



Auditor General

A REVIEW OF MANAGEMENT AND OPERATIONS
OF THE INTERNATIONAL FERTILITY RESEARCH

PROGRAM FINANCED BY AID GRANT

AID/PHA-G-1198 AND AID CONTRACT

AID/PHA-C-1172

The contract and grant agreements between A.I.D. and International Fertility Research Program (IFRP) amounting to about \$31.8 million did not include measurable goals or budget controls against which performance can be compared. In our view, the project implementation agreements and the working relationship between AID's Office of Population and IFRP need to be revised with more finite criteria developed to measure and control performance and costs.

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AUDIT OF INTERNATIONAL FERTILITY RESEARCH PROGRAM

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AUDIT
OF THE
INTERNATIONAL FERTILITY
-- RESEARCH PROGRAM

INTERNATIONAL FERTILITY RESEARCH PROGRAM

EXECUTIVE SUMMARY

Introduction

The International Fertility Research Program (IFRP) is a non-profit corporation providing comparative research studies on contraceptives and other related activities under several AID contracts and grants totalling approximately \$31.8 million. The primary purposes of the program were to evaluate fertility control methods by means of standardized comparative studies and special studies. For example, special studies were to be done when there was a need to advance specific and new fertility control methods to a clinical stage.

The purpose of our review was to determine (1) the extent to which IFRP has become a viable organization capable of carrying out AID's research activities and (2) whether IFRP was meeting its contractual obligations in terms of performance and cost control.

Scope

Our examination included an assessment of the results of the program thus far; and a review of (1) IFRP procedures and operating controls, (2) the effectiveness of program implementation, and (3) compliance with the terms and conditions of the agreements and AID regulations. Our examination included a review of AID files, IFRP records and operations, discussions with IFRP and AID project management personnel and such other tests and auditing procedures as we considered necessary in the circumstances.

Conclusions

AID has been the major financial contributor to IFRP since it began operations in 1975. Since that time IFRP has developed into a viable organization although its survival is still dependent on AID contract and/or grant support. IFRP is reasonably well managed and is capable of providing the services required by AID.

The relationships that have developed between IFRP and AID have become too informal, and AID approval requirements which affect IFRP operating discussions, in our opinion, are excessive and exceed what would normally be expected under a grant or contract. Current relationships fit the cooperative type of agreement which establishes a close working relationship. (page 5)

International Fertility Research Program

The contractual agreement does not provide for adequate control over research activities because there are no measureable goals or budgetary controls against which IFRP's performance can be compared to determine whether the activities are being done efficiently and at the least cost to AID. This is important because the contract was let based on predominant capability. The contract in effect is providing general support normally associated with a grant agreement. (page 10)

The quantifiable goals included in the project paper were not included in the grant agreement. In our view this weakened the performance requirements of the grant. (page 7)

The research studies in less developed countries have been successful in gathering data to evaluate contraceptives. However, we found that neither AID nor IFRP have been verifying the reliability of the data collected. Moreover, assurances for the protection of the human subjects participating in the research have not been evaluated. While IFRP has taken certain in-house steps to check and compare the validity of the data received, they have not been systematically verifying the data in the field to see that the data are supported by subjects and records. (page 11)

Also, while IFRP has established some procedures for protecting human subjects, they have not systematically determined that the procedures are being followed. For example, IFRP does not assure that participants are notified of the risks associated with their participation in the research studies. (page 13)

The report also contains findings on subgrant activities and on IFRP management and operations.

Recommendations

To improve the contractual documents and to formalize the relationship with IFRP we recommend that the Bureau for Program and Management Services, Office of Contract Management (SER/CM) consider combining the present agreements into a cooperative agreement or agreements. The Assistant Administrator, Bureau of Development Support, should closely review Office of Population (DS/POP) relationship with IFRP with a view toward relaxing approval controls over IFRP operations, documenting all requests for IFRP assistance originating in AID, and documenting disapproval of IFRP requests for studies and activities to be financed. (page 7)

To insure that quantifiable goals, included in project papers, get into the supporting implementation contract or grant agreement, SER/CM should reemphasize to all Bureaus the need for and expectance of assuring that quantifiable goals are carried forward into grant and contract statements of work. (page 9)

International Fertility Research Program

To provide better control over IFRP research activities and performance we recommend that DS/POP require IFRP to develop more definitive criteria to measure and control research performance and costs. (page 11)

To improve the reliability of research data and to insure the protection of the human subjects participating in the research, DS/POP should require IFRP to establish a system of independently checking the reliability of research data and the preparation of the volunteer's consent forms. (pages 13 and 15 respectively)

Recommendations related to the findings related to subgrant activities and IFRP management and operations are found on Exhibit A.

