

PROGRESS REPORT

Cooperative Agreement No. AID/DPE-3005-A-00-3003-00

17 May 1983 - 29 February 1984

The Population Council
One Dag Hammarskjold Plaza
New York, New York 10017

June 1984

Population Council Progress Report
 Cooperative Agreement No. AID/DPE-3005-A-00-3003-00

17 May 1983 - 29 February 1984

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I. Introduction and Summary

This is the first progress report on activities supported under Cooperative Agreement No. DPE-3005-A-00-3003-00. The agreement, effective 17 May 1983, is in support of a program in Family Planning Services for the period 17 May 1983 through 31 December 1987. This report includes narrative progress reports and financial information for each subaward, subcontract, and in-house activity supported under the agreement during the period 17 May 1983 through 29 February 1984. The progress reports are presented by region and in-house activities (including subawards and subcontracts entered into as part of Council in-house activities under the agreement and the summary of activities is divided into inter-regional activities, regional activities, and country specific activities. During the reporting period, thirteen (13) in-house projects and eleven (11) subawards/subcontracts were active.

Interregional Activities

Interregional activities supported by the Cooperative Agreement included contraceptive development, pre-introduction of advanced Copper-T IUDs, management consulting for contraceptive technologies, pre-introduction of NORPLANT® contraceptive subdermal implants and a seminar on NORPLANT® contraception.

Contraceptive development activities supported included projects on levonorgestrel subdermal implants; contraceptive vaginal ring; levonorgestrel releasing IUD device, analogs of luteinizing hormone releasing hormone; and inhibin. In connection with these projects, support was provided under subcontracts and subawards for studies on comparative use effectiveness of NORPLANT® and NORPLANT®-2 contraceptive implants; the carcinogenicity of Estrogen-Progestin combinations delivered intravaginally to rabbits; medical performance study of contraceptive rings; comparative use effectiveness and safety of levonorgestrel and TCu 380Ag IUDs; the ability of LHRH-13 to inhibit ovulation; sperm suppression with LHRH-13 Agonist; and fractionation and purification of inhibin.

Support was provided for Population Council in-house projects to prepare for international introduction of the advanced Copper-T intra-uterine devices, the TCu 380 and TCu 380Ag; to provide management consulting to AID and AID-supported organizations in the development and regulatory approval of contraceptive technologies; and to initiate pre-introductory activities designed to make NORPLANT® contraceptive subdermal implants available on a global basis. Support was also provided for a seminar to inform health professionals, family planning program managers, and policymakers about NORPLANT® subdermal implants, to discuss experiences with this contraceptive method based on clinical studies conducted in several countries, and to explore future implications of NORPLANT® subdermal

implants for international family planning efforts.

Regional Activities

Support was provided for a Population Council in-house project to design, test, and provide technical assistance in monitoring and evaluation of existing family planning programs in Sub-Saharan Africa and to develop and expand family planning programs in Sub-Saharan Africa. In Latin America, support was provided for the Population Council's office located in Bogota, Colombia to monitor and provide technical assistance for AID funded population activities in the Andean Region.

Country-Specific Activities

In Bogota, Colombia, support was provided for a project to test the costs and use-effectiveness of integrating natural family planning methods into comprehensive health delivery systems.

II. COOPERATIVE AGREEMENT NO. AID/DPE-3005-A-00-3003-00

A. Progress Reports on Awards Active During Reporting Period
- by Region

1. Latin America and the Caribbean

Population Council Award No. 184.07A

To: Fundacion Santa Fe de Bogota,
Bogota, Colombia

Period: January 1, 1984 - December 31, 1984

Amount: \$72,995

Approved by AID: March 9, 1984

Status: Current

Purpose: To test the cost and use effectiveness of integrating natural family planning methods into comprehensive health delivery systems.

Work on this project did not begin until January 1, 1984 and activities were just getting underway during this reporting period. We will be able to report fully on the progress of this project in the next progress report.

B. Population Council In-House Activities and
Project Categories

Population Council In-House Project

Project: Contraceptive Development

Period: May 17, 1983 - May 16, 1984

Amount: \$630,000(a)
\$141,000(b)

Approved by AID: July 29, 1983 (a)
May 14, 1984 (b)

Purpose: To pursue the development of selected approaches to new contraceptive methods, including subdermal implant, contraceptive vaginal ring, levonorgestrel releasing intrauterine device, luteinizing hormone releasing hormone analogs, and inhibin.

Subproject: Levonorgestrel subdermal implants (\$209,176). Phase III comparative trials of the 6 capsule system (NORPLANT^R) and the two covered rod system (NORPLANT^R-2) are ongoing in 5 countries including three clinics in the U.S. Enrollment is complete except in two of the U.S. clinics. Also ongoing in separate studies are comparisons of levonorgestrel blood levels for the two dosage forms. The performance of the two forms is nearly identical to date and judged to be highly satisfactory. The findings are expected to permit registration of the NORPLANT^R-2 system with regulatory agencies.

