

PROJECT DATA SHEET

1. TRANSACTION CODE 10-11-277
 A = Add
 C = Change
 D = Delete
 Amendment Number 32252

DOCUMENT CODE 3

2. COUNTRY/ENTITY
 Worldwide

3. PROJECT NUMBER
936-3041

4. BUREAU/OFFICE
 ST/POP 36

5. PROJECT TITLE (maximum 40 characters)
 Family Health International

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)
 MM DD YY
09 30 96

7. ESTIMATED DATE OF OBLIGATION
 (Under 'B.' below, enter 1, 2, 3, or 4)
 A. Initial FY 85 B. Quarter 3 C. Final FY 89*

8. COSTS (\$000 OR EQUIVALENT \$1 =)

A. FUNDING SOURCE	FIRST FY <u>85</u>			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total	8,700		8,700			167,900
(Grant)	(8,700)	()	(8,700)	()	()	(167,900)
(Loan)	()	()	()	()	()	()
Other U.S. 1.						
Other U.S. 2.						
Host Country						
Other Donor(s)						
TOTALS	8,700					167,900

9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT (FY 85-89)	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
		(1)					58,500		58,500*
(2)									
(3)									
(4)									
TOTALS					58,500		58,500*		

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)

11. SECONDARY PURPOSE CODE

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code
 B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

Improve family planning technology available for use in developing countries and improve understanding of such technologies.

14. SCHEDULED EVALUATIONS

Interim MM YY 06 89 Final MM YY 06 93

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000 941 Local Other (Specify) 935

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a page PP Amendment)

*LOP cost over ten year period FY 85-94 is \$167,900,000. Authorization of S&T funding of \$58,500,000 is requested for the first five years of this action.

17. APPROVED BY	Signature <u>Steven W. Sinding</u>	18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION MM DD YY
	Title <u>Steven W. Sinding</u> <u>Director S&T/POP</u>	
	Date Signed MM DD YY <u>02 11 85</u>	

PROJECT AUTHORIZATION

Country: Interregional

Project: Family Health International

Project No.: 936-3041

1. Pursuant to Section 104 of the Foreign Assistance Act of 1961, as amended, I hereby authorize the centrally funded project, Family Health International, involving planned obligations not to exceed \$58,500,000 in grant funds over a five-year period from the date of authorization, subject to the availability of funds in accordance with the A.I.D. OYB/allotment process, to help in financing foreign exchange and local currency costs for the project.

2. The purpose of the project is to improve family planning technology available for use in developing countries and improve understanding of such technologies.

3. The agreement(s) which may be negotiated and executed by the officer(s) to whom such authority is delegated in accordance with A.I.D. regulations and Delegations of Authority shall be subject to the following terms and conditions, together with such other terms and conditions as A.I.D. may deem appropriate.

4. Source and Origin of Commodities, Nationality of Services

a. Commodities financed by A.I.D. under the project shall have their source and origin in the cooperating country* or the United States, except as A.I.D. may otherwise agree in writing. Except for ocean shipping, the suppliers of commodities or services shall have the cooperating country or the United States as their place of nationality, except as A.I.D. may otherwise agree in writing.

b. The aggregate cost of all goods and services procured under each subagreement in a cooperating country may not exceed \$750,000.

*Each country where research, training, technical, or other assistance takes place under the project shall be deemed to be a cooperating country for the purpose of permitting local cost financing of goods and services for the activity being conducted in such country. Such activities may be undertaken in any country included in A.I.D. geographic code 935.

c. Ocean shipping financed by A.I.D. under the project shall, except as A.I.D. may otherwise agree in writing, be financed only on flag vessels of the United States.

J. Peter McPherson
J. Peter McPherson
Agency Administrator *for*

Date *4/3/85*

Clearances:

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S&T/PO, GEaton *For*
S&T/HP, JESarn *3/1/85*
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AGENCY FOR INTERNATIONAL DEVELOPMENT

WASHINGTON, D. C. 20523

19 1985

SENIOR ASSISTANT ADMINISTRATOR

ACTION MEMORANDUM FOR THE ADMINISTRATOR

THRU: AA/PPC, Richard A. Derham *Richard A. Derham*

FROM: S&T, N. C. Brady *N.C. Brady*

SUBJECT: Family Health International (FHI) Project, 936-3041

Action: Your approval is requested to authorize S&T Bureau funding in the amount of \$58,500,000 from the Population account for the first five years of the Family Health International Project, 936-3041.

Discussion: The ability of individuals in the developing world to choose voluntarily the number and spacing of their children is seriously impeded by the current family planning technology available to them. Accordingly, research to develop improved methods of family planning has been recognized as a particular A.I.D. priority in recent years. This need was also reflected in the White House instructions accompanying the Policy Statement prepared for the International Conference on Population in Mexico City, August 1984. In addition to the development of improved family planning methods, a number of related activities are also crucial to enhancing individual choice. These include: technology transfer, safety studies, survey approaches to help understand the dynamics of the use of these technologies, and institution strengthening in research on family planning technology.