Management Comments

The Office of Population stated in its response to the report that a number of improvements can be made in order to ensure future performance. In the most part the report's recommendations are constructive and useful. The Office of Population considers the close working relationship with IFRP a definite asset. It not only allows measurement of the results, but, allows integration into overall programmatic family planning effort. DS/POP believes the results are measured through annual reports, public presentation, scientific publication, daily technical monitoring, advisory committees, Office of Population evaluations, and ultimately by the impact IFRP's findings have on the methods of fertility control used by AID and others around the world. These comments are discussed more fully in the report.

INTRODUCTION

Background

On June 30, 1971 the Agency for International Development (AID) entered into a contract with the University of North Carolina (UNC), contract No. AID/csd-2979, in the initial amount of \$3,106,000 to establish an International Fertility Research Program within the University. The primary purposes of the program were to evaluate fertility control methods by means of standardized comparative studies, and special studies.

Standardized comparative studies were geared to focus on technology, under use conditions, in four areas: intrauterine devices, sterilization, pregnancy termination and steroids.

Special studies were to be conducted when there was a need to advance specific and new fertility control methods to a clinical stage; or, when there was a need to evaluate clinical use of methods in more detail than possible under the standardized comparative studies.

Contract No. AID/csd-2979 required the University of North Carolina to establish a flexible administrative system with responsibility focused within the International Fertility Research Program (IFRP), and to provide adequate backstopping to successfully meet and manage contract requirements. In this connection the contract identified the positions of Project Director and Program Administrator as key positions to be established.

The Project Director of the University-affiliated IFRP was directly responsible for the administrative direction, the reporting requirements, and the coordination and management of the program. The Project Director was also directly responsible for the financial and performance agreements with subcontractors, collaborating individuals and institutes and overseas contributors.

To avoid overburdening Carolina Population Center's administrative resources the contract required the establishment of a Program Administrator position.

One of the provisions of contract No. AID/csd-2979 restricted diversion of key personnel to other programs without the written consent of AID's contracting officer. However, the Project Director and the Program

Administrator of the University IFRP were, on October 4, 1973, two of the three incorporators of a non-profit corporation. This non-profit organization, incorporated in North Carolina, was named the International Fertility Research Programme, Inc.

Official documents are sketchy as to whether program input and funds were channeled from the University IFRP supported by AID to the non-profit IFRP established by key personnel working under the AID contract. Nevertheless, on August 28, 1974, the University's Vice Chancellor of Business and Finance issued instructions that no expenditures were to be made from any of the trust fund accounts held by UNC on behalf of the University IFRP. The reasoning behind the Vice Chancellor's decisions was:

"...questions have been raised with respect to relationships between the University's International Fertility Research Program and two North Carolina corporations..."

The two "North Carolina corporations" were the International Pregnancy Advisory Services, Inc. and the International Fertility Research Programme, Inc.

During this period Vice Chancellors of UNC were also concerned about the implications of AID policy statement (PD-56) and the provision in the AID contract amendment concerning abortion. On October 7, 1974 top officials of AID and the University of North Carolina determined that the work to be performed under contract No. AID/csd-2979 could best be performed without the constraints of an educational institution. Subsequently, on December 19, 1974 the Program Administrator of the University IFRP (an incorporator of the non-profit IFRP) transmitted a draft proposal to AID's contracting officer to recognize the non-profit IFRP, Inc. as the successor in performing the work of the contract; and requested a novation agreement for transfer of the contract to the non-profit IFRP, Inc. on or about February 1, 1975.

The present IFRP organization under contract with AID consists of about 100 individuals. At novation IFRP continued to perform the services required under contract No. AID/csd-2979 until contract expiration on August 2, 1977. Support for IFRP research services continued under contract No. AID/pha-C-1172 effective August 3, 1977 which is still active. AID also awarded a contract No. AID/pha-C-1111 to IFRP, effective June 30, 1975, for specific services requiring IFRP to develop new and improved IUDs with the objective of improving IUD performance and user acceptance in developing countries.

Under these contract-related activities IFRP attracted a network of developing country physicians (contributors) who were qualified and willing to perform clinical trials of new contraceptive techniques and who furnished IFRP data from the studies at agreed to rates per data form submitted and accepted. These data formed the basis of IFRP comparative evaluations of research results. IFRP converted the data into publishable information and disseminated such information to the contributors and worldwide through papers, conferences, seminars and through support of an international publication, the International Journal of Gynecology and Obstetrics.

An offshoot of the research activities was that contributors began to communicate with each other, sharing experiences and exchanging knowledge to a point that loose-knit regional groups of contributors evolved.

In support of these "Mini-IFRPs" and other developmental efforts AID awarded a grant (No. AID/pha-G-1198) to IFRP on September 30, 1977. This grant is still active. An additional small grant (No. AID/DSPE-G-0012) was awarded to IFRP on September 29, 1978 for a specific one-time study.

