

I. PROJECT IDENTIFICATION

1. PROJECT TITLE
Advanced Technology Fertility Clinics (ATFC's)

APPENDIX ATTACHED
 YES NO *428*

2. PROJECT NO. (M.O. 1095.2)
932-11-580-604

3. RECIPIENT (specify)
 COUNTRY **Worldwide**
 REGIONAL INTERREGIONAL

4. LIFE OF PROJECT
 BEGINS FY **73**
 ENDS FY **77**

5. SUBMISSION
 ORIGINAL **3/16/73** DATE
 REV. NO. DATE
 CONTR./PASA NO.

II. FUNDING (\$300) AND MAN MONTHS (MM) REQUIREMENTS

A. FUNDING BY FISCAL YEAR	B. TOTAL \$	C. PERSONNEL		D. PARTICIPANTS		E. COMMODITIES \$	F. OTHER COSTS \$	G. PASA/CONTR.		H. LOCAL EXCHANGE CURRENCY RATE: \$ US (U.S. OWNED)		
		(1) \$	(2) MM	(1) \$	(2) MM			(1) \$	(2) MM	(1) U.S. GRANT LOAN	(2) COOP COUNTRY (A) JOINT (B) BUDGET	
1. PRIOR THRU ACTUAL FY												
2. OPRN FY 73	3,208	1,750	-	--	-	1,365	88					
3. BUDGET FY 74	5,039	2,350	-	--	-	2,159	530					
4. BUDGET +1 FY 75	5,249	2,675	-	--	-	2,359	215					
5. BUDGET +2 FY 76	2,250	--	-	--	-	2,250	-					
6. BUDGET +3 FY												
7. ALL SUBQ. FY												
8. GRAND TOTAL	15,744	6,775				8,133	833					

9. OTHER DONOR CONTRIBUTIONS

(A) NAME OF DONOR	(B) KIND OF GOODS/SERVICES	(C) AMOUNT

III. ORIGINATING OFFICE CLEARANCE

1. DRAFTER PHA/POP/MI, Gerald F. Winfield <i>GFW</i>	TITLE Associate Chief	DATE 3/16/73
2. CLEARANCE OFFICER PHA/POP/MI, Alvin S. Lackey <i>ASL</i>	TITLE Chief	DATE 3/16/73

IV. PROJECT AUTHORIZATION

1. CONDITIONS OF APPROVAL
Twelve to eighteen months after the initiation of this project there will be a review to determine the progress in establishing an International Consortium of Medical Institutions with adequate LDC and other donor participation required to realize the objectives of this program. In the event that significant progress is not realized, appropriate recommendations will be made for redesigning the program prior to obligation of any additional funds.

2. CLEARANCES

BUR/OFF.	SIGNATURE	DATE	BUR/OFF.	SIGNATURE	DATE
PHA/POP	W. Boynton <i>W. Boynton</i>	3-26-73	PHA/POP	R. Backlund <i>RB</i>	26/3/73
PHA/POP	R. T. Ravenholt <i>RTR</i>	3-26-73			
PHA/PRS	G. Coleman <i>GMC</i>	4-26-73	AA/PPC	P. Birnbaum <i>PB</i>	

3. APPROVAL AAS OR OFFICE DIRECTOR SIGNATURE AA/PHA, J. A. Kieffer <i>JAK</i> TITLE AA/PHA	DATE 5/8/73	4. APPROVAL A/AID (See M.O. 1025.1 VI C) SIGNATURE A/ATD, J. A. Hannah <i>JAH</i> ADMINISTRATOR, AGENCY FOR INTERNATIONAL DEVELOPMENT	DATE 5-14-73
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ADVANCED TECHNOLOGY FERTILITY CLINICS (ATFC's)

A. Statement of the Goal

1. The Goal

The Goal of this activity is to establish many hundred clinics where the most technologically advanced and comprehensive services for fertility management are provided.

2. Measurements of Goal achievement

- a. Enumeration will show that many hundred such clinics are operating.
- b. Effectiveness will be measured by the decline in births using the rates that are most appropriate and feasible in each country.

3. Assumptions about goal achievement

- a. In many LDC's there is already demand for fertility control sufficient to have a significant effect in reducing birth rates if more advanced and powerful means of fertility management are made extensively available.
- b. Attitudes towards sterilization and abortion in many LDC's are sufficiently liberalized to allow the diffusion of these new fertility management techniques. In many places this liberalization is likely to accelerate.

B. Statement of project purpose

1. Project Purpose

- a. Increase the number of LDC Ob/Gyn specialists and other surgically qualified physicians, in both the public and private sectors,

2. Conditions expected at end of of the project

- a. About 1,500 physicians will have been trained and about 1,100 Advanced Technology Fertility Clinics (ATFC's)

who are capable of delivering the most advanced and comprehensive fertility management services.

- b. Provide for LDC Ob/Gyn specialists and other surgically qualified physicians a program of clinician training and clinic development.
 - c. Institutionalize the teaching of advanced technology in the management of fertility in LDC schools of medicine, and other training centers so it becomes available to physicians and their assistants through undergraduate, specialty, and continuing education.
3. Basic assumptions about achievement of purpose
- a. A number of new advanced clinical technologies for fertility management exist which would make a powerful contribution to family planning if they were widely used.
 - b. Advanced Technology for Fertility Management (ATFM) is being taught in undergraduate, specialty and continuing programs of medical colleges and other training centers engaged in the education of medical personnel.
- will be functioning in LDC's using sophisticated, rapid, outpatient, clinical procedures for the diagnosis, prevention or termination of pregnancy.

- b. There are a large number of physicians and medical institutions, including Ob/Gyn specialists, that are not now using these advanced techniques for fertility management (ATFM). The provision of training and equipment will be readily accepted and will result in these institutions sharply increasing their contribution to lowering birth rates.
- c. These technologies are of such a nature that they will tend to spread and to generate additional demand for their use because they meet the needs of both physicians and patients.
- d. Research and field experience will further develop these and similar techniques so they will become a significant part of the long-term practice of reproductive gynecology.
- e. Because of their nature these technologies will be highly effective in helping to lower birth rates.

C. Statement of outputs and output indicators

1. Project outputs

- a. Trained personnel qualified to run Advanced Technology Fertility Clinics.
- b. Training programs for teaching Advanced Technology for Fertility Management in LDC medical schools and other training centers.

2. Output indicators

- a. Number of physicians that have been certified as competent to operate ATFC's.
- b. A considerable number of LDC medical schools and other training centers have incorporated ATFM into their regular teaching programs.

3. Basic assumptions about production of outputs

- a. The present state of the art has already developed all necessary components for the organization of ATFC's. It is therefore feasible

to organize a program to bring these components together so that many ATFC's can be generated.

