

Fiscal Data

PIO/T No.	:	7361150
Appropriation No.	:	72-1171021.4
Budget Plan Code	:	DDPA-87-13600-KG11
Allotment No.	:	744-36-099-00-81-71
Project No.	:	936-3041
Amount Obligated	:	\$7,000,000
Cumulative Obligation	:	\$29,362,774
Funding Source	:	AID/W
DUNS No.	:	06-718-0786
IRS Employer ID No.	:	23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

AUG 22 1986

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047
Amendment No. 5

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the subject Cooperative Agreement is hereby amended to provide an additional nine hundred forty-five thousand dollars (\$945,000) to provide support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies, as described in the Schedule (Attachment 1) of this Cooperative Agreement and Attachment 2, entitled "Program Description."

This subject Agreement is further amended as follows:

A. Attachment 1 - Schedule

1. Under Article II - Funds Obligated, Payment and Total Estimated Cost, delete paragraph "A. Funds Obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$22,362,774. It is anticipated that this amount will support Recipient performance of the Program Description through 31 December 1987."

2. Under Article III - Substantial Involvement Understandings, add the following phrase at the end of item "F":

"(See Article IV- Reports and Evaluation, A.4.)"

3. Under Article IV - Reports and Evaluation, paragraph "A. Reports," make the following revisions:

- a. Add a new subparagraph "4" as follows:

38

"4. International Travel

1. FHI will submit in draft to the AID CTO semiannual travel plans which outline proposed travel and purpose of travel for each six month period.

2. Travel schedules listing staff and consultant trips planned over the immediate four to six week period should be submitted to the AID CTO and updated on approximately a weekly basis. As appropriate, after AID/W approval is received, FHI is responsible for obtaining cooperating country clearances and AID mission clearances for its personnel and contractors. Exceptions to this policy may be made on a country by country basis depending upon the desires of specific missions.

3. Prior to initiating international travel, FHI will submit a letter for final approval of the CTO. The request should indicate the purpose of the travel, dates of travel, and a copy of the approval telex from the AID mission."

b. Renumber the existing subparagraph "4" to read "5."

4. Under Article IV - Financial Plans, in the Budget table, delete the first sentence and insert the following in lieu thereof:

"Funds in the amount of \$22,362,774 have been obligated to fully fund the first and second years' budgets and provide partial funding for year three."

The total cumulative obligation of funds to this Cooperative Agreement is now \$22,362,774 which shall apply to commitments made by the Recipient in furtherance of program objectives during the period September 30, 1984 through December 31, 1987.

The total estimated cost of this Agreement is \$63,400,000 for a period of six years. Additional funding for the program will be provided in the future, subject to the availability of funds.

Except as expressly herein amended, the subject Agreement is in all respects ratified, confirmed and continued in full force and effect in accordance with its terms.

Please sign the original and eight (8) copies of this Agreement to acknowledge your acceptance of the conditions contained herein. Thereafter, please return the original and seven (7) copies of this Agreement to the Office of Acquisition and Assistance Management.

Sincerely yours,



Judith D. Johnson
Contracting Officer
Chief, Health and Population
Branch
AID/W Projects Division
Office of Procurement

ACKNOWLEDGEMENT:

FAMILY HEALTH INTERNATIONAL

BY: D. Malcolm Potts

TYPED NAME: D. Malcolm Potts

TITLE: President

DATE: 8/9/84

FISCAL DATA

Appropriation No. : 72-11X1012
Budget Plan Code : GSHX-85-21685-KG-13
PIO/T No. : 50140
Project No. : 685-0248
Amount Obligated : \$77,000
Funding Source : Senegal

Appropriation No. : 72-11X1012
Budget Plan Code : GSHX-85-21685-KG-13
PIO/T No. : 50140 A#1
Project No. : 685-0248
Amount Obligated : \$26,000
Funding Source : Senegal

Appropriation No. : 72-1161021.4
Budget Plan Code : QDAA-86-27388-BG-3
PIO/T No. : 60046
Project No. : 388-0050
Amount Obligated : \$567,000
Funding Source : Bangladesh

Appropriation No. : 72-1161021.4
Allotment No. : 644-36-099-00-81-61
Budget Plan Code : DDAA-86-13600-BG11
PIO/T No. : 6361184 A#1
Project No. : 936-3041
Amount Obligated : \$130,000
Funding Source : AID/W

FUNDS AVAILABLE

VMS
AUG 26 1986
OK 4/90

Program Acctg. Fin. Division
Office of Financial Management

Appropriation No. : 72-1161021
Budget Plan Code : LDAA-86-25522-CG13
PIO/T No. : 60090
Project No. : 522-9108
Amount Obligated : \$45,000
Funding Source : Honduras

Appropriation No. : 72-1161021.4
Allotment No. : 644-63-398-00-69-61
Budget Plan Code : QDAA-86-37398-BG12
PIO/T No. : 6632011
Project No. : 398-0048
Amount Obligated : \$100,000
Funding Source : Regional (Yemen)

FUNDS AVAILABLE

Holland
AUG 26 1986
OK 4:90

Program Acctg. Fin. Division
Office of Financial Management

Total Obligation This Action : \$945,000
Cumulative Obligation : \$22,362,774
Total Estimated Cost : \$63,400,000
DUNS No. : 06-718-0786
IRS Employer ID No. : 23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

APR 18 1986

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047
Amendment No. 4

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the subject Cooperative Agreement is hereby amended to provide an additional seven million eight hundred seventeen thousand seven hundred and seventy-four dollars (\$7,817,774) to provide support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies, as described in the Schedule (Attachment 1) of this Cooperative Agreement and Attachment 2, entitled, "Program Description."

This subject Agreement is further amended as follows:

A. Attachment 1 - Schedule

1. Under Article II - Funds Obligated, Payment and Total Estimated Cost, delete paragraph "A. Funds Obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$21,417,774. It is anticipated that this amount will support Recipient performance of the Program Description through 30 September 1987."

HZ

2. Under Article VI - Financial Plan, in the Budget table, delete the first sentence and insert the following in lieu thereof:

"Funds in the amount of \$21,417,774 have been obligated to fully fund the first and second years' budgets and provide partial funding for year three."

The total cumulative obligation of funds to this Cooperative Agreement is now \$21,417,447 which shall apply to commitments made by the Recipient in furtherance of program objectives during the period September 30, 1984 through September 30, 1987.

The total estimated cost of this Agreement is \$63,400,000 for a period of six years. Additional funding for the program will be provided in the future, subject to the availability of funds.

Except as expressly herein amended, the subject Agreement is in all respects ratified, confirmed and continued in full force and effect in accordance with its terms.

Please sign the original and eight (8) copies of this Agreement to acknowledge your acceptance of the conditions contained herein. Thereafter, please return the original and seven (7) copies of this Agreement to the Office of Acquisition and Assistance Management.

Sincerely yours,



Judith D. Johnson
Contracting Officer
Chief, Health and Population Branch
Science and Technology Division
Office of Acquisition & Assistance
Management

ACKNOWLEDGEMENT:

FAMILY HEALTH INTERNATIONAL

BY: D. Malcolm Potts

TYPED NAME: D. Malcolm Potts

TITLE: President

DATE: 1 Feb 86

FISCAL DATA

Appropriation No.	: 72-11M1037
Budget Plan Code	: NESA-83-23263-KG13
PIO/T No.	: 30099
Project No.	: 263-0144
Amount Obligated	: \$267,774
Funding Source	: USAID/Egypt
Appropriation No.	: 72-1161021.4
Allotment No.	: 644-36-099-00-81-61
Budget Plan Code	: DDAA-86-13600-BG11
PIO/T No.	: 6361184
Project No.	: 936-3041
Amount Obligated	: \$7,550,000
Funding Source	: AID/W
Total Obligation This Action	: \$ 7,817,774
Cumulative Obligation	: \$21,417,774
Total Estimated Cost	: \$63,400,000
DUNS No.	: 06-718-0786
IRS Employer ID No.	: 23-741-3005

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

AUG 27 1985

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No. DPE-0537-A-00-4047
Amendment No. 2

Dear Dr. Potts:

Pursuant to the authority of the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the subject Cooperative Agreement is hereby amended to provide an additional eight million seven hundred thousand dollars (\$8,700,000) to provide support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies, as described in the Schedule (Attachment 1) of this Cooperative Agreement and Attachment 2, entitled, "Program Description."