AID funds obligated to support activities have been:

<u>Contract/Grant</u>	<u>Grantee</u>	<u>Signed</u>	<u>Applicable Period</u>	<u>Cumulative Amount</u>
Contr No. AID/csd-2979	UNC	6/30/71	6/30/71-2/14/75	\$ 6,405,610
Contr No. AID/csd-2979	IFRP	2/25/75	2/14/75-8/2/77	12,100,610
Contr No. AID/pha-C-1111	IFRP	6/30/75	6/30/75-4/30/79	864,000
Contr No. AID/pha-C-1172	IFRP	8/3/77	8/3/77-7/31/80	10,190,266
Grant No. AID/pha-G-1198	IFRP	9/30/77	9/30/77-9/29/79	2,255,208
Grant No. AID/DSPE-G-0012	IFRP	9/29/78	9/29/78-12/31/79	<u>35,164</u>
				<u>\$31,850,858</u>

Purpose and Scope

The purpose of our review was to determine (1) the extent to which IFRP has become a viable organization capable of carrying out AID's research activities and (2) whether IFRP was meeting its contractual obligations in terms of performance, management and cost control.

Our examination included an assessment of the results of the program thus far; and a review of IFRP procedures and controls; the effectiveness of program implementation, and compliance with the terms and conditions of the agreements and AID regulations. The audit included a review of AID files, IFRP records and operations, discussions with IFRP and AID project management personnel, and such other tests and auditing procedures as we considered necessary.

FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

AID/IFRP Relationships Need to Be Reviewed

The relationships and controls that have developed over the past five years are too informal, and include too many approval requirements and are not commensurate with what one would expect under grant or contract agreements. As a result, AID sometimes uses IFRP and its facilities to meet AID's own needs which are not covered by the scope of work of the contract or grant.

AID presently has two major agreements with IFRP - Grant No. 1198 and Contract No. 1172. The same types of research are being funded under both agreements. For example, both may involve collection of data for the same contraceptive. There is a distinction between the two agreements in that the grant allows subgrant budget support and in-country specific research whereas the contract does not. The grant can also be used to support non-research activities such as training.

For each subgrant activity funds are budgeted and costs are accumulated by subgrant agreement. The contract on the other hand provides general support with no budget or cost control by type of research activity. IFRP theoretically can be paid the same amount for 10 research studies or for 100. All research costs charged to the contract are lumped into one cost center. As a result, IFRP could not show whether the research was being done efficiently, whether more can be done for the same cost, whether the number of employees is consistent with the work effort or whether the relative costs of research studies are consistent (See section entitled "Performance Controls Should be Strengthened").

Under the grant, AID requires tight subgrant cost control over each activity whereas under the contract there is no sub-research control. In other words cost controls governing the grant and the contract are reversed from what one would expect.

Under both agreements, IFRP charges a considerable amount of time to AID to develop new activities. The contract and grant have no quantifiable goals or controls other than total dollars budgeted for eight study areas defined in the scope of work. IFRP must develop study activities in these eight areas to support budget levels established in the agreements. The incentive is to spend the money budgeted by developing activities, not to hold costs and expenditures down. AID in effect is providing general support funding although financing is by a performance contract and a specific support grant.

AID maintains a very close working relationship with IFRP which at times is too informal and exceeds what we feel to be normal under an arms-length contractual and grant arrangement. For example, AID uses IFRP and its facilities to meet its own needs which are not covered by the scope of work of the contract or grant. One such instance was using an IFRP doctor to help make an evaluation of a USAID-financed project in Tunisia. Another was providing editing assistance on a paper written by an AID employee

based on data from IFRP research studies. Both requests were not supported by documentation from AID. We believe this places IFRP in an awkward position in accounting for the costs of these activities. IFRP indicated it frequently gets these requests which are often time consuming. Moreover, the requests are often made by telephone directly to the working level thereby bypassing IFRP management.

The AID approval process for IFRP proposed activities is inconsistent. Written approvals are documented whereas disapprovals usually are not. This leaves IFRP without documented evidence that a proposal has been disapproved. Also the approval process has on occasion taken inordinate periods of time. For example, the new cost system in operation over a year remains unapproved.

The levels of approval appear excessive. AID not only approves each research study but each individual study center that is to participate in the study. The agreements require AID approval to hire employees over a grade 4 (there are 10 grades). IFRP indicated that several excellent candidates have been lost because of AID's delay in approval.

Currently every subgrant, whether for \$9 or \$900,000 requires the same paper work and AID clearances.

The Research Division of the Office of Population made the following comments to this section of the report:

There is a good distinction between the contract and grant activities...Although there is some conceivable overlap in the grant-funded National Fertility Research Program clinical trials and the contract-funded studies, this is of little consequence.