Subcontracts:

CB83.53A/ICCR Professional Staff Association of the LAC/USC Medical Center	(\$42,134)
CB83.61A/ICCR Professional Staff Association of the LAC/USC Medical Center	(\$14,000)
CB84.01A/ICCR Centro Nacional de la Familia	(\$31,000)

Subproject: Contraceptive Vaginal Ring (\$201,000). Some 2300 rings were manufactured by mechanized techniques and manufacturing and control specifications developed. Phase III clinical trials using the rings have been organized but not yet initiated. Two animal toxicology studies to support a United States New Drug Application (NDA) filing have been continued. The study in rabbits is in its second year. The monkeys have been sacrificed in the study in that species and arteries and organs are being examined.

Subcontracts and Awards:

CB83.54A/ICCR George Washington University	(\$39,232)
B84.02A/ICCR Emory University School of Medicine	(\$72,689)

Subproject: Levonorgestrel releasing IUD device (\$80,000). Phase III trials comparing the levonorgestrel IUD and the Copper T Model 1Cu 380AG are ongoing in 6 countries. Enrollment of subjects is complete except in the U.S. clinic. The pregnancy rates with both devices have been extremely extremely low to date and the continuation rates satisfactory. A study in rabbits to examine the effects of levonorgestrel release in the uterus is ongoing. The study is entering the second of a scheduled 2 years. The project is considered to be progressing satisfactorily and on schedule.

Subcontracts:

CB83.66A/ICCR Professional Staff Association of the LAC/USC
Medical Center (\$47,520)

Subproject: Analogs of luteinizing hormone releasing hormone (\$65,742). Trials of acute administration by the intranasal and subcutaneous routes of the LHRH agonist designated LHRH-13 have confirmed the high potency of the analog in gonadotropin release. Trials of effectiveness in inhibiting ovulation are underway. Animal studies of an LHRH antagonist revealed side effects that have caused us to investigate other antagonistic analogs. Research on improved dosage forms for delivery of both agonists and antagonists is underway.

Subcontracts and Awards:

CB83.72A/ICCR Professional Staff Association of the LAC/USC Medical
Center (\$13,772)

B84.07A/ICCR Urologische Abteilung Landeskrankenhäuser Salzburg
(\$ 8,000)

Subproject: Inhibin (\$203,277). Small amounts of a peptide with inhibin activity have been isolated in pure form from ram rete testes fluid. Delays have occurred in obtaining more fluid but arrangements for doing so are now believed to be in place.

Awards:

B83.37A/ICCR Salk Institute for Biological Sciences (\$ 83,297)
B83.79A/ICCR Salk Institute for Biological Sciences (106,000)

Subproject: FDA filing assistant (\$11,000). This assistant aided with the filing of two Investigational New Drug Applications, an NDA supplement and three progress reports to the U.S. Food and Drug Administration.

Progress reports on the subcontracts and awards are on the following pages in the order indicated above.

Population Council Subcontract No. CB23.53A/ICCR

To: Professional Staff Association of the LAC/USC Medical Center,
Los Angeles, California

Period: July 1, 1983 - June 30, 1984 Amount: \$42,134

Approved by AID: July 29, 1983 Status: Current

Purpose: To conduct a comparative study on "Comparative Use Effectiveness
of NORPLANT^R and NORPLANT^R-2 Contraceptive Implants."

This project is aimed at obtaining data on the performance of subdermal implants releasing levonorgestrel to support a U.S. NDA. The protocol called for enrolling 210 subjects.

Enrollment was completed in June 1983. 166 subjects continue in the study as of May, 1984.

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Population Council Subcontract No. CB83.61A/ICCR

To: Professional Staff Association of the LAC/USC Medical Center,
Los Angeles, California

Period: October 1, 1983 - September 30, 1984 Amount: \$14,000

Approved by AID: September 30, 1983 Status: Current

Purpose: To conduct a comparative study on the "Use Effectiveness of
NORPLANT^R and NORPLANT^R-2 Contraceptive Implants."

This project is aimed at obtaining data on the performance of NORPLANT^R-2 implants that can be used in applying for a U.S. NDA. It increases the number of subjects to be enrolled at this site by 140 beyond those enrolled earlier. (CB83.53A/ICCR.)

Enrollment has been completed. All but 2 subjects are continuing in the study as of May 1984.

Population Council Subcontract No. CB84.01A/ICCR

To: Centro Nacional de La Familia,
Santiago, Chile

Period: February 1, 1984 to January 31, 1985

Amount: \$31,000

Approved by AID: February 2, 1984

Status: Current

Purpose: In support of the project entitled "Comparative Use-Effectiveness
of NORPLANT^R and NORPLANT^R-2 Contraceptive Implants."

The objective of this project is to compare the clinical performance of the NORPLANT^R and NORPLANT^R-2 dosage forms and to accumulate data to permit filings for registration of NORPLANT^R-2 with regulatory agencies. The protocol called for enrolling 210 subjects at this site.

The enrolling of subjects has been completed. 202 are continuing in the study as of May, 1984.

Population Council Subcontract No. CB83.54A/ICCR

To: George Washington University,
Washington, D.C.

Period: July 1, 1983 - June 30, 1984

Amount: \$39,232

Approved by AID: July 29, 1983

Status: Current

Purpose: In support of project entitled "The Carcinogenicity of Estrogen-Progestin Combinations Delivered Intravaginally to Rabbits."