The subject Agreement is further amended as follows:

A. Cover Letter

1. Delete the total estimated agreement cost of "\$4,900,000" wherever it appears and insert in lieu thereof "\$63,400,000."
2. Delete the estimated completion date of "September 29, 1985" and insert in lieu thereof "September 30, 1990."

HS

B. Attachment 1 - S

1. Under Article II - Funds Obligated, Payment and Total Estimated Cost:

a. delete paragraph "A. Funds Obligated," in its entirety and insert the following in lieu thereof:

"A. Funds Obligated

The amount obligated by this Agreement is \$13,600,000. It is anticipated that this amount will support Recipient performance of the Program Description through September 30, 1986."

b. Delete the dates "September 29, 1985" and "March 31, 1986" from paragraph "B. Subagreement Funding," and substitute therefor "September 30, 1990" and "March 31, 1991," respectively.

c. Delete the amount "\$4,900,000" from paragraph "C. Total Estimated Cost," and insert in lieu thereof "\$63,400,000."

2. Under Article IV - Reports and Evaluation, insert a new paragraph "5," as follows:

"5. Five copies of all publications shall be provided to designated staff of S&T/POP on a quarterly basis."

46

3. Under Article V - Key Personnel, delete the listing of key personnel under paragraph "A," and insert the following in lieu thereof:

1. Malcolm Potts, President
2. John Ganley, Executive Vice President
3. (Vacant) , Director of Development
4. Edward Whitehorne, Director of Scientific Support
5. JoAnn Lewis, Director of Field Development and Training
6. James Higgins, Senior Researcher, Biostatistics Group
7. Al Siemens, Director of Clinical Trials
8. Lynda Cole, Project Leader in Clinical Trials
9. Michael Rosenberg, Director of Reproductive Epidemiology
10. Nancy Williamson, Director of Program Evaluation
11. Barbara Janowitz, Associate Director of Program Evaluation
12. Jack Lippes, Vice President for Research
13. Paula B. Pendergrass, Associate Director of Clinical Trials

14. Peter R. Lamptey, Associate Medical
Director of Clinical Trials"

4. Under Article VI - Financial Plan:

- a. In the paragraph preceding the Budget table, delete the first sentence and insert the following in lieu thereof:

"Funds in the amount of \$13,600,000 have been obligated to fully fund the first and second years' budgets."

- b. Delete the Budget table in its entirety and insert in lieu thereof the Budget set forth in Attachment A, attached hereto and incorporated herein.

5. Under Article VIII - Special Provisions, delete paragraph "B," in its entirety and insert the following in lieu thereof:

"B. The use of consultants is authorized under this Agreement subject to the technical concurrence of the CTO that the proposed individual is suitable for the task assigned. Fees paid to consultants and reimbursed hereunder shall be reasonable in accordance with the paragraph of the applicable cost principles entitled, "Professional Service Costs," and shall not exceed, without specific

HS

approval of the Agreement Officer, the maximum daily rate of a Foreign Service 1 (FS-1)."

6. Under Article IX - Standard Provisions:

- a. Delete paragraphs "D." and "E." in their entirety and substitute therefor Attachment B, which sets forth Standard Provisions No. 16, 17 and 18, entitled "Voluntary Participation," "Prohibition on Abortion-Related Activities," and "Voluntary Participation Requirements for Sterilization Programs," attached hereto and incorporated herein.
- b. Renumber paragraphs "F." and "G." as paragraphs "D." and "E.," respectively.
- c. Delete from the new paragraph "E.," the amount of "\$100,000" wherever it appears and insert in lieu thereof "\$200,000."

C. Attachment 2, Program Description

Under "B. Plan of Work," paragraph "1.," insert the following after subparagraph "(i)":

"(j) Reproductive Health Studies

The program will include reproductive health studies encompassing a variety of social science approaches to family planning technology and other areas of reproductive health including pregnancy. Studies will be conducted including using survey-type

methodology to assess issues such as user and provider perspective of contraceptive use, demand and acceptability. Other studies included in this area are related to the impact of different workers and methods of family planning acceptance and continuation and studies related to maternal and child health such as assessments of maternal and infant mortality, and the health consequences of pregnancy and high fertility.

(k) Field Development and Training

Activities will be carried out aimed at institution strengthening and improving research capabilities in developing countries. The largest part of these activities will include support for Family Health Research Centers (FHRCs). FHRCs are research institutions based in developing countries which carry out many of the research activities carried out by FHI. Currently six centers in Asia and the Near East are being provided core support and support for specific studies. These centers also carry out research for other organizations who contract with them.

Other activities related to field development and training which will be carried out include providing microcomputer equipment technology and appropriate training for use in evaluating research in developing countries; conducting workshops and seminars to train investigators on methods for conducting epidemiology and clinical trial research; technical assistance where necessary in preparing manuscripts for publication; and support for provision of clinical training to investigators such as techniques for insertion of NORPLANT implants or IUDs.

(1) Miscellaneous Activities

The program will undertake other activities related to the development, evaluation and introduction of family planning technology. These include drug and device regulatory filings such as Investigational New Drug exemptions (INDs) and New Drug Applications (NDAs), the development of relevant laboratory tests, certain activities related to infertility problems, and to a limited extent the provision of family planning technology."

The total cumulative obligation of funds to this Cooperative Agreement is now \$13,600,000 which shall apply to commitments made by the Recipient in furtherance of program objectives during the period September 30, 1984 through September 30, 1986.

The total estimated cost of this Agreement is \$63,400,000 for a period of six years. Additional funding for the program will be provided in the future subject to the availability of funds.

Except as expressly herein amended, the subject Agreement is in all respects ratified, confirmed and continued in full force and effect in accordance with its terms.

Please sign the original and seven(7) copies of this Amendment to acknowledge your acceptance of the conditions contained herein. Thereafter, please return the original and six(6) copies of this Agreement to the Office of Contract Management.

Sincerely yours,



Judith D. Johnson
Agreement Officer
Chief, PE Branch
Central Operations Division
Office of Contract Management

Attachments:

- Attachment A - Budget
- Attachment B - Standard Provisions

ACKNOWLEDGEMENT:

FAMILY HEALTH INTERNATIONAL

BY: Robert W Hughes

TYPED NAME: Robert W. Hughes

TITLE: Contracts Administrator

DATE: 9 September 1985

Fiscal Data

Appropriation No. : 72-1151021.4
Allotment No. : 544-36-099-00-81-51
Budget Plan Code : DDAA-85-13600-BG11
PIO/T No. : 5361266
Project No. : 936-3041
Amount Obligated : \$7,800,000

Appropriation No. : 72-1151021.4
Allotment No. : 544-36-099-00-51
Budget Plan Code : DDAA-85-13600-BG11
PIO/T No. : 5361266 A#1
Project No. : 936-3041
Amount Obligated : \$900,000

Amount Obligated this Action : \$8,700,000
Cumulative Obligation : \$13,600,000
Total Estimated Cost : \$63,400,000
Duns No. : 06-718-0786
IRS Employer ID No. : 23-741-3005
Funding Source : AID/W

ATTACHMENT A
FINANCIAL PLAN
(\$000)

	<u>9/30/84- 9/29/85</u>	<u>9/30/85- 9/29/86</u>	<u>9/30/86- 9/29/87</u>	<u>9/30/87- 9/29/88</u>	<u>9/30/88- 9/29/89</u>	<u>9/30/89- 9/29/90</u>	<u>TOTAL</u>
Clinical Trials	\$2,045	\$3,470	\$3,670	\$ 4,360	\$ 4,920	\$ 5,570	\$24,135
Contraceptive Safety	838	1,250	1,440	1,720	1,880	2,240	9,468
Contraceptive Development	94	220	340	500	680	900	2,734
Reproductive Health	598	1,120	1,200	1,310	1,420	1,570	7,218
Natural Family Planning	746	1,300	1,500	1,730	1,950	2,310	9,536
Field Development and Training	<u>579</u>	<u>1,640</u>	<u>1,750</u>	<u>1,880</u>	<u>2,050</u>	<u>2,410</u>	<u>10,309</u>
TOTAL.	<u>\$4,900</u>	<u>\$9,200</u>	<u>\$9,900</u>	<u>\$11,500</u>	<u>\$12,900</u>	<u>\$15,000</u>	<u>\$63,400</u>

FY 87

54

STANDARD PROVISION TO BE USED IN GRANTS AND
COOPERATIVE AGREEMENTS WITH U.S.
NONGOVERNMENTAL ORGANIZATIONS

VOLUNTARY POPULATION PLANNING (JULY 1985)

(This provision is applicable to all grants involving any aspect of voluntary population planning activities.)