It is necessary for the language of the contract to be flexible because one doesn't know at the outset what new methods may become available or what new techniques or priorities for evaluation may arise. AID approval is required for each research protocol and each specific study. This system allows both the appropriate amount of flexibility and control. Within the overall area of research, however, we agree that more cost centers would be useful in order to help evaluate performance in specific research areas. The avenue of a single funding agreement is worth exploring as long as it continues to allow the current flexibility and control.

We consider our close working relationship a definite asset. Good technical monitoring in such a complex area with the requirement for responsiveness to AID's needs as they arise, requires a close professional working relationship. The current practice of technical monitor approval on all projects is essential for good monitorship.

In addition, AID mission clearance must generally be obtained on specific studies. Although we regard the present research approval process as essential, we are quite willing to explore some loosening of approval requirements on personnel and positions.

Conclusions and Recommendations

AID has been doing business with IFRP since its inception over four years ago. Since that time, IFRP has grown into a responsible and reliable organization capable of providing the services required by AID. We, therefore, believe it is time to take a close look at the contractual agreements, the relationships that have developed and the close control that AID continues to exercise at all levels of IFRP operations.

One type of agreement should be used to fund all AID activities thereby simplifying not only record keeping but cost control. We believe the cooperative agreement better fits the general support currently being provided under the contract and also allows for close working relationships not normally associated with a grant agreement. More finite controls to measure IFRP's performance and costs of research units need to be developed.

The approval requirements need to be reviewed to determine whether they are still valid for an organization that has proven it can provide the required services and AID originated requests for assistance should be formalized and documented.

Recommendation No. 1

AA/DS should (1) closely review DS/POP relationship with IFRP with a view toward a more controlled involvement only in critical areas and (2) formalize DS/POP procedures by documenting all requests for IFRP assistance originating in DS/POP and by documenting disapproval of IFRP requests for subgrants, studies and other contract or grant-related activities.

Recommendation No. 2

SER/CM should consider replacing the present IFRP contract and grant agreements with a cooperative agreement or agreements.

Measurable Performance Goals Were Excluded From the Grant Agreement

The governing project paper (No. 932-0537) generally contains specific targets that should have been used to measure IFRP programs and performance. However, grant No. AID/pha-G-1198 does not include these targets. Consequently, IFRP is not contractually bound to attain

the targets; nor can IFRP be expected to compare and report on actual accomplishments with the established goals in accordance with OMB Circular A-110 procedures for monitoring and reporting program performance of recipients.

Although OMB Circular A-110 allows recipients to report based on the findings of an investigator, we believe that when goals have been set forth in project papers, performance should be measured against such goals.

The following examples are illustrative of goals not included in the grant agreement:

- The logical framework of the project paper specifies that six to nine fertility research programs will be initiated during fiscal years 1978 through 1981. The grant does not contain this provision.
- The logical framework of the project paper specifies that two to six prevalence surveys will be executed. The grant does not contain this specification.
- The project paper requests support to assist developing countries in evaluating contraceptive delivery systems and targets. The logical framework indicates such assistance is to cover four to eight delivery systems during the project period. The grant does not quantify this assistance.
- For clinical training, the logical framework specifies that 500 LDC practitioners are to be trained. This specification is not contained in the grant. The logical framework also envisions subscriptions of 10,000 individuals receiving the international medical journal but the target is not repeated in the grant.
- For evaluation of subgrants the project paper specifies that each written subgrant proposal contain "...9.evaluation plan for measuring the achievements of the subgrantee". This clause is omitted from the grant.
- For IFRP evaluations of its fertility research programs (FRPs) the project paper states that IFRP has created a three-member evaluation team to evaluate FRPs in terms of management capability, clinical skill and research techniques. The grant is silent on this matter.

Conclusion and Recommendation

OMB Circular A-110 contains instructions that when measurable goals exist grantees are to (a) compare actual accomplishments with goals established for the period and (b) show reasons why established goals were not met. This cannot be done when the agreements do not include such goals.

In our opinion AA/SER should require the Bureaus to include in contract/grant instruments those goals that are specified in project papers for accomplishment.

Recommendation No. 3

AA/SER should reemphasize to all Bureaus the need for and expectance of assuring that quantifiable goals included in project papers are carried forward into grant and contract statements of work.

Research Activities Financed by Contract AID/pha C-1172

The services being provided by IFRP under the contract are to evaluate on an international basis the safety, effectiveness, and acceptability of methods of fertility control obtained from clinical trials performed throughout the world. The program is to focus on technology under use conditions in six major areas: (1) intrauterine devices; (2) systemic contraceptives; (3) male and female sterilization; (4) barrier contraceptives; (5) menstrual regulation and pregnancy termination; and (6) equipment integral to fertility control technology.