This project is aimed at evaluating the effect of chronic vaginal delivery of levonorgestrel and estradiol on the reproductive organs of the rabbit. It is expected that the results will help fulfill toxicology requirements for an NDA filing on the contraceptive vaginal ring.

The project was begun under Award No. CB81.54A/ICCR. Sacrifice of the animals is scheduled for September 1984. Five test and six control animals died because of the accumulation of hair balls in their stomachs. A high fiber diet appears to have solved this problem. A pronounced decidual reaction involving stromal cells of the endometrium was observed in all animals that died in the test group. Subsequently, two other test animals became anorexic and were found to have marked decidual reactions. The protocol has been modified to include intensive studies of the endometria at sacrifice or in case of additional deaths. Protocols have been developed for other experiments to evaluate factors controlling the endometrial changes.

Population Council Award No. B84.02A/ICCR

To: Emory University School of Medicine,
Atlanta, Georgia

Period: March 1, 1984 - May 31, 1985

Amount: \$72,689

Approved by AID: February 23, 1984

Status: Current

Purpose: In support of the project entitled "Medical Performance Study
of Contraceptive Rings."

The objective of this project is to obtain information on the performance of a contraceptive vaginal ring manufactured by mechanized techniques and designed for 1 year use. The data is to be used in filing for a U.S. NDA.

Start of the project has been delayed at Council initiative while evaluating findings from animal toxicology studies.

Population Council Contract No. CB83.66A/ICCR

To: Professional Staff Association of the LAC/USC Medical Center,
Los Angeles, California

Period December 1, 1983 - November 30, 1984 Amount: \$47,520

Approved by AID: November 28, 1983 Status: Current

Purpose: In support of the project entitled "Comparative Use Effectiveness
and Safety of Levonorgestrel and TCU 380Ag IUDs."

This project is aimed at obtaining information which can be used in support of an NDA filing in the U.S. on the safety and effectiveness of the levonorgestrel IUD and the TCU 380Ag IUD. 200 subjects are to be enrolled on each device.

As of May 1, 1984, 25 subjects had been enrolled in the study. This is a slower enrollment rate than expected but a considerable number of patients are currently scheduled for IUD placement.

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Population Council Subcontract No. CB23.72A/ICCR

To: Professional Staff Association of the LAC/USC Medical Center
Los Angeles, California

Period September 1, 1983 - February 29, 1984 Amount: \$13,772

Approved: December 12, 1983 Status: Current

Purpose: To conduct studies to determine the ability of LHRH-13 to
inhibit ovulation.

The study is designed to determine the dose of LHRH-13 (an LHRH-agonist) required to inhibit ovulation when administered by nasal spray and to identify side effects associated with its use. Up to ten women are to be enrolled on each of three dose levels, depending on response.

Results are available on two women at the lowest dose level and on three at the intermediate dose level. The lowest dose level appears inadequately effective.

Population Council Award No. B84.07A/ICCR

To: Urologische Abteilung Landeskrankenanstalten Salzburg,
Salzburg, Austria

Period of Award: March 1, 1984 - February 28, 1985 Amount: \$8,000

Approved by AID: March 2, 1984 Status: Current

Purpose: In support of the study entitled "Sperm Suppression with LHRH-13
Agonist."

This project was undertaken to determine whether an LHRH agonist can be used successfully to suppress spermatogenesis when delivered by the intranasal route and supplemented by enough exogenous androgen to support secondary sex function. Ten subjects are to be enrolled.

Subjects have been recruited.

Population Council Award No. B83.37A/ICCR

To: Salk Institute for Biological Studies,
San Diego, California

Period: May 17, 1983 - December 16, 1983

Amount: \$83,297

Approved by AID: October 27, 1983

Status: Expired

Purpose: To provide support for project entitled "Fractionation and
Purification of Inhibin."

This project was aimed at isolating inhibin using ram rete testis fluid as a source.

See report on B83.79A/ICCR.

Population Council Award No. B83.79A/ICCR

To: Salk Institute for Biological Studies,
San Diego, California

Period: December 1, 1983 - April 30, 1984

Amount: \$106,000

Approved by AID: February 6, 1984

Status: Current

Purpose: In support of the project entitled "Fractionation and Purification of Inhibin."

The aim of this project is to isolate inhibin using ram rete testes fluid as a source.

A process of isolation and purification has been developed and a small quantity of pure compound with inhibin activity has been prepared. The current need is to harvest enough ram rete testes fluid to isolate sufficient quantities of inhibin for structural studies.

Population Council In-House Project

Project: Fundacion Santa Fe de Bogota In-House Costs

Period: January 1, 1984 - December 31, 1984

Amount: \$15,194

Approved by AID: March 9, 1984

Status: Current

Purpose: To cover in-house costs in connection with Population Council
Award No. I84.06A to Fundacion Santa Fe de Bogota, Bogota, Colombia.

See report on Award No. I84.07A.

Population Council In-House Project

Project: Pre-Introduction of Advanced Copper-T IUDs

Period: May 17, 1983 - December 31, 1983(a)
Extended to June 30, 1984(b)

Amount: \$75,000(a)

Status: Current

Approved by AID: August 1, 1983(a)
April 10, 1984(b)

Purpose: To prepare for international introduction of the advanced
Copper-T intrauterine devices, the TCu 380 and TCu 380Ag.