(a) Voluntary Participation

The grantee agrees to take any steps necessary to ensure that funds made available under this grant will not be used to coerce any individual to practice methods of family planning inconsistent with such individual's moral, philosophical, or religious beliefs. Further, the grantee agrees to conduct its activities in a manner which safeguards the rights, health and welfare of all individuals who take part in the program.

(b) Voluntary Participation Requirements For Sterilization Programs

(1) None of the funds made available under this grant shall be used to pay for the performance of involuntary sterilization as a method of family planning or to coerce or provide any financial incentive to any person to practice sterilization.

(2) The grantee shall ensure that any surgical sterilization procedures supported in whole or in part by funds from this grant are performed only after the individual has voluntarily gone to the treatment facility and has given informed consent to the sterilization procedure. Informed consent means the voluntary, knowing assent from the individual after being advised of the surgical procedures to be followed, the attendant discomforts and risks, the benefits to be expected, the availability of alternative methods of family planning, the purpose of the operation and its irreversibility, and the option to withdraw consent anytime prior to the operation. An individual's consent is considered voluntary if it is based upon the exercise of free choice and is not obtained by any special inducement or any element of force, fraud, deceit, duress, or other forms of coercion or misrepresentation.

(3) Further, the grantee shall document the patient's informed consent by (i) a written consent document in a language the patient understands and speaks, which explains the basic elements of informed consent, as set out above, and which is signed by the individual and by the attending physician or by the authorized assistant of the attending physician; or (ii) when a patient is unable to read adequately a written certification by the attending physician or by the authorized assistant of the attending physician that the basic elements of informed consent above were orally presented to the patient, and that the patient thereafter consented to the performance of the operation. The receipt of the oral explanation shall be acknowledged by the patient's mark on the certification and by the signature or mark of a witness who shall be of the same sex and speak the same language as the patient.

(4) Copies of informed consent forms and certification documents for each voluntary sterilization procedures must be retained by the grantee for a period of three years after performance of the sterilization procedure.

(c) Prohibition on Abortion-Related Activities

(1) No funds made available under this grant will be used to finance, support, or be attributed to the following activities: (i) procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning; (ii) special fees or incentives to women to coerce or motivate them to have abortions; (iii) payments to persons to perform abortions or to solicit persons to undergo abortions; (iv) information, education, training, or communication programs that seek to promote abortion as a method of family planning; and (v) lobbying for abortion.

(2) No funds made available under this grant will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of, abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extent or consequences of abortions is not precluded.

(d) Ineligibility of Foreign Nongovernmental Organizations That Perform or Actively Promote Abortion As A Method of Family Planning:

(1) The recipient agrees that it will not furnish assistance under this grant to any foreign nongovernmental organization which performs or actively promotes abortion as a method of family planning in AID-recipient countries or which

provides financial support to any other foreign nongovernmental organization that conducts such activities. For purposes of this paragraph (d), a foreign nongovernmental organization is a nongovernmental organization which is not organized under the laws of any State of the United States, the District of Columbia or the Commonwealth of Puerto Rico.

(2) Prior to furnishing funds provided under this grant to another nongovernmental organization organized under the laws of any State of the United States, the District of Columbia, or the Commonwealth of Puerto Rico, the recipient shall obtain the written agreement of such organization that the organization shall not furnish assistance under this grant to any foreign nongovernmental organization except under the conditions and requirements that are applicable to the recipient as set forth in this paragraph (d).

(3) The recipient may not furnish assistance under this grant to a foreign nongovernmental organization (the subrecipient) unless;

(i) the subrecipient certifies in writing that it does not perform or actively promote abortion as a method of family planning in AID-recipient countries and does not provide financial support to any other foreign nongovernmental organization that conducts such activities, and

(ii) the recipient obtains the written agreement of the subrecipient containing the undertakings described in subparagraph (4), below.

(4) Prior to furnishing assistance under this grant to a subrecipient, the subrecipient must agree in writing that;

(i) The subrecipient will not, while receiving assistance under this grant, perform or actively promote abortion as a method of family planning AID-recipient countries or provide financial support to other foreign nongovernmental organizations that conduct such activities.

(ii) The recipient and authorized representatives of AID may, at any reasonable time, (A) inspect the documents and materials maintained or prepared by the subrecipient in the usual course of its operations that describe the family planning activities of the subrecipient, including reports, brochures and service statistics; (B) observe the family planning activity conducted by the subrecipient; (C) consult with family planning personnel of the

subrecipient; and (D) obtain a copy of the audited financial statement or report of the subrecipient, if there is one.

(iii) In the event the recipient or AID has reasonable cause to believe that a subrecipient may have violated its undertaking not to perform or actively promote abortion as a method of family planning, the recipient shall review the family planning program of the subrecipient to determine whether a violation of the undertaking has occurred. The subrecipient shall make available to the recipient such books and records and other information as may be reasonably requested in order to conduct the review. AID may also review the family planning program of the subrecipient under these circumstances, and AID shall have access to such books and records and information for inspection upon request.

(iv) The subrecipient shall refund to the recipient the entire amount of assistance furnished to the subrecipient under this grant in the event it is determined that the certification provided by the subrecipient under subparagraph (3), above, is false.

(v) Assistance to the subrecipient under this grant shall be terminated if the subrecipient violates any undertaking in the agreement required by subparagraphs (3) and (4), and the subrecipient shall refund to the recipient the value of any assistance furnished under this grant that is used to perform or actively promote abortion as a method of family planning.

(vi) The subrecipient may furnish assistance under this grant to another foreign nongovernmental organization (the sub-subrecipient) only if (A) the sub-subrecipient certifies in writing that it does not perform or actively promote abortion as a method of family planning in AID-recipient countries and does not provide financial support to any other foreign nongovernmental organization that conducts such activities and (B) the subrecipient obtains the written agreement of the sub-subrecipient that contains the same undertakings and obligations to the subrecipient as those provided by the subrecipient to the recipient as described in subparagraphs (4)(i)-(v), above.

(5) Agreements with subrecipients and sub-subrecipients required under subparagraphs (3) and (4) shall contain the definitions set forth in subparagraph (10) of this paragraph (d).

(6) The recipient shall be liable to AID for a refund for a violation of any requirement of this paragraph (d) only if (i) the recipient knowingly furnishes assistance to a subrecipient which performs or actively promotes abortion as a method of family planning, or (ii) the certification provided by a subrecipient is false and the recipient failed to make reasonable efforts to verify the validity of the certification prior to furnishing assistance to the subrecipient, or (iii) the recipient knows or has reason to know, by virtue of the monitoring which the recipient is required to perform under the terms of this grant, that a subrecipient has violated any of the undertakings required under subparagraph (4) and the recipient fails to terminate assistance to the subrecipient, or fails to require the subrecipient to terminate assistance to a sub-subrecipient which violates any undertaking of the agreement required under subparagraph (4)(vi), above. If the recipient finds, in exercising its monitoring responsibility under this grant, that a subrecipient or sub-subrecipient receives frequent requests for the information described in subparagraph (10)(iii)(A)(II), below, the recipient shall verify that this information is being provided properly in accordance with subparagraph (10)(iii)(A)(II) and shall describe to AID the reasons for reaching its conclusion.