Largely due to IFRP efforts the adequacy of various contraceptive methods have been successfully documented. In addition, significant innovations to existing contraceptive methods have been made under IFRP auspices. For example, IFRP modified an IUD that enabled it to be used immediately after delivery and significantly reduced the expulsion rate of the IUD as had been experienced heretofore. Due to IFRP studies there have been modifications made to new equipment that will benefit both physician and patient.

IFRP has collected data on over 250,000 deliveries and 25,000 spontaneous abortions making it the first institution to collect worldwide data of this type. As of July 31, 1979, IFRP had established 68 research centers through which IFRP worldwide clinical trials are conducted and about 100 active contributors as of September 1979. The total number of contributors is approximately 500 but all were not active in the conduct of pending studies. During the period August 1, 1978, to July 31, 1979 148,929 data forms were loaded into the computer and there were 85 IFRP publications ranging on subjects such as pregnancy termination, menstrual regulation, male and female sterilization and barrier methods. During this same period there were 34 papers completed by IFRP contributors.

As part of our review of program activities, we also looked closely at the IFRP cost and performance controls with regard to research activities, the control over reliability of the research data being published and the procedures being followed to protect the human subjects that are participating in the research studies. Discussions on these areas are detailed in the following paragraphs.

Performance Controls Should Be Strengthened

The use of overseas sources for conducting research studies according to IFRP officials can be cost effective. It is estimated by IFRP that gathering the data in this way costs about one-tenth what it would cost in the U.S. Another advantage is that research results are more pertinent because the data are gathered in less developed countries where the contraceptives are to be used. In addition to developing information on contraceptive safety and effectiveness, the acceptability of contraceptives, which is significant, is also being determined. A further advantage is that the studies allow testing of devices acceptable in other countries but not approved for use in the U.S.

IFRP's costs of supporting the overseas studies cannot be determined. We were unable to ascertain how much a study area cost or how the actual cost compared to estimates because IFRP does not accumulate or retain such data in its normal course of operations. We were unable to correlate the staff size to the number of studies being made because there were no man-hour measurements, or study targets in the contract document. The contract document essentially requires no quantifiable performance. IFRP can recoup all of its costs not chargeable elsewhere from the AID contract. In other words, IFRP does not have to be efficient or competitive in its performance under the contract.

In response to our report the Office of Population indicated the contract clearly does control overall research and performance cost. Furthermore, the contract does call for measurable results. It calls for studies in at least eight different areas and gives specific details. The results are measured through annual reports, publications, and the Office of Population Evaluation.

We agree that these documents provide data on some of the studies and activities that are in process and provide some results. However, they do not provide data on how many studies are in process, the reasonableness of study costs, whether they are being completed on schedule, whether the number of forms received and in process is as planned. The annual report indicates the publications published but does not indicate the number planned, the number in process, the number written but not published. In our opinion, these documents do not reflect how well IFRP performed what it planned to do, and whether the work was done within budgeted time and dollar limits.

Conclusion and Recommendation

There should be some basis for measuring whether research costs are reasonable to ensure the efficient and economic expenditure of public monies. One form of control would be to budget funds by research activity similar to the subgrant budget control under the grant agreement and measure actual cost against budget estimates. Another would be to control research by man-hours of effort. Establishing study time frames with measurement against such limits might be considered. A combination of cost control and time estimates may be effective. Some unit of measure should be developed to insure efficient performance. This is especially true since the agreements with IFRP are based on predominant capability rather than competition.

Recommendation No. 4

DS/POP should require IFRP to develop more finite criteria to measure and control IFRP's performance and costs for research activities.

Reliability of Research Data

IFRP is not independently checking the reliability of research data and the in-house system for maintaining the integrity of the data is in our opinion loose.

All research data results published by IFRP are developed from data provided by data collectors called contributors. A contributor can be an organization or a doctor within a clinic or hospital. IFRP establishes the research parameters, develops the data collection forms, provides any equipment or devices, analyzes the data collected and publishes the results. The reliability and accuracy of the data is primarily under the control of the contributor.

In-house, IFRP has certain checks to see if the data is accurate and complete. These checks are done visually when the data forms are scanned and are done by the computer when the forms are processed into the data bank. However, whether all the forms contain data on actual volunteers is unknown. IFRP tries to determine if the data is reasonable by making certain comparisons between countries and contributors, but the question of validity still remains.

IFRP indicated that it contracts only with professional, reliable and reputable persons to provide data; therefore, the possibility of the data not being collected and reported as agreed is remote. IFRP also indicated that the amounts paid for data forms (ranging from \$.50 to \$10.00) does not make it worthwhile to submit forms for the money alone.