The specific objectives of this program are to:

- 1) negotiate licensing agreements with international manufacturers or developing country government organizations for the manufacturing and distribution of the advanced Copper T IUDs.
- 2) obtain approval of the U.S. Food and Drug Administration.
- 3) inform decision makers, clinicians, family planning managers and potential users of the advantages of these new IUDs.

Licensing agreements have now been reached with several manufacturers that ensure the worldwide availability of both the Copper T 380A and Aq models. Food and Drug Administration (FDA) review of the New Drug Application (NDA) for the 380A is complete and approval is imminent. A package of informational materials for decision makers, clinicians, fieldworkers, and potential acceptors of the Copper T 380 has been developed, and its distribution to family planning leaders in international population organizations and developing countries will begin with FDA approval.

Population Council In-House Project

Project: Management Consulting for Contraceptive Technologies

Period: July 1, 1983 - June 30, 1984

Amount: \$7,800

Approved by AID: October 24, 1983

Status: Current

Purpose: To provide management consulting to AID and AID-supported organizations in the development and regulatory approval of new contraceptive technologies.

The objective of this project is to provide management guidance to AID and AID supported organizations in the development and regulatory approval of new contraceptive technologies.

During the reporting period consultation was provided to Family Health International (FHI), and The Program for Applied Research in Fertility Regulation (PARFR) on the development of a long-acting, progestin-releasing, micro capsule injectable contraceptive. Advice was given on the planning and coordination of pharmaceutical development, drug safety, clinical trials, and regulatory activities related to development of the potential products. Assistance was given to FHI in identifying and recruiting a senior person experienced in industrial pharmaceutical management. This individual now serves as director of clinical trials and is responsible for the overall management of the project. Periodic guidance was provided on the planning of phase III clinical trials, and on negotiations with a private sector manufacturer interested in the program.

Of all the goals in the introduction program, the Council places the highest priority on assuring that physicians and paramedical personnel are appropriately trained in the use of the NORPLANT® method before it is introduced widely into family planning programs. For example, the Council's senior physician, based in our regional office in Bangkok, in collaboration with the Indonesia National Family Planning Coordinating Board (BKKBN), in introducing training programs in Jakarta for physicians and nurse midwives throughout Indonesia. Physicians from other countries in the region will also come to this center for initial training. We are currently communicating with interested representatives of leading institutions in selected countries in Asia, Latin America and North Africa to plan the establishment of similar resource centers for training and information dissemination in those countries.

In most cases, the centers will conduct pre-introduction trials to evaluate the training experience and to ascertain the acceptability of the method among health care providers and women in specific country settings.

Population Council In-House Project

Project: Seminar on NORPLANT^R Contraception

Period: September 15, 1983 - December 31, 1983

Amount: \$20,000

Approved by AID: November 18, 1983

Status: Expired

Purpose: To inform health professionals, family planning program managers, and policymakers about NORPLANT^R subdermal implants; to discuss experiences with this contraceptive method based on clinical studies conducted in several countries; and to explore future implications of NORPLANT^R subdermal implants for international family planning efforts.

On December 9, 1983, the Population Council, in coordination with the Centro de Investigaciones y Servicios en Reproduccion Humana y Anti-concepcion (CINSERHA) held a seminar to review the most recent scientific and programmatic experience with NORPLANT[®] contraceptive subdermal implants. The program included description of the method, its mode of action, side effects, safety, and insertion and removal, as well as discussion of clinical experience with the method in several countries (Egypt, Sweden, Dominican Republic, Indonesia and Ecuador, including a summary of world-wide experience). A major element of the program was consideration of programmatic issues as plans for international pre-introduction activities proceed.

The seminar was attended by approximately 85 people from over 25 countries. Participants included representatives of developing country family planning programs and Ministries of Health.

The seminar was successful in stimulating the interest of representatives from developing country institutions in collaborating with the Council in pre-introduction activities using the NORPLANT[®] system. Negotiations are in process to initiate pre-introduction evaluation trials in several countries beginning in 1984.

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Population Council In-house Project

Project: Design, Implementation, and Evaluation of Family Planning
Projects in Sub-Saharan Africa

Period: June 1, 1983 - May 31, 1984(a)
Extended to December 31, 1984(b)

Amount: \$134,911(a)

Status: Current

Approved by AID: October 14, 1983(a)
March 14, 1984(b)

Purpose: To design, test, and provide technical assistance in monitoring
and evaluation of existing family planning programs in Sub-Saharan
Africa and to develop and expand family planning programs in
Sub-Saharan Africa.

During this period, ongoing technical assistance was provided in Rwanda,
and project development commenced in Mali. Contact was maintained in
Zimbabwe for the development of an operations research project with the
Child Spacing and Family Planning Association.

