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AN EVALUATION OF
THE INTERNATIONAL FERTILITY
RESEARCH PROGRAM

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EDITOR'S NOTE

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EXECUTIVE SUMMARY

The International Fertility Research Program (IFRP) was established on July 1, 1971. Its stated primary goals are to conduct comparative field trials of new fertility regulation methods in developing countries, to disseminate the information generated during these trials, and to improve the research capabilities of developing countries. To carry out its mandate, the IFRP developed an international network of more than 250 collaborating investigators who work in more than 30 countries. It also established standard methods for gathering and reporting clinical data; documented the short-term safety and effectiveness of a number of fertility regulation methods; and determined the relative appropriateness of the different methods and procedures for people living in a variety of cultural and medical environments.

In September 1977, following a Research Advisory Committee (RAC) review and a RAC subcommittee site visit, the IFRP made a number of changes in both staffing and administrative procedures. Many of these changes were in line with recommendations proffered by the RAC. As new IFRP interests developed, support for a wider range of objectives was sought and eventually secured, in 1977, in the form of an Agency for International Development (AID) grant.

In September 1980, the American Public Health Association (APHA) recruited an evaluation team to review the IFRP and its activities. Various documents containing background information were provided to the members of the team. From September 29 until October 1, 1980, the team visited the IFRP offices in Research Triangle, North Carolina. Individual and group interviews were held with members of the various divisions, and additional staff interviews were conducted later in New York. The team also talked with members of the Board of Directors and the Technical Advisory Committee (TAC).

The team compared staffing plans and the organization chart with the proposed future program to determine whether or not the size, composition, relationships, and constellation of talents and backgrounds of the staff were relevant and adequate.

Following extensive review and deliberation, the team concluded that the IFRP was continuing to make progress in dealing with the recommendations of the RAC subcommittee and AID. In addition to continuing its earlier work in evaluating fertility regulation methods, the IFRP developed new areas of interest using grant funds. The team particularly supports further testing of postpartum intrauterine devices (IUDs), studies on female sterilization, and mid- to long-term safety studies of contraceptives and surveillance for serious adverse effects. It regards favorably the plans for developing new data processing systems and appropriate software for use in the developing world, as well as in-country short-term training to design research and to use processing systems. The team also feels that many of the IFRP's recent

moves in new directions (exemplified by the RAMOS approach) hold promise for the future.

The team's general impression is that the IFRP has made a considerable number of improvements since the 1977 RAC review, but it believes, too, that organization, staffing, and research can be strengthened further. Therefore, it offers a series of recommendations to improve these areas. The team believes that by making these changes the IFRP will be able to continue to grow and develop, and to maintain and strengthen its contributions to the field of population.

ABBREVIATIONS

APHA	American Public Health Association
DMPA	Depot Medroxyprogesterone Acetate
FRP	Fertility Research Program
HHS	Health and Human Services
IFFH	International Federation for Family Health
IFRP	International Fertility Research Program
IJGO	International Journal of Gynecology and Obstetrics
IUD	Intrauterine Device
MAC	Medical Advisory Committee
MCH	Maternal Child Health
MR	Menstrual Regulation
NICHD	National Institute of Child Health and Development
NIH	National Institutes of Health
RAC	Research Advisory Committee
RAMOS	Reproductive Age Mortality Survey
TAC	Technical Advisory Committee
TSS	Toxic-Shock Syndrome
UNC	University of North Carolina
USAID	United States Agency for International Development

I. TEAM GOALS, OBJECTIVES, AND PROCEDURES

Evaluation of Earlier Program

The International Fertility Research Program (IFRP) was established on July 1, 1971. Its stated primary goal is to conduct comparative field trials of new fertility control methods, especially in developing countries. To better understand the current activities of the IFRP and to make appropriate and constructive recommendations for the future, the evaluation team first reviewed the original IFRP grant. Additional information was obtained when the team visited North Carolina.

Evaluation of Current Program

At the request of the Agency for International Development (AID), an evaluation team from the American Public Health Association (APHA) visited the headquarters of the IFRP at Research Triangle, North Carolina. During the review (September 29 - October 1, 1980), the three-member team was joined by Drs. Duff Gillespie and James Shelton, of DS/POP/R. The findings presented in this report are exclusively those of the APHA evaluation team. They are based on discussions and observations at the IFRP and at Columbia University, where five sessions were held subsequently. The evaluation team focused on three general areas: contract activities, grant activities, and the IFRP's organizational structure.

A. Contract Activities

1. What is the scope of IFRP contract activities?
2. What has been accomplished? What activities are being planned?
3. Do these activities comply with AID's intentions and needs to provide contract funds for fertility regulation research?

B. Grant Activities

1. What is the scope of IFRP activities under the grant?
2. What has been accomplished?

3. What future activities are being planned?
4. Is the IFRP in compliance with the needs and the intentions of AID to provide grant funds for programmatic research and support activities?

C. Organizational Structure

1. Is the administrative structure of the IFRP conducive to the proper management of both contract- and grant-supported activities?
2. Is the IFRP's institutional role in stimulating research projects, disseminating research findings, and transferring research technology being developed and performed adequately and effectively?

Evaluation of Proposed Future Program

During its site visit and at subsequent meetings in New York City, the team considered the IFRP's ambitious future program. The draft document, "Scientific Directions 1980-1981," was especially useful. It outlines the extensive range of current scientific activities of the Research Division and the International Projects Division and lists the IFRP's priorities for the immediate future.

The team assessed staffing plans and the organizational chart in relation to the proposed program to determine the appropriateness and adequacy of the size, composition, relationships, and constellation of talents and backgrounds and to assess the prospects for success. In addition, the team reviewed the amount and distribution of the IFRP's proposed future funding.

Evaluation Procedures

The members of the evaluation team received numerous documents that contain background information. These included annual contract and grant reports for 1978, 1979, and 1980; the current IFRP table of organization; project descriptions; the forms and procedure for research; and a publications list.

After reading this material, the team made a site visit to the IFRP, arriving on the evening of September 28, 1980. For the next three days the team, and Drs. Shelton and Gillespie, met with IFRP staff. Staff working in the Office of the Executive Director and in the divisions of International Projects, Administration and Support Services, and Research, were interviewed. Initially, members of the various divisions met as a group for the interviews. Later, the team requested individual meetings with staff to discuss in depth their particular areas of interest.

During the site visit, the need to talk with certain key staff members who were out of the country at the time became apparent. Therefore, on October 27, 1980, three additional staff interviews were held at Columbia University in New York City. The team also talked with members of the Board of Directors and the Technical Advisory Committee (TAC) to obtain their views on the current status and future plans of the IFRP. Additional documents, including more detailed financial information, minutes of Board meetings, and copies of trip reports, were requested and reviewed.

The team consulted frequently by telephone and met again on November 12, 21, and 24, and on December 4, to discuss other activities and to work on the final report. Despite the considerable differences in their academic backgrounds and work experiences, the team reached unanimous agreement on all the major issues it reviewed and presents in this report.

II. GOALS AND OBJECTIVES OF THE IFRP

Original Goals

When the IFRP was established nearly ten years ago, its primary goal was to determine the short-term safety and efficacy of various methods of fertility regulation in developing countries. To accomplish this goal, it conducted a large number of clinical trials, using both straight and comparative studies. In the process, it established a widespread network of research collaborators and contributors throughout the developing world.

A second goal of the IFRP is to improve the research capabilities of IFRP investigators in developing countries and, through them, the quality of the institutions in which they work. The IFRP is committed to the dissemination of its investigators' findings. Research is made known at meetings and conferences and in publications.

Current Goals and Objectives

As the interests and activities of the organization developed and evolved, support for a wider range of objectives was sought and secured. The principal mechanism of support is the AID grant, the first of which was awarded in September 1977, and subsequently extended for four years. After reviewing the IFRP program as a whole, the evaluation team concluded that the organization's primary objectives at this time are (1) to provide direction, assistance, and support for biomedical and social science research in fertility regulation, primarily in developing countries; (2) to encourage, support, and develop the research capabilities of its counterparts in developing countries to follow IFRP research protocols and to design research protocols appropriate to their own countries and regions; (3) to evaluate fertility regulation methods and the systems used to deliver them to shorten the time between the development and actual introduction of such methods into family planning programs; (4) to develop procedures for data collection and analysis that can be transferred with the necessary technology to developing countries; (5) to conduct training and to organize meetings to support specific research projects or to facilitate the acceptance of particular research findings; and (6) to aid in the dissemination of research findings relevant to program and policy development at both the national and international levels.

Future Goals and Objectives

By building on its past experiences and on the skills of its staff, the IFRP plans to continue as well as expand a number of its projects. Training

and the transfer of technology will continue to be emphasized. Technological transfer involves (1) shortening the time between evaluation and the introduction of new methods of fertility regulation into national programs; (2) training investigators in research design (epidemiology) and biostatistics; and (3) continuing a vigorous information dissemination program. To these ends, the IFRP intends to organize data processing systems and appropriate software in key fertility research programs (FRPs) in the developing world. In-country, short-term training for FRP staff in research design and the use of data processing systems is contemplated also. The IFRP's ultimate aims are to make the FRPs independent and to provide more opportunities for developing and testing indigenous hypotheses.

A new area of emphasis will be mid- and long-term safety studies of contraceptives and surveillance to identify serious adverse effects. Less emphasis will be placed on open-ended data collection; more emphasis will be placed on carefully designed clinical trials or other types of studies for which the number of subjects is specified at the outset after the likely statistical requirements are considered. Research findings must be translated into programmatic activity. Information can be disseminated through "Network," the quarterly newsletter.

There are plans to examine and probably reorder the composition and role of the Technical Advisory Committee so that it can better serve the present and future needs of the IFRP. The Board of Directors has already been expanded, and it will be enlarged further. The recruitment of new individuals with a suitable constellation of skills and familiarity with the developing world will be emphasized especially.