At any point in time many family planning methods are available for evaluation. From whatever source these methods come, a vehicle will be necessary to assess, introduce, and adapt them to developing countries. A method suitable in one setting may not be suitable in another. Therefore, a mechanism is needed to evaluate multiple methods in multiple settings.

Family Health International (FHI) (formerly the International Fertility Research Program) is a non-profit research organization in Research Triangle Park, North Carolina. Its mandate is specifically to carry out the research and related activities described above. Since 1971, FHI has been the Agency's principal vehicle for the assessment and transfer of new and improved family planning technology appropriate for developing countries. It is a unique institution with a unique

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critical mass of scientific talent capable of carrying out the variety of family planning technology activities critical to A.I.D.-supported family planning efforts. Consistent with FHI's clearly unapproached capabilities and the common interest of FHI and AID in furthering the understanding and use of family planning technology, we anticipate a five year extension of the current one year Cooperative Agreement with FHI.

The extension of the FHI project will continue these valuable functions:

1. Contraceptive Development - animal and/or early human studies aimed at developing new or improved technologies.
2. Clinical Trials - later human studies, typically with a few hundred subjects at any one site. This is the backbone of the FHI project and includes a significant technology transfer component.
3. Contraceptive Safety - epidemiologic and other safety studies relevant for developing countries.
4. Reproductive Health - primarily studies using social science techniques to understand the dynamics of family planning technology use.
5. Field Development and Training - activities aimed at developing country institution strengthening in family planning.
6. Natural Family Planning (NFP) - studies and other activities aimed at developing and improving NFP methods. The NFP component was started in response to A.I.D. emphasis on NFP. While it is recognized that initiatives are underway specifically aimed at NFP, we believe it is important also to assess NFP in the scientific context of other family planning methods.

External evaluations in 1981-82 and 1984 concluded that FHI was fulfilling the mission mandated by A.I.D. Responses to a November 1984 worldwide cable to the field describing the FHI project and proposed extension were received from 30 countries and were extremely positive.

Approximately \$38,000,000 were obligated to the FHI project between FY 79 and FY 84 under project 932-0537. The FHI project has an estimated total cost of \$58,500,000 for the period FY 85 - FY 89, reflecting the Agency priority for this area and the highly promising new methods close at hand. The project calls for \$8,700,000 in the first year.

V

Agency Policy: The project will be implemented in accordance with relevant Agency policies including those on abortion, voluntary sterilization and human subjects research.

Justification to Congress: An Advice of Program Change is in process. This project is cited as project 932-0537 on page 71 of Annex V, Centrally Funded Programs, of the Congressional Presentation for FY 1985.

Clearances Obtained: A ten-year Project Paper (FY 85 - FY 94) was prepared in close collaboration with regional bureau staff and has been reviewed and strongly endorsed at all levels of the Agency. However, we are only requesting authorization for the first five years at this time. This five-year authorization (a) reflects no commitment on your part to go beyond five years and (b) will encompass activities which can be accomplished in five years. Comments from the regional bureaus, S&T Bureau, GC, and PPC have been solicited and incorporated into the PP as appropriate. The Population Sector Council reviewed the project on January 29, 1985 and unanimously recommended approval. Minutes of that review are attached.

Recommendation: That you sign the attached Project Authorization.

Attachments:

1. Project Authorization
2. Project Paper (936-3041)
3. Minutes of the Population Sector Council Meeting, January 29, 1985

Clearances:

ST/POP, SWSinding AWA
 ST/PO, GEaton [Signature]
 ST/HP, JESarn [Signature]
 GC/CP, HFry [Signature]
 PPC/PDPR, Bullander [Signature]
 A. Rosenberg [Signature]

KBP

Drafted by: ST/POP/R:JDSheilton:vle:2/15/85:x59686:1001Z
on disk

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Family Health International

(FHI)

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I. Summary

One clear way to improve AID's support to family planning programs is to develop and introduce better, safer, more varied, and more acceptable methods of family planning. The availability of improved technology can greatly enhance the freedom of individuals to choose voluntarily the number and spacing of their children. Present family planning methods have severe limitations and a variety of methods better than those available today is urgently needed. Long a significant component of AID's Population Program, the development of new and improved family planning methods has recently been recognized as a particular Agency priority. This included the White House instructions accompanying the Policy Statement prepared for the International Conference on Population in Mexico City, August 1984.

"There should be higher international priority for biomedical research into safer and better methods of fertility regulation, especially natural family planning ..."

Consistent with this policy, support for such research has increased markedly in recent years.

Family Health International (FHI) (formerly the International Fertility Research Program) is a non-profit research organization in Research Triangle Park, North Carolina. Since 1971, FHI has been the Agency's principal vehicle for the assessment and introduction of new and improved family planning technology appropriate for developing countries. It has played an invaluable role in the past, and the need for such a program appears clear for the foreseeable future. A number of new and improved methods are close at hand. These include the NORPLANT^R subdermal implant, a new three-month microsphere injectable contraceptive, a new clip for female sterilization, a new vaginal contraceptive tablet, and advanced IUDs such as the Copper T 380A. Collectively, the effective development and introduction of these new methods can have a major future impact on family planning programs.