(7) In submitting a request to AID for approval of a recipient's decision to furnish assistance to a subrecipient, the recipient shall include a description of the efforts made by the recipient to verify the validity of the certification provided by the subrecipient. AID may request the recipient to make additional efforts to verify the validity of the certification. AID will inform the recipient in writing when AID is satisfied that reasonable efforts have been made. If AID concludes that these efforts are reasonable within the meaning of subparagraph (6) above, the recipient shall not be liable to AID for a refund in the event the subrecipient's certification is false unless the recipient knew the certification to be false or misrepresented to AID the efforts made by the recipient to verify the validity of the certification.

(8) It is understood that AID also may make independent inquiries, in the community served by a subrecipient or sub-subrecipient, regarding whether it performs or actively promotes abortion as a method of family planning.

(9) A subrecipient must provide the certification required under subparagraph (3) and a sub-subrecipient must provide the certification required under subparagraph (4)(vi) each time a new agreement is executed with the subrecipient or sub-subrecipient furnishing assistance under the grant.

(10) The following definitions apply for purposes of this paragraph (d):

(i) Abortion is a method of family planning when it is for the purpose of spacing births. This includes, but is not limited to, abortions performed for the physical or mental health of the mother but does not include abortions performed if the life of the mother would be endangered if the fetus were carried to term or abortions performed following rape or incest (since abortion under these circumstances is not a family planning act).

(ii) To perform abortions means to operate a facility where abortions are performed as a method of family planning. Excluded from this definition are clinics or hospitals which do not include abortion in their family planning programs.

(iii) To actively promote abortion means for an organization to commit resources, financial or other, in a substantial or continuing effort to increase the availability or use of abortion as a method of family planning.

(A) This includes, but is not limited to, the following:

(I) Operating a family planning counseling service that includes, as part of the regular program, providing advice and information regarding the benefits and availability of abortion as a method of family planning;

(II) providing advice that abortion is an available option in the event other methods of family planning are not used or are not successful or encouraging women to consider abortion (passively responding to a question regarding where a safe, legal abortion may be obtained is not considered active promotion if the question is specifically asked by a woman who is already pregnant, the woman clearly states that she has already decided to have a legal abortion, and the family planning counsellor reasonably believes that the ethics of the medical profession in the country requires a response regarding where it may be obtained safely);

(III) Lobbying a foreign government to legalize or make available abortion as a method of family planning or lobbying such a government to continue the legality of abortion as a method of family planning;

(IV) Conducting a public information campaign in AID-recipient countries regarding the benefits and/or availability of abortion as a method of family planning.

(B) Excluded from the definition of active promotion of abortion as a method of family planning are referrals for abortion as a result of rape, incest or if the life of the mother would be endangered if the fetus were carried to term.

(C) Action by an individual acting in the individual's capacity shall not be attributed to an organization with which the individual is associated, provided that the organization neither endorses nor provides financial support for the action and takes reasonable steps to ensure that the individual does not improperly represent that the individual is acting on behalf of the organization.

(iv) To furnish assistance to a foreign nongovernmental organization means to provide financial support under this grant to the family planning program of the organization, and includes the transfer of funds made available under this grant or goods or services financed with such funds, but does not include the purchase of goods or services from an organization or the participation of an individual in the general training programs of the recipient, subrecipient or sub-subrecipient.

(v) To control an organization means the possession of the power to direct or cause the direction of the management and policies of an organization.

(11) In determining whether a foreign nongovernmental organization is eligible to be a subrecipient or sub-subrecipient of assistance under this grant, the action of separate nongovernmental organizations shall not be imputed to the subrecipient or sub-subrecipient, unless, in the judgment of AID, a separate nongovernmental organization is being used as a sham to avoid the restrictions of this paragraph (d). Separate nongovernmental organizations are those that have distinct legal existence in accordance with the laws of the countries in which they are organized. Foreign organizations that are separately organized shall not be considered separate, however, if one is controlled by the other. The recipient may request AID's approval to treat as separate the family planning activities of two or more organizations, which would not be considered separate under the preceding sentence, if the recipient believes, and provides a

written justification to AID therefor, that the family planning activities of the organizations are sufficiently distinct as to warrant not imputing the activity of one to the other.

(12) Assistance may be furnished under this grant by a recipient, subrecipient or sub-subrecipient to a foreign government even though the government includes abortion in its family planning program, provided that no assistance may be furnished in support of the abortion activity of the government and any funds transferred to the government shall be placed in a segregated account to ensure that such funds may not be used to support the abortion activity of the government.

(e) The grantee shall insert this provision, except paragraph (d), in all subsequent subgrants and contracts involving family planning or population activities which will be supported in whole or part from funds under this grant. Paragraph (d) shall be inserted in subagreements and sub-subagreements in accordance with the terms of paragraph (d). The term subagreement means subgrants and subcooperative agreements.

62

AGENCY FOR INTERNATIONAL DEVELOPMENT
WASHINGTON, D.C. 20523

JUL 26 1984

Dr. Malcolm Potts
President
Family Health International
Research Triangle Park, NC 27709

Subject: Cooperative Agreement No.
DPE-0537-A-00-4047-00

Dear Dr. Potts:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977, the Agency for International Development (hereinafter referred to as "A.I.D."), hereby provides to Family Health International (hereinafter referred to as "FHI" or "Recipient"), the sum of four million nine hundred thousand dollars (\$4,900,000) to provide support for a program directed towards fostering the development, introduction, assessment and evaluation of fertility control technologies, as described in the Schedule (Attachment 1) of this Cooperative Agreement and Attachment 2, entitled, "Program Description."

This Cooperative Agreement is effective September 30, 1984. Obligation is made as of the date of this letter and shall apply to commitments made by the Recipient in furtherance of program objectives during the period September 30, 1984 through September 29, 1985.

The total estimated cost of this Agreement is \$4,900,000 for the period September 30, 1984 through September 29, 1985.

FHI

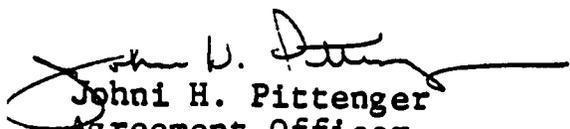
DPE-0537-A-00-4047-00

-2-

This Cooperative Agreement is made to FHI on the condition that funds will be administered in accordance with the terms and conditions as set forth in Attachment 1, Schedule; Attachment 2, Program Description; and Attachment 3, Standard Provisions; which have been agreed to by your organization.

Please sign the original and seven (7) copies of this letter to acknowledge your acceptance of the conditions herein. Thereafter, please return the original and six (6) copies to the Office of Contract Management.

Sincerely,


John H. Pittenger
Agreement Officer
Chief, PE Branch
Central Operations Division
Office of Contract Management

Attachments:

1. Schedule
2. Program Description
3. Standard Provisions

ACKNOWLEDGEMENT:

Family Health International

BY: _____



TYPED NAME: MALCOLM POTTS

TITLE: PRESIDENT

DATE: 14 AUGUST 1984

104

FHI
DPE-0537-A-00-4047-00

-3-

Fiscal Data

Appropriation No.:	72-1141021.4
Allotment No.:	444-36-099-00-81-41
Budget Plan Code:	DDAA-84-13600-BG11
PIO/T No.:	3641400
Project No.:	932-0537
Total Estimated Cost:	\$4,900,000
Amount Obligated:	\$4,900,000
IRS Employer ID No.:	23-741-3005
Duns No.:	06-718-0786
Funding Source:	AID/W

65

SCHEDULE

TABLE OF CONTENTS

Article I	- Purpose and Program Description
Article II	- Funds Obligated, Payment and Total Estimated Cost
Article III	- Substantial Involvement Understandings
Article IV	- Reports and Evaluation
Article V	- Key Personnel
Article VI	- Financial Plan
Article VII	- Negotiated Indirect Cost Rate
Article VIII	- Special Provisions
Article IX	- Standard Provisions

STANDARD PROVISIONS

The Standard Provisions applicable to this Cooperative Agreement are AID 1420-52 entitled, "U.S. Grantees and U.S. Subgrantees NonProfit Organizations - Other than Educational Institutions," dated February, 1982.