It is clear that the IFRP will become more involved in Africa as a region and that increased involvement will offer considerable opportunity to develop relevant research studies and fertility control programs. As is stated in "Scientific Directions 1980-1981," a major effort will be made to assign relative priority to and establish schedules for the completion of activities. It is recognized, however, that certain projects may move more slowly or more quickly than anticipated.

III. A REVIEW OF THE EARLIER PROGRAM

Initial Mandate

In 1971, in accordance with the terms of its contract, the IFRP was charged with developing a substantial set of short-term data on new major technologies and procedures for fertility regulation by performing straight and comparative field trials, primarily in developing countries.

Program Results

To carry out this mandate, the IFRP developed an international network of more than 250 collaborating investigators working in more than 30 countries, most of which are in the developing world. This group of investigators conducted trials in six major areas: systemic contraception, including oral preparations; intrauterine contraception; menstrual regulation; pregnancy termination; male sterilization; and female sterilization.

The IFRP established standard methods for gathering and reporting clinical data and gradually amassed a considerable volume of information. As a result, it was able to document the short-term safety and effectiveness and certain major and minor side effects of several fertility regulation methods now in use. In addition, it was able to determine the relative appropriateness of the different methods and procedures for patients who live in a variety of cultural and medical environments.

Research Advisory Committee Evaluation

The IFRP's renewal proposal was reviewed by members of AID's Research Advisory Committee (RAC) in March 1977. At that time, a number of issues were raised by the various members of the RAC, and funding was not approved, pending further study. On September 6-7, 1977, at the request of AID, a RAC subcommittee visited the IFRP. This subcommittee made repeated inquiries about the validity and reliability of the methods for collecting and analyzing data and for testing hypotheses. It concluded that, although the data were satisfactory in both regards, the information was not subjected to more than rudimentary analysis. In considering the utility of continued efforts to collect additional, similar data, the subcommittee concluded that, when the required number of cases is reached and the necessary amount of data is obtained, further enrollment of study cases should be stopped.

The subcommittee also reviewed a second proposal which would have expanded the IFRP's functions to include an analysis of alternative community-based delivery systems. After careful consideration of this proposal, the

subcommittee concluded that such an undertaking would take the IFRP away from its original and unique role in research on family planning technology and move it into the broad fields of program administration and implementation. The subcommittee felt that this move would require procedures and skills quite different from those which the IFRP has developed and it therefore recommended that this step not be taken.

A third area of proposed activity is program evaluation. IFRP staff have designed evaluation procedures based on surveys of clients, staff, and volunteers in its programs. In the view of the RAC subcommittee, the IFRP's capability to conduct such research is extremely limited; personnel trained in management analysis and organization theories are not represented on the staff at all. The subcommittee therefore concluded that the IFRP offers no special comparative advantage in program evaluation. It recommended that the IFRP not expand into this area until specific research proposals are approved by the RAC or by AID.

The subcommittee noted that none of the senior staff has training and experience in basic research in reproductive biology and biomedical statistics. It further noted that the Board of Directors and the Medical Advisory Committee (MAC) comprise a mix of staff members and outside consultants. Many of the latter are AID-funded. Moreover, neither group includes senior members of the two disciplines mentioned above. The subcommittee therefore concluded that the appointment of individuals with these specific skills might well be considered in future planning.

At the conclusion of its site visit, the RAC subcommittee made a number of recommendations, including those that follow:

- The IFRP should set a ceiling on the number of participating centers, the amount of data to be generated, and the duration of data collection for each study. It should terminate those studies when sufficient data have been gathered.
- The IFRP should devote less effort to but be more selective in maintaining a repository of data for future use. It should develop more complex study designs and use more sophisticated analytical techniques in processing existing data.
- The IFRP should continue to place its greatest emphasis on Phase III research and on studies of the clinical services needed to implement the various fertility regulation techniques.
- The IFRP should not attempt to cover the much broader administrative components (i.e., community and social

aspects) of family planning program development and operation, except in pilot projects, and then only after review and approval by AID.

- The IFRP should reassess its staffing pattern and the makeup of its consultative groups to ensure that the future needs of the program will be met.
- Similarly, the IFRP should reassess its overall structure and its internal administrative mechanisms to be sure that they are designed to produce the desired results with the least possible expenditure of time and effort.
- The amount of IFRP funding should be reduced from that requested in the February 1977 proposal in accordance with the above contractions of the scope of work, which more strictly limits activities to the primary goal of "pure research."
- In the future, only the research components of the IFRP (to be undertaken with AID funding) should be reviewed by the RAC for approval before they are implemented.

Redirection of Program

Following receipt of the report of the RAC subcommittee and after further consultation with AID staff, the IFRP made a number of changes in both staffing and administrative procedures. Its steps were in accordance with the RAC's recommendations. A number of the research elements of the program were selected and a new contract was written to cover these areas. The IFRP also applied for and received funds under a new grant. With these funds the IFRP will be able to undertake other programmatic activities.

IV. A REVIEW OF THE CURRENT PROGRAM

Structure

In 1977, separate funding mechanisms--a contract and a grant--were established to rationalize and reflect changing IFRP activities. Under the contract, funds are provided to support the continuation of biomedical research in fertility regulation, the primary mandate of IFRP since its inception, and of research in the social sciences. Under the grant, a considerably broader range of activities is funded, including institutional development of fertility research and programmatic support for family planning services. The structure of the IFRP largely mirrors the distinct operational mandates of these separate funding mechanisms.

The administrative organization of the IFRP is shown in Appendix A. It consists of the Office of the Executive Director and Administration and Support Services. It appears that the Research Division is the principal mechanism for implementing contract activities and that the International Division is the principal mechanism for conducting activities under the grant. Both divisions follow similar operational procedures; that is, they award subcontracts and subgrants to fund specific activities. Task forces in specific subject areas provide substructures for developing particular research projects in which staff from all divisions participate.

The two divisions' purposes and practices overlap considerably. For example, research activities often are funded with subgrants conducted with the assistance of the Research Division. Similarly, subcontract activities often involve elements of institutional development to ensure that research protocols are followed properly.

Depending on the leadership that is provided and the individual personalities who are involved, interactions between the two divisions may be either harmonious or fractious. Given the existing structure, the separate divisions may either complement or conflict with each other.

The IFRP's relationship to its international network of contributors is another structural element of the organization. Although relations with FRPs in specific countries are largely a product of the people and protocols involved, the aim at this time is to relate the FRPs directly to the International Division. However, staff from the Research Division are more often directly involved in a particular FRP project.

The International Federation for Family Health (IFFH) was developed recently to meet certain internal administrative needs. It functions as a coordinating body for the FRPs and is funded under a subgrant from the International Division. It is now a separate structure within the IFRP, but there are plans to move it to Indonesia, where it will be under the direction of contributors involved in FRPs in developing countries.

An additional element that overlaps all structural boundaries within the IFRP's organization is the division between biomedical and social science researchers. At this time, there is no established mechanism to effectively alleviate the stresses and strains which this situation creates.

Staff

As a result of the RAC review, the IFRP took the recommended step of reorganizing and reducing its staff. The team is concerned about the recent high turnover rate. A review of IFRP statistics reveals that this rate was close to 25 percent during the period August 1979 through July 1980. Many of those who left the organization occupied high-level positions. For example, in 1979-1980, 16 positions at grades 5 and above were left vacant; only eight persons have been hired to fill these vacancies. There has been a noticeable shift to personnel in lower-level positions. Staff are being recruited for several high-level positions. At this writing, the position of deputy director has been filled by an individual with developmental experience and broad management skills.

There are other vacancies in high-level positions in the International Projects and Research Divisions. It is possible that one position for a scientist will be filled soon by a qualified epidemiologist. Other vacant positions appear to have gone unfilled for too long. This is most conspicuous in the International Projects Division, where the objective is to hire senior program associates and station them in their respective regions.

The IFRP has standing and ad hoc task forces made up of key staff members who meet to develop and conduct various kinds of research. These groups cross over the divisions.

Projects

Since its founding, the IFRP has changed the type of work it does. Certain changes were made following review by the RAC and revision of the program. Many more changes were made after the new grant was awarded.

In accordance with the RAC's recommendations, the number of clinical centers was reduced, and the amount of data which they report was also reduced. The centers are required now to report only the data needed for continued analysis. Attempts were made to improve the quality of the data being sent to the IFRP, and the methods of statistical evaluation were changed to encompass more sophisticated techniques.

With the award of the grant, increasing emphasis was placed on social science research. Also, the groundwork was laid for additional expansion in

this area in a number of countries. Although some Phase III studies will be continued, it is envisioned that a higher percentage of Phase IV studies will be undertaken in the future.

A. Maternity Care Record

To date, medical information has been collected on 300,000 deliveries and incomplete abortion cases in hospitals and other delivery settings in 40 countries around the world. The IFRP began to monitor obstetric events first in large institutions, but it has extended its monitoring to rural institutions that are supervised by medical auxiliaries (e.g., nurses and midwives). Information is collected once and recorded on one-page forms (short and long).

In many instances, the implementing institution uses the form as a basic medical record. The form is said to provide a programmatic entree, especially in African countries, where there is special concern for maternal and child health (MCH) and less, though increasing, interest in family planning services. In addition to its use as a research tool, the record can be a training tool to prepare staff in developing countries to conduct more sophisticated studies.

Beyond querying inconsistencies in forms received in North Carolina, the IFRP has not been able to check routinely the source of basic information. Such checks are impossible to make if the forms are the basic medical record or if deep rural or urban slum-dwelling women cannot be located again for a repeat interview.

The number of maternity care forms that are processed has declined in recent years. In 1979-1980, less than 10,000 forms were processed by the IFRP.