FHI also plays a crucial role in the better understanding of current methods. There is a growing recognition of the need for improved information on safety as well as a number of factors related to acceptability and "user perspective." Such information is especially needed with reference to developing countries. The area of Natural Family Planning (NFP) including breastfeeding is also gaining increased attention. In response to this increased emphasis, FHI has begun a major thrust in NFP.

The new ten-year project will continue FHI's crucial role in family planning technology. Major activities will include:

- Clinical Trials
- Contraceptive Development
- Contraceptive Safety Studies
- Natural Family Planning (including breastfeeding)
- Reproductive Health Research
- Field Development and Training

Results of FHI research will be disseminated widely through a number of mechanisms. These include articles in independent scientific journals; monographs; international meetings, workshops and symposia; and FHI's own publication "Network". A variety of reports and ongoing communication with AID will also facilitate incorporation of FHI research findings into ongoing AID supported service delivery programs.

FHI has clearly unapproached capability for carrying out this range of activities. The Agency benefits from the critical mass of research talent available at FHI and the economics of scale

from carrying out these activities with this institution. No other organization even approaches this specialized capability.

AID's relationship with FHI to carry out these activities appears most compatible with a Cooperative Agreement and this is anticipated to be the funding mechanism.

The estimated ten-year cost of \$167,900,000 reflects some increase over previous years. This is a result of increased Agency priority for this area of endeavor (including NFP), a number of highly promising new methods close at hand, increased emphasis on certain components such as contraceptive safety, and an increased complexity and cost for carrying out these activities.

II. Background

A. Role of FHI in AID's Population Program

Contraceptive development research has historically been a strong and integral component of AID's Population Program.

In recent years such research has received even further emphasis and appears destined to continue to do so. This was recently articulated in the White House instructions accompanying the Policy Statement prepared for the International Conference on Population in Mexico City, August 1984.

"There should be higher international priority for biomedical research into safer and better methods of fertility regulation, especially natural family planning ..."

In accordance with the principals of voluntarism and informed choice, and recognizing that no single method will ever satisfy the needs of all family planning users worldwide, AID's research program is directed toward wide availability and accessibility of multiple methods of contraception. Further, a variety of safe and effective methods beyond those currently available is urgently needed.

Family Health International (previously called the International Fertility Research Program - Project 932-0537) is a nonprofit research organization located

in Research Triangle Park, North Carolina. Since 1971, FHI has been AID's principal vehicle and final common pathway for the assessment and introduction of new and improved family planning technology.

Potential new methods of family planning may come from a variety of sources. From whatever source such new methods come, a vehicle will be necessary to assess, introduce and adapt them to developing countries. A method suitable in one setting may not be suitable in another. Therefore, a mechanism is needed to evaluate methods in multiple settings. Further, understanding more about the safety, efficiency and acceptability of these methods will enhance our efforts to provide them and increase the ability to exercise intelligent choice and understanding of such methods by users. Historically, FHI has carried out these functions, and there is a clear need for such an organization for the foreseeable future.

B. FHI's Historical Contribution

FHI's contribution has had a major impact on individual country programs and the Agency's worldwide family

planning effort. Notable examples include development, evaluation and widespread introduction of improved female sterilization methods, and the evaluation of numerous oral contraceptives, IUDs, and vaginal methods. Some of these studies have provided invaluable information to the Agency in recent decisions to provide low estrogen oral contraceptives, progestin-only oral contraceptives for lactating women, foaming vaginal contraceptive tablets, and advanced copper IUD's. FHI has also been invaluable in helping to decide what methods not to use in family planning programs including a number of sterilization techniques, numerous IUD's and the contraceptive vaginal sponge which appears less appropriate for developing countries than foaming tablets.

Other notable contributions have included useful epidemiologic studies on the safety of the injectable contraceptive depo-provera and various studies documenting the health advantages of contraception vis-a-vis pregnancy in developing countries. Social science contributions have included contraceptive prevalence type surveys, primarily

in Latin America, and sterilization access surveys documenting a significant unsatisfied demand for sterilization in various settings. FHI's flexibility, willingness, and ability to respond to changing needs in fertility control techniques has been amply demonstrated in recent initiatives in the area of natural family planning and breastfeeding.

An extensive external evaluation of the FHI in 1981-82 concluded that FHI was fulfilling the mission mandated by AID while also offering a number of recommendations aimed at improving performance. A more limited external evaluation in 1984 found that FHI appeared to be continuing to accomplish its goals and had made a number of significant improvements in accord with previous recommendations. The last AID audit of FHI (in 1983) found no audit exceptions and actually raised only one issue (which was related to property inventory.)

A November 1984 worldwide cable to the field described the FHI project and proposed extension. Responses were received from 30 countries. Mission comments on the whole were extremely positive. Some quotes from individual countries are listed below.