SCHEDULE

Article I - Purpose and Program Description

A. Purpose

The purpose of this Agreement is for the Recipient to carry out a program directed towards fostering the development and introduction of methods of fertility control, the assessment and evaluation of fertility control technologies, and the strengthening of such capabilities on an international basis, as set forth in the Recipient's technical proposal dated June, 1984, entitled, "Development and Evaluation of Contraceptive Methods and Issues Related To Their Safety."

B. Program Description

The Program Description is attached hereto as Attachment 2.

Article II - Funds Obligated, Payment, and Total Estimated Cost

A. Funds Obligated

The amount obligated by this Agreement is \$4,900,000. It is anticipated that this amount will support Recipient performance of the Program Description through September 29, 1985.

B. Subagreement Funding

Funds provided under this agreement shall not be available for obligation of costs for new subagreement activity after September 29, 1985 or, subject to an extension of this agreement or the award of a new agreement, for reimbursement of expenditures made in behalf of ongoing subagreement activities after March 31, 1986.

C. Total Estimated Cost

The total estimated cost of this agreement is \$4,900,000. Costs are subject to Standard Provision No. 1 entitled, "Allowable Costs and Contributions," and No. 6 entitled, "Revision of Financial Plans."

D. Payment

The payment mechanism applicable to this agreement is the Letter of Credit/Treasury Financial Communications System (LOC/TFCS).

Article III - Substantial Involvement Understandings

It is anticipated that performance of the workscope requires substantial involvement by A.I.D. Specific areas of involvement include, but are not limited to, the following:

- A. Approval by the A.I.D. Cognizant Technical Officer (CTO) of all activities carried out under this agreement including study strategies, protocols, subagreements, training and information dissemination activities.
- B. Collaborative involvement of the A.I.D. CTO in the development of specific research studies and other activities to be carried out under this agreement.
- C. As appropriate, A.I.D. CTO involvement in the analysis and publication of research findings.

68

- D. Site visits for A.I.D. technical participation in reviews of program progress and future strategy.
- E. Approval of consultancies for short-term technical assistance.
- F. Approval of international travel.
- G. A.I.D. evaluations of Recipient performance, as specified.
- H. Consultations with, and approval of, A.I.D. CTO, as appropriate, on technical and administrative procedures.

Article IV - Reports and Evaluation

A. Reports

The Recipient shall submit reports as follows:

1. Two reports will be submitted annually consisting of interim activity reports submitted in May of each year (beginning May 1985) for the previous six-month period ending in March and formal progress reports for the previous Agreement year's activity submitted within 60 days of the end of the Agreement Year.

All reports shall be submitted to the A.I.D. CTO in seven copies covering completed ongoing activities during the report period, with one additional copy

sent to the Agreement Officer. The reports should include, but not be limited to, a description of studies and other activities, publications, accomplishments, and problems in the areas of program development and execution. It shall also include a critical analysis of the progress being made in achieving the aims of the program.

2. All financial reports and vouchers for payment and reporting of expenditures will conform to standard A.I.D. regulations and procedures. (See Standard Provision No. 7A, "Payment - Letter of Credit.")
3. Under this Agreement, international travel shall require approval by the CTO for project development, monitoring, compliance, technical assistance and other project-related visits made by the Recipient's personnel or consultant personnel. In each instance, approval to use A.I.D. funds is made with the understanding that trip reports are required of each traveler. One copy of each trip (both international and domestic) report is to be submitted to the A.I.D. CTO not later than 30 days after completion of each trip. The report shall state the objectives of the visit and describe activities undertaken, findings and end results. It shall identify the person(s) who conducted the

visit, locations visited, persons contacted and describe project-related problems, accomplishments and any other information related to the activity. When appropriate, the A.I.D. CTO will make copies of the trip report available to A.I.D. Regional Bureaus, Contract Management and USAID Population Officers.

4. In addition to these reports, the Recipient shall immediately notify the A.I.D. CTO and the Agreement Officer in writing, in the event that circumstances arise that have or may have an adverse impact on the timely performance of this Agreement or the incurrence of unanticipated costs under this Agreement. This provision is applicable to the subrecipients as well as to the Recipient.

B. Evaluation

1. A.I.D. may exercise the option to initiate one or more external evaluations of the project by a team of experts. The evaluation will focus on the extent to which the Recipient has achieved program goals which are reflected in the workscope. Such reviews may result in changes in direction, emphasis or administrative procedures of this program. Costs of such evaluation shall be borne outside of this Agreement.

2. From time to time, A.I.D. may request special evaluations of the Recipient's management of the Cooperative Agreement or selected subagreement projects according to CTO management requirements.
3. The Recipient will conduct ongoing evaluation of the respective subprojects in achieving the purposes of the program.
4. These evaluation plans may be altered during the course of the project period to conform to A.I.D. directives unrelated to this specific project.

Article V - Key Personnel

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

1. Malcolm Potts, President
2. John Ganley, Executive Vice President
3. Peter Donaldson, Director of Development
4. Edward Whitehorne, Director of Scientific Support Services
5. Robert Wheeler, Director of Quality Assurance
6. JoAnn Lewis, Director of Field Support
7. James Higgins, Senior Researcher, Biostatistics Group
8. Al Siemans, Director of Clinical Trials

9. Lynda Cole, Project Leader in Clinical Trials
10. Michael Rosenberg, Director of Contraceptive Safety Research
11. Barbara Janowitz, Director of Health and Demographic Research
12. Nancy Williamson, Director of Natural Family Planning Research

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 Recipient shall notify the Agreement 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 agreement to either add or delete personnel, as appropriate.

- C. 1. The Recipient shall obtain A.I.D.'s approval to change the key personnel, or to continue the work hereunder during a continuous period in excess of three months without the participation of the above-listed key personnel.

2. The Recipient shall consult with A.I.D. if the key personnel plan to, or become aware that he/she will, devote substantially less effort to the work than anticipated in the Program Description. If A.I.D. determines that the reduction of effort would be so substantial as to impair the successful execution of the project, A.I.D. may request a change of key personnel, terminate the project or make any other appropriate modification to the Agreement.

Article VI - Financial Plan

Funds in the amount of \$4,900,000 have been obligated to fully fund this Agreement. The budget indicated below sets limitations for reimbursement of dollar costs for individual items. The Recipient agrees to furnish data which the Agreement Officer may request on costs expended or accrued under the Cooperative Agreement in support of the budget information provided herein.

Budget
(9/30/84 - 9/29/85)

<u>Category</u>	<u>Total</u>
Salaries and Wages	\$1,252,768
Fringe Benefits	288,137
Consultants	64,000
Travel	302,000
Equipment	10,000
Materials and Supplies	33,576
Service Center Costs	483,974
Other Direct Costs	263,800
Subagreements	1,022,480
General & Administrative	1,179,265
TOTAL	<u>\$4,900,000</u>

Article VII - Negotiated Indirect Cost Rates

Pursuant to the Standard Provision of the Agreement entitled, "Negotiated Overhead Rates," a rate or rates shall be established for each of the Recipient's accounting periods during the term of the Agreement. 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>Type of Rate</u>	<u>Rate</u>	<u>Period</u>
Provisional amended	33.4%	9/30/84 - until

Base of Application

Modified Total Direct Costs^{1/}

^{1/} Total direct costs less equipment and the first \$25,000 of each subcontract or subgrant.

Article VIII - Special Provisions

A. The Recipient shall put the following information of each voucher submitted under this Agreement:

Cooperative Agreement No.: DPE-0537-A-00-4047-00
Project No.: 932-0537
Project Officer: ST/POP/R
Obligation No.: 3641400

75

B. Consultants, both U.S. and other nationals, may be employed by the Recipient to provide expertise needed for the conduct of work under this Agreement. Approval is hereby given for the use of individual consultants for up to three person-days per year. The total number of days which may be used under this blanket approval is 120 days per calendar year. For consultants to be used more than three (3) but less than 120 days during any calendar year, the Recipient will request approval for each consultant from the Agreement Officer before the consultant is employed.