Rwanda

Technical assistance to the Office National de la Population du Ministere
de la Sante (ONAPO) continued. Dr. Margaret McEvoy travelled to Rwanda
in July and August 1983 to design and pre-test the service statistic rep-
orting system in twenty pilot clinics, as well as the supervisory and
monitoring systems by region. In November 1983, Ms. Maria Elena Casanova
conducted a two-week training program for the IE&C division in the design
and pre-testing of audio-visual materials. An excellent brochure on
primary health care and contraceptive methods was produced in addition
to the first ONAPO calendar. A future visit is planned to design brochures
by method. Ongoing technical assistance is planned for the training and
design of operation research projects as well as the analysis of the 1983
service statistics data.

Mali

Dr. McEvoy travelled to Mali in February 1984 to follow up potential project
leads which had been identified by Dr. George Brown during previous visits.
Technical assistance was provided to the Association Malian de la Protection
et Promotion de la Famille (AMPPF) in the revision of their service statistic
forms and monthly reporting systems. A request was made to the Council to
assist in the development of a rural outreach program; however, the infra-
structure of the AMPPF is not strong enough to permit program development
at this time. Discussions with the Ministry of Health resulted in a request
that the Council assist in the development of non-literate training materials,
as well as in streamlining their general service statistics forms. Follow-up
on these two requests is in progress.

Zimbabwe

Dr. McEvoy has been following up on preliminary discussions with the

Child Spacing and Family Planning Association to design an operations research project in family planning service delivery at the rural level. A request has come from the Government of Zimbabwe to incorporate this component into the pilot program of the Kubatsirana Women's Training Center which will link family planning with other development activities. This project will be developed in June 1984.

Population Council In-House Project

Project: Local Office Expenses, Bogota Office,
Bogota, Colombia

Period: May 17, 1983 - April 30, 1984

Amount: \$30,000

Approved by AID: August 2, 1983

Status: Current

Purpose: To monitor and provide technical assistance for AID-funded
population activities in the Andean Region.

AID funding for this period has been used to support the maintenance of the Population Council Bogota office covering rent, supplies, local staff support, in-country travel and computer time expenditures. Professional staff is not supported under this project.

The Bogota office activities in the Andean region have centered on:

- (1) completion of the final phase of the PROFAMILIA rural experimental community based distribution (CBD) project. During the final months of this project, activities will be carried out in areas programmed for the project that had not been covered at all or inadequately covered by both the team and the promoters with incentives.
- (2) submission of a proposal to AID for a complementary project designed to test the cost-effectiveness of a commercial social marketing (CSM) contraceptive delivery strategy to replace PROFAMILIA's CBD program in urban marginal and rural areas of Colombia.
- (3) completion of the Spanish publications program with the Corporacion Centro Regional de Poblacion.
- (4) development of a Natural Family Planning (NFP) project to (a) increase contraceptive use among poor marginal families through the provision of family planning services in an urban area of Bogota, (b) identify a cost and use-effective delivery strategy for NFP within the context of an integrated health program and (c) detect user satisfaction with NFP contraceptive methods and the service delivery system tested.
- (5) in Peru, a seminar on population projections at the Consejo Nacional de Poblacion and Instituto Nacional de Estadistica.

The Population Council representative and advisor in Colombia, Dr. Marcia Townsend, left the Council in January 1984 after seven years of service. Dr. John Townsend was appointed to replace her. He comes to the Council from the Institute of Nutrition of Central America and Panama. He will provide consultancy services to AID-funded projects in Peru, Honduras and Guatemala as well as assist with the ongoing activities listed above.

III. FINANCIAL INFORMATION ON AWARDS, SUBCONTRACTS AND PROJECTS

1. Fiscal Report #1 for the period 5/17/83 - 9/30/83
2. Fiscal Report #2 for the period 10/1/83 - 12/31/83

NOTE: The fiscal report for the period 1/1/84-3/31/84
will be submitted as soon as it is available.

THE POPULATION COUNCIL

Cooperative Agreement No. AID/DPE-3005-A-00-3003-00

Fiscal Report #1

For the Period 5/17/83 - 9/30/83

<u>In House Projects</u>	<u>Budget</u>	<u>Expenditures</u>	
<u>Center for Biomedical Research</u>		<u>5/17/83 - 9/30/83</u>	
• <u>Contraceptive Ring</u>	<u>5/17/83 - 5/16/84</u>		
Salaries & Benefits	\$ 59,768.00	\$ 44,371.81	
Rabbits and Animal Maintenance	20,000.00	-0-	
Laboratory Supplies	1,000.00	82.88	
Awards & Subcontracts	<u>119,232.00</u>	<u>-0-</u>	
<u>Total Direct Costs</u>	200,000.00	44,454.69	
<u>Indirect Costs @ 34.4%</u>	<u>68,800.00</u>	<u>15,292.41</u>	
#1 <u>Total Direct & Indirect Costs</u>	<u>268,800.00</u>	<u>59,747.10</u>	
• <u>Levonorgestrel IUD</u>	<u>5/17/83 - 5/16/84</u>		
Salaries & Benefits	31,280.00	23,809.55	
Laboratory Supplies	1,200.00	-0-	
*Awards & Subcontracts	<u>47,520.00</u>	<u>-0-</u>	
<u>Total Direct Costs</u>	80,000.00	23,809.00	
<u>Indirect Costs @ 34.4%</u>	<u>27,520.00</u>	<u>8,190.49</u>	
#2 <u>Total Direct & Indirect Costs</u>	<u>107,520.00</u>	<u>32,000.00</u>	
*CB.83.54A George Washington University	39,232.00		
• <u>Sub Dermal Implants</u>	<u>5/17/83 - 5/16/84</u>		
Salaries & Benefits	117,042.00	75,635.23	
Laboratory Supplies	5,000.00	-0-	
*Awards & Subcontracts	<u>77,958.00</u>	<u>-0-</u>	
<u>Total Direct Costs</u>	200,000.00	75,635.23	
<u>Indirect Costs @ 34.4%</u>	<u>68,800.00</u>	<u>26,018.52</u>	
#3 <u>Total Direct & Indirect Costs</u>	<u>268,800.00</u>	<u>101,653.75</u>	
*CB.83.53A Professional Staff Association		42,134.00	
*CB.83.61A Professional Staff Association		<u>14,000.00</u>	
Total		<u>56,134.00</u>	