B. Prevalence Studies

On several occasions, the IFRP has responded to requests for assistance in developing and conducting prevalence studies in the developing world. Many of these studies have been concerned with measuring contraceptive prevalence in particular areas, but some have been concerned with other fertility-related factors. For example, the IFRP provided financial and technical support for contraceptive prevalence surveys in Brazil and to gather longitudinal service statistics in Tunisia and Morocco to facilitate the evaluation of household or community-based family planning distribution projects in those countries. The IFRP also provided assistance to conduct a prevalence survey of female circumcision throughout the Sudan. More recently,

an IFRP subgrant was awarded to conduct a prevalence survey of breastfeeding and contraceptive practices in Lagos, Nigeria.

C. Reproductive Age Mortality Survey

Successful clinical trials of particular contraceptive modalities should logically be followed by studies of the long-term effects of the same modalities on the same populations. The IFRP has conducted many of the clinical trials but has only recently taken an interest in conducting studies of long-term effects. Moreover, although several studies of long-term effects have been undertaken in developed nations, few have been made in the developing world. The IFRP has conceptualized a research design--the Reproductive Age Mortality Survey (RAMOS)--to try to redress this shortcoming in research.

RAMOS combines several research strategies in a single design. A surveillance system is put in place in a specific region to recover all deaths of women of reproductive age over a fixed period of time. Subsequently, reproductive and contraceptive histories and the symptoms of the final illness are compiled retrospectively from interviews with surviving relatives and from collections of relevant data from other available sources. An effort is made to determine the cause of death by submitting information on an individual's complex of symptoms to appropriate medical authorities. The analysis of this information is blind, as far as possible, to contraceptive use.

In data analysis, the prevalence of particular causes of mortality or symptomatic syndromes is compared with particular patterns of contraceptive usage or non-usage. The objective is to develop odds-ratios of occurrences of reproductive age mortality in terms of contraceptive histories. RAMOS is at a preliminary stage of implementation in Egypt, and is being prepared for implementation in Bali, and is being considered as an appropriate strategy for use in Sri Lanka.

D. Fertility Regulation Methods

1. Hormonal Methods

The IFRP is developing several studies of women who have taken depot medroxyprogesterone acetate (DMPA) over long periods of time. One study in Indonesia will attempt to locate 1,100 women who began using DMPA one to six years ago. Endometrial biopsies and other clinical investigations are planned. Women seeking sterilization who have never used a hormonal method of contraception will comprise a comparison group. A similar

study is planned in Thailand. The underlying objectives of these studies are to collect information on the subjective and objective side effects of an injectable contraceptive; to determine why women discontinue using DPMA; and to determine whether there is any association between the use of DPMA and endometrial changes, and whether there are any adverse health effects. A third study, now under consideration in Atlanta, Georgia, will seek to identify serious adverse outcomes in preparation for a case-control study.

Clinical trials of oral contraceptives continue. Among them are trials to assess symptoms following a change from high- to low-dose estrogen-combined pills; to compare the symptoms associated with the use of high- and low-dose estrogen-combined oral contraceptives, regardless of the dosage of estrogen; and to compare symptoms among users of various low-dose estrogen-combined oral contraceptives where only the amount of progesterone varies. The designs for these studies vary, but all follow a randomized, controlled format. There is a crossover in the first type of trial. A study to assess the role of vitamins in alleviating, or possibly preventing, early side effects reported by pill-takers is underway.

The effects of progesterone-only oral contraceptives on lactating women and their infants are being studied. The comparison group will be lactating women who use non-hormonal methods.

During the team's site visit, there was a discussion of the IFRP's interest in a case-control study of the association between congenital anomalies and hormonal contraceptives. A site is being sought in the developing world for this study.

2. Intrauterine Devices

At its April 1978 review of the IFRP, a member of the RAC commented that 34 studies on IUDs were underway, that many were studies of single devices, and that more studies were planned. The RAC felt that the number of studies was too large and that more studies should be devoted to the collection of comparative data. The current program appears to be responding to this concern.

One of the current IUD programs involves the study of the suture loop as a postpartum device. The expulsion rate for this device seems to be extremely low: for the first 341 insertions reported in April 1979, the rate was 5.3 percent at six months. Recruitment of patients and data analysis are continuing.

Preliminary data on a new device, the Nylon T, show a pregnancy rate of 2.2 ± 1.5 and a continuation rate of 93.7 at 12 months. The use of the Delta Loop immediately after delivery also looks promising. Further work on these devices is planned.

3. Barrier Methods

The IFRP has conducted research on barrier methods that has included studies of the collatex sponge and Neo-Sampon foaming tablets. Because interest in this area is increasing, the organization is drafting plans for several future projects.

4. Sterilization

Analysis is partially complete on a large sample of women in developing countries who were monitored following their sterilization. Because many types of sterilization procedures are represented, the data are expected to yield information on the relative risks of intrauterine pregnancy, ectopic pregnancy, and other serious adverse effects.

The IFRP recently subcontracted with Kaiser-Permanente (in California) to study a large number of vasectomized men for subsequent illness and disease. A non-vasectomized control population will be identified for comparison.

The IFRP has sponsored or will initiate a series of small trials, with short-term follow-up, to investigate new techniques of female and male sterilization. Among these are:

- An evaluation of the laprocator, using standard laparoscopic procedures as opposed to open laparoscopy. Follow-up will extend to one month after the procedure.
- An evaluation of the spring-loaded clip and the KL-1 tubal ring delivered by minilaparotomy. Performance and short-term safety and effectiveness will be evaluated. Follow-up will extend to 24 months following sterilization.
- An evaluation of the laprocator, using a procedure known as suprapubic endoscopy. Discomfort with and without the use of topical anesthesia will be assessed. Follow-up will extend to one month after the procedure.
- Several studies to determine the usefulness of quinacrine for non-surgical sterilization. These include:
 - * studies of monkeys to identify fetal malformations and maternal toxicity;

- * insertions of quinacrine-carrying IUDs in women who are planning to have a hysterectomy, with a detailed examination of uterine tissue to assess the degree of tubal occlusion and possible adverse effects; and
- * uterine insertion of quinacrine pellets to establish early safety and effectiveness.
- * a small trial to test the acceptability, safety, and effectiveness of percutaneous vas injection with a formaldehyde-ethanol solution. Follow-up will be extended to 24 months.

5. Abortion

Considerable work has been done by the IFRP on the study of induced abortion. Menstrual regulation (MR) and vacuum aspiration procedures have been thoroughly investigated by the IFRP and others. No further refinement of these procedures is believed to be necessary.

6. Other Methods

During the evaluators' site visit, there was discussion about monitoring a study of natural family planning, possibly in the Philippines. In this study, the quality of cervical mucus as a guide to ovulation and for identifying "unsafe" days would be evaluated.

7. Pregnancy Testing

The IFRP is committed to helping to bring into use effective, but less expensive, pregnancy tests. To date, interest has been focused on the Lau electrical method. An evaluation in the United States and Chile has shown that this method has no more advantages than disadvantages.

Information Dissemination

One important activity of the IFRP is the dissemination of information and the distribution of scientific publications, especially among IFRP col-

laborators in developing countries. The IFRP maintains a small library which is under the direction of a professional librarian. It also publishes the International Journal of Gynecology and Obstetrics (IJGO). This journal offers IFRP collaborators additional opportunities to publish their data, often with the help of IFRP staff. In the near future, the responsibility for publication of the IJGO will be shifted outside, to Elsevier, a major European publisher of biomedical journals of international interest.

To provide information on IFRP activities and developments, a quarterly newsletter entitled "Network" is published and distributed. In addition, IFRP staff members, often in conjunction with IFRP contributors, regularly publish articles on their fertility research in appropriate scientific journals.

Another component of the program of information dissemination is scientific meetings to present important findings on IFRP research and programmatic evaluations. Among the presenters are investigators from the developing world and IFRP staff.

The IFRP sponsors, often in concert with other U.S. or international organizations, small meetings to discuss fertility control. Special sessions are sometimes organized at larger meetings to discuss topics of interest. For example, a conference was held recently in Mexico to discuss the status, problems, and opportunities for family planning services in poor urban areas of developing countries. Smaller meetings for health professionals from Africa are being planned, as is a conference in Brazil on IUDs.

Board of Directors

Since the last review, three new members have been added to the Board. These new members bring additional expertise to the group.

The current major functions of the Board are:

- To make policy decisions on finances and programs.
- To hire and fire the executive director.
- To evaluate staff.
- To raise funds and establish relationships with current and prospective donors.

The Board now meets four times a year, but the number of meetings may be reduced to three.

Technical Advisory Committee

The Technical Advisory Committee is the mechanism for the periodic, outside expert reviews of fertility research proposals and IFRP activities. The TAC consists primarily of physicians with experience in international fertility research. Two social scientists also sit on the committee, providing some balance. The committee meets annually to discuss and prepare a general overview of the research activities of the organization.

Financial Considerations

When the IFRP was first established, it received virtually all its financial support from AID. Today, it receives its funding from several sources. These are:

<u>Sources of Funding</u>	<u>Percent</u>
Contract (AID)	55.1
Grant (AID)	36.2
NIH	4.7
Private Funds	2.6
Other Contract Research	<u>1.4</u>
	100.0%

The summary budget for 1981 is shown in Appendix B. The AID/pha-C-1172 budgets for 1977-1981 are shown in Appendix C.

V. OBSERVATIONS AND CONCLUSIONS

Structure

The IFRP is funded by AID under two mechanisms, a contract and a grant. The original intent behind this division of funding, which followed the RAC review, was to house all research projects under the contract and all other IFRP activities under the grant. In the opinion of the team, this seemed to be a reasonable and practical solution to the problems raised by the RAC subcommittee, but it has been both advantageous and disadvantageous to the overall IFRP program.