The request for approval shall include:

- a. Name of the proposed consultant
- b. Curriculum Vitae
- c. Purpose(s) for which the consultant will be used
- d. Daily rate of compensation and the basis for its calculation
- e. The number of days the consultant previously worked for the Recipient and the daily rate of compensation approved

The provisions of the paragraph apply to members of the Technical Advisory Committee and Protection of Human Subjects Committee (Institutional Review Board) as well as to other consultants.

Compensation for consultants shall not exceed, without specific approval of the Agreement Officer, (1) the current compensation or the highest rate of annual compensation received by the consultant during the full year of the immediately preceding three years or (2) the maximum daily rate of a Foreign Service 1 (FS-1), whichever is less.

Note: The daily rate of a Foreign Service 1 is determined by dividing the annual salary by 260 days.

C. New positions and replacements for all direct cost personnel in the Recipient's salary Grade 6 or above working under this contract must be approved by the A.I.D. CTO.

D. Technical Directions

Performance of the work hereunder shall be subject to the technical directions of the cognizant A.I.D. Scientific/Technical Office indicated on the Cover Page. As used herein, "Technical Directions" are directions to the Recipient which fill in details, suggest possible lines of inquiry, or otherwise complete the general scope of the work. "Technical Directions" must be within the terms of this Agreement and shall not change or modify them in any way.

E. After the Recipient has obtained A.I.D. approval of a subagreement proposal, the Recipient may revise individual subagreement budgets, within 15% of the approved subagreement budget total, without obtaining additional A.I.D. approval. Any budget increase affected under this provision must be less than \$15,000. All subagreements, budget revisions in excess of \$15,000, or revisions which would result in total subagreement budgets of more than \$100,000, must be approved by the Agreement Officer. The Recipient may also grant no-cost extensions of approved subagreements of up to six months without prior A.I.D. approval. The Recipient will inform the CTO of these actions as they occur. (See Standard Provision No. 22 entitled, "Subordinate Agreements.")

F. Monitoring of Subcontracts

The Recipient shall be responsible for monitoring all subcontracting instruments (i.e., subcontracts, agreements, pilot studies) entered into on or before September 16, 1984 and expiring no later than September 30, 1985 under contract AID DPE-0537-C-00-1028-00. All vouchers for payment shall cite the contract number and the appropriate accounting and appropriation data.

G. Emergency Locator Information

The Recipient agrees to provide the following information to the Mission Administrative Officer on or before the arrival in the host country of every Agreement employee or dependent:

1. The individual's full name, address, and telephone number;
2. The name and number of the Agreement, and whether the individual is an employee or dependent;
3. The Recipient's name, home office address, and telephone number, including any after-hours emergency number(s), and the name of the Recipient's home office staff member having administrative responsibility for the Agreement;
4. The name, address, and telephone number(s) of each individual's next of kin; and,
5. Any special instructions pertaining to emergency situations such as power of attorney designees or alternate contact persons.

Article IX - Standard Provisions

The Standard Provisions, contained in Attachment 3, are applicable to this Agreement with the exception of the modifications made hereunder.

A. Delete the following provisions in their entirety:

1. 5A. Negotiated Overhead Rates - Predetermined;
2. 7B. Payment - Periodic Advance;
3. 7C. Payment - Reimbursement;
4. 10A. Procurement of Goods and Services Under \$250,000;
5. 11. Local Cost Financing with U.S. Dollars;
6. 13B. Title To and Care of Property (U.S. Government Title);
and,
7. 13C. Title To and Care of Property (Cooperating Country Title).

B. Standard Provision No. 7A entitled, "Payment - Federal Reserve Letter of Credit (FRLC) Advance," is hereby deleted in its entirety and a new Standard Provision No. 7A entitled, "Payment - Letter of Credit," attached hereto, is incorporated in lieu thereof.

C. Standard Provision No. 15 entitled, "Termination," is hereby amended to read, "Termination and Suspension," and to incorporate the following paragraph therein:

"(d) Suspension: Termination for Changed Circumstances. If at any time A.I.D. determines (1) that disbursement by A.I.D. would be in violation of applicable law, or (2) that continuation of funding for a program should be suspended or terminated because such assistance is not in the national

80

interest of the United States, then A.I.D. may, following notice to the Grantee, suspend this Grant and prohibit the Grantee from incurring additional obligations chargeable to this Grant other than necessary and proper costs in accordance with the terms of this Grant during the period of suspension. If the situation causing the suspension continues to pertain for 60 days or more, then A.I.D. may terminate this Grant on written notice to the Grantee and cancel that portion of this Grant which has not been disbursed or irrevocably committed to third parties. Financial settlement of this Grant shall be governed by the termination procedures specified in paragraph (c) above."

D. Standard Provision No. 16 entitled, "Voluntary Participation," is amended to delete the applicability statement and substitute the following therefor:

"(This provision is applicable to all grants involving any aspect of family planning or population assistance activities.)"

E. Standard Provision No. 17 entitled, "Prohibition on Abortion-Related Activities," is hereby deleted in its entirety and the following is inserted in lieu thereof:

"Standard Provision No. 17 - Prohibition on Abortion-Related Activities"

"(This provision is applicable to all grants involving any aspect of family planning or population assistance activities.)

1. No funds made available under this Grant shall be used to finance, support, or be attributed to the following activities:
 - a. Procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning;.
 - b. Special fees or incentives to women to coerce or motivate them to have abortions;
 - c. Payments to persons to perform abortions or to solicit persons to undergo abortions;
 - d. Information, education, training or communication programs that seek to promote abortion as a method of family planning;
 - e. Any biomedical research which relates, in whole or in part, to methods of, or the performance of abortions or involuntary sterilizations as a means of family planning (epidemiologic or descriptive research to assess the incidence, extent or consequences of abortion is not precluded); or,
 - f. Lobbying for abortion.



2. The Grantee shall insert the substance of this clause in any subgrants, subcontracts, purchase orders, and other subordinate agreements hereunder whenever appropriate to the goods or services to be provided under such agreements."

F. Standard Provision No. 20 entitled, "Patents," is hereby deleted in its entirety and a new Standard Provision No. 20 entitled, "Patent Rights (Small Business Firms and Nonprofit Organizations (March 1982)," is incorporated herein and attached hereto.

G. Standard Provision No. 22 entitled, "Subordinate Agreements," is hereby amended to require Agreement Officer approval for subordinate agreements only in excess of \$100,000. For subordinate agreements up to \$100,000, the Recipient shall seek approval from the Cognizant Technical Officer. Upon receipt of written instructions from the A.I.D. CTO directing the suspension of such subagreement(s), the Recipient shall immediately terminate the designated subagreements.

PROGRAM DESCRIPTION

A. Objective

The Recipient shall perform a program directed towards fostering the development and introduction of methods of fertility control, the assessment and evaluation of fertility control technologies, and the strengthening of such capabilities on an international basis. The Recipient shall use its established research system and network of clinical investigators to evaluate, on an international basis, the safety, effectiveness and acceptability of methods of fertility control and the delivery systems through which they are made available.

In this connection, the Recipient shall serve as a center for: (1) maintaining a network of international investigators; (2) developing study designs and research data collection instruments to study various means of fertility control under use conditions and to determine long-term effects; (3) analyzing and evaluating research data which is collected from various countries and cultural settings by contributors who are conducting field trials; (4) conducting studies to evaluate fertility control methods and develop fertility control methods to the level where clinical trials are appropriate; and

developing prototypes of equipment which show promise as being useful in the field of fertility control; (5) disseminating information and technology on methods of fertility control; and (6) training and other capability strengthening activities related to the assessment, development and introduction of fertility control technology.

B. Plan of Work

1. Study Areas

The program shall focus on studies and other activities related to the assessment, development and introduction of fertility control technology. These studies shall concentrate on clinical trials and field studies (particularly so-called Phase III studies on the order of fifty to several hundred subjects) but also include earlier phase developmental studies, and postmarketing studies. The program shall focus on (but not be limited to) the following areas: (1) intrauterine devices; (2) systemic contraceptives; (3) female sterilization; (4) male sterilization; (5) barrier contraceptives; (6) natural family planning; (7) equipment integral to fertility control technology; (8) appropriate special studies including developmental research; and (9) postmarketing studies including epidemiologic safety studies. As appropriate, the work shall include the following:

85

(a) Intrauterine Device Studies

Data shall be collected on an international scale under use conditions and analyzed on IUDs utilizing new material, chemicals and/or physical shape. Performance of new IUDs shall be compared with older generation IUDs. Double-blind techniques shall be used when appropriate and the number of insertions shall be established for each device studied which will allow for statistically significant calculation by lifetable techniques of: (1) continuation rates; (2) expulsion rates; (3) removal rates; (4) tabulation of side effects; (5) pregnancy rates; and (6) analyses of the above factors according to clinic, investigator, age and parity of acceptor and relevant personal and cultural factors.