- b. The most important single element required to start ATFC's is qualified physicians, assisting, and auxilliary personnel.
 - c. Such personnel can be rapidly and effectively produced in specially designed, intensive, short training courses.
 - d. Necessary equipment can be supplied and maintained at favorable levels of cost effectiveness.
 - e. A major output that will flow from the process of starting the ATFC's will be the introduction of training in ATFM into many medical schools and other centers for training medical personnel.
- D. Statement of project inputs
1. Inputs
 - a. International Consortium of Medical Institutions (ICMI)

This program requires a strong intermediary institution to provide leadership and management. An ICMI will be organized to perform this function.

 - (1) Inputs required to organize the ICMI
 - (a) Grant to suitable Educational institution to design, obtain institutional participation, and organize the ICMI. (For options of how the ICMI might be constituted see Attachment A.)
 - (b) Budget to fund grant. (See Attachment B.)

(2) Inputs by ICMI

(a) Professional leadership of Total Program

1. Board of Directors (Official Representatives of institutions that comprise consortium). Policy formulation, educational and operational standards, program evaluation, approval of annual budgets and work plans.
2. Director-general, executive staff, and necessary support staff. (See Attachment C for budget.)

(b) Overall budget of the program and management of funds

1. Fiscal processes and final fiscal responsibility through one of the member institutions.

(c) Supervision or management of a central supply and logistics operation that would handle equipment and supplies for the program.

(d) Selection, oversight, coordination, and sub-financing of the net of ATF Training Centers.

b. ATF Training Centers -- An international net of 9 or 10

Each Training Center would make the following inputs :

- (1) Full and part-time instructional and support staff.
(See Attachment D for typical staffing pattern.)
- (2) Facilities to conduct training
- (3) Academic and clinical training programs to qualify physicians and staffs to establish and run ATFC's.
- (4) Follow-up professional technical assistance in establishing and operating ATFC's.

- (5) Coordinate a system for obtaining and evaluating the clinical and service records of ATFC's established by graduates.
 - (6) Provide continuing information on technological advances.
 - c. Central supply and logistics operation inputs. (See Attachment E for Functions and Budget of Supply Unit)
 - (1) Operating staff.
 - (2) Procurement of prescribed equipment and supply package
 - (3) Warehousing of equipment.
 - (4) Distribution of equipment on long-term loan to approved institutions where trained physicians operate ATFC's, and a system for assisting trained physicians acquire equipment to use in private practice.
 - (5) Provide spare part and maintenance back-up where required.
 - d. AID-Inputs.
 - (1) Necessary financial support, in conjunction with other possible donors, to operate the program. See budget.
 - (2) Over-all monitoring of the program through the ICMI.
 - (3) Evaluation of the program.
2. Budget.

The budget is presented in two ways: A "Schedule of Expenditures" shows the estimates for each program component for fiscal years 73 through 77 and the totals per component and per year. A "Schedule of Obligations" indicates how funds will be obligated. FY 73 funds will be obligated by AID/W through a work order and four contracts, as follows:

Grant to a suitable institution of \$60,000 to fund the staff the staff and services needed to organize the ICMI.

SUMMARY OF EXPENDITURES

Item	FY 73	FY 74	FY 75	FY 76	FY 77	
I. ICM						
A. Phase I	29,332	53,668				
B. Phase II Core Costs		100,000	215,000	215,000	215,000	845,000
I. Central Supply						
A. Core Costs	42,000	84,000	84,000	84,000	84,000	378,000
B. Procurement	200,000	850,000	1,700,000	2,050,000	2,250,000	7,050,000
C. Shipping & Operations	20,000	85,000	170,000	205,000	225,000	705,000
I. Training Centers						
A. Hopkins	-----	-----	-----	225,000	225,000	450,000
B. Washington University	125,000	250,000	250,000	250,000	250,000	1,125,000
C. Pittsburgh University	125,000	250,000	250,000	250,000	250,000	1,125,000
D. AUB	-----	100,000	200,000	200,000	200,000	700,000
E. 5th	-----	125,000	250,000	250,000	250,000	875,000
F. 6th	-----	-----	250,000	250,000	250,000	750,000
G. 7th	-----	-----	250,000	250,000	250,000	750,000
H. 8th	-----	-----	-----	250,000	250,000	500,000
I. 9th	-----	-----	-----	250,000	250,000	500,000
TOTALS	\$ 541,332	\$1,902,668	\$3,619,000	\$4,729,000	\$4,949,000	\$15,741,000
Number of Graduates -	40	170	340	410	450	TOTAL 1,410

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SCHEDULE OF OBLIGATIONS

Item	FY 73	FY 74	FY 75	FY 76	Total
I. ICOMI -	AID Contracts	ICOMI Ops			
A. Phase I Same	88,000	-----	-----	-----	88,000
B. Phase II Core	-----	530,000	215,000	-----	745,000
Contracting Authority	-----	4,509,000	5,034,000	2,250,000	11,798,000
II. Central Supply		For-	For-	For-	
A. Core	210,000	84,000	34,000	-----	328,000
B. Procurement	1,050,000	1,700,000	2,050,000	2,250,000	7,050,000
C. Shipping	105,000	375,000	225,000	-----	705,000
	<u>1,365,000</u>	<u>2,159,000</u>	<u>2,359,000</u>	<u>2,250,000</u>	<u>6,133,000</u>
III. Training Centers					
A. Hopkins	-----	225,000	225,000	-----	450,000
B. Washington University	625,000	250,000	250,000	-----	1,125,000
C. Pittsburgh University	625,000	250,000	250,000	-----	1,125,000
D. AUB	500,000	-----	200,000	-----	700,000
E. 5th	-----	625,000	250,000	-----	875,000
F. 6th	-----	500,000	250,000	-----	750,000
G. 7th	-----	500,000	250,000	-----	750,000
H. 8th	-----	-----	500,000	-----	500,000
I. 9th	-----	-----	500,000	-----	500,000
	<u>1,750,000</u>	<u>2,350,000</u>	<u>2,675,000</u>	<u>-----</u>	<u>6,775,000</u>
TOTAL	\$3,203,000	\$5,039,000	\$ 5,249,000	\$2,250,000	\$15,741,000

- b. Contract with a central supply unit - \$1,365,000 - to cover procurement and operations for fiscal years 73 and 74.
- c. Contracts for ATF Training centers at (1) Washington University, (2) Western Pennsylvania Hospital and the University of Pittsburgh, and (3) American University in Beirut, total \$1,750,000. Total obligations FY 73 -- \$3,203,000.

FY 74 obligations will all be to the Consortium, of which \$530,000 is for core costs for FY 74,75 and 76, and \$4,509,000 for subcontracting authority to cover the items listed for Central Supply and Training Centers. FY 75 and 76 obligations will be handled in a similar manner.

- 3. Basic assumptions about management of inputs.
 - a. To be effective in generating ATFC's this program needs centralized management coupled with wide international involvement of a variety of institutions that are directly related to obstetrics and gynecology.
 - b. It is feasible to organize an international consortium to provide the leadership and coordination to manage the inputs of this program. This can be accomplished in 12 months.
 - c. An international consortium will be superior to a U.S. consortium because it will involve the receiving countries in goal setting, planning, review of management and evaluation to improve realism and acceptability.
 - d. Suitable packages of all types of instruments and supplies needed for ATFC can be procured, delivered and maintained to meet the needs of this program.