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<u>•LHRH Analogs</u>		<u>5/17/83 - 5/16/84</u>		
Salaries & Benefits	30,000.00		30,000.00	
*Awards & Subcontracts	31,000.00		-0-	
	<u>Total Direct Costs</u>	61,000.00	30,000.00	
	<u>Indirect Costs @ 34.4%</u>	20,984.00	10,320.00	
#4	<u>Total Direct and Indirect Costs</u>	81,984.00		40,320.00
*CB.83.72A Professional Staff Association			13,772.00	
 <u>•FDA Filing Assistance</u>		 <u>5/17/83 - 5/16/84</u>		
Consultant	20,000.00		4,050.00	
#5	* <u>Total Direct Costs</u>	20,000.00		4,050.00
	*No Indirect Costs Allowed			
 <u>•INHIBIN</u>				
Salaries & Benefits	7,314.00		7,114.00	
Laboratory Supplies	5,000.00		1,687.01	
*Awards & Subcontracts	197,686.00		-0-	
	<u>Total Direct Costs</u>	210,000.00	8,801.01	
	<u>Indirect Costs @ 34.4%</u>	72,240.00	3,027.55	
#6	<u>Total Direct & Indirect Costs</u>	282,240.00		11,828.56
*CB.83.37A Salk Institute		83,297.00		
 <u>Total Costs Center for Biomedical Research</u>				<u>\$249,599.45</u>

International Programs

<u>•Pre-Introduction Copper-T IUD</u>		<u>5/17/83 - 12/31/83</u>		
Salaries & Benefits	35,066.00		13,263.00	
Contraceptive Supplies	15,000.00		-0-	
Communications & Supplies	1,500.00		480.00	
Travel	5,000.00		1,151.00	
Meetings	434.00		298.00	
Legal Fees	18,000.00		11,745.00	
	<u>Total Direct Costs</u>	75,000.00	26,937.00	
	<u>Indirect Costs @ 33.28%</u>	24,960.00	8,964.63	
#7	<u>Total Direct & Indirect Costs</u>	99,960.00		35,901.63
 <u>•Norplant Seminar</u>		 <u>9/15/83 - 12/31/83</u>		
Travel & Per Diem	15,426.00		-0-	
Equipment Rental	1,133.00		-0-	
Seminar Luncheon	871.00		-0-	
Translators	570.00		-0-	
Other Direct Costs	2,000.00		1,742.65	
	<u>Total Direct Costs</u>	20,000.00	1,742.65	
	<u>Indirect Costs @ 33.28%</u>	6,656.00	579.95	
#8	<u>Total Direct & Indirect Costs</u>	26,656.00		2,322.60

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	<u>Management Consultant</u>	<u>7/1/83 - 6/30/84</u>		
	Forrest Greenslade	7,800.00	4,310.03	
	<u>Total Direct Costs</u>	<u>7,800.00</u>	<u>4,310.03</u>	
	<u>Indirect Costs @ 33.28%</u>	<u>2,596.00</u>	<u>1,434.38</u>	
#9	<u>Total Direct & Indirect Costs</u>	<u>10,396.00</u>		<u>5,744.41</u>

•Design, Implementation, Evaluation
 of Family Planning Projects in
 in Sub-Saharan Africa

	<u>6/1/83 - 5/31/84</u>			
Salaries	46,463.00	10,716.39		
Fringe Benefits	11,848.00	2,732.69		
Consultants	20,800.00	-0-		
Travel & Per Diem	51,300.00	1,805.28		
Educational Materials	3,000.00	--0-		
Communications	1,500.00	172.97		
	<u>Total Direct Costs</u>	<u>134,911.00</u>	<u>15,427.33</u>	
	<u>Indirect Costs @ 33.28%</u>	<u>44,898.00</u>	<u>5,134.22</u>	
#10	<u>Total Direct & Indirect Costs</u>	<u>179,809.00</u>		<u>20,561.55</u>