(b) Systemic Contraceptive Studies

Straight and comparative studies of systemic contraceptives shall be conducted with data collected under use conditions in different cultural settings. These may include steroidal methods such as oral contraceptives, injectables, implants, vaginal rings, suppositories, intrauterine carriers, and "paper pills" or other new delivery techniques and patterns. The safety, effectiveness and acceptability of various systemic fertility control techniques in a variety of cultural and service delivery settings shall be evaluated.



(c) Female Sterilization Studies

Evaluation shall be made of internationally comparable data obtained from clinical trials on new techniques for female sterilization to determine the efficacy of procedure, reversibility, side effects, correlated with information on age, parity, clinics, investigators and other relevant personal and cultural factors.

(d) Male Sterilization Studies

Evaluations shall be done of internationally comparable data obtained from clinical trials on new techniques for male sterilization, including reversible sterilization techniques, to determine efficacy of procedure, reversibility, side effects, correlated with information on age, parity, clinic costs, investigators and other relevant personal and cultural factors.

(e) Barrier Contraceptives

Straight and comparative studies of chemical agents (foams and creams, tablets and suppositories, both melting and foaming) as well as mechanical methods (diaphragms, natural and synthetic sponges, and intracervical devices) shall be conducted with data collected under use conditions. Data shall be analyzed and the method evaluated for safety, effectiveness and acceptability in a variety of cultural and service delivery settings. Evaluations may include evaluation of the agents for prevention of sexually transmitted diseases.

(f) Natural Family Planning

Evaluation shall be made of fertility control methods such as "natural" family planning methods (including total or partial reliance on periodic abstinence and lactation) to determine their safety, effectiveness and acceptability.

(g) Equipment Integral to Fertility Control Technology

Straight and comparative studies as well as other laboratory-type studies of fertility control devices and of surgical and other equipment used in the delivery of fertility control will be conducted with data collected under use conditions. Data will be analyzed and the equipment evaluated for safety, cost benefits and other factors present in service delivery systems.

(h) Special Studies and Activities

The program shall include special studies and other activities toward the development and advancement of fertility control technology including developmental research to: (1) bring specific methods to clinical trial state; (2) evaluate clinical use of methods under test in greater depth than provided for under the standard comparative studies protocol; and (3) determine acceptability of various techniques, methods and approaches to fertility control.

(i) Postmarketing Studies

The program shall include postmarketing studies including epidemiologic safety studies and various survey techniques to determine the health effects, acceptability, availability and attitudes toward various methods of fertility control and various other reproductive events.

Conduct of the above studies shall include field trials at one or more centers from which data will be collected and loaded into computer banks. When sufficient data on each study has been collected, publications of findings shall be prepared by or for the Contributor(s) (collaborating investigators) in the center(s) conducting the field trials for dissemination. The Recipient shall analyze pooled data from two or more Contributors and disseminate findings in scientific journals, at international conferences and through other available avenues in order to assure, to the extent practicable, that program managers and technicians are informed of the relatively safety, effectiveness and acceptability of each fertility control-related technology.

2. Research Design and Methodology

Through organization, administration, coordination and general program direction, the Recipient shall assure that:

(a) A network of study contributors from the U.S. and other countries is maintained to collect data under use conditions.

(b) A Technical Advisory Committee (TAC) is established, including technical experts in each of the fertility control methods, who may be drawn from the United States, other developed countries, and developing countries. This Committee is to be consulted at least annually concerning the overall direction of the program. Subcommittees of TAC and ad hoc advisory groups will provide further technical review and assistance to the research activities.

(c) Statistical and epidemiologic techniques are established which employ standardized data collection formats and control analyses of data, similar to the following: For each fertility control method area studies, uniform records shall be perfected which will allow a comparative trial of methods. Data on an appropriate number of cases shall be collected from contributors to allow accurate epidemiologic and statistical analysis of findings. The records shall be printed in a manner to provide an appropriate number of copies. A copy shall be kept with the clinic record. Generally, the original will be sent to the Recipient's headquarters for coding, coding check, punching and tabulation or, consistent with local

capability, data may be encoded in-country and provided to the Recipient in a machine readable form. Data analysis may also be performed in-country.

A standard statistical data analysis for the various studies shall be developed and carried out. The requisite logic and procedures shall be developed and the computer programs will be written and tested.

The data forms for each study shall pass through an edit process (including additional coding as required). The data shall be machine edited and then transferred to a storage file. Finally, the data for each study shall be generally run through the previously developed standard data analysis program to provide output for analysis of research results. In selected instances, data may be developed and refined in a manner suitable for presentation to regulatory bodies and submitted for regulatory approval of various fertility control technologies.

(d) The preliminary development of standardized, straight, comparative and special studies and improvements in the quality of data to be collected as these studies progress shall be initiated and monitored by the Recipient.

(e) The research design for epidemiologic studies, standardized comparative and special studies, the analysis of modular studies related to larger studies, and additional analyses, as needed, shall be carried out.

(f) A training program shall be established to train personnel from other countries in the use of new fertility control techniques including as needed to carry out research methodology.

(g) Preliminary studies shall be undertaken of selected new methods to help select those for more extensive trials.

(h) All research shall be conducted in accordance with A.I.D. policy governing human research after recommendation by the Technical Advisory Committee and approval by the A.I.D. Project Monitor.

(i) Short-term technical consultation and advice shall be provided to study contributors and others as needed to carry out research methodology.

(j) The Recipient shall seek full information and coordinate its activities concerning ongoing research programs of other donor agencies including A.I.D., NIH, WHO, the Population Council, Ford Foundation, PARFR, etc. in order to

carry out a scientific program which complements, but does not unnecessarily duplicate, existing research programs. The Recipient shall coordinate with and utilize the resources of these other research programs as appropriate and respond to possible A.I.D. requests to concentrate research funds in specified research areas.

(k) The contributor network shall be continuously upgraded through training of appropriate Contributors in research technology, by dropping those Contributors from whom the quantity or quality of data submitted is below acceptable standards and by adding new Contributors, as replacements, who have the capability of generating adequate quantities of top quality research data.

(l) Dissemination of Findings - Findings made as a result of activity outlined above shall be given the widest practicable distribution. This shall include, but is not limited to, sponsorship or conduct of training programs, conferences and workshops, participation in conferences or workshops conducted by others, publication of reports and articles in appropriate journals (such as the "International Journal of Obstetrics and Gynaecology"), the preparation and distribution of monographs and the distribution of information through journals and publications such as "Network." The Recipient shall, in consultation with the A.I.D. Cognizant

Technical Officer (CTO), plan and implement dissemination strategies to maximally involve Contributors from developing countries and to rapidly disseminate research findings to scientific investigators, practicing clinicians and to program leadership and policymakers. The Recipient shall make his best efforts to disseminate important findings via public media.

3. Implementation of Studies

(a) The Recipient shall continuously follow all developments affecting fertility and its management and, in consultation with the Technical Advisor Committee and its Subcommittees, identify needs for testing and research. Priorities for each identified need shall be set in consultation with the A.I.D. CTO and summarized approximately once a year in the publication Scientific Directions after consultation with the A.I.D. CTO. Working from assigned priorities, the Recipient shall submit to the A.I.D. CTO for approval, study strategies and protocols with at least the following information:

- (1) Recipient's study identification number
- (2) Study title
- (3) Abstract
- (4) Statement of the hypothesis to be tested
- (5) Study population size and characteristics
- (6) Study design, including sample size
- (7) The number of research centers to be used

- (8) The proposed starting date of the study and the time period for collection of data and for data analysis
- (9) A detailed work plan

(b) The A.I.D. CTO shall review the study strategies and protocols and inform the Recipient in writing of his/her approval or disapproval.