At this time, projects funded under the contract are almost entirely research projects. However, a number of studies supported by grant monies are also research projects, but they are not reviewed by the RAC. In addition, the IFRP conducts a number of small projects which one might best term "program introductions."

The primary advantages of the approach are mobility and speed of funding, which are of considerable importance in areas such as program introduction, where speed is essential. The primary disadvantage of two sources of funds is that staff seem to lose sight of their personal identities and of where they belong. While the work of certain individuals falls clearly into one division, that of others does not; this creates considerable tension among the latter group.

The team believes that the new organization may compound the disadvantages of the two funding sources. The International Division is at this time supported primarily by the grant. It is responsible for coordinating and administering most Research Division projects, regardless of whether they are funded under the grant or the contract. Many of these projects are, however, supported by the contract, over which the International Division has no control. Even after the several staff vacancies are filled (preferably with people who understand both biomedical and social science research), this is likely to remain a continuing source of conflict. The team believes that, given the anomalous organization of the Executive Director's Office, senior-level scientists will not be used to maximum benefit. The team is especially concerned that the director of field epidemiology and the medical director are not well integrated into the overall program of the IFRP.

Another continuing source of tension is the IFFH. The exact role and function of this group vis-a-vis the IFRP are unclear. This situation does not benefit the staff in North Carolina, and it appears to be even more detrimental to the international contributors who, it is reported, do not know to whom they owe their primary allegiance. This uncertainty appears to be

decreasing their effectiveness. The reorganization of this group of international contributors, under their own direction in a semi-autonomous structure, may be expected to open up new sources of multi- and bilateral funding and to provide another forum for sharing ideas and findings.

The team feels that the proposed move of the IFFH secretariat to Indonesia is appropriate and should be made soon to relieve existing tensions and uncertainties. The research ties between the IFRP and the FRPs, however, must be maintained and strengthened. This will be to both groups' advantage, and it will benefit those in this field of research. To support the relocated IFFH secretariat, the IFRP should offer the full range of its expert services. It is crucial that the IFFH leadership be in the hands of people who truly represent the interests of the FRPs and the IFRP.

The IFRP's task forces are intended to concentrate scientific expertise on specific subject areas and to operate across divisional and disciplinary lines. Although they were not explicitly appointed to help weld together the divisions of the organization, they could be reorganized for this purpose. The selection of these groups should reflect consideration of the need to unite disparate factions behind common research goals.

Although individual staff have academic connections with certain local institutions, the IFRP has no strong programmatic ties to any of the universities in the area. The team believes that the development of such links would be mutually beneficial. As an example, the universities could be of help in recruiting or identifying candidates for staff positions.

Focus

The principal focus of IFRP contract activities is the development of protocols and funding proposals and the provision of technical support for biomedical research on particular modalities. The contract provides both the mechanism and the mandate for continued efforts in this direction. The evaluation team is not convinced, however, that sufficient effort has been made to go beyond the short-term clinical trials which have been the predominant research interest of the IFRP since its inception. The need for field and clinical studies of the long-term impact of fertility regulation techniques in developing countries is urgent. Though some efforts are underway, the IFRP should further shift the focus of its contract activities to undertake more studies of this type.

An agency like the IFRP, which has contacts throughout the world, needs not only an agenda that specifies what it wants to accomplish in the area of contraceptive research, but also the capability to respond to needs, as they arise, in the countries in which it is working. The grant enables the IFRP to respond to the various countries' needs through institution-building,

training, provision of support for particular types of service-oriented studies, and occasionally provision of required supplies. The grant gives the IFRP the flexibility it needs to expand its efforts to include new types of studies (e.g., long-term field studies) and to move into new regions, primarily Africa.

Africa offers to the IFRP numerous opportunities to provide assistance in fertility research and to build research capabilities. The grant gives the IFRP sufficient flexibility to respond to diverse needs in Africa, and current IFRP-supported activities in the Sudan, Tunisia, Morocco, and Egypt will provide a solid base for further expansion. Several additional projects being planned in Mali, Tunisia, and Egypt will further enhance this capability. As it continues to expand its network of collaborators and as the IFRP staff acquire more experience in the region, the IFRP can be expected to play an important role in developing fertility policies and programs in Africa. However, these efforts will be handicapped until a strong candidate for the position of African regional coordinator is identified and recruited.

Sometimes, grant activities must necessarily deviate significantly from contract efforts, but their focus should be contract-supported work. It is imperative that studies be made of the long-term safety and effectiveness of fertility regulation methods, and it also is crucial that the grant be used to develop and support the network that can conduct such studies. It would be a mistake to use the flexibility built into the grant as a mandate for pursuing new objectives. Using this flexibility to provide and promote support for the new directions in which contract activities must move will enhance the IFRP's ability to conduct fertility research in the developing world.

To avoid the temptation of trying to be all things to all people, an assessment of IFRP activities and the needs of the countries it is assisting is needed to determine whether outreach should be limited. The stimulation of programs in new countries is useful, but the IFRP appears to be spreading itself fairly thin. With a document similar to "Scientific Directions 1980-1981" but focusing on countries rather than research projects, the IFRP might be able to identify countries where there is likely to be adequate backstopping from a local FRP or where the FRP itself clearly has sufficient resources to follow through on a project.

Staff

Recent changes in staffing, particularly the shift to lower-level positions, were described in a preceding chapter. The high turnover and the shift to lower-level positions may have been inevitable, given the recent changes in structure (see Appendix A), but the net effect, in the team's

judgment, has been the IFRP's impaired ability to attain fully its research and development objectives. Major gaps exist in biomedical staffing. Staff without training in biomedical research are not likely to represent well the needs of such research in the field. It is urgent that existing vacancies be filled soon.

In the rich local context in which it operates, the IFRP appears now to be far too isolated from those who could help ensure the success of its ambitious and varied research program. The IFRP should hire immediately persons to augment the biomedical staff. These persons should be employed under fixed contractual arrangements. Among them might be personnel from local institutions. With the addition of these staff, the IFRP's ability to recruit able people to fill several vacancies would be improved. The presence on the TAC of scientists from neighboring institutions also might help the IFRP to reestablish links with the academic organizations.

In response to the perceived need for improved administrative leadership, a new position--Deputy Director--has been created and filled. The new deputy director has a background in business and administration in agencies in the developing world. His credentials seem to be appropriate, given the IFRP's current needs.

Projects

A. Maternity Care record

With its focus on maternal care and as a method of entree to other research, the Maternal Care Record has been useful; however, it has been disappointing as a research tool. Although limited surveillance of serious hazards associated with pregnancy and delivery is possible, the catchment area of the institution is often ill-defined and the population that is covered in that area may not be representative. It is thus difficult to make meaningful generalizations using only these records; nevertheless, such generalizations are being made. There is serious doubt about the quality of the basic information in these records. Because the form is administered only once, much longitudinal information on morbidity and mortality of mothers and infants is lost.

It is time to consider longitudinal follow-ups of a limited number of cases in a favorable setting, and to stop replicating the existing form. Countries that continue to favor the basic, one-time form should be able to process it without further assistance. Processing should not be the IFRP's responsibility.

B. Prevalence Studies

At the request of particular countries, the IFRP has participated in several prevalence surveys. The purpose of these surveys has been to evaluate the services of particular family planning projects. The IFRP should not give such studies high priority. Other agencies are more experienced in and committed to this type of research.

During these surveys, contraceptive use and service delivery from the user's perspective are explored, and the surveys sometimes provide valuable information for those responsible for decisions about both national and international policies and programs. The Lagos survey, for example, may document contemporary changes in West African society that may in turn facilitate changes in family planning policy and program acceptance in areas beyond Nigeria. The social survey approach should be applied during studies of the long-term effects of contraceptive use. This method would link the social and biomedical components of the IFRP and constitute a more worthwhile approach to prevalence studies.

The team recognizes that the IFRP sometimes becomes involved in research activities which appear to be tangential to its main research interests. These projects sometimes prove to be of considerable value, but they should be scrutinized carefully before they are undertaken.

C. RAMOS

RAMOS, an interesting and innovative effort to provide information about the long-term risks and benefits of contraceptive use in the developing world, signifies the IFRP's initial interest in studies that go beyond short-term clinical trials. Several factors that are crucial to the success of this effort should be emphasized. Just as experts from many relevant fields were invited to the IFRP in June of 1979 to participate in the initial formulation of the research design, so experts outside the IFRP should be asked to contribute regularly and systematically to RAMOS as it develops and unfolds. Similarly, efforts must be made to ensure that RAMOS continues to benefit from the research experiences and skills of the IFRP staff. A permanent committee similar to the IFRP task forces could be appointed to ensure that IFRP staff from all disciplines contribute to RAMOS.

Although the combination of research strategies comprising RAMOS is commendable, the approach does not use to full advantage the data and insights derived from anthropological research. Anthropologists with experience in the selected study areas in the field should be contracted as consultants to the project. In addition, the IFRP should seriously consider funding community-level field studies on the qualitative aspects of reproductive age mortality

and contraceptive use in selected areas. The results would prove to be highly interesting and supplement the largely quantitative findings that RAMOS now provides.

RAMOS should be recognized as only one of several approaches to the study of the long-term effects of contraceptive use in developing countries. In some areas, appropriate data sets may already exist for conducting longitudinal studies of mortality among women of reproductive age. In other areas, modern medical data systems may be sufficiently complete to permit a case-control study. Regardless of the particular strategies used, the IFRP has the flexibility and capability to mobilize funds and staff for such studies, and it could assume a leading role in investigations of the long-term results of contraceptive use in the developing world.