- e. There are at least 10 institutions in the U.S. and the LDC's that have the personnel, clinical material, and interest to operate Training Centers for physicians and their assistants.
- f. AID is not the only donor which would be ready to support this program. The Consortium can expect to find support from other governments, foundations, and international organizations.
- g. The key resource, money, which AID and other donors can supply, will quickly and effectively channel the energies of top people and institutions in the Ob/Gyn specialty into activities with a high level of effectiveness in lowering birth rates.
- h. The program need not lose time while the Consortium is being organized, since key parts can be initiated by grant and later integrated into the Consortium. These parts will begin to produce the trained people and provide the equipment needed to start ATFC's.
- i. ATFC's will have to have the following ingredients in order to function.
 - (1) Trained and dedicated personnel.
 - (2) Necessary basic equipment.
 - (3) An institutional base in the community where the service is to be rendered.
 - (4) Necessary start-up financial support at least in some cases.

E. Rationale

The rationale of this program is essentially simple. It is this: the widespread use of advanced technologies for fertility management can make an important contribution to the lowering of birth rates and to the reproductive well-being of families in the LDC's. The problem is to quickly

make these new, well demonstrated technologies widely available in sufficient quantity to be somewhat commensurate with the size of the problem of lowering birth rates and do it quickly enough to be significant.

This program depends on the following salient factors:

1. The Advanced Technologies for Fertility Management (ATFM)

A set of reliable advanced technologies for the clinical management of fertility have come into being. They relate to the diagnosis, prevention and termination of pregnancy. In situations in Japan, Eastern Europe and the U.S. they have proved to be powerful tools for improving the reproductive well-being of individuals and populations. Where they have been applied on a wide scale, over-all fertility rates have fallen rapidly, infant and maternal mortality have declined, induced, incomplete, and infected abortions have practically disappeared.

These technologies, for female sterilization and pregnancy termination, are rapid, safe, and can be applied to large numbers on an out-patient basis with minimum hospital back up. Usually they do not require general anesthesia. While sterilization is usually non-reversible it has the advantage of a single action to terminate risk of pregnancy for women who have had the children they desire. They are highly cost effective. (See Attachment F.)

2. The Ob/Gyn Specialty and Family Planning by ATFM

These advanced technologies must be used by a trained Ob/Gyn specialist or by personnel he trains and supervises. The utilization of these technologies is dependent on the involvement of this specialty. While many Ob/Gyn specialists have played leading roles in the P/FP movement, as a whole world-wide, this specialty is not deeply committed to or

engaged in the effort to lower birth rates. A major objective of this program is to stimulate the involvement of Ob/Gyn people, and to guide the transformation of the practice of gynecology toward increased emphasis on fertility management. Judging by the extensive response of Ob/Gyn people to the announcement of the training program at Johns Hopkins, there is every reason to believe that this program can succeed rapidly, involving Ob/Gyn specialists in effective limitation of fertility.

3. Advanced Technology Fertility Clinics (ATFC's).

The end-of-line output of this program is to be about 1,100 clinics providing services to patients. To become functional these clinics must have (1) trained personnel, (2) necessary equipment, (3) a suitable operating base and, (4) necessary start-up money, in at least some cases. This program is designed to provide 1, 2 and 4, and to select trainees who have or can easily establish 3. It is also designed to have a follow-up relation of Training Centers and Consortium with operating ATFC's. This follow-up relationship will be of three kinds - (1) a flow of records from ATFC's back to Centers and Consortium, (2) follow-up assistance with equipment maintenance and repair from Consortium to Clinic, (3) technical assistance consultation and information follow-up from Training Center to Clinic.

4. Attitude Toward Sterilization and Pregnancy Termination.

An important factor in probable success is the attitudes of various national, religious, and other groups toward sterilization and abortion. A study by the WHO published in the Spring of 1972 reported that abortion is now the most widespread means of fertility regulation in the world. Attitudes about abortion are changing rapidly. Since

India passed her liberalized abortion law about half of the women of the LDC's live in countries where abortions are legal. In countries where abortions are illegal a wide range of differences obtain as to how strictly the laws are enforced. In most Muslim and Catholic countries the incidence of self-induced or illegal abortions, with many incomplete and infected ones, is high and probably rising. Typically 30 to 50% of all admissions to the gynecology wards of hospitals in Latin American and Muslim countries are for incomplete or infected abortions. This shows the desperation with which women seek relief from unwanted pregnancies and indicates the size of the public health problem created by illegal abortion. These are the forces that are driving the change in attitude toward liberalizing both the practice and legal status of medically safe abortion. Since suction curettage, that this program will teach, is the preferred method for treating incomplete and infected abortions, the teaching of this procedure is acceptable no matter what the legal status of abortion.

Female sterilization is rapidly gaining favor in many parts of the world. The new methods made possible by the operative laparoscope and culdoscope give evidence that this method of eliminating the risk of pregnancy will ⁱⁿ be/increasing demand as the facilities for providing such sterilization become more widely available.

In sum, currently available evidence indicates that the demand for and the social and legal conditions that bear on the spread of sterilization and abortion strongly supports the position that there will be ample demand for this program in most parts of the world so that it need not fear failure as a result of adverse attitudes and legal constraints.

5. Leadership and Administration

This program proposes to establish an International Consortium of Medical Institutions to provide over all leadership, coordination and administration. Attachment A outlines the major characteristics of this Consortium and defines a procedure for getting it organized. This section presents the rationale of why it needs to be set up.

- a. The size and complexity of this program requires an adequate full time leadership and administrative group. This function must be performed by a suitable intermediary. No intermediary, that has all the features that such a body should have, exists. It is therefore planned to organize an International Consortium of Medical Institutions to perform this function.
- b. International participation in over-all planning and policy formation is needed. To fully tap the extensive resources, institutional, human, and infrastructural, that this program seeks to mobilize, there needs to be a mechanism for the participation of institutions and outstanding people from many countries both from the donor group and the LDC's. The Consortium will provide an effective mechanism to do this and to bring both skill and prestige to bear for achieving the purposes of this activity.
- c. A single purpose organization is required. A major reason for the consortium is to make it a single purpose organization to stimulate and lead the Ob/Gyn specialty in becoming fully engaged in the management of fertility for reproductive well-being at patient and community/society levels. If this program is attached to or operated by existing organizations its focus and single driving purpose will almost certainly be diluted by other needs and goals to the delay and detriment

of getting the ATFM's widely disseminated and used by large numbers of physicians and clinics.

- d. Strength to meet fiscal responsibility. The Consortium must have fiscal strength and the ability to manage several million dollars each year. This can be attained by making the Consortium a semi-independent part of an American University in the pattern of the Applied Physics Laboratory at Johns Hopkins, which is specially financed and has its own directors and administration.
- e. Sufficient size and strength to coordinate effectively with other related programs. By channeling resources into a body that has relationships with 18 to 21-member institutions the Consortium could have world-wide prestige to lead and guide the coordination of effort with many other programs such as the AVS, IPPF, WHO, AAGL, etc.
- f. Concentration and drive to get rapid and important results. All of this taken together can insure that a significant quantum jump in applying these powerful new technologies is achieved and the quality of births is improved as the number of births is reduced.