BANGLADESH

"FHI activities here have been highly valuable to USAID population programs ... Over the next 5 years, there is no question that we will often call on FHI expertise."

THAILAND

"FHI assistance to Thailand has developed skills and capabilities of Thai researchers for conducting internationally-accepted research which has made an important contribution to the National Family Planning Program and to the field of contraceptive technology in general."

INDIA

"We believe this organization has provided an invaluable contribution to scientific knowledge of various contraceptive methods."

MEXICO

"FHI contribution to the Mexican Family Planning Program has been significant and (FHI) has always been responsive to GOM needs."

PANAMA

"USAID Panama appreciates the effective and efficient assistance provided by FHI personnel during the past years and looks forward to their continued support."

HAITI

"FHI is a valued contributor to family planning technology in Haiti."

CAMAROOON

"(FHI) has been carrying out clinical trials with a research/lecturer at the Medical Faculty of the University of Yaounde. Based on feedback from the researcher, Mission feels it would be beneficial for FHI project to be renewed."

ZAIRE

"Mission has appreciated FHI's previous research efforts in Zaire and is supportive of new proposal for five year extension."

EGYPT

"USAID Population Office would like to suggest specific research effort in Egypt to determine IUD continuation rates and reasons for apparently low continuation."

Quality of patient education could also be assessed.

MOROCCO

"The MOPH is very interested in undertaking clinical fertility control research in connection with the operation of its National Center for Reproductive Health."

III. Detailed Project Description

A. Purpose

The purpose of this project is to improve family planning technology available for use in developing countries and to improve the understanding of such technologies. Toward that end, FHI will carry out a program directed toward fostering the development and introduction of methods of fertility control, the assessment and evaluation of such technology, and the strengthening of such capabilities on an international basis.

B. Major Project Outputs

The following are the major activities planned under this project:

1. Clinical Trials

Clinical trials are systematic, prospective studies of interventions conducted according to predetermined design in a clinical or quasi-clinical setting. In the family planning context used herein they typically involve a few hundred men or women and focus on assessing efficacy, acceptability and safety. These will continue to be the backbone of the FHI project. The widespread assessment, introduction and adaptation of family planning technology through clinical field trials in an extensive variety of settings will continue to be an integral part of the Agency's research program in family planning technology. This will include studies on IUD's, systemic contraception, female sterilization, male sterilization and barrier/vaginal contraception.

Current priorities for clinical trials include: the NORPLANT^R subdermal implant; controlled release

microsphere injectable contraceptives; evaluation of the Filshie clip and tubal rings for female sterilization; studies of low-dose, triphasic, and progestin only OC's.; a vaginal contraceptive foaming tablet using a new spermicide; and studies of advanced IUD's including a hormone-releasing (levonorgestrel) IUD and the Copper T 380A. These methods are expected to constitute the bulk of the clinical trial portfolio for the next several years. With the exception of the male contraception area for which no suitable new methods are far enough along, these methods are fairly comprehensive in covering almost all approaches to contraception. Their introduction and addition to family planning programs are expected to have a major beneficial impact.

Studies will also be undertaken in instances where no new generalized knowledge is expected. For example, studies of standard IUD's may be undertaken for the purpose of simply gaining experience in a particular setting or to train new investigators who express an interest in clinical trial research.

2. Contraceptive Development

This activity includes product development such as animal and early human testing which comes prior to the stage of clinical field trials. It has traditionally been a small component of the FHI project but substantial growth is anticipated. Major activities are expected to include nonsurgical sterilization using intrauterine installation of tetracycline and longacting quinocrine. Other potential development include new spermicides such as propanalol, as well as immunological approaches to contraception such as an anti-zona pellucida vaccine.

3. Contraceptive Safety and Health

This area focuses on the long term consequences of family planning technology and its impact on maternal and child health. It includes activities sometimes referred to as "postmarketing studies" such as epidemiologic safety studies as well as a variety of issues in reproductive health. Priorities include studies of cancer in relation

to fertility control technology, particularly in developing country settings; health consequences of sterilization; the relationship of contraception and sexually transmitted disease; and contraceptive needs of women with chronic diseases particularly prevalent in developing countries such as rheumatic heart disease and sickle cell disease.

4. Natural Family Planning (including breast feeding)

NFP is a priority area for the Agency. Further, it is an approach with many unanswered questions involving training and service delivery. Therefore, FHI will need to investigate a wide variety of research issues. These include improved methods of ovulation prediction and detection, the evaluation of current NFP methods, the cost effectiveness of different approaches to NFP service delivery, mechanisms to better integrate NFP into ongoing family planning programs, and various approaches for increasing the contraceptive effectiveness of breastfeeding. It is recognized that the Agency has other initiatives in NFP and FHI will coordinate its activities with these other initiatives. At the same time it is

recognized that the evaluation of NFP can benefit from an acknowledged expertise in evaluation of other family planning methods.

