

**PROJECT SUMMARY**

**Project Title :** Family Planning Research and Evaluation Center  
(Contract AID/csd-1573: Proposed amendment)

**Proposed Contractor :** The Pathfinder Fund  
1575 Tremont Street, Boston, Massachusetts

**Principal Investigator:** Elton Kessel, M.D.  
Executive Director, The Pathfinder Fund

**Duration :** Extension from 3 years to 5 years  
(July 1, 1967 to June 30, 1972)

**Estimated Cost:** Total (5 years) **\$3,352,350.**

Funded for use in FY 1968 & FY 1969	\$194,000 ✓
Approved for use in FY 1970	99,844
<b>Total Approved</b>	<b>\$293,844</b>

Estimated Expenditure Dec. 31, 1968	\$ 174,000
Additional funds requested	3,158,350
includes \$99,844 approved for FY 1970	
excludes \$20,000 funded and unexpended as of Jan. 1, 1969.	

<b>Funding Requirements</b>	
FY 1969	<b>\$1,958,350</b>

\$280,785 for use in FY 1969  
(Jan. 1 - June 30)  
777,565 for use in FY 1970  
900,000 for use in FY 1971

FY 1971 for use in FY 1972	<b>\$1,200,000</b>
----------------------------	--------------------

**Recommendation:** Support for next 30 months (Jan. 1, 1969-June 30, 1971, in the amount requested (\$1,958,350), with further extension and funding to be considered at a later date.

**Action Officer:** R. T. Ravenholt, M.D., WOH/PS

**1. Description of Proposed Project Amendment**

This proposal has the objective of shortening the time span for development, evaluation and broad use of improved contraceptives

especially intrauterine contraceptive devices (IUD). In the first year of the project, an extensive field testing program was established for IUDs and a relationship established with the bio-engineer inventor of a promising new IUD, the M-device, and New York Medical College, where the M-device was first tested. The increased activities proposed in this amendment are directed primarily to:

A. Development of New Contraceptive Devices

These include:

1. Modifications of the M-device, an intrauterine contraceptive device (IUD) with low expulsion rate.
2. An improved inserter for IUDs.
3. An early post-partum IUD.
4. A device for intrauterine release of medications.
5. A reversible vasectomy device.

The development of these and other contraceptive devices will use the unique engineering capabilities that developed the M-device.

B. Expansion of Evaluation Efforts

These include:

1. Clinical and laboratory evaluation of prototype contraceptive devices developed in A, above.
2. Epidemiological evaluation through double blind field tests of promising new contraceptive devices.
3. Evaluation of the expanding Pathfinder Fund-supported family planning service programs.
4. Development of Evaluation Sub-centers in developing countries.

C. Training

This will include:

1. Fellowships to train key personnel in Boston for B-4 above.
2. Development of training aids, including -
  - a) Training films, slides, flip-charts, etc.
  - b) IUD insertion manikin.

Training will be primarily related to evaluation and use of new developments in contraceptive technology. Pathfinder-supported family planning service programs will provide opportunities for rapid dissemination of improved contraceptives, new training materials and valid approaches to the organization of family planning services.

## 2. Significance of Project to A.I.D. Objectives

A prime objective of the War on Hunger is combating malnutrition in less developed areas of the world. The ability of these areas of the world to meet their food needs, or general economic development, will be largely determined by their rate of population growth. For this reason the War on Hunger has given increased emphasis to assistance to family planning programs, including contraceptive supplies.

While there is much that can be done with presently available methods of contraception, there is a great need for improved methods that will not require sustained motivation for successful use. Intrauterine contraceptive devices and reversible vasectomy devices are, therefore, areas of research with high priority.

As A.I.D. resources are committed to helping less developed areas develop their family planning programs, it becomes desirable to have an independent organization study various approaches to providing family planning services. The Pathfinder Fund supports a wide variety of family planning services and is in an ideal position to make such a study.

## 3. Relevance of Project to Existing Knowledge

The effectiveness of intrauterine contraceptive devices has been studied with precision only for the past seven years. Only a few devices have been adequately studied and practically no engineering talent has been applied to the design of IUDs. Borrowing heavily from the experience of the Cooperative Statistical Program for the Evaluation of Intrauterine Contraceptive Devices, The Pathfinder Fund has developed an extended field testing program, known as the International IUD Programme. Among the devices tested by this Programme is the M-device, invented by an engineer. This device has a spontaneous expulsion rate far below other devices tested to date.

This project proposes to build on this breakthrough, to further improve this device to lower its side effects, such as pain and bleeding.

Careful studies of effectiveness of different approaches to providing family planning services is limited to a few countries and the variety of approaches studied is even more limited. Some of the parameters needing

investigation are:

1. Centralized vs. decentralized administration.
2. Planning from above vs. planning from recipient community.
3. Degrees of involvement of recipient community in decision-making process related to development of services.
4. Private vs. public sponsorship.
5. Quotas vs. non-quotas for health workers.
6. Incentives vs. extension education approach.
7. Individual incentives vs. community incentives.
8. Clinic vs. non-clinic settings.
9. Physician vs. para-medical personnel.
10. Mobile clinic vs. stationary clinic and mobile team.

4. Evaluation of Experimental Design and Research Methods

The first phase of the research program for improved contraceptive devices is the development of prototypes by an engineer, based on feedback of data of both a clinical and epidemiological nature. This information will be collected in the International IUD Programme of The Pathfinder Fund, in the case of IUDs.