6. Equipment and supply.

This program requires that the large number of physicians it trains are equipped with the instruments and supplies that ATFM's require. A system to do this and to see that spare parts and maintenance is available is provided for. About half the cost of the project will go into equipping and supplying the ATFC's. This supply operation will be begun in FY 73 with a separate contract and later will function under the Consortium.

There are two issues to be resolved in setting up the regulations under which the laparoscopes, culdoscopes, and their associated instruments, suction equipment and the like, needed to equip ATFC's, are made available.

- a. Procedure by which equipment is made available to public and non-profit organizations
- b. How can private physicians be effectively assisted to acquire such equipment?

It is proposed that these issues be resolved as follows:

- a. That the power to supply such equipment be delegated to the Consortium. The Consortium will obtain its supply of equipment by large scale procurement through GSA to specifications developed by AID and the Consortium. The Consortium, on written recommendation of the Training Centers, which will certify that specific trainees are qualified to use designated procedures and equipment, will supply the sets of equipment to the public or non-profit institution on whose staff the certified trainee serves. It will be supplied on long term loan with title retained by the Consortium. The Consortium will have the right to repossess the equipment if it is used other than by the institution to which it is loaned or if the Consortium has evidence it is being used for purposes other than those for which it was originally loaned, namely for the management of fertility, broadly construed. At the end of five years the equipment will be deemed to have fulfilled its useful life, it will be written off the Consortium record, and its return will not be required.
- b. The Consortium will also be empowered to assist certified trainees who wish to use such equipment as a major portion of their private practice. This assistance might take a number of forms that would be designed to make it feasible for the physician to pay for the equipment on easy interest-free terms with only enough add-on to the whole-sale price and shipping costs to cover the actual costs to the

Consortium of procuring warehousing, keeping records and collecting payments. The Consortium would make every effort to assist the trained physicians to get the equipment into their home country with the lowest legal import duty. The Consortium would use the moneys received as payments from private physicians to purchase additional equipment to replace that sold, thus avoiding the use of money supplied by A.I.D. to assist private physicians for their own monetary gain. The Consortium would be empowered to seek other sources of funding to cover this type of assistance to private physicians. Because of the need to make ATFM services available on the widest basis to the most couples possible, it is desirable to assist private physicians to establish privately owned ATFC's.

7. Assistance with Start-up Costs.

Most institutions and private individuals who wish to start ATFC's should either already have or be able to finance the acquisition of the space, clinic furnishings and other items as well as meet the salaries of personnel necessary to start a clinic. Many clinics should be self-supporting from fees, subsidies, or donations from public or private sources. However, there may well be instances where start-up financial assistance is required. The Consortium will be authorized to use A.I.D. supplied money, sums to be specified, and to seek support from other donors to have funds which can be granted or loaned to institutions, partnerships, or individuals to assist them to start ATFC's.

8. Training and Technical Assistance.

The heart of this program is trained and dedicated people. The 9 or 10 Training Centers that will be developed through the program will be

the means of generating and giving technical assistance to the necessary personnel. The Johns Hopkins program, funded as part of a research grant, is already pioneering how this can best be done. Each center, most of them located overseas, will be able to make its own unique contribution while fulfilling the basic program that will be defined and coordinated by the Consortium. This will provide a network that will continue to improve these aspects of the program.

9. Field testing and dissemination of new technologies.

This worldwide network of Training Centers can also serve as a net for the rapid field testing and pass-on to service delivery clinics of improvements in existing techniques and of new ones which will surely make their appearance as research continues.

F. Course of Action

1. Implementation Plan.

The implementation of this program is complicated by the following urgencies:

- a. The need to get training started as rapidly as possible to:
 - (1) Have an impact on the application of the ATFM to family planning as rapidly as possible. Every birth prevented now is more effective in lowering birth rates than those prevented next year or later.
 - (2) Work out the problems of such training as early as possible in pilot training centers so that when additional centers are planned they can benefit.
- b. The lead time required to organize the ICMI and get it functioning as the intermediary is estimated to be 12 months.

To meet these requirements the following plan will be followed. PHA/POP/MI will manage the necessary work to commit FY 73 money to accomplish the following actions:

- a. Make a grant to a suitable institution of \$88,000 to provide staff and other services required to do the necessary work in connection with developing the design and organization of the International Consortium of Medical Institutions.

- b. Develop the action necessary to contract for the beginning stage of a Central Supply Organization that can commence to handle and distribute the equipment the program will supply trainees at Hopkins and the other training centers. This contract to provide that the management of this function will become the responsibility of the Consortium to be continued with this contractor if he is willing and his performance is satisfactory. This contract should commit \$1,365,000.

- c. Produce the necessary PIO/Ts to make possible grants to Washington University, St. Louis; Western Pennsylvania Hospital and Pittsburgh University; and the American University of Beirut to establish Training Centers in conformity with the principles outlined in this PROP and presently being tested at Johns Hopkins. The moneys required for funding these contracts for three years are estimated at \$1,750,000. The contracts will stipulate that future funding, coordination, and evaluation of activity will become the responsibility of the Consortium when it begins functioning.

FY 74 money would be committed to the Consortium. It must be organized early enough to be able to accept responsibility for

this action. These moneys would defray the core-costs of the consortium and provide sub-contracting authority as shown in the Schedule of Obligations on page 9.

Attachment A

Options for Organizing the International Consortium of Medical Institutions

The reasons for needing to organize an International Consortium of Medical Institutions are set forth in the rationale section of the PROP. This attachment will outline some options for organizing the consortium and suggests a procedure for doing so.

Major Characteristics

The consortium must achieve the following three major characteristics:

1. It must have prestige in medical education and in the OB-GYN specialty in order to command the respect and cooperation which is required.
2. It must have the fiscal capacity and strength to handle the finances of this size of an operation.
3. It must achieve dedication to drive forward with the purpose of getting advanced technology fertility management widely known and used.

Functions to be Performed

The consortium must be organized to effectively perform the following functions:

1. Trusteeship and fund handling for fiscal responsibility.
2. Operational policy and liaison with other cognate medical and family planning agencies.
3. Executive management of the program.
4. Line functions
 - a. Educational coordination
 - b. Program and accounting
 - c. Central supply and logistics

Options for Ways of Organizing the Consortium

Option 1. Contract through a U.S. university for fiscal responsibility with a consortium of medical institutions to provide operational policy guidance and liaison with other agencies.

This option is modeled after the Applied Physics Laboratory of Johns Hopkins University. The organization on this model is shown in the attached chart "Organization of International Consortium for Medical Institutions."