Reproductive Health

Reproductive Health encompasses a variety of social science approaches to family planning technology and other aspects of reproductive health including pregnancy. It often utilizes survey methodology to assess user and provider perspective, focusing on such things as contraceptive use, demand and acceptability. It also studies the impact of different workers and methods on family planning acceptance and continuation. Included in this area are activities related to maternal and child health such as assessments of maternal and infant mortality, and the health consequences of pregnancy and high fertility.

Field Development and Training

Field development and training activities are aimed at institution strengthening and otherwise improving research capabilities in developing countries. The largest single

activity in this area is the support for Family Health Research Centers (FHRC's). FHRC's are indigenous research institutions designed to carry out many of the same research activities carried out by FHI. They are intended to directly impact on family planning practice and policy in their respective country. Centers are currently being supported in Bangladesh, Thailand, Sri Lanka, Indonesia, Sudan and Egypt. FHI provides both core support and support for specific studies.

Several FHRC's have demonstrated growth and maturity. Some have shown a considerable increase in technical and managerial expertise as well as a capability to generate support from other sources and to affect program and policy. In other FHRC's progress has been more slow. While it is difficult to measure the impact precisely, our sense is that support to FHRC's does pay off in terms of near-term research output and long-term institution development. Where appropriate, support for the current FHRC's which have demonstrated maturity and independence will be gradually reduced. Priority regions for support of new FHRC's will be Africa and Latin America.

Training activities are aimed at improving the skills of developing country researchers and other scientists. Activities include workshops on contraceptive technology and reproductive health as well as specific courses on clinical trial methods, contraceptive safety, epidemiologic methods, and research management. Activities to disseminate information on family planning technology will also be undertaken. In addition to publication of research results in appropriate scientific journals, FHI supports "Network", which describes its own research and related activities, and the International Journal of Gynaecology and Obstetrics (IJGO). This support has been approved by the AID Communications Review Board.

Miscellaneous Other Activities

As appropriate, a number of other activities related to the development, evaluation, and introduction of family planning technology will be undertaken. These include drug and device regulatory filings such as Investigational New Drug exemptions (IND's) and New Drug Applications (NDA's), the provision of family planning technology, the

development of relevant laboratory tests, and activities similar to those described in this and preceding sections directed towards the problems of infertility.

We view part of FHI's role to be flexible and responsive to Agency needs related to the contraceptive technology area including various activities where alternative support mechanisms may be lacking. This is particularly true for various survey and training activities and studies on the interrelationship of contraception and health. It is also true for new technologies which may emerge but are not currently envisioned.

While the ultimate aim of FHI activities is to improve understanding and choice of family planning technology in developing countries, a significant component of FHI activities, particularly studies on methods in the early phases of development, will take place in developed countries.

IV. Implementation Plan

A. Project Implementation Mechanism

FHI clearly has capability for performing these activities related to contraceptive technology which is not even approached by any other eligible institution. This capability has resulted from extensive experience in carrying out these kinds of activities since 1971. It includes a vast network of developing country clinician and other research contributors; a highly specialized in-house scientific staff; staff with extensive experience with research and family planning programs in developing countries, experience with regulatory filings with the F.D.A.; extensive equipment, computer and software capability, and numerous contacts in the general area of contraceptive technology. The Agency benefits from the critical mass of family planning technology research talent at FHI, as well as the considerable economies of scale derived from carrying out these related

activities through this one institution. No other organization comes near to approaching FHI's capability.

FHI does not qualify as a small business, disadvantaged or minority owned firm. Nevertheless, it does have an ongoing Affirmative Action Plan for employment within the organization and a specific ongoing plan for business with small businesses and disadvantaged firms.

AID's support for FHI has been through a series of primary contracts from FY 71 to FY 83 and a somewhat smaller Grant from FY 77 to FY 84. Grant support has been more directed toward the institution strengthening, training, and reproductive health activities. In FY 84 the functions of the previous contract were assumed under a new one year Cooperative Agreement.

For a number of reasons, AID's relationship with FHI continues to appear most compatible with a cooperative agreement. AID and FHI have common goals dedicated toward the development, evaluation, and introduction of fertility control technology. We wish to assist FHI by supporting numerous studies and other activities on an ongoing and flexible basis with substantial involvement of AID staff.

Therefore, we anticipate incorporating the activities previously funded under the Grant into the current Cooperative Agreement for an additional five years.

B. Modus Operandi of the Project

As in previous years, the implementation of the project will rely heavily on the technical expertise of the AID project manager and ST/POP/R. The project manager will have significant impact on the direction of the program and the emphasis and selection of various research activities. The project manager will draw on inputs from ongoing AID supported family planning service programs to help determine which promising family planning methods to study and the important other research questions to answer. One of AID's major strengths in the field of family planning technology research is its close connection with family planning service delivery programs. The project manager will draw upon a series of formal and informal relationships to help provide expert scientific and relevant guidance for the project. These include other members of the research community such as N.I.H., W.E.O., F.D.A. and C.D.C.; pharmaceutical and other

companies in the private sector; and numerous other individuals and institutions including many involved in family planning service delivery.