The AID Project Officer in addition to supporting IFRP's statements also indicated the following:

- IFRP carries out studies with multiple contributors, and their consistency with each other is checked.
- Within a different study center, several people are involved.
- Some checking of forms is currently carried out by IFRP staff during visits to contributors.
- All data in scientific research is subject to falsification but the preponderance of evidence in all fields of science indicates that deception and falsification are fairly uncommon.

We agree that the above factors are valid; but, we believe that systematic checking should be undertaken to provide assurance that the data being purchased represents actual research on volunteers selected specifically for the study and that the data are supported by clinical or hospital records. Such checks can be minimal if the method of selection is properly developed. For example, selecting forms at IFRP at random, then checking the forms to their source documents in the field would be a reasonable control.

Although the Project Officer believes the reliability of IFRP data is quite good, he agrees that a more systemized form of checking should be undertaken.

IFRP is attempting to make a reliability test on its Maternity Care Monitoring (MCM) records. IFRP has requested that randomly selected centers resubmit MCM forms based on the centers' records without reference to the original MCM forms submitted. The purpose of the test is to try to determine that the data on the original submission was accurate and based on the centers' records. The only weakness with this test is there is no assurance that the requested forms will be prepared independently of the original form.

This is an initial effort by IFRP at trying to develop a check on the reliability of data, but, again the problem is the reliability of the test because someone independent of the center is not making the check.

One of the areas we feel is the most vulnerable to falsification is long term follow-up financed under certain studies because payments are greater, sometimes more than twice the admission payment; the basic data is already available on the volunteer; and the data is more easily falsified because it generally relates to after-the-fact complications. This data, however, may have great importance for measuring long-term effects of the procedures being tested. Moreover, this type of testing may become more prevalent in the future.

The data published by IFRP can influence the use of contraceptives and can have long-range impact on population programs and users in developing countries. Therefore, controls that will enhance the validity of the data base will be of great value.

Another area of concern is the ability of IFRP employees to change or add data without identifying the source of the change or who made the change. We reviewed data forms with data added and with changes made with no indication as to why the changes were made or by whom.

IFRP employees indicated there is no reason why an IFRP employee would want to alter or change data. We agree that this is probably true; however, changes to data should be made only by those authorized to do so. At present there is no way of telling who made the changes or whether the person was authorized. Maintaining the integrity of the data in-house and publishing the data in an unbiased way is an important element of research reliability.

Conclusion and Recommendation

We believe procedures should be developed to ensure to the extent possible, that data is valid and reliable. As a minimum, IFRP should spot check forms to source documents in the field and should review its in-house procedures to ensure that integrity of data is maintained.

Recommendation No. 5

DS/POP should require (1) that IFRP establish systematic procedures for checking the validity of research data, and (2) that IFRP review its in-house data control procedures.

Protection of Human Subjects

IFRP's policies and procedures related to protection of human subjects are generally adequate. However, we are concerned that the procedures are not being consistently applied by contributors at overseas locations because IFRP is not systematically checking to see that consent forms are prepared for each volunteer.

Federal and AID regulations establish requirements to protect human subjects participating in research activities. These requirements have been incorporated into the AID contracts and grants with IFRP. The requirements in part provide that no work shall be initiated for support of research involving human subjects unless the research is given initial and continuing review and approval by an appropriate committee of the supported institution. These reviews are to assure that (a) the methods used to obtain consent are adequate, and (b) the risks and potential medical benefits of the investigation are assessed. The AID agreements further state that for sterilization programs IFRP must ensure that informed consent, which explains the basic elements and risks, be

documented either by a written consent document signed by the volunteer; or if the volunteer is illiterate, by a written certification by the attending physician that the basic elements were orally presented and acknowledged by the volunteer's signature or mark.

IFRP has established a committee to provide independent and continuing review of the risks and potential risks of research activities on human subjects. The committee consists of from five to seven members from outside IFRP. Minutes of the meetings approving research proposals and establishing recommendations for consent forms, etc., are recorded and prepared by an IFRP employee. The committee members then have an opportunity to review the minutes before the next meeting to make suggested changes, if any. The minutes of the next meeting include a statement that the prior minutes were approved. Since the committee is to be independent of IFRP, we feel the minutes should be signed by the members of the committee; thereby validating the minutes as their official record in addition to protecting the independence of the committee. IFRP has agreed that the chairperson will sign the approved minutes of each meeting.

IFRP procedures require the preparation of volunteer consent forms for all persons who participate in the research activities. Although we were told that checks have been made, IFRP has no established system for routinely checking to see if the forms are actually prepared, or, if prepared, whether the patient was accurately informed.

There is some evidence that forms are not always prepared and that patients are not being adequately informed. For example, a draft report of an evaluation review that was never published, made in Cairo, stated that the contributor said, "All patients sign a consent form, but, the only information given to the patient is, 'This is the only up-to-date abortion you can get.'" He said, "If he explained the risks, he would not get any patients." In Jakarta, Indonesia, the reviewer indicated no informed consent forms were prepared. Since the research has certain risks, it is imperative that IFRP make every effort to ensure that the volunteers are adequately informed.