D. Fertility Regulation Methods

1. Hormonal Methods

In the opinion of the team, the designs for two of the proposed DMPA studies need to be reviewed. Studies on the side effects and discontinuation of DMPA are available in Thailand. The data on similar studies in Indonesia may not be reliable. Neither the proposed risk of pathological endometrial changes nor the statistical rationale for the proposed number of study subjects is clear. Because pre-malignant and malignant endometrial changes are rare among DMPA users, a study of the proposed size would reveal only large, relative risks, if, in fact, such risks do exist. Because smaller risks would not be detected, there is a strong possibility that the suggested study would be falsely reassuring. A case-control design might be far more efficient and also more instructive to local principal investigators than the proposed series of endometrial biopsies. The third study in Atlanta seems to be better founded.

The current and proposed clinical trials of oral contraceptives and the study of the effects of progesterone-only pills on lactating women are important and should continue, but only if the management of their complex designs can be monitored adequately by current IFRP personnel.

Given the considerable evidence that the use of oral contraceptives, even during early pregnancy, is not associated with congenital anomalies, the team feels that the case-control study proposed by the IFRP should be given low priority. The management of differential recall is a formidable source of bias in such investigations and must be considered in the design. If such a study is strongly desired by a contributor, it might be justified as a learning experience in the intricacies of epidemiological design.

2. Intrauterine Devices

A number of IUD studies are underway or are being planned for the future. The most important of these is probably the evaluation of two postpartum devices, the sutured LLD and the sutured Cu-T. The performance of these devices will be compared with the performance of their non-sutured counterparts. The time of insertion will vary from 10 minutes to more than 36 hours and less than 6 weeks. Hand and inserter techniques will also be studied in the postpartum period. The use of sutured LLD immediately after a mid-trimester abortion also will be evaluated.

This program appears to be moving slowly. In the original protocol, it was estimated that 11,000-12,000 cases were recruited after approximately two years of work. This relatively small number of cases suggests that, despite statements to the contrary, the project has not been accorded high priority.

A preliminary study of a T device wrapped with 200 square millimeters of nylon has shown a pregnancy rate of 2.2 and a continuation rate of 94 percent at the end of one year. This device will be compared with the T Cu-200 to determine whether copper IUDs are effective because of the copper or because the surface area is increased.

The original data look promising, but this project does not separate out the possible side effects of nylon per se. A polyethylene strand .25 millimeters in diameter (the copper T provides 200 square millimeters of surface area) should be wound onto the basic polyethylene T device, and all three devices should then be compared.

There is considerable concern about the role that the monofilament tails in IUDs may play in inducing upper genital tract infections. To assess this situation, Copper T-200 LB devices with and without tails will be inserted, and the rates of pelvic infection will be observed. The outcome of this study, which should be made promptly using standard definitions of upper tract infection, is most important.

It has been found that the placement of copper on a silver core will prevent the copper wire from fragmenting as the copper dissolves. The result, it is thought, is a copper device effective for 16 years. A study to compare the T Cu-380 Ag with the Multiload Copper 250 or the Cu-7 is planned.

Since blood loss is a problem with most IUDs, trasylol or tranexamic acid will be added to a modified Lippes Loop D to determine whether the 90-day release of these agents will decrease the amount of blood loss, and the results will be compared to those for controls wearing non-medicated devices. This study will provide valuable information. However, the expectations for data on quantitative blood loss (440 patients in 6-8 centers, with at least 4 determinations per patient) may be unrealistic. To obtain

such data, it will be necessary to enlist the aid of highly motivated physicians in private practice. The projected loss to follow-up--15 percent at the end of the first year in most of the projects--seems to be quite low.

The team believes that these are important studies which should be done. It is hoped that they will be given sufficient administrative and staffing priorities, and that careful attention will be given to their design, to ensure that they are carried out promptly and effectively and monitored continuously.

3. Barrier Methods

The IFRP is considering several methods of female barrier contraception for future study. The safety, effectiveness, and accessibility of these methods will be evaluated in these studies. The IFRP plans to conduct Phase II clinical trials of custom-made cervical caps, if National Institutes of Health (NIH) funding becomes available. Phase III trials of the collatex vaginal sponge and a comparative study of C-film and Neo-Sampoon are planned also. Spermicides and other barrier methods will be evaluated in straight and comparative studies. The effectiveness of these methods in reducing the rate of venereal infection will be determined as well. An evaluation of the suggested protective effect of barrier methods against carcinoma of the cervix and its precursor is recommended.

The team believes that these studies are important and that they fall clearly under the IFRP's primary mandate. Because of the recent identification of toxic shock syndrome (TSS), however, these protocols must be carefully reevaluated; long-term methods such as the cervical cap may have to be altered or discontinued.

To date, the IFRP has not been involved in studies of condoms. However, because of current political pressure to develop efficacy data on all contraceptive methods, the organization may initiate studies on this method.

4. Sterilization

The IFRP's data series on tubal ligation in the developing world may be unique. The data on the safety of surgical sterilization in the mid-term will be published soon. Unfortunately, the effort to follow up this cohort of women has been largely passive and uncoordinated. The decrease in the number of women followed may seriously compromise the findings. Although it is far from clear that better follow-up is possible, more rigorous attention needs to be given to maintaining the histories of these women as a reporting cohort well beyond the two years following surgery.

As newer sterilization procedures emerge, the cohort may need to be enlarged.

The team recognizes the value of the IFRP/Kaiser-Permanente study of long-term complications of vasectomy, but no comparative study is being made in the developing world. Closed male populations, which may be suitable for a retrospective longitudinal study of the longer-term complications of vasectomy, exist in some Asian countries and should be evaluated.

Existing data suggest that use of intrauterine quinacrine solution for female sterilization will not be successful. If the quinacrine pellet studies do not soon show greater signs of success, the team thinks that the IFRP should consider abandoning the approach. Another mode of delivery is the quinacrine-loaded IUD, which is now being developed and evaluated. If it proves to be feasible, this approach may enjoy widespread use.

The other sterilization studies that have been mentioned seem to be useful, although the percutaneous vasectomy trial of a formaldehyde-ethanol solution should be evaluated carefully in studies of acceptability and short-term safety.

5. Abortion

It has long been believed that the development of a self-administered technique for early abortion would have a major impact on population growth. Prostaglandin vaginal suppositories have been found to be useful, but they have an unacceptable level of side effects. Some of the new prostaglandin analogs (PGE₂) appear to be promising and will be evaluated by the IFRP.

Before a fetus can be aborted, the cervix must be dilated. The IFRP has early data on a new osmotic dilator which appears to be effective and may well replace the use of laminaria. It seems likely that this method of dilation may reduce the risk of later reproductive problems. Studies to determine such long-term risk should be considered by the IFRP.

The IFRP plans to continue its analyses of post-abortion contraceptive services. Various approaches will be taken, and the need, use, and effectiveness of such services will be evaluated. The team believes that these studies are important and should be pursued.

6. Other Methods

The team does not feel that the proposed studies in fertility awareness offer much by way of acceptability and effectiveness in developing countries. It recommends, therefore, that they be given a low priority.

The use of traditional methods (e.g., withdrawal) may be worth investigating in certain settings.

7. Pregnancy Testing

The team supports the IFRP's commitment to identify effective, inexpensive pregnancy tests. When promising methods appear, staff resources should be made available for additional field-tests.

Technology Transfer and Training

The interest and commitment of IFRP staff in transferring computer capability to national fertility research programs in developing countries are commendable and timely. With the advent of minicomputers, the effective transfer of technology appears to be more likely. Not only will computers cost less; they also will be simpler to use and maintain. Efforts to support IFRP staff in upgrading their own skills and capabilities in this rapidly developing technology should be supported.

Effective technological transfer must be accompanied by commensurate efforts to transfer the skills required to use that technology. For example, considerable attention must be given to training FRP contributors in the technical and statistical skills required to use minicomputers effectively. In more general terms, suitable training must be provided for FRP staff. A short-term visit cannot be substituted for formal training. In many cases, the visitor may be more administratively than scientifically oriented. Much of the training will fall into one of two categories: research design (epidemiological) and biostatistical training for clinicians. The training can be short-term (say, two weeks), provided in-country and, in many cases, conducted, at least in part, in the trainees' native language.

Effective technological transfer and training are crucial to the long-term success of IFRP activities. The objective is not just to supply and maintain people who can contribute data for IFRP research protocols. The ultimate goal of the IFRP should be to support and train researchers who can actively collaborate with IFRP staff as equal partners in the development and operation of well designed and appropriate research projects.

Information Dissemination

The effective dissemination of information requires the use of different formats and distinct channels of communication. Publication of the

quarterly newsletter "Network" was viewed by the team as a necessary and welcome addition to IFRP efforts to disseminate information. The newsletter was judged to be good in substance and content. The attractive booklet on RAMOS is another indication that the IFRP has learned that not all matters of scientific interest need to be conveyed in scholarly publications.

Over the years, the IJGO has been a forum for IFRP contributors and collaborators who wish to publish their research findings. The responsibility for publishing this journal has been shifted to an outside agency. This will greatly alleviate the financial burden of managing the publication. In addition, the move may enable IFRP staff to devote more attention to editorial functions that will further enhance the journal's value.

IFRP staff, often jointly with IFRP contributors, publish scientific articles on a wide variety of subjects in a number of respected journals. In a recent year, staff published, either singly or jointly, 81 scientific articles. The papers ranged from biomedical reports on clinical trials to epidemiological investigations based on pooled IFRP data, from explanations and investigations of new contraceptive procedures to broad considerations of medical and social attitudes affecting the acceptance of contraceptives. The range and number of IFRP contributors to scientific journals are impressive. Although their quality varies, these publications are improving consistently.