By the same token, FHI will maintain an active surveillance of ongoing developments in the field of family planning technology research as well as the perceived needs of family planning programs. Augmented by a Technical Advisory Committee (TAC) and other experts in specific areas, FHI will put forward proposed research activities considered relevant. The ultimate research program will be developed collaboratively between FHI and AID as described below.

The Agency currently supports two other major activities in contraceptive technology development. The Population Council develops new methods throughout all phases of product development. The Program for Applied Research on Fertility Regulation (PARFR), focuses almost exclusively on early phases of contraceptive development. To some extent, FHI is complimentary to PARFR, focusing on later phases of development.

While it is clearly important not to unnecessarily duplicate research, it is also important not to be unduly rigid in establishing artificial limits on research and alternative approaches. Further, it is clear that the most pressing need in the field of contraceptive development generally is in the generation of new ideas and in the early phases of research. Therefore, the FHI program will include a substantially expanded component of early phase research.

In part it will be responsibility of the AID project manager to help insure that a proper balance of both "pluralism" and collaboration is maintained. For example FHI is currently working jointly with the Population Council on NORPLANT^R development and with PARFR on the microsphere injectable contraceptive.

C. AID Monitoring and Cooperation

Primary technical and administrative responsibility will rest with the Research Division, Office of Population (ST/POP/R). The AID cognizant technical officer (CTO) will provide FHI with overall technical guidance and insure that project

implementation is consistent with the design set forth in this PP. Consistent with the "substantial involvement" concepts underlying a cooperative agreement, the CTO will exercise the following functions:

1. Collaborative involvement in the development of specific research studies and other activities to be carried out under the Agreement.
2. Approval of all activities carried out under this Agreement including study strategies, protocols, subagreements, training and information dissemination activities, consultancies, and international travel.
3. As appropriate, involvement in analysis and publication of research findings.
4. Participation in site visits, the Technical Advisory Committee (TAC), other workshops and meetings, and evaluations to review program progress and future strategy.

The AID CTO will undertake appropriate coordination with other offices in the Agency such as ST/POP/FPSD, ST/POP/CPSD, ST/H, PPC, the Regional Bureaus, and AID missions, particularly to help determine priority technology needs and issues to be addressed by the project. The CTO will arrange for appropriate mission clearances for proposed activities.

D. FHI Responsibilities

As described above, many aspects of FHI's responsibilities will be carried out in collaboration with the AID CTO. FHI will develop annual workplans to carry out the workscope. Currently entitled "Scientific Directions" this document will lay out the priorities and overall plans for the coming year. FHI will also develop detailed strategies, protocols, and studies aimed at particular areas. In addition to involvement of the CTO, FHI will utilize a Technical Advisory Committee (TAC) to review the annual workplan and other specific topics as appropriate. Also, as appropriate, FHI will utilize outside experts and expert meetings on specific topics to provide advice and guidance on proposed activities. FHI staff will consult with appropriate AID missions to determine their perceived needs and where appropriate, develop periodic workplans for specific country activities.

FHI will seek full information and coordinate its activities concerning ongoing research programs of other donor and executing 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. Similarly, in the areas of Operations Research, Survey Research, Policy Research and NFP FHI will complement ongoing activities and any forthcoming new initiatives. FHI will 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.

E. Evaluation

The project will be closely monitored and evaluated on a continuing basis by the technical staff of the Research Division including periodic management reviews. In addition, intensive external evaluations are anticipated in the fourth and eighth year of the project. These will include outside experts and focus on detailed assessment of project organizations, management, project output, research procedures and recommendations for project improvement.

F. Agency Policies

The project will be implemented in accordance with relevant Agency policies including those on abortion, voluntary sterilization and human subjects research.

V. Financial Plan

Office of Population support for FHI from FY 1979 to FY 1984 is shown in Table 1. The annual average for these 6 years was just over \$5.2 million. Starting in 1984 annual funding has been increased to \$6.6 million (actual '84) \$7.6 million ('85 OYB) and \$8.2 million ('86 proposed). Support is projected to grow over the next several years for the following reasons:

- 1) Increasing priority set by the Agency for Contraceptive Development Research and Technology Transfer.

- 2) A formidable group of important new methods which will clearly require extensive evaluation and introduction over the next few years. These include NORPLANT[®], the family of microsphere injectable preparations, the Filshie Clip for female sterilization, the contraceptive vaginal tablet containing the spermicide menfegol, and advanced IUD's such as the Copper T 380A.
- 3) An increased role for FHI with respect to U.S. regulatory submissions. For example it is anticipated that FHI will submit the U.S. New Drug Application for some or all of the microsphere injectables. Such activities require considerable effort and resources.
- 4) Markedly increasing need to carry out studies to satisfy developing country regulatory requirements.
- 5) Increased emphasis on contraceptive epidemiology and other safety studies in the project.
- 6) Anticipated increase in "Contraceptive Development" activities.
- 7) Increased emphasis by the Agency on Natural Family Planning which is expected to account for about 15% of AID's support to FHI.
- 8) Inflation.