Under this option the overall contract for the program would be made with the Board of Trustees of a U.S. host university. Major responsibility for seeing that the program was managed with complete fiscal responsibility would rest with the President of that University. He might well opt to appoint, with the concurrence of his Board of Trustees, a Board of Visitors specifically for the consortium which would be responsible to review the way the consortium was organized and to examine how it was achieving its program and managing its funds. The President of the University with the concurrence of A.I.D. would be responsible for hiring the consortium director who would be responsible for the executive management of the program. The consortium would retain the services of a legal counsel to help it discharge its duties particularly with respect to the subcontracting of its funds to other groups such as the central supply and logistics operation and the net of training centers.

For the formation of operational policy and liaison with other medical and family planning agencies there would be formed a consortium of medical institutions. The key group of this part of the organization would consist of a Board of the Consortium which would be made up of one representative

from each institutional member of the consortium. The members of the consortium might consist of some such mix as U.S. universities, OB-GYN chairmen - 6, LDC universities, OB-GYN chairmen - 6, European Universities, OB-GYN chairmen - 2, OB-GYN Federations - 2, Regional Associations of Medical Schools - 5, for a total voting membership of 21. In addition, the Board might well have non-voting associate members from donor, health and family planning agencies to the number of 7 or so.

This Board would meet regularly, have a series of standing committees and function in guiding the executive manager by providing advice which would not be entirely binding but would have to be considered seriously in carrying out the operations of the organization. Final responsibility of the executive management would flow back through the University President and the Board of Trustees to discharge obligations to see that the program operates effectively.

At the line operation level there would be three operating divisions as follows:

1. Education coordination, headed by the Deputy Director who would also be the Educational Officer of the program,
2. Program and accounting with a Program Officer and a Fiscal Officer,
3. A Central Supply and Logistics Section with a manager, assistant manager, records accountant, warehouseman and secretary. This third unit might be integrally organized as a part of the operation or it might represent a subcontract. This latter possibility relates to the fact that this portion of the operation must be put into motion as rapidly as possible.

and cannot wait for the organization of the International Consortium of Medical Institutions before it is started. It will be started with the clear understanding that it will either be integrated into the organization of the consortium as indicated in this organization chart or be continued with a very close association under subcontract.

Option 2. Contract through a general science agency such as the National Science Foundation or the National Academy of Science to supply fiscal responsibility, with a consortium of medical institutions to provide operational policy guidance in liaison with other agencies.

This second option would have a table of organizations very similar to the one shown for Option 1, the difference being the substitution of the selected science agency for the U.S. host university.

Option 3. Form a consortium of medical institutions and organize a Board of Trustees of public minded citizens which would provide the basis for the consortium carrying its own fiscal responsibility.

This third option would have a table of organization very similar to Option 1 except that it would have its own Board of Trustees substituting for the combination of the Board of Trustees of the host university, the President and the Board of Visitors for the consortium.

These three different options are outlined to emphasize the fact that it is not now possible to determine which approach would be the most advantageous and the easiest to carry forward. It will require a considerable amount of study, exploration and negotiation to determine which of these options might be the best. It is estimated that it will require at least twelve months of work to do the necessary studies, make the recommendations and proceed with the organization so that the consortium

can become functional. Furthermore it is obvious that PHA/POP/MI does not have enough staff time available to it to carry out the necessary studies to resolve these problems.

Procedure for Resolving Questions in Organizing the Consortium

It is therefore planned that a work order will be issued to the American Association of Medical Colleges to provide the necessary staff skills and time to do the study and carry out the organization of the consortium under the guidance of PHA/POP/MI.

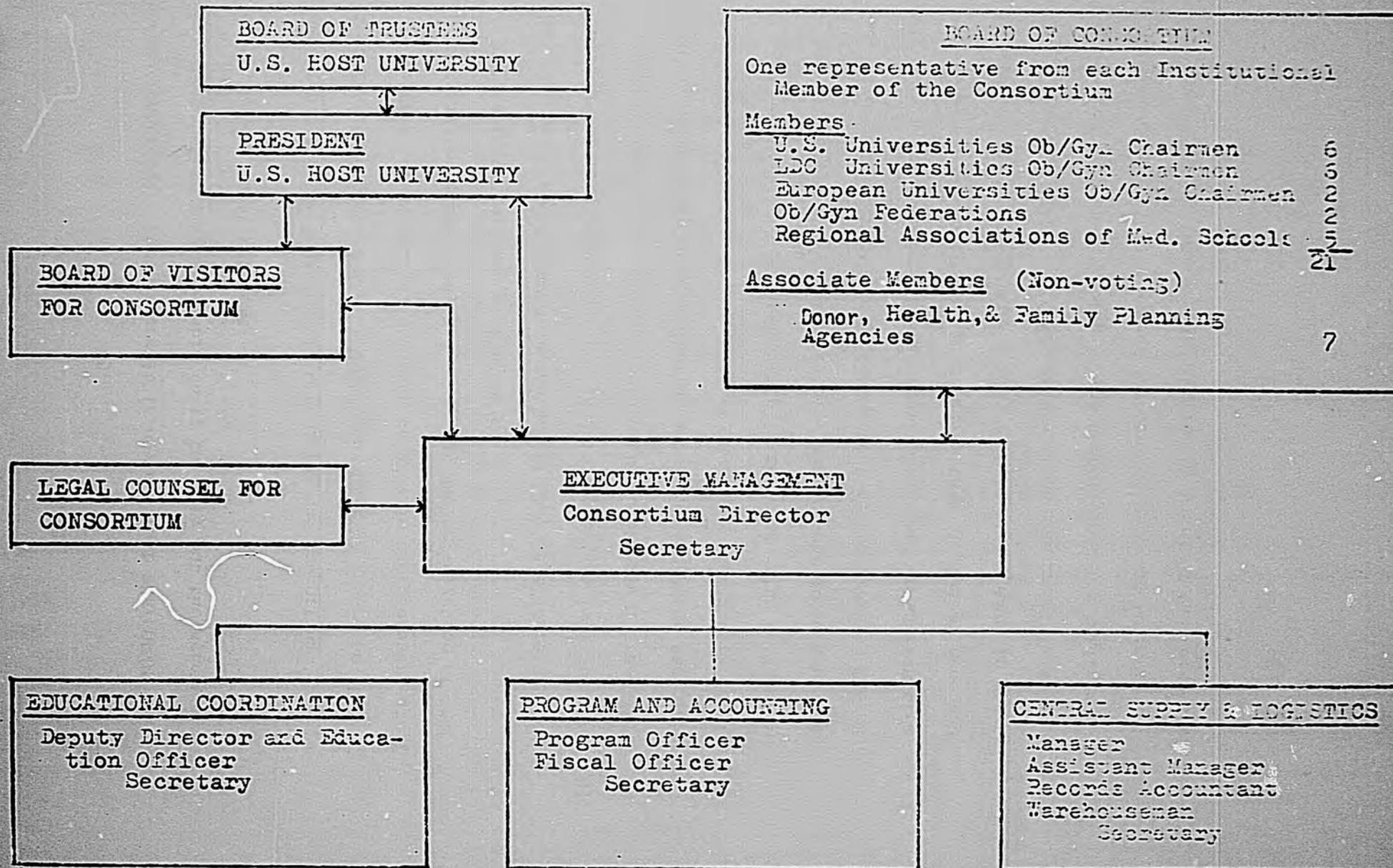
This work order would provide a senior officer and a secretary for full time work on this program as outlined in the budget (see Attachment B).