It is clear that meetings can be useful, especially if they are regional or in-country meetings and if they are conducted, at least partially, in local languages. The team feels that such meetings should be short, limited to a small number of participants, and emphasize structured (and unstructured) discussion and the presentation of formal papers by local investigators. Where feasible, attendees should represent diverse biomedical and social science backgrounds. Population research tends to cross disciplinary boundaries and, among clinicians, for example, it is the province of internists and surgeons as well as gynecologists.

Board of Directors

The Board recognizes that its membership should represent other disciplinary skills. Consequently, it is seeking individuals from the academic community, especially in North Carolina. It has expressed also a desire for senior-level people from government agencies in developing countries.

In the past, the Board met four times a year to deal with fiscal problems and the recent administrative reorganization. Current plans call for only three meetings a year, now that the several audits have been completed and the financial situation is stable.

The Board has several continuing concerns, which are noted in discussions with Board members, in minutes of meetings, and in trip reports. The principal concerns are relationships among staff and the IFRP's relationships with its contributors.

Technical Advisory Committee

As presently constituted and used, the TAC does not sufficiently serve the IFRP's needs for systematic reviews of particular research proposals and projects. Because it meets only once a year, the TAC can provide only an overview of IFRP activities and general suggestions on current research. To make further use of their scientific and programmatic research skills, members of the TAC should be asked to review specific proposals more systematically. To do this, the committee may have to meet two or three times a year. Social scientists with broader international experience than is now represented should be appointed to the committee. Areas of special expertise should be given specific representation. Given the type of research which is of high priority to the IFRP, it would be advisable to appoint both an epidemiologist and an internist-endocrinologist to this review committee. It would also be desirable to include members of local academic institutions on the TAC.

To function more effectively, the TAC should be more concerned with reviewing specific projects than with providing a general overview of IFRP activities. The members should be consulted more often and routinely about the development of research proposals. The committee should convene more than once a year, and members should be requested to respond to research proposals by mail.

Financial Considerations

The IFRP has been successful in increasing the percentage of funds for fieldwork. To continue this trend (a step which the team feels would be most appropriate), a strong field staff is needed.

The team is aware of and concurs with the Board's and staff's concern about unexpended funds in both the grant and the contract. The team believes that, by recruiting additional required staff, programmatic activity will increase, with the result that these and future funds will be expended.

The recent fiscal audits were completed successfully. The team believes that the new mechanism for reporting the amount of time spent on various projects will facilitate future internal and external audits.

VI. RECOMMENDATIONS

Structure

1. After careful review and considerable reflection, the team concluded that there are several areas where problems are impairing the IFRP's effectiveness. It therefore recommends that serious consideration be given to partial reorganization to solve certain of these problems. If an effort is made to restructure the organization, the team recommends that:
 - there be a clear division between the biomedical and social sciences;
 - care be taken that the particular source of funds (i.e., grant or contract) not prescribe organizational arrangements; and
 - an autonomous international coordinating unit, separate from but closely linking together the biomedical and social sciences divisions, be established. This unit should be placed directly under administrative control and have high-level staff in North Carolina and in the field.
2. The team recommends that attention be given to the design and function of the various task forces to ensure that all staff who can contribute to the accomplishment of the assigned tasks are involved, that disciplinary lines are bridged, and that the assigned members are seriously committed to their tasks.
3. The team recommends joint travel whenever feasible to promote collegial relations and to enhance the effectiveness of research projects in the field.
4. The team recommends that the IFFH secretariat be transferred as soon as possible to Indonesia, where it will be under the control of the principal investigators of the FRPs. Careful and sustained attention should be given to maintaining the link between the entire staff in North Carolina and the international contributors associated with the IFFH.

Focus

1. The team recommends that the IFRP put more emphasis on the development of studies of the long-term effects of fertility regulation methods now in use in the developing world. An emphasis on other than tests of new technology does not preclude additional comparative clinical field trials to determine the short-term risks of new contraceptives. It does require, however, that more attention be given to other types of epidemiological research designs.
2. Certain programmatic activities may not require further active replication (e.g., Maternity Record), and others (e.g., evaluation of research on routine family planning programs) might best be handled by other institutions. Though the team recognizes that these efforts may offer practical opportunities for institutional development, it recommends that the IFRP support fewer such activities in the future.

Staff

To provide a more adequate constellation of disciplines and capabilities for its program, the IFRP should take the following action:

A. Research Division

1. Recruit as soon as possible a senior scientist with broad biostatistical and epidemiological training. This individual need not be a physician, but (s)he should possess an adequate background in biology.
2. Recruit immediately a junior scientist with a firm background in research design and biostatistics. The addition of such a person will strengthen further the division's capabilities.
3. Appoint a scientist to be the permanent leader and eliminate the rotation system. This will ensure continuity and firmer direction.
4. Establish formal links with local universities, including the UNC-SPH, to ensure availability of skills crucial to the IFRP's research program.

B. International Projects Division

1. Given the existing structure, additional scientists, especially biomedical scientists with research experience, are needed to develop and monitor adequately IFRP field activities. With the addition of such individuals, who should be based overseas and in North Carolina, existing regional coordinators will become more effective.

C. General

1. The establishment of contractual links with consultants, including consultants from local institutions, should be explored to alleviate the IFRP's personnel shortages.
2. More attention should be given to collegial relationships within the IFRP. Retreats and sensitivity training could improve relations.

Projects

A. Maternity Care Record

1. The team feels that the Maternity Care Record should be designed and packaged for implementation by the interested countries themselves. Less technical assistance would be required of the IFRP if a simpler record were available. The IFRP should intensify its efforts in this area. The design and provision of follow-up procedures for a sample of maternity cases in several country settings where such longitudinal efforts are feasible are also highly recommended.

B. Prevalence Studies

1. The team recognizes the value of IFRP participation in studies of contraceptive use and in timely, interesting, and innovative efforts that result in the establishment of a population policy or programmatic changes in particular regions. Nevertheless, it recommends that these studies not be allowed to become a routine component of IFRP research and

that they not be emphasized to the exclusion of other kinds of research.

C. RAMOS

1. The team feels that RAMOS is well conceived and a promising vehicle for research. It should be recognized, however, that initial applications of this approach may reveal more about the usefulness of the methodology itself than about the substantive effects of long-term contraceptive usage. The team feels that smaller, more carefully monitored, limited efforts would be more appropriate and provide better information on the efficacy of RAMOS as a methodology.
2. The team recommends that efforts be made to maintain the spirit of interdisciplinary cooperation with which RAMOS was initiated. Mechanisms should be established to encourage the active participation of researchers from within and without the IFRP who have knowledge and experience that can be applied to this innovative approach.

D. Fertility Regulation Methods

1. The team recommends that the IFRP continue its current and planned clinical trials of new, low-dose estrogen oral contraceptives.
2. The team recommends that the IFRP reconsider the designs for two of the planned studies on the long-term effects of DMPA.
3. The team recommends that the IFRP mobilize its resources to study the relationship between hormonal contraceptives and carcinogenesis.
4. The team recommends more aggressive implementation of the current trial to evaluate intrauterine devices developed for insertion immediately after delivery.
5. The team shares the IFRP's conviction that barrier methods have been too long neglected, and it recommends that important issues other than efficacy (e.g., protection against venereal disease and cervical neoplasia) receive special attention.

6. The team recommends that the IFRP organize efforts to follow up and continue analyzing women who have been sterilized to supplement and enrich its unique data on this subject.
7. The team considers the long-term effects of vasectomy in the developing world to be a priority issue and recommends that the IFRP undertake an organized effort to research this topic.
8. The team commends the IFRP on its development of a new osmotic cervical dilator and recommends early clinical evaluation. If the trials are successful, longer-term comparative studies with laminaria and other methods of dilation will be necessary.

Technology Transfer and Training

1. The team believes that the IFRP's interest in providing minicomputers for FRPs and the necessary software packages and training is timely and worthwhile. It therefore recommends continued work in this area.
2. The team recommends that the IFRP conduct more short-term, formal training courses in settings in the developing world. The objective should be to provide more systematic and regular opportunities for actual and prospective contributors to improve their research skills.

Information Dissemination

1. The team commends the IFRP for making available quickly to its scientific audience the findings from its own studies and the studies of its contributors. It recommends that these efforts be continued.
2. The team finds "Network" to be an especially useful publication for presenting short, accurate summaries of scientific information. This publication might be more stimulating if principal investigators contributed articles and if issues were translated into key local languages and distributed more widely by the FRPs. The team recommends that these efforts be pursued.

Board of Directors

1. The team recommends appointing to the Board new members who have expertise in the biomedical sciences, social sciences, and program administration. A major effort should be made to recruit persons from the local academic community.
2. The team recommends that the Board continue its efforts to communicate with all IFRP staff in order to ensure the establishment of effective policy and control over fiscal matters.
3. The team recommends that the Board continue its fundraising efforts in order to diversify, insofar as possible, the IFRP's financial base.

Technical Advisory Committee

1. The team strongly recommends that all research proposals be subjected to thorough and rigorous review by a revitalized and reoriented TAC.