(c) After approval of the Study Protocol by the A.I.D. CTO, the Recipient shall proceed with development of the data collection instrument, including any necessary pretesting, and select the Contributors for data generation and collection. Subagreements or Service Agreements plus any other relevant information for implementation of studies and for generation and collection of data shall be submitted to the A.I.D. Project Monitor prior to study initiation. Only after approval in writing by the A.I.D. CTO of the subagreements or service agreements and the data collection instrument, may the Recipient make commitments to Contributors and initiate the study.

(d) The subagreements or service agreements will define the scope and period of services to be procured, the data to be collected, including number of forms to be completed, the size of the sample for which data is collected, the frequency and the schedule for the collection of the data, reporting requirements,

the estimated unit cost for the services, and a provision for immediate suspension or termination of the agreement upon notification by either party without cause or penalty.

7A. Payment - Letter of Credit (July 1984)

(This provision is applicable only when the following conditions are met: (i) the total advances under all the grantee's cost-reimbursement contracts and assistance instruments with AID exceed \$120,000 per annum, (ii) AID has, or expects to have, a continuing relationship with the grantee for at least one year; (iii) the grantee has the ability to maintain procedures that will minimize the time elapsing between the transfer of funds and the disbursement thereof; (iv) the grantee's financial management system meets the standards for fund control and accountability required under the standard provision of this grant, entitled "Accounting, Audit, and Records" and, either (v) the foreign currency portion of the total advance under this grant is less than 50% or (vi) the foreign currency portion of the total advance under this grant is more than 50% but more than one foreign currency country is involved.)

(a) Payment under this grant shall be by means of a Letter of Credit (LOC) in accordance with the terms and conditions of the LOC and any instructions issued by AID's Office of Financial Management, Program Accounting Division (M/FM/PAD).

(b) As long as the LOC is in effect, the terms and conditions of the LOC and any instructions issued by M/FM/PAD constitute payment conditions of this grant, superseding and taking precedence over any other provision of this grant concerning payment.

(c) Reporting:

(1) A "Financial Status Report" SF-269, shall be prepared on an accrual basis and submitted quarterly no later than 30 days after the end of the period, in an original and two copies to AID/M/FM/PAD, Washington, D.C. 20523. If the grantee's accounting records are not normally kept on the accrual basis, the grantee shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand. The final report must be submitted within 90 days after the conclusion of the grant to M/FM/PAD. In cases where grants are Mission funded, the Grantee will forward an information copy to the AID Mission accounting station at the same time the original and one copy are mailed to M/FM/PAD, AID/Washington.

**PATENT RIGHTS (Small Business Firms and
Nonprofit Organizations) (March 1982)
(OMB Circular A-124)**

a. Definitions

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code.

(2) "Subject Invention" means any invention of the grantee conceived or first actually reduced to practice in the performance of work under this grant.

(3) "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

(4) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(5) "Small Business Firm" means a small business concern as defined at Section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this provision, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

(6) "Nonprofit Organization" means a university or other institution of higher education or an organization of the type described in Section 501(c)(3) of the Internal Revenue Code of 1954 (26 USC 501(c)) and exempt from taxation under Section 501(a) of the Internal Revenue Code (26 USC 501(a)) or any nonprofit scientific or education organization qualified under a state nonprofit organization statute.

b. Allocation of Principal Rights

The grantee may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this provision and 35 U.S.C. 203. With respect to any subject invention in which the grantee retains title, the Federal Government shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or

d. Conditions When the Government May Obtain Title

(1) The grantee will convey to AID, upon written request, title to any subject invention:

(i) If the grantee fails to disclose or elect the subject invention within the times specified in paragraph c. of this provision, or elects not to retain title.

(ii) In those countries in which the grantee fails to file patent applications within the times specified in paragraph c. of this provision; provided, however, that if the grantee has filed a patent application in a country after the times specified in c. of this provision, but prior to its receipt of the written request of AID, the grantee shall continue to retain title in that country.

(iii) In any country in which the grantee decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

e. Minimum Rights to Grantee

(1) The grantee will retain a nonexclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title except if the grantee fails to disclose the subject invention within the times specified in paragraph c. of this provision. The grantee's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the grantee is a party and includes the right to grant sublicenses of the same scope to the extent the grantee was legally obligated to do so at the time the grant was awarded. The license is transferable only with the approval of AID except when transferred to the successor of that party of the grantee's business to which the invention pertains.

(2) The grantee's domestic license may be revoked or modified by AID to the extent necessary to achieve expeditious practical application of the subject invention pursuant to an application for an exclusive license submitted in accordance with applicable provisions in the Federal Property Management Regulations. This license will not be revoked in that field of use or the geographical areas in which the grantee has achieved practical application and continues to make the benefits of the invention reasonably accessible to the public. The license in any foreign country may be revoked or modified at the discretion of AID to the extent the grantee, its licensees, or its domestic subsidiaries or affiliates have failed to achieve practical application in that foreign country.

g. Subcontracts and Subgrants

(1) The grantee will include this provision suitably modified to identify the parties, in all subcontracts and subgrants, regardless of tier, for experimental developmental or research work to be performed by a small business firm or nonprofit organization. The subcontractor or subgrantee will retain all rights provided for the grantee in this provision, and the grantee will not, as part of the consideration for awarding the subcontract or subgrant, obtain rights in the subcontractor's or subgrantee's subject inventions.

(2) With respect to any subcontract or subgrant with a profit making organization, regardless of tier, the clause specified in Sec. 1-9.1 of the Federal Procurement Regulations (41 CFR 1-9.1) shall be used for such subcontracts, and the provision specified in Appendix 4C, provision 28, Patents, of AID Handbook 13 shall be used for such subgrants. With respect to any subcontract or subgrant with any small business firm or nonprofit organization, regardless of tier, this provision's requirements shall apply.

(3) In the case of subcontracts or subgrants, at any tier, when the prime award with AID was a grant (but not a contract), AID, subcontractor or subgrantee, and the grantee agree that the mutual obligations of the parties created by this provision constitute a contract between the subcontractor or subgrantee and AID with respect to those matters covered by this provision.

h. Reporting on Utilization of Subject Inventions

The grantee agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the grantee or its licensees or assignees. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the grantee, and such other data and information as AID may reasonably specify. The grantee also agrees to provide additional reports as may be requested by AID in connection with any march-in proceeding undertaken by AID in accordance with paragraph j. of this provision. To the extent data or information supplied under this section is considered by the grantee, its licensee or assignee to be privileged and confidential and is so marked, AID agrees that, to the extent permitted by 35 USC 202(c)(5), it will not disclose such information to persons outside the Government.

i. Preference for United States Industry

Notwithstanding any other provision of this provision, the grantee agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject

(1) Rights to a subject invention in the United States may not be assigned without the approval of AID, except where such assignment is made to an organization which has as one of its primary functions the management of inventions and which is not, itself, engaged in or does not hold a substantial interest in other organizations engaged in the manufacture or sale of products or the use of processes that might utilize the invention or be in competition with embodiments of the invention provided that such assignee will be subject to the same provisions as the grantee;

(2) The grantee may not grant exclusive licenses under United States patents or patent applications in subject inventions to persons other than small business firms for a period in excess of the earlier of:

(1) five years from first commercial sale or use of the invention; or

(ii) eight years from the date of the exclusive license excepting that time before regulatory agencies necessary to obtain premarket clearance, unless on a case-by-case basis, AID approves a longer exclusive license. If exclusive field of use licenses are granted, commercial sale or use in one field of use will not be deemed commercial sale or use as to other fields of use, and a first commercial sale or use with respect to a product of the invention will not be deemed to end the exclusive period to different subsequent products covered by the invention.

(3) The grantee will share royalties collected on subject invention with the inventor; and

(4) The balance of any royalties or income earned by the grantee with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions, will be utilized for the support of scientific research or education.

1. Communications

Communications concerning this provision shall be addressed to the AID Grant Officer at the address shown on the face of this grant.