Accordingly, the budget presented in Table 2 reflects the approximate amount available in FY 85 with a growth of about 12% in successive years. For the first five years this totals \$53.5 million and for the ten year period - \$167.9 million. Table IV presents estimated obligations by operational category.

The previous FHI Grant and Contract were predominantly funded through ST/POP and this is also anticipated for the Cooperative Agreement. However, we anticipate that there will be opportunity for mission and regional bureau "buy-ins" over the project period. This may be especially appropriate for support of the Family Health Research Centers (FHCs).

TABLE I
 AID, OFFICE OF POPULATION SUPPORT TO
 FAMILY HEALTH INTERNATIONAL
 FY 1979-1984
 (\$000)

	<u>1979</u>	<u>1980</u>	<u>1981</u>	<u>1982</u>	<u>1983</u>	<u>1984</u>
Contract	3,400	3,000	2,640	3,750	3,379	4,900
Grant	<u>1,835</u>	<u>1,800</u>	<u>2,260</u>	<u>1,200</u>	<u>1,471</u>	<u>1,677</u>
Total	5,235	4,800	4,900	4,950	4,850	6,577

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Table II
 Estimated Obligations by Functional Category

Years I-V

(\$000)

	<u>Year I</u>	<u>Year II</u>	<u>Year III</u>	<u>Year IV</u>	<u>Year V</u>	<u>Total</u>
Clinical Trials	3,170	3,670	4,360	4,970	5,920	22,090
Contraceptive Safety	1,300	1,440	1,720	1,930	2,240	8,630
Contraceptive Development	220	340	500	680	900	2,640
Reproductive Health	1,120	1,200	1,310	1,420	1,570	6,620
Natural Family Planning	1,300	1,500	1,730	1,950	2,310	8,790
Field Development and and Training	<u>1,590</u>	<u>1,750</u>	<u>1,880</u>	<u>2,050</u>	<u>2,460</u>	<u>9,730</u>
Total	8,700	9,900	11,500	13,000	15,400	58,500

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Table III

Estimated Obligations by Functional Category

Years VI-X

(\$000)

	<u>Year VI</u>	<u>Year VII</u>	<u>Year VIII</u>	<u>Year IX</u>	<u>Year X</u>	<u>Total</u>
Clinical Trials	6,680	7,540	8,480	9,530	10,700	43,020
Contraceptive Safety	2,500	2,860	3,200	3,580	4,010	16,150
Contraceptive Development	1,000	1,130	1,260	1,410	1,580	6,380
Reproductive Health	1,760	1,970	2,210	2,470	2,770	11,180
Natural Family Planning	2,580	2,900	3,240	3,630	4,070	16,420
Field Development and and Training	<u>2,680</u>	<u>2,900</u>	<u>3,210</u>	<u>3,580</u>	<u>3,880</u>	<u>16,250</u>
Total	17,200	19,300	21,600	24,200	27,100	109,400
			Years I-V		58,500	
			Years VI-X		109,400	
			Grand Total		167,900	

6
109,400

TABLE IV

Estimated Obligations by Major Operational Category

Years I-V, FHI

(\$000)

	<u>Year I</u>	<u>Year II</u>	<u>Year III</u>	<u>Year IV</u>	<u>Year V</u>	<u>Total</u>
Personnel	2,700	2,950	3,250	3,600	4,000	16,500
Service Centers	600	650	700	750	800	3,500
Travel	500	550	600	675	750	3,075
Other Direct	200	225	250	300	350	1,325
Subagreements	2,900	3,550	4,550	5,275	6,850	23,125
G & A	<u>1,800</u>	<u>1,975</u>	<u>2,150</u>	<u>2,400</u>	<u>2,650</u>	<u>10,975</u>
Total	8,700	9,900	11,500	13,000	15,400	58,500

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PROJECT DESIGN SUMMARY
LOGICAL FRAMEWORK

Life of Project:
From FY 84 to FY 94
Total U.S. Funding \$167,900
Date Prepared: December, 1984