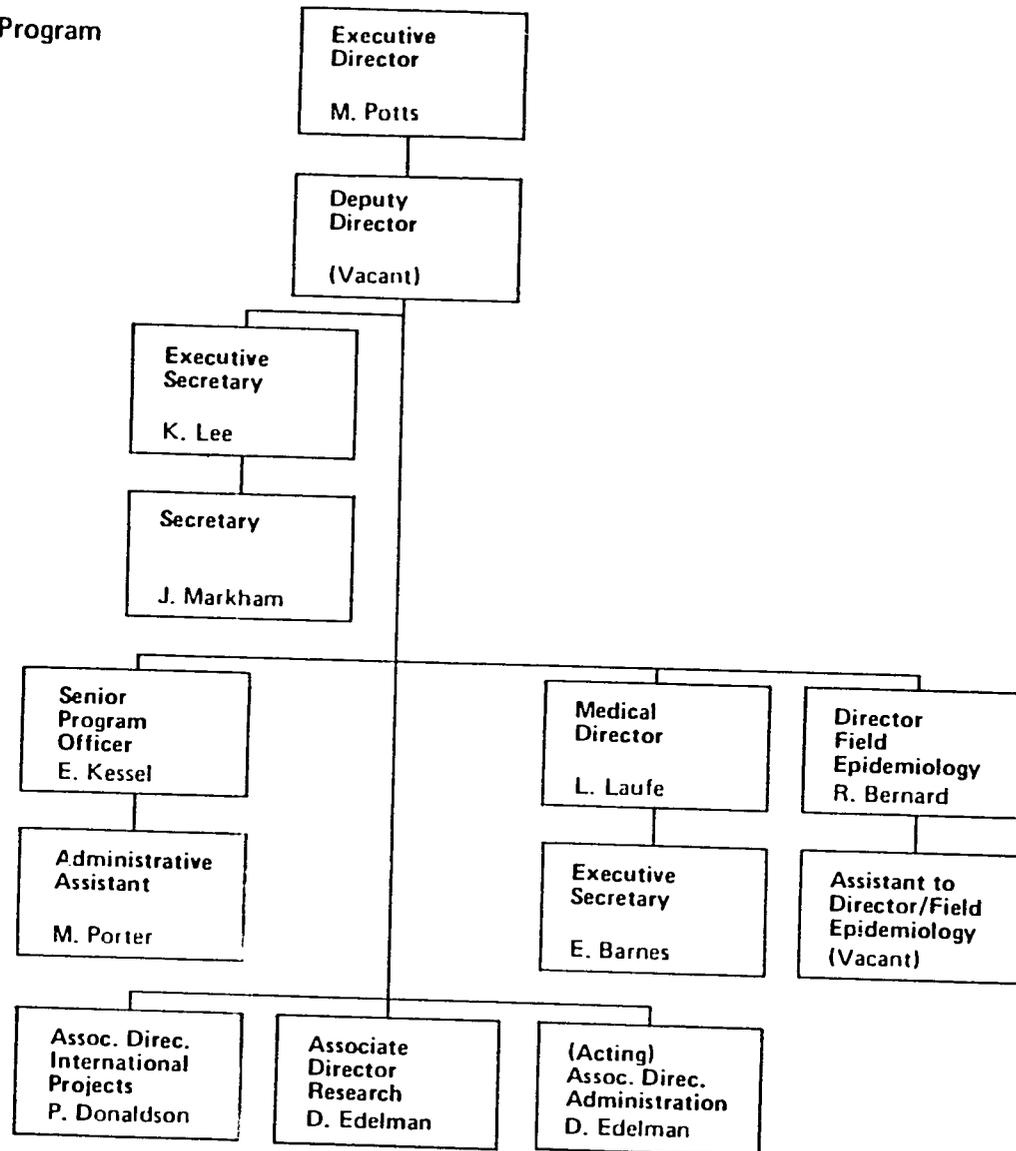
Financial Considerations

1. The team recommends that future funding be allocated to the IFRP after careful and thorough analysis of actual and proposed programs.
2. The team recommends that sufficient funds be made available to hire staff and consultants with competence in specific areas to meet the needs and objectives of the program.
3. The team recommends that more IFRP funds be allocated for training, and raising the level of competence of, IFRP staff and contributors in the field.

APPENDICES

Appendix A
ORGANIZATION OF THE IFRP

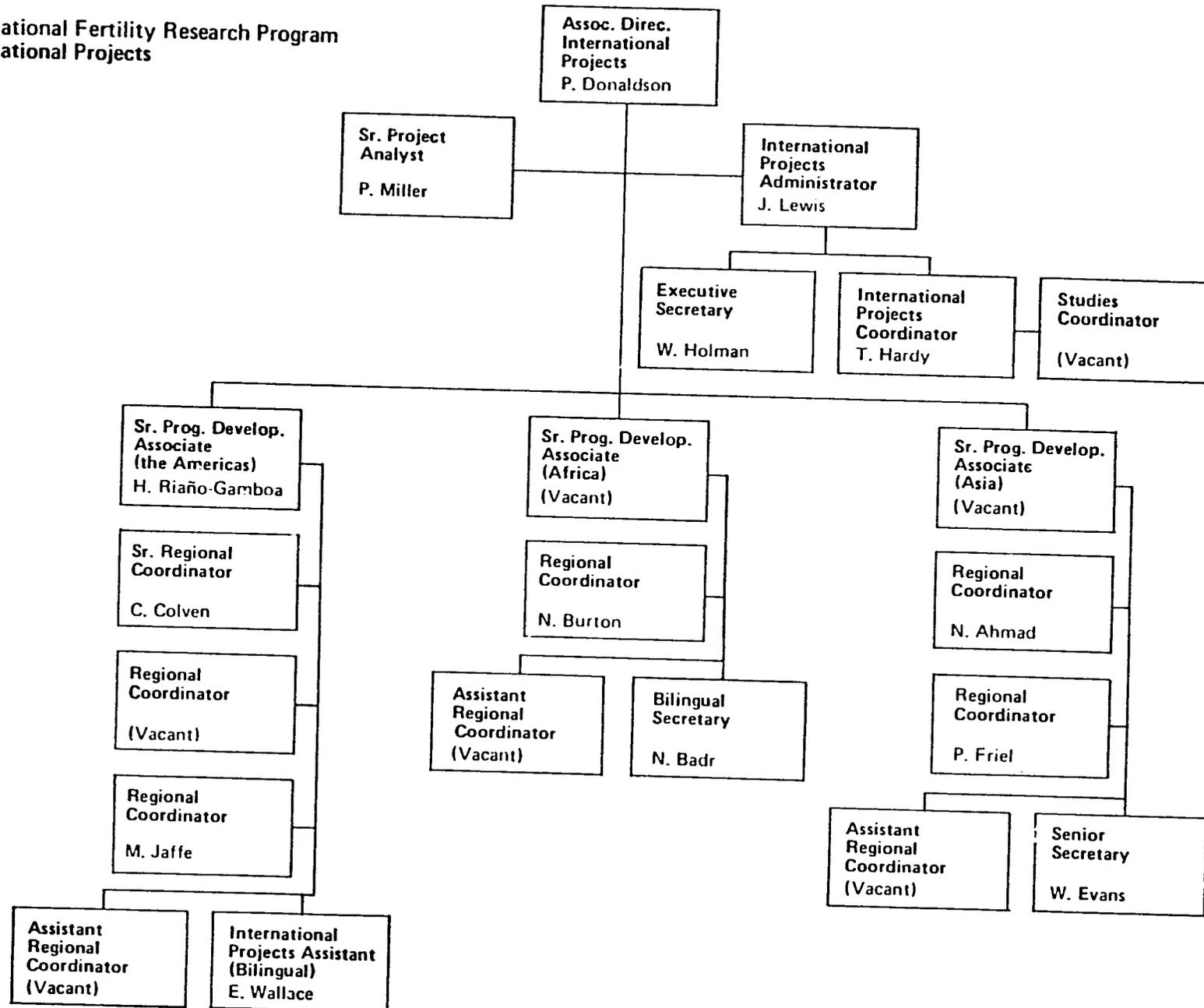
International Fertility Research Program
Office of Executive Director



T-1

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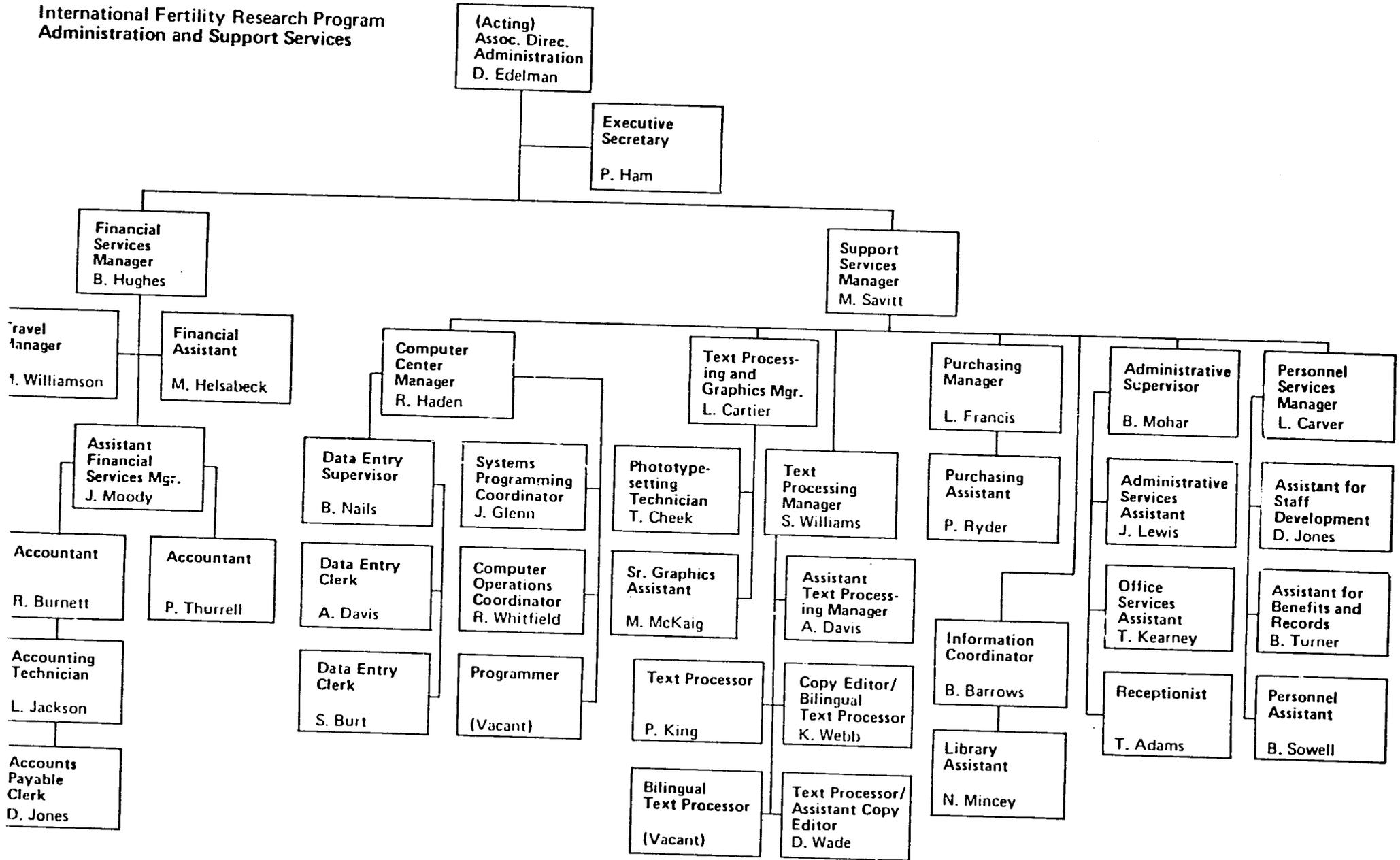
International Fertility Research Program
International Projects