In the second phase, prototype contraceptive devices will be tested in mechanical and biological laboratory models. IUD prototypes will be tested in women before elective hysterectomy.

In the third phase, promising prototypes will be manufactured and entered in double blind field tests. Information from such testing will be used in phase one.

Field testing will be the responsibility of The Pathfinder Fund. Development of prototype devices will be the responsibility of Medical Research Foundation. Early testing of prototype devices will be done at New York Medical College.

In the study of approaches to provision of family planning services, only a few parameters will be studied, in the first instance. These will be rates of contraceptive acceptance and continuation by age and parity. From such a survey of a wide variety of approaches, a few selected hypotheses may be suggested for study in depth.

## 5. Evaluation of Research Competence of Investigators

The principal investigators who are employed by the Pathfinder Fund have been working closely with the A.I.D. population program efforts since its commencement during the 1966-67 period. Actual official working relations were established with the Pathfinder Fund when a contract with the Fund was initiated on July 1, 1967 for providing support for the activities of the Family Planning Research and Evaluation Center of the Pathfinder Fund. Dr. Kessel, who has been the executive director of the Pathfinder Fund from 1966 to the present period, has demonstrated singular competence in organizing and managing the action of the research programs of the Fund. In addition to lengthy experience in private and public medical health work in the United States, he has had lengthy overseas experience in India with shorter periods in other countries.

Dr. Roger Bernard brings to the Pathfinder Fund a European background in medicine and research until 1965-67 when he earned his master of science degree in preventive medicine at the University of Washington. In 1967 he joined the Pathfinder Fund with special responsibility for the international IUD program of that organization. In this connection, he has set up research and evaluation activities which are formalized in the attached interim report (summer 1968).

Mr. Mark Chافت of the Medical Research Section is an engineer who has a very important variation of the IUD, the so called M-device. He also developed what appears to be the best IUD inserter to date.

As indicated in the proposal, the Pathfinder Fund uses a wide and varied group of consultants and consequently brings significant expertise to the research programs that are contemplated. Further, the international aspect of the Fund's operations assists the staff in developing and working toward research objectives which are meaningful for population/family planning efforts in the less developed areas of the world.

## 6. Appraisal of Research Resources and Budget

The Pathfinder Fund has developed field testing facilities capable of carrying out the anticipated trials.

Medical Research Foundation has modern fabrication facilities capable of working in both metals and plastics.

New York Medical College, particularly through their Laboratory for Reproductive Pharmacology, has available all needed resources to test prototype devices.

The Pathfinder Fund, through the wide variety of family planning service programs it support, has a natural public health laboratory in which to study various approaches to family planning services.

Additional funds are required to carry the program into FY 1972 under the operating plan furnished by the Pathfinder Fund in its present contract, the detailed expenditures are approved by WOH/PS. It is planned that this project will continue. Such an arrangement ensures a very tight control principle and yet permits flexibility in proceeding with deserving activities as they are formulated.

#### 7. Technical and Scientific Review of the Project

The Pathfinder Fund works closely with WOH/PS and also with the A.I.D. regional officers and mission personnel responsible for formulating and operating population/family planning programs. It is the consensus within A.I.D. that the Pathfinder Fund's research, evaluation, and action programs are well directed and are consonant with A.I.D. objectives.

The Pathfinder Fund maintains close working relationships with the Population Council, the Ford Foundation, the Rockefeller Fund, the Margaret Sanger Research Bureau, the IPPF and other organizations involved in population work. While no specific evaluation of the work of the Fund has been requested from these organizations, A.I.D. has been satisfied that the professional expertise and dedication of Dr. Kessel and staff is well known and respected by his professional colleagues.

#### 8. Summary Evaluation

In the formulation and development of the A.I.D. posture and action programs in population/family planning, the existence and experience of the Pathfinder Fund in the international field has been a tremendous plus. This organization, using a very low-key approach in its international family planning activities, has actually set up programs where U.S. Government or other bilateral and perhaps international efforts would be unwelcome. The vital information relating to the incidence of the IUD use and rejection rates have been quantified in the evaluation study which the Fund is administering. The Fund will likewise be able to initiate research and evaluation studies relating to oral contraceptive use. A very important role will continue to be played with respect to the provision of contraceptives, oral and IUD, when such actions are deemed essential in the various LDC's where population/family planning programs are being carried out. The testing of new contraceptives is a basic and integral part of the world program which is essential to accomplish one of the basic objectives of the A.I.D. population assistance program. The Pathfinder Fund is the single most effective agency for this operation and within the next decade is expected to play an even larger role than its present one.

Attachment

WOH/PS: M.D. Lieberman:10-11-68; revised 10-25-68

Proposed Budget

	<u>FY 1969</u>	<u>FY 1970</u>	<u>FY 1971</u>
1. Salaries	\$96,825	\$276,815 ✓	\$290,582
2. Travel	11,500	23,000 ✓	23,000
3. Rent and Supplies	35,500 ✓	73,475 ✓	123,475
4. Fellowships		12,000 ✓	12,000
5. Alterations & Renova- tions	5,000	10,000 ✓	2,000
6. Data Processing & Reports	30,000	60,000 ✓	110,000
7. Publications	2,000	4,000 ✓	6,804
8. Sub-contract Services	<u>119,960</u>	<u>318,275</u> ✓	<u>332,139</u> ✓
Total	<u>\$300,785*</u>	<u>\$777,565</u>	<u>\$900,000</u>

\*\$20,000 of this available from previous funding.