Using these funds and in close coordination with POP/MI, the AAMC would set up an advisory group to refine questions and guide the plans for the study and organization phases. It would confer widely with institutions that should be considered for membership in the consortium to determine capability and interest. It would examine each of the above-mentioned options and perhaps some others as to the best one to pursue. The study would produce a recommended organizational plan based on ascertaining feasibility and a high degree of probability that it will be acceptable to all vital elements. When such a plan is brought together in approximately five or six months' time, the AAMC would continue to assist in carrying the plan into effect by participating in the negotiations for taking the legal steps to produce the FIO/T required for the contract and to recruit the necessary institutions into memberships in the board of the consortium.

ORGANIZATION OF INTERNATIONAL CONSORTIUM OF MEDICAL TELETYPE

FISCAL RESPONSIBILITY

OPERATIONAL POLICY AND LIAISON



Attachment B

ICMI Phase I Budget

<u>Senior Officer, Full time, 12 months @ \$3000 per month,</u>	
Including all benefits	\$36,000
<u>Secretary, Full time, 12 months @ \$600 per month,</u>	
Including all benefits	7,200
<u>Consultants</u>	10,000
<u>Travel and Per Diem</u>	
Foreign and domestic	12,600
<u>Communications</u>	1,000
<u>Overhead</u>	
49% of salaries	<u>21,200</u>
<u>Total</u>	\$88,000

Attachment C

ICMI Phase II Core Costs Budget

(Note: This budget does not include the core costs of the central supply and logistics unit. See Attachment B.)

Salaries		Man/Months
<u>Director</u>	\$35,000	12
<u>Deputy Director & Education Officer</u>	28,000	12
<u>Program Officer</u>	23,000	12
<u>Fiscal Officer</u>	20,000	12
<u>Secretary</u>	7,500	12
<u>Secretary</u>	6,500	12
<u>Secretary</u>	<u>6,500</u>	12
Total	\$126,500	
Fringe Benefits @ 14%	\$ 17,700	
Space	5,000	
Furnishings	5,000	
Travel	18,000	
Consultants and Fees	22,800	
Overhead	<u>20,000</u>	
Grand Total	\$215,000 per annum	

Attachment D - Functions and Staffing Pattern of ATF Training Centers

Functions

The principal function of each ATF Training Center is to organize and deliver special intensive training programs for OB-GYN and surgical specialists lasting 4 to 6 weeks during which the Advanced Technology Fertility Management procedures dealing with the diagnosis, prevention and termination of pregnancies are taught. Each trainee gets didactic and practical experience with special emphasis on all surgical procedures that can be used on an outpatient basis for sterilization and pregnancy termination. Each Center will train from forty to eighty physicians each year at an all-inclusive cost for training, travel and maintenance of about \$5,000 per trainee.

Staffing Pattern

The typical staffing pattern of a Center includes:

Senior Clinical Faculty

Usually made up of the part-time services

of several staff people

1 man year

Associate Professor to Resident level

Clinical staff

1 to 2 man years

Executive Officer (Administrative)

1 man year

Senior Nurse Practitioner

1 man year

Health and Other Instructors

1/2 man year

Consultants

1/2 man year

Usually the Director of the program is a Senior Clinical Faculty man who receives none or at most 10% of his salary from this project.

At the Associate Professor level there is usually one man who gives full time to this program and is designated Training Officer for the program.

Attachment E - Functions and Budget of the Central Supply and Logistics Unit

Functions

1. Procurement of standard equipment and supply sets.
2. Warehousing and control of sets.
3. Shipment of sets to trainees on authorization of each training center.
4. Issuance and monitoring the long time loan documents on equipment provided public or non-profit institutions.
5. Sale of equipment to physicians for use in their private practice when they plan to make fertility management a major part of their practice.
6. Collection of payments from private physician sales.
7. Providing assistance for the maintenance and repair of all equipment loaned or sold.
8. Collecting data and feeding it back to manufacturers to improve the standard equipment packages.

Budget

Salaries

<u>Manager</u> per year	\$18,000
<u>Assistant Manager</u>	15,000
<u>Accountant</u>	12,000
<u>Warehouseman</u>	12,000
<u>Secretary</u>	<u>6,000</u>
Total Salaries	63,000
Office and Warehouse Space	<u>21,000</u>
Total per annum	\$84,000

Attachment F

Estimate of the Cost per Birth Averted for the ATFC Program

This program is designed to train 1,410 Ob/Gyn and surgical specialists in the use of advanced techniques for preventing and terminating pregnancies. They will be trained in five years. It will provide each trained physician with the necessary packages of equipment to operate Advanced Technology Fertility Clinics. It is estimated that 1,128 or 80% of the physicians will operate clinics.

If on the average each of these clinics performs female sterilizations and abortions as follows:

Year After Training	Sterilizations		Abortions	
	No. per Week (50 Weeks)	Total for Year	No. per Week (50 Weeks)	Total for Year
1	15	750	15-50	750-2,500
2	28	1,400	25-50	1,550-2,500
3	40	2,000	35-60	1,750-3,000
4	40	2,000	35-60	1,750-3,000
5	40	2,000	35-60	1,750-3,000
		<u>8,150</u>		<u>7,550-14,000</u>

Five years is taken as the limit to charge to this project because that will be about the life of the equipment supplied.

The 1,100 clinics will perform about 9.2 million sterilizations and from 8.3 to 16 million abortions. For a ten year program in which all clinics are established and have a minimum of 5 years' experience, an estimated 14 million sterilizations could be performed and abortions could fall between 13 and 23 million. At the end of eight years all clinics would be established and operating at an optimum capacity. At this point the yearly sterilizations they could collectively do would be about 2 million and abortions could range from 2-3 million each year.

If the sterilizations are performed on women about 35 who have had 4 or more children each sterilization will prevent 1.7 births. If the sterilizations are done on younger women after only two or three children each sterilization will prevent 3.5 births. If the abortions are not used to back up other contraceptives and abortion alone is used for birth control each abortion is conservatively estimated to prevent 0.3 births. If it is used as a back-up for contraceptive failure each abortion is estimated to prevent 1.0 birth.

With these assumptions the following estimates of total births prevented by this program are obtained:

	From	To
By Sterilization	23,800,000	49,000,000
By Abortion	<u>3,900,000</u>	23,000,000
Totals	700,000	72,000,000

This program is estimated to cost a total of \$15,700,000 for training the doctors and equipping the 1,100 clinics. The cost borne by this project would therefore fall somewhere between 21 and 56 cents per pregnancy prevented. It should be emphasized that this is by no means all the cost of preventing these births--but only the physician training and equipment components. Even if these estimates of births averted are too generous by 50% we would still have a cost of only 42 cents to \$1.12 per birth averted. This is a high degree of cost effectiveness.