Total Costs - International Programs \$ 64,530.19

•Management Support Services
 Bogota Office

	<u>5/17/83 - 4/30/84</u>			
Personnel	10,000.00	4,989.91		
Travel	7,000.00	997.48		
Expendable Supplies	2,000.00	129.03		
Rent	6,000.00	2,475.00		
Communication	2,000.00	530.61		
Other Direct Costs	3,000.00	625.56		
	<u>Total Direct Costs</u>	<u>30,000.00</u>	<u>9,747.59</u>	
	<u>Indirect Costs @ 12%</u>	<u>3,600.00</u>	<u>1,169.71</u>	
#11	<u>Total Direct & Indirect Costs</u>	<u>33,600.00</u>		<u>10,917.30</u>

Total Management Support Services \$ 10,917.30

TOTAL ALL DIVISIONS

\$325,016.02

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

By: George A. Babb

Title: Assistant Treasurer and Comptroller

BEST AVAILABLE COPY

The Population Council

COOPERATIVE AGREEMENT No. AID/DPE-3005-A-00-3003-00
STATEMENT OF EXPENDITURES

For the Period October 1, 1983 to December 31, 1983

	Budget 5/17/83- 5/16/84	Expended To Date 12/31/83	Expended This Period 10/1/83-12/31/83
<u>In-House Projects</u>			
<u>Center for Biomedical Research</u>			
<u>Contraceptive Ring</u>			
Salaries and Benefits	\$ 77,988.00	\$ 59,768.00	\$ 15,396.19
Rabbits and Animal Maintenance	2,000.00	-	-
Laboratory Supplies	1,000.00	1,000.00	917.12
Awards and Subcontracts*	111,921.00	19,616.00	19,616.00
Technology Transfer	8,896.00	8,896.00	8,896.00
<u>Total Direct Costs</u>	201,805.00	89,280.00	44,825.31
<u>Indirect Cost @ 34.4%</u>	69,421.00	30,712.32	15,419.91
<u>Total Direct and Indirect Costs</u>	<u>\$271,226.00</u>	<u>\$119,992.32</u>	<u>\$ 60,245.22</u>
* CB83.54A/ICCR-The George Washington University-\$39,232.00.			
<u>Levonorgestrel IUD</u>			
Salaries and Benefits	\$ 31,280.00	\$ 31,042.00	\$ 7,232.45
Awards and Subcontracts*	47,520.00	23,760.00	23,760.00
Laboratory Supplies	1,200.00	-	-
<u>Total Direct Costs</u>	80,000.00	54,802.00	30,992.45
<u>Indirect Costs @ 34.4%</u>	27,520.00	18,851.89	10,661.40
<u>Total Direct and Indirect Costs</u>	<u>\$107,520.00</u>	<u>\$ 73,653.89</u>	<u>\$ 41,653.85</u>
* CB83.66A/ICCR-Professional Staff Association of LAC/USC Medical Center-\$47,520.00.			
<u>Subdermal Implants</u>			
Salaries and Benefits	\$121,224.00	\$117,042.00	\$ 41,406.77
Laboratory Supplies	818.00	818.00	818.00
Awards and Subcontracts*	87,134.00	35,067.00	35,067.00
<u>Total Direct Costs</u>	209,176.00	152,927.00	77,291.77
<u>Indirect Costs @ 34.4%</u>	71,957.00	52,606.89	26,588.37
<u>Total Direct and Indirect Costs</u>	<u>\$281,133.00</u>	<u>\$205,533.89</u>	<u>\$103,880.14</u>
* CB83.53A/ICCR-Professional Staff Association of LAC/USC Medical Center-\$43,134.00. CB83.61A/ICCR-Professional Staff Association of LAC/USC Medical Center-\$14,000.00.			

	Budget 5/17/83- 5/16/84	Expended To Date 12/31/83	Expended This Period 10/1/83-12/31/83
<u>LHRH Analogs</u>			
Salaries and Benefits	\$ 30,000.00	\$ 30,000.00	\$ -
Awards and Subcontracts*	31,000.00	-	-
<u>Total Direct Costs</u>	61,000.00	30,000.00	-
<u>Indirect Costs at 34.4%</u>	20,984.00	10,320.00	-
<u>Total Direct and Indirect Costs</u>	<u>\$ 81,984.00</u>	<u>\$ 40,320.00</u>	<u>\$ -</u>

* CB83.72A/ICCR-Professional Staff Association of LAC/USC Medical Center-\$13,772.00.

<u>Food and Drug Administration Filing Assistant</u>			
Consultant Fees	\$ 11,000.00	\$ 11,000.00	\$ 6,950.00
<u>No Indirect Costs</u>			

<u>Inhibin</u>			
Salaries and Benefits	\$ 7,314.00	\$ 7,314.00	\$ 200.00
Laboratory Supplies	5,000.00	5,000.00	3,312.99
Awards and Subcontracts*	197,686.00	83,297.00	83,297.00
<u>Total Direct Costs</u>	210,000.00	95,611.00	86,809.99
<u>Indirect Costs @ 34.4%</u>	72,240.00	32,890.19	29,862.64
<u>Total Direct and Indirect Costs</u>	<u>\$282,240.00</u>	<u>128,501.19</u>	<u>116,672.63</u>
<u>Total Direct Costs Center for Biomedical Research</u>		433,620.00	246,869.52
<u>Total Indirect Costs @ 34.4% Center for Biomedical Research (Less Consultant Fees)</u>		145,381.29	82,532.32
<u>Total Direct and Indirect Costs Center for Biomedical Research</u>		<u>\$579,001.29</u>	<u>\$329,401.84</u>

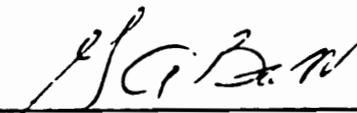
* CB83.37A-Salk Institute, Biological Study-\$83,297.00.
CB83.79A-Salk Institute, Biological Study-\$106,666.00.