Based on our discussion with the Regional Coordinators, we found that three of the four questioned made no checks to see if the volunteers are being informed and that the one that did made no record of the checks. We were also told that there is no requirement to check the forms.

Conclusion and Recommendation

Verification is the only way to assure that volunteer consent forms are being prepared. We, therefore, recommend that a formal system of checking be established. Such a system should incorporate selecting those

volunteers to be checked from IFRP records. Just to ask to see consent forms when visiting a center is not adequate: specific forms should be looked at based on preselection.

As part of the testing process, it is advisable to query some of the volunteers to see if they were adequately informed where there is evidence the volunteer could not read.

Recommendation No. 6

DS/FOP should request that IFRP systematically spot check volunteer consent forms and document such checks.

IFRP Grant Activities Financed by Grant AID/pha-G-1198

The specific objectives of the Grant are to:

- A. Provide limited clinical training, equipment and evaluation services to facilitate incorporating into new or existing programs of less developed countries (LDC) fertility control technologies that have been shown to offer better protection from unwanted pregnancy than technologies in general use in the country.
- B. Provide initial core costs for newly established national fertility research programs in Africa, Asia and Latin America and to strengthen institutional capabilities in LDCs.
- C. Provide limited supplies not available in LDCs for collaborating investigators to continue programs initiated as field trials until other sources of supply can be developed.

During the first two years of the AID grant, IFRP has funded 26 subgrant activities in ten different countries. The activities include support for six fertility research programs, provision of supplies, clinical training, and evaluation of family planning programs.

In addition to the country related activities, IFRP has supported through subgrants the International Federation of Family Health (IFFH) and the International Journal of Gynecology and Obstetrics (IJGO). IFRP support to IFFH has been in the form of personnel and financial assistance to develop an institutional structure capable of independent activities.

The IJGO subgrant was designed to support staff and facilities necessary to obtain a larger number of manuscripts for review, to increase circulation, to improve the efficiency of the review process and to develop effective manuscript management procedures. The number of manuscripts received in FY 1979 have increased 60 percent from 75 to 120. Circulation has increased from less than 1,000 when support was started to almost 4,000 in 1979. New reviewers have been hired and review guidelines and office procedures have been improved.

In general, the management and financial control over subgrant activities was good. Several areas, however, which we believe need to be addressed, are discussed in the following paragraphs.

Evaluations of Subgrants Need to Be Systemized

IFRP evaluations of AID-financed subgrants need to be improved and the evaluation function needs to be identified and established within the organization.

Evaluations of the two major subgrants - Columbia Regional Fertility Research Program (PRIF) and Bangladesh Fertility Research Program (BFRP) - did not review several important areas adequately. The evaluations did not measure whether the subgrantee was meeting agreed-to goals and did not fully evaluate administrative capability or research capability. The PRIF evaluation made by three IFRP employees was much more comprehensive than the BFRP evaluation made by one IFRP employee. But, the PRIF evaluation still lacked details and problems related directly to subgrant implementation.

A very good set of "Guidelines for the Evaluation of Regional Programs" was developed by IFRP; however, the guidelines were not fully addressed in the PRIF report and were apparently not used in the BFRP evaluation. These guidelines if used and commented upon in the evaluation report will result in a fairly comprehensive report of accomplishments, problems and corrective actions needed to improve future program activities.

There are several important areas, however, that have not been fully addressed in the evaluation guidelines. One is whether the volunteer consent forms are being prepared and signed by the volunteers. The second is whether the research data forms being paid for by IFRP are supported by hospital or clinical records.

The Project Paper (PP) for the major AID contract and grant indicates that IFRP has created a three-member evaluation team which will begin site visits early in fiscal year 1979. The team will evaluate the subgrants in terms of management capability, clinical skill and research techniques.

An evaluation team is required to make the evaluations; however, the responsibility for the evaluation effort must be established to ensure that evaluations are planned and carried out by the team. This has not been done.

Conclusion and Recommendation

We therefore believe IFRP should develop an evaluation strategy and should assign the responsibility for carrying out the strategy to one employee. This employee should have responsibility for implementing evaluation activities. If there is no employee within the organization with evaluation expertise, training should be considered. We do not believe evaluation is a full-time job which will require an additional employee; however, it is a responsibility which must be developed and assigned as a responsibility.

Recommendation No. 7

DS/POP should request that IFRP assign the responsibility to a specific employee or control point to ensure evaluations are scheduled and carried out in accordance with established guidelines.