Project Title & Number: Family Health International

NARRATIVE SUMMARY	OBJECTIVELY MEASURABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS																								
<p>Program or Sector Goal: The broad objective to which this project contributes:</p> <p>(1) Enhance the freedom of individuals in LICs to choose voluntarily the number and spacing of their children; and</p> <p>(2) Encourage population growth consistent with the growth of economic resources and productivity.</p>	<p>Measure of Goal Achievement:</p> <p>1. LIC couples' actual and desired fertility are consistent. Safe, affordable contraceptives available to all couples desiring to use them.</p> <p>2. Steady economic and social development is not hindered by excessive population growth.</p>	<p>Census information, vital statistics, demographic and family planning surveys, impact studies. Sector assessments, qualitative verification of actual availability of supplies and services.</p>	<p>Assumptions for achieving goal targets:</p> <p>1. Couples wish to voluntarily choose the number and spacing of children, and will utilize acceptable and accessible means of family planning.</p> <p>2. Excessive population poses a threat to sustained economic and social development.</p>																								
<p>Project Purpose:</p> <p>To improve family planning technology available for use in developing countries and to improve understanding of such technologies.</p>	<p>Conditions that will indicate purpose has been achieved: End of project status.</p> <p>1. New and improved technologies introduced in developing country settings.</p> <p>2. Better knowledge and appropriate use of methods of family planning.</p> <p>3. Improved portfolio of family planning methods provided by AID.</p>	<p>1. Published articles and final reports of various studies.</p> <p>2. Evaluation and assessments of various studies and overall project.</p> <p>3. Existence of new and/or improved methods in family planning programs and provided by AID.</p> <p>4. Feedback from family planning programs.</p>	<p>Assumptions for achieving purpose:</p> <p>1. New and improved technologies can be developed.</p> <p>2. Technologies will be feasible for use in developing countries.</p> <p>3. Better knowledge of family planning technologies will result in better use of various methods.</p> <p>4. Program need & will introduce new & improved methods.</p>																								
<p>Outputs:</p> <p>1. Improved methods developed and tested.</p> <p>2. Improved knowledge and use of family planning methods.</p> <p>3. Current & improved methods introduced into developing country programs.</p> <p>4. Documentation & dissemination of information on family planning technology.</p> <p>5. Increased developing country capability to assess family planning technology.</p>	<p>Measures of Outputs:</p> <p>300 studies that will contribute to improved knowledge and program introduction and improved use</p> <p>3 major methods introduced</p> <p>350 publications</p> <p>12 Developing Country Family Health Research Centers developed or maintained.</p>	<p>1. as above (1,2,3,4)</p> <p>2. Existence of Family Health Research Centers</p>	<p>Assumptions for achieving outputs:</p> <p>1. As above (1,2,3,4)</p> <p>2. Competent researchers and institutions capable of developing into Family Health Research Center can be found.</p>																								
<p>Inputs:</p> <table border="0"> <tr> <td>AID/W</td> <td>68T</td> <td>163,900</td> </tr> <tr> <td>AID/W</td> <td>Regional Bureaus</td> <td>1,000</td> </tr> <tr> <td></td> <td>USAID Missions</td> <td>3,000</td> </tr> <tr> <td></td> <td></td> <td>167,900</td> </tr> <tr> <td>International / Consultants</td> <td></td> <td>47,400</td> </tr> <tr> <td>Travel and Per Diem</td> <td></td> <td>8,800</td> </tr> <tr> <td>Subagreements</td> <td></td> <td>66,400</td> </tr> <tr> <td>Other</td> <td></td> <td>45,300</td> </tr> </table>	AID/W	68T	163,900	AID/W	Regional Bureaus	1,000		USAID Missions	3,000			167,900	International / Consultants		47,400	Travel and Per Diem		8,800	Subagreements		66,400	Other		45,300	<p>Implementation Target (Type and Quantity)</p>		<p>Assumptions for providing inputs:</p> <p>1. Congressional appropriations permit programming AID/W funds at planned levels.</p> <p>2. USAID able to provide limited logistical/financial support.</p> <p>3. Participating LICs able to pay part of local research costs.</p> <p>4. AID/W technical staff available.</p> <p>5. AID resources available in a timely/flexible manner.</p>
AID/W	68T	163,900																									
AID/W	Regional Bureaus	1,000																									
	USAID Missions	3,000																									
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Subagreements		66,400																									
Other		45,300																									

Topic: Project Paper, Family Health International, 936-4041
10 year project with 5 year Authorization
LOP funding \$167,000,000, Authorized level \$58,500,000

Discussion: This project continues the function begun in 1971 with slight modifications. It fulfills a vital need for developing and assessing new technologies in family planning. The primary part of the project is clinical trials with emphasis on contraceptive safety, NFP, and reproductive health. S&T/POP has received strong support from USAIDs for this project.

Council concerns:

Whether there will be an annual work plan -- There will be country plans and overall work plans.

- Whether there is a strategy for Africa -- No specific strategy has been developed for Africa, but the project will be responsive to USAID needs, including infertility prevention.

- Dissemination of the research results, particularly how to get the information to family planning policy makers in LDCs -- There is a new policy project specifically designed to disseminate research findings to the LDC policymaking level. Also, FHI's Director, Malcolm Potts, is a very effective communicator on contraceptive technology and research.

- Whether the Agency policy on abortion/research has been addressed -- Legal interpretation is that descriptive studies are permitted. The project will comply with Agency policy on abortion.

- Whether the results of the 1984 evaluation had been disseminated -- The 1984 evaluation team felt that S&T/POP is the best organization for research management because of the strong coordination of service delivery and research. They found a steady flow of research findings to the field.

Action: Council endorsed the project. Because FHI is such a strong source of technical assistance, both in developing local capability for research and in dissemination of information, Council members would like to see FHI play a leadership role with LDC counterparts in identification of priorities, training of local staff, and building in-country capability for rapid analysis of research data.