Pert Plan - Major Tasks
Advanced Technology Fertility Clinics

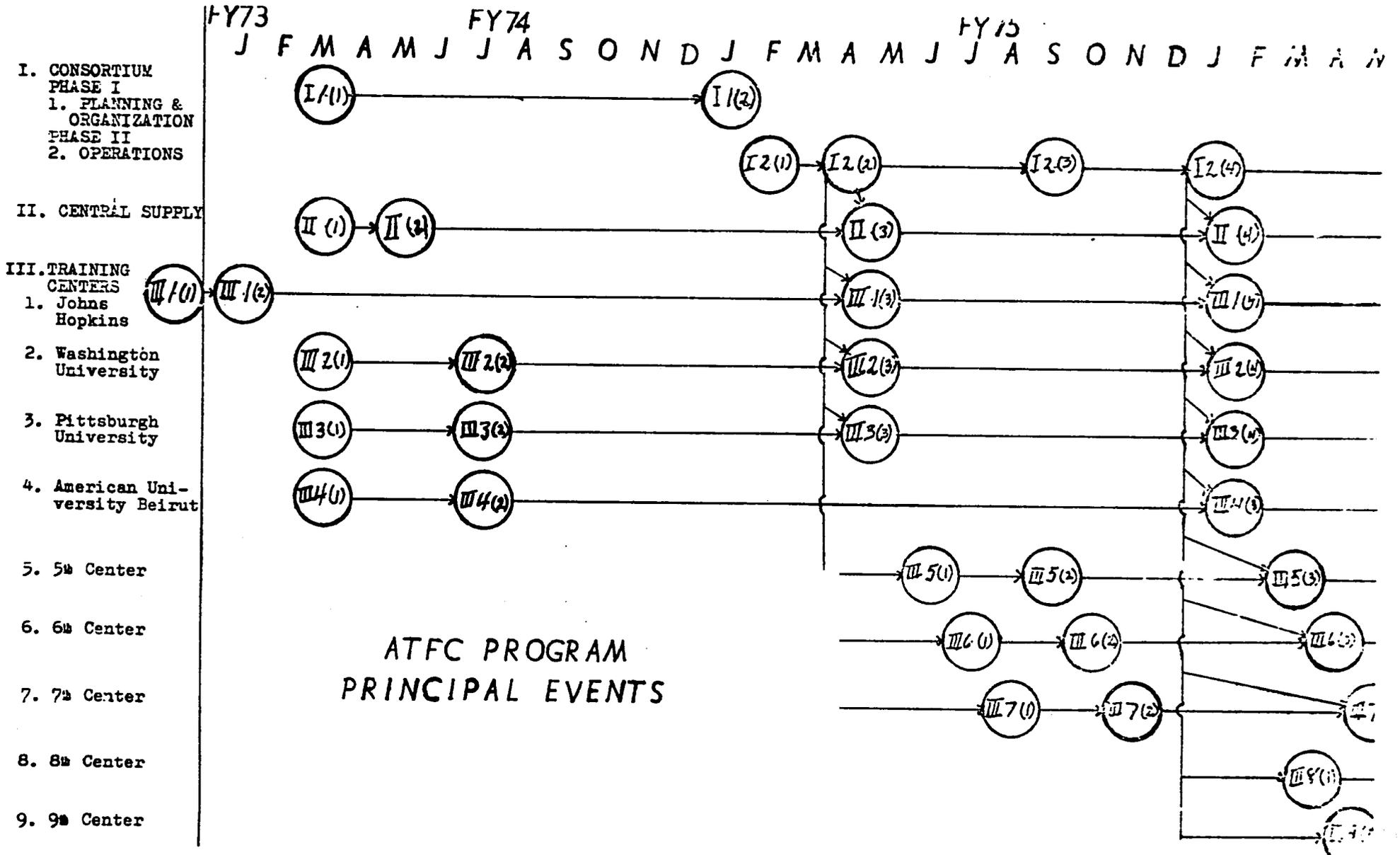
Note: Months marked at top of Principal Events Chart provides the time frame.

<u>Event</u>	<u>Description</u>	<u>Responsible Agent</u>	<u>Time Months</u>
I 1 (1)	Grant to supply support staff to organize ICMI.	POP/MI	1
I 1 (1) to (2)	Action to organize Consortium.	Grantee	10
I 1 (2)	Consortium Agreement and AID Contract with Consortium signed. Phase I completed.		
I 2 (1)	Consortium Staff organized and ready to begin work.	ICMI	1-2
I 2 (2)	Consortium assumes responsibility for Central Supply (II) and training Centers (III). Provides FY 74 funds by sub-contract to II or III.	ICMI	A,M,J
I 2 (3)	FY 75 Funds transferred to Consortium	AID	
I 2 (3)-(4)	FY 75 Funds supplied to II and III by subcontract. Centers 5, 6, and 7 started. Evaluation begun to determine if program will extend beyond 5 years.	ICMI	5
I 2 (5)	FY 76 funds available to Consortium. Decision made to continue or terminate program.	AID	A,S
I 2 (6)	FY 76 funds supplied to II and III.	ICMI	O,N,D
I 2 (7)	FY 77 funds available to Consortium if program continued. Close out plans put into effect if program discontinued.	AID	
I 2 (8)	FY 77 funds supplied to II and III if program is continued.	ICMI	
I 2 (9)	Termination or Phase-out of Consortium if program is discontinued.	ICMI	

<u>Event</u>	<u>Description</u>	<u>Responsible Agent</u>	<u>Time Months</u>
II (1)	Contract for procurement, warehousing distributing and keeping records on equipment. Funding for two years.	AID	M,A,M
II (2)	Central Supply begins functioning.		M,J
II (2)-(3)	Operates to meet program equipment needs.		10-11
II (3)	Central Supply comes under Consortium. Receives FY 74 funding if required.	ICMI	
II (4)	Receives FY 75 funding from Consortium.	ICMI	
II (5)	Receives FY 76 funding from Consortium.	ICMI	
II (6)	Receives FY 77 funding from Consortium if program is continued.	ICMI	
II (7)	Phase-out if program is not continued.		
III 1 (1)	Training program for LDC physicians funded as Project VI under Contract AID/csd-3627 with Johns Hopkins Dept. OB/CYII. June 1972. Funded for 3 years. This is pilot Training Center.		
III 1 (2)	First class accepted Nov. 1972.		
III 1 (2) - (3)	Training Center operates under Contract AID/csd-3627 reporting directly to POP.		15-17
III 1 (3)	Hopkins Center comes under supervision of Consortium. FY 74 money added to fund FY 76 activity.		
III 1 (4)	FY 75 money added to fund FY 77 activity.	ICMI	
III 1 (5)	Decision made whether individual Training Center will be discontinued even if program is continued.	ICMI	
III 1 (6)	Termination of Training Center if Program is discontinued.	Hopkins	