IFRP Involvement in IFFH Activities Needs Review

IFRP involvement in International Federation of Family Health (IFFH) affairs may be excessive, is in contravention of IFFH bylaws and may be construed as a potential conflict of interest. At least six key officers and employees of IFRP are involved in IFFH affairs.

They are:

- An IFRP Board of Directors member and Vice President,
- IFRP's former President -- now titled IFRP Founder and Senior Consultant,
- IFRP's current Executive Director,
- IFRP's Director of Field Epidemiology,
- IFRP's Senior Program Development Associate, and
- A Senior Program Officer of IFRP.

Other IFRP personnel have maintained books and records and have expended labor effort on behalf of IFFH. For example, IFRP's Controller prepared

and maintained IFFH records up to April 30, 1979. (However, we were told that these services were not performed during IFRP working hours.) An IFRP Administrative Assistant currently maintains files of IFFH at IFRP. Labor effort of an IFRP Scientist and IFRP's Assistant to the Associate Director was spent on IFFH's behalf. The effect of diverting IFRP management and employee time on behalf of IFFH is highlighted by the number of IFRP individuals serving on IFFH Standing Committees. At least, five IFRP individuals attend various Executive and General Assembly meetings of IFFH held worldwide. The resultant costs of travel, per diem and associated expense are ultimately paid by AID. We believe that the number of IFRP individuals participating in IFFH organization meetings is unreasonable. A representative or two from IFRP should suffice at a given meeting.

Although the IFFH constitution and bylaws excluded associate members from voting or holding office, IFFH resolved at its organizational meeting of November 26, 1977, that IFRP (an associate member) be designated as the Federation's Secretariat and that its "Director" be appointed as the IFFH Executive Secretary. Consequently, this office was assumed by the then President of IFRP in contravention of IFFH constitution and bylaws.

Since that time IFRP officers have changed. At the top management level IFRP created, in addition to the Office of President, the Office of Executive Director. It is not clear which of these offices now fit the description of "Director" as resolved by IFFH. Regardless, the current IFRP employee holding the position of Executive Secretary is neither the President nor the Executive Director of IFRP.

The IFRP Executive Director is the principal operating officer of IFRP. As such, he is empowered to sign "...any contracts or other instruments, reasonably required for the corporate administration and to carry out the scope of work under a plan or budget approved..." This power includes approving subgrants and budget level support to IFFH.

The IFRP Executive Director also serves as a member of IFFH's Budget and Finance Committee. A potential conflict of interest may exist due to powers delegated to this member as IFRP's Executive Director in granting funds to IFFH while serving on the Budget and Finance Committee of IFFH. At the very least, it is good business sense to avoid situations that might be misinterpreted by potential donors and other critics. We believe that IFRP representation on IFFH committees should be limited to those which do not create potential conflict of interest situations.

Conclusion and Recommendations

IFRP involvement in IFFH raises questions of excessiveness, legality and appropriateness which we believe should be addressed and resolved.

Recommendation No. 8

DS/POP should instruct IFRP that its representation on IFFH be kept in accordance with IFFH constitution and bylaws and that participation be restricted to activities that cannot be construed as potential conflicts of interest.

Recommendation No. 9

SER/CM and DS/POP should determine those IFRP personnel that AID will finance to work on IFFH activities and require IFRP compliance.

Support for the International Journal of Gynecology and Obstetrics (IJGO) Needs Reevaluation

Although IFRP has taken steps to improve circulation of IJGO and make its operations more efficient, the prospects of making IJGO a self-supporting journal is remote. To make IJGO available to the developing world's scientists, subsidized subscription rates will have to continue. The prospects for increasing revenues through advertising are poor because as an international journal with diverse readership, IJGO is not appealing to major advertisers. Heavy editorial support is also required because many papers submitted to the journal are written in foreign languages. Moreover, IFRP does not have the capability in-house to significantly increase the number of subscribers. Costs run high for a single copy publisher such as IFRP. During fiscal year 1979 the journal expenses totalled \$225,820, exceeding revenues of \$115,825 by \$110,045.

IFRP cannot absorb the cost of operating the journal, therefore, if the journal is to continue, AID support will be required for many years to come.

Conclusion and Recommendation

We believe the continued publication of IJGO should be looked at closely. As a minimum, a long-range forecast of the cost of the journal should be made to determine the cost of continued publication in relationship to its current and future distribution prospects. This will provide some indication as to what AID's long-term commitment will be and may indicate that some other method of funding or publication of the papers may be advisable.

Recommendation No. 10

DS/POP in conjunction with IFRP should look closely at the long-range cost of publishing IJGO with a view toward decreasing costs by use of other publication methods or possibly by curtailment if a satisfactory cost benefit ratio cannot be developed to justify continuation.

IFRP Management and Operations

We closely reviewed IFRP activities that provide an overview of how effectively IFRP manages its personnel, operations and assets. In