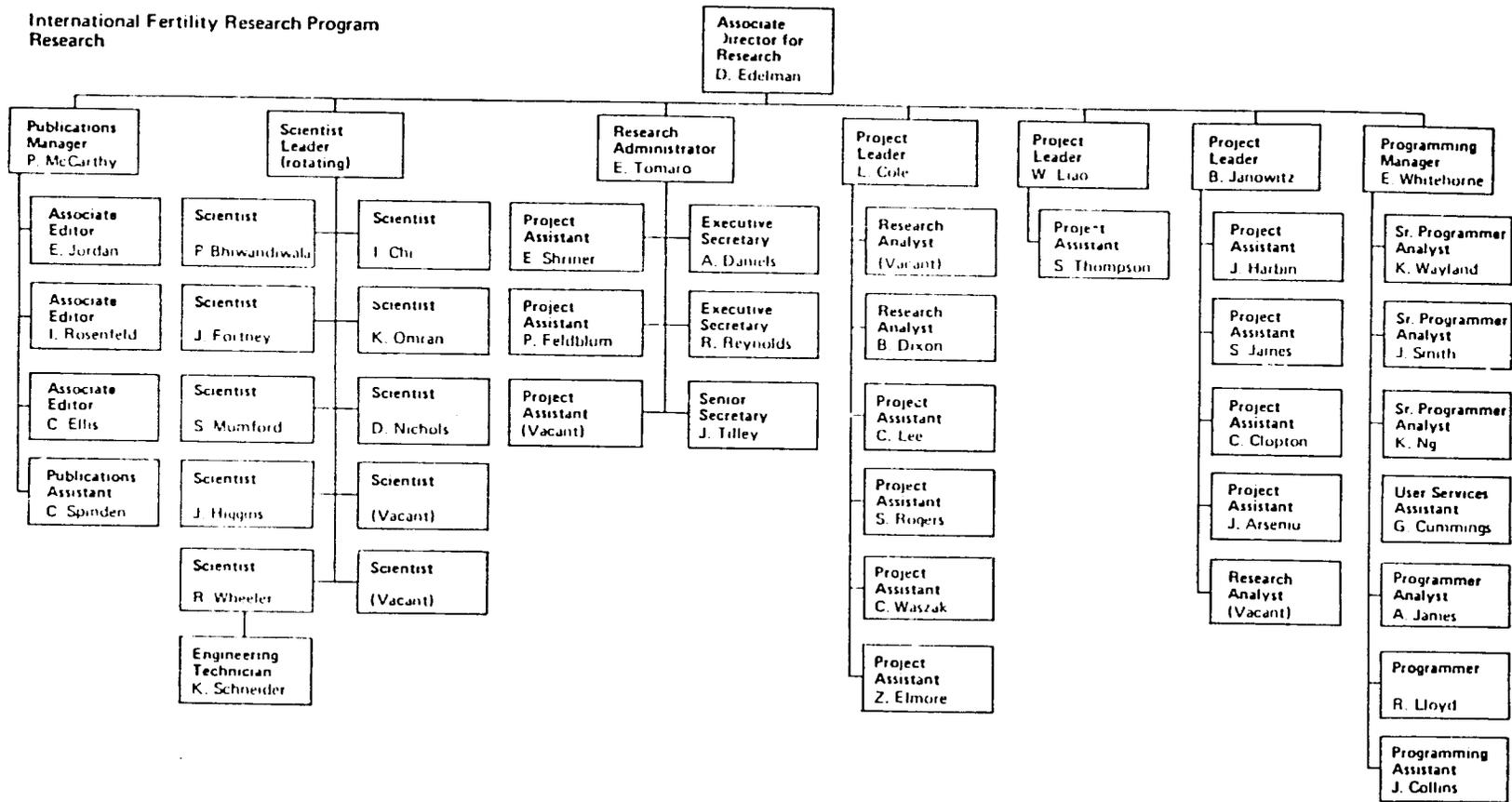
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International Fertility Research Program
Administration and Support Services



International Fertility Research Program
Research



A-4

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Appendix B
CORPORATE BUDGET SUMMARY
(Fiscal Year 1981)

INTERNATIONAL FERTILITY RESEARCH PROGRAM
CORPORATE BUDGET SUMMARY/FISCAL YEAR 1981

Description	Total	AID Contracts	AID Grant	NIH Contracts	Non-gov't Projects	Corporate Activities	Home Dept. Indirect	Service Centers	G & A
REVENUE									
Gov't Contract/Grant	\$6,497,201	\$3,743,406	\$2,455,821	\$297,974					
Non-gov't Projects	—								
Contributions	2,250					2,250			
Interest Income	17,200					17,200			
Unrelated Business	145,300					145,300			
Transfer (To) From	—				31,486	(31,486)			
Transfer Fixed Fee	—	(60,689)		(10,273)		70,962			
Total Revenue	\$6,661,951	\$3,682,717	\$2,455,821	\$287,701	\$ 31,486	\$204,226			
EXPENSE									
Salaries & Wages	\$1,838,745	\$ 685,065	\$ 343,630	\$ 52,246	\$ 10,094	\$ 2,858	\$152,923	\$183,866	\$ 408,063
Fringe Benefits	772,474	287,802	144,363	21,949	4,241	1,200	64,244	77,243	171,432
Consulting/Prof Fees	49,025	16,008	4,000	4,341			8,176		16,500
Purchased Services	31,373	25,248	1,000					3,500	1,625
Domestic Travel	82,459	27,026	6,631	5,318		3,197	8,832	4,350	27,375
Foreign Travel	181,612	103,475	74,362						3,775
Supplies	301,978	99,500	109,955	37,953			1,600	15,156	37,814
Equipment	18,700	9,000	5,700						4,000
Freight & Postage	79,394	7,000	11,500	394					60,500
Data Purchases	304,792	145,000	60,000	99,792					
Subcontracts/Grants	1,640,928	541,414	1,099,514						
Printing	37,878	22,750	13,700	1,128	300				
Conference Expense	180,000	180,000							
IJGO Expense	127,000	127,000							
Occupancy Expense	198,325						86,981	48,279	63,065
Depreciation Expense	120,393						211	120,018	164
Other	201,238	33,039	1,265	120		6	17,725	10,978	138,105
Utilities	68,000							15,000	53,000
Maint. Rental	213,835						6,096	183,389	24,350
Insurance Expense	21,034							5,264	15,770
Building Lease	130,500					130,500			
Interest Expense	43,018					43,018			
Expense Subtotal	\$6,642,701	\$2,309,327	\$1,875,350	\$223,241	\$ 14,635	\$180,779	\$346,788	\$667,043	\$1,025,538
ALLOCATION									
Home Department	—	227,904	109,493	16,864	3,454	—	(357,715)	—	—
G & A	—	549,838	275,799	41,933	8,101	2,295		147,572	(1,025,538)
Service Centers	—	595,648	195,179	5,663	5,296	1,902	10,927	(814,615)	—
Total Charges	\$6,642,701	\$3,682,717	\$2,455,821	\$287,701	\$ 31,486	\$184,976	0	0	0

Appendix C
BUDGETS FOR AID/pha-C-1172
(1971-1981)

BUDGETS FOR AID/pha-C-1172
(1971-1981)

C-1

Research Area	1977-78		1978-79		1979-80		1980-81	
	\$	%	\$	%	\$	%	\$	%
Sterilization	\$1,074,610	41	\$ 954,600	43	\$ 640,900	29	\$ 615,120	22
IUD	786,300	30	577,200	26	618,800	28	754,920	27
Pregnancy Tests/ PT/MR	288,310	11	177,600	8	132,600	6	111,840	4
Systemics/Injectables	183,470	7	244,200	11	331,500	15	503,280	18
Barrier/Fertility Awareness	131,050	5	266,400	12	353,600	16	531,240	19
Maternity Record/ Hospital Abortion*	157,260	6						
Other (projects encompassing multiple research areas)**					132,600	6	279,600	10
TOTAL Direct Costs/ Contract Year	<u>\$2,621,000</u>		<u>\$2,220,000</u>		<u>\$2,210,000</u>		<u>\$2,796,000</u>	

* Maternity Record and incomplete abortion studies funded under the contract. Studies in the next year were funded under Grant 1198.

** Includes projects such as RAMOS, Contraceptive Use and Congenital Abnormalities, Survey of Pharmacists, etc.

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