<u>Event</u>	<u>Description</u>	<u>Responsible Agent</u>	<u>Time Months</u>
III 2 (1)	Contract signed with Washington U. St. Louis AID to start 2nd Center. Three year funding FY 73, 74 & 75.		Mr. AP or My
III 2 (1) - (2)	Start up time		2-4
III 2 (2)	Receives first trainees.		
III 2 (3)	Center comes under supervision of Consortium. FY 74 money added to fund FY 76.	ICMI	
III 2 (4)	FY 75 money added to fund 77.	ICMI	
III 2 (5)	Termination of training if program discontinued.	Wash. U.	
III 3 (1)	Contract signed with Pittsburgh U. and Western Penn. Hospital. Three year funding FY 73, 74, 75.	AID	Ma Ap or My
III 3 (1) - (2)	Start-up time		2-4
III 3 (2)	Receives first trainees.	Pitt U.	
III 3 (3)	Center comes under supervision of Consortium, FY 74 money added to fund FY 76 activity.	ICMI	
III 3 (4)	FY 75 money added to fund FY 77 activity.	ICMI	
III 3 (5)	Termination of training if program discontinued.	Pitt. U.	
III 4 (1)	Contract signed with American University Beirut, three year funding FY 73, 74 and 75.	AID	Mr., Ap, My
III 4 (2)	First trainees received.	AUB	
III 4 (3)	FY 75 money added to fund FY 76 and FY 77		
III 4 (4)	Termination of training if program discontinued.		

<u>Event</u>	<u>Description</u>	<u>Responsible Agent</u>	<u>Time Months</u>
III 5 (1)	5th Center established by the Consortium Three year funding.		
III 5 (2)	First trainees received.		
III 5 (3)	Additional funding through Consortium.		
III 5 (4)	Termination of training if program discontinued.		
III 6 (1)	6th Center established by the Consortium. Three year funding.		
III 6 (2)	First trainees received.		
III 6 (3)	Additional funding through Consortium.		
III 6 (4)	Termination of training if program dis- continued.		
III 7 (1)	7th Center established by the Consortium. Three year funding.		
III 7 (2)	First trainees received.		
III 7 (3)	Additional funding through Consortium.		
III 7 (4)	Termination of training if program dis- continued.		
III 8 (1)	8th Center established by Consortium. Two year funding.		
III 8 (2)	Termination of training if program dis- continued.		
III 9 (1)	9th Center established by Consortium. Two year funding.		
III 9 (2)	Termination of training if program dis- continued.		



PROJECT DESIGN SUMMARY
LOGICAL FRAMEWORK

Life of Project:
From FY 73 to FY 77
Total U. S. Funding \$15,000,000
Date Prepared: 10/1/72

Project Title & Number: Advanced Technology Fertility Clinics (ATFC's)

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NARRATIVE SUMMARY	OBJECTIVELY VERIFIABLE INDICATORS	MEANS OF VERIFICATION	IMPORTANT ASSUMPTIONS
<p>Program or Sector Goal: The broader objective to which this project contributes: Is to establish many hundred clinics where the most technologically advanced and comprehensive services for fertility management are provided.</p>	<p>Measures of Goal Achievement: Many hundred such clinics are in operation. Effectiveness will be measured by the decline in births using rates that are most appropriate and feasible to use in each country.</p>	<p>Enumeration of the clinics. Study of the vital rates that are applicable.</p>	<p>Assumptions for achieving goal targets: a. In many LDC's demand for fert. control sufficient for sig. effect in reducing birth rates if advanced & powerful means are made extensively available b. Attitudes towards sterilization and abortion are sufficiently liberalized to allow diffusion these fertility mgmt. techniques. In many places this liberalization is likely to accelerate.</p>
<p>Project Purpose: a. Increase the number of LDC Ob/Gyn specialists and other surgically qualified physicians, in public & private sectors, qualified to deliver most advanced and comprehensive fertility management services. b. Provide a program of clinician training and clinic development. c. Institutionalize the teaching of advanced technology in the management of fertility in LDC schools of medicine, & other centers, so it becomes available in undergrad, specialty and continuing education.</p>	<p>Conditions that will indicate purpose has been achieved: End of project status. a. About 1,500 physicians will have been trained and about 1,100 ATFC's will be functioning using sophisticated rapid, outpatient, procedures for the diagnosis, prevention or termination of pregnancy. b. ATFM is being taught in undergrad., specialty and continuing programs of medical colleges and other training centers engaged in the education of medical personnel in the LDC's.</p>	<p>Records of the training centers where they will have been trained. Survey of medical schools and other training centers.</p>	<p>Assumptions for achieving purpose: a. Number ATFM's exist which make powerful contribution to FP if wisely used. b. Many physicians and clinics not using ATFM's. Provision training & equipment acceptable, will result in sharp increase to lowering birth rates. c. Nature of technologies such that they will spread and generate addition demand. d. Research & field experience will develop these and similar techniques to become significant part long-term practice reproductive Evnecoloogy.</p>
<p>Outputs: a. Trained personnel qualified to run Advanced Technology Fertility Clinics. b. Training programs for teaching Advanced Technology Fertility Management in many LDC medical schools and other training centers.</p>	<p>Magnitude of Outputs: About 1,500 physicians directly trained and a much larger number trained by those who are directly trained by this program. b. A considerable number of LDC medical schools and other training centers will have incorporated ATFM into their regular teaching programs.</p>	<p>Records of the training centers and survey of trainees to determine how many physicians and assistant personnel they have trained. Survey of medical schools and other training centers that have been assisted by this program.</p>	<p>Assumptions for achieving outputs: a. Present state of the art has all components for ATFC's so feasible organize program. b. Key element is qualified physicians, assisting and auxiliary personnel. c. Personnel can be rapidly produced in special, short, intensive training courses. d. Equipment can be supplied and maintained at favorable levels of cost effectiveness. e. Many med. schools and other centers beyond those directly establish in this program will introduce ATFM as a result of this program.</p>
<p>Inputs: 1. Inter. Con. Med. Insts. (ICMI). a. Work order and budget to organize ICMI b. Professional leadership; policy; staff; budget and fiscal mgmt.; supervision central supply; selection, oversight, financing, of training centers. 2. Training center inputs: Staff, facilities, training programs, follow-up technical assistance, evaluation system. 3. Central supply: Staff, procurement, warehousing & dist. equipment and supplies, AID-Inputs. 4. Funding, monitoring ICMI, evaluation.</p>	<p>Implementation Target (Type and Quantity) 1. Consortium organized and Operating by March 1974. 2. Training Centers: 4 started FY 73, 1 in FY 74, 2 in FY 75, 2 in FY 76. 3. Central Supply: established FY 73. Trainees graduated: FY 73 40 74 170 75 350 76 410 77 450</p>	<p>Operating records and site visits. Evaluation reports.</p>	<p>Assumptions for providing inputs: a. Program needs centralize management. b. Feasible to organize an ICMI to provide. c. ICMI will be superior to a U.S. Econ. by involving the receiving countries in planning, goal setting & evaluation. d. At least 10 institutions have needed assistance to develop training centers. e. Not only donor training centers attracted to support the ICMI. f. AID and other money will continue draw a large number of people and institutions in C/LDC into this project.</p>