<u>International Programs</u>			
<u>Pre-Introduction of Copper-T IUD</u>			
Salaries and Benefits	\$ 35,066.00	\$ 36,950.00	\$ 23,687.00
Contraceptive Supplies	15,000.00	-	-
Communications and Supplies	1,500.00	1,303.97	823.97
Travel	5,000.00	2,489.00	1,338.00
Meetings	434.00	586.16	288.16
Legal Fees	18,000.00	24,370.28	12,625.28
<u>Total Direct Costs</u>	75,000.00	65,699.41	38,762.41
<u>Indirect Costs @ 33.28%</u>	24,960.00	21,864.76	12,900.13
<u>Total Direct and Indirect Costs</u>	<u>\$ 99,960.00</u>	<u>\$ 87,564.17</u>	<u>\$ 51,662.54</u>

	Budget 5/17/83- 5/16/84	Expended To Date 12/31/83	Expended This Period 10/1/83-12/31/83
<u>Morplant Seminar</u>			
Travel and Per Diem	\$ 15,426.00	\$ 5,410.81	\$ 5,410.81
Equipment Rental	1,133.00	-	-
Seminar Luncheon	871.00	9,600.11	9,600.11
Translation	570.00	-	-
Other Direct Costs	<u>2,000.00</u>	<u>3,123.61</u>	<u>1,380.96</u>
<u>Total Direct Costs</u>	20,000.00	18,134.53	16,391.88
<u>Indirect Costs @ 33.28%</u>	<u>6,656.00</u>	<u>6,035.17</u>	<u>5,455.22</u>
<u>Total Direct and Indirect Costs</u>	<u>\$ 26,656.00</u>	<u>\$ 24,169.70</u>	<u>\$ 21,847.10</u>
<u>Management Consultant</u>			
Forrest Greenslade	\$ 7,800.00	\$ 3,617.34	\$ (692.69)
<u>Indirect Costs @ 33.28%</u>	<u>2,596.00</u>	<u>1,203.85</u>	<u>(230.53)</u>
<u>Total Direct and Indirect Costs</u>	<u>\$ 10,396.00</u>	<u>\$ 4,821.19</u>	<u>\$ (923.22)</u>
<u>Design, Implementation, Evaluation of Family Planning Projects in Sub-Saharan Africa</u>			
Salaries and Benefits	\$ 58,311.00	\$ 16,535.42	\$ 3,086.34
Consultants	20,800.00	2,760.00	2,760.00
Travel and Per Diem	51,300.00	9,369.54	7,564.26
Educational Materials	3,000.00	267.10	267.10
Communication	<u>1,500.00</u>	<u>359.04</u>	<u>186.07</u>
<u>Total Direct Costs</u>	134,911.00	29,291.10	13,863.77
<u>Indirect Costs @ 33.28%</u>	<u>44,898.00</u>	<u>8,829.55</u>	<u>3,695.33</u>
<u>Total Direct and Indirect Costs</u>	<u>\$179,809.00</u>	<u>38,120.65</u>	<u>17,559.10</u>
<u>Total Direct Costs International Programs</u>		116,742.38	68,325.37
<u>Total Indirect Costs @ 33.28% International Programs (Less Consultant Fees)</u>		<u>37,933.33</u>	<u>21,820.15</u>
<u>Total Direct and Indirect Costs International Programs</u>		<u>\$154,675.71</u>	<u>\$ 90,145.52</u>

	Budget 5/17/83- 5/16/84	Expended To Date 12/31/83	Expended This Period 10/1/83-12/31/83
<u>Management Support Service</u>			
<u>Bogota Office</u>			
Personnel	\$ 10,000.00	\$ 8,406.60	\$ 3,416.69
Travel	7,000.00	465.05	(532.43)
Expendable Supplies	2,000.00	226.80	97.77
Rent	6,000.00	3,825.00	1,350.00
Communication	2,000.00	1,527.72	997.11
Other Direct Costs	3,000.00	1,822.78	1,197.22
<u>Total Direct Costs</u>	30,000.00	16,273.95	6,526.36
<u>Indirect Costs @ 12%</u>	3,600.00	1,952.87	783.16
<u>Total Direct and Indirect Costs</u>	\$ 33,600.00	\$ 18,226.82	\$ 7,309.52
<u>Total Direct Costs All Divisions</u>		\$566,636.33	\$321,721.25
<u>Total Indirect Costs All Divisions</u>		185,267.49	105,135.63
<u>TOTAL DIRECT AND INDIRECT COSTS ALL DIVISIONS</u>		\$751,903.82	\$426,856.88

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

By:  Title: Assistant Treasurer
 George A. Babb and Comptroller

Date: May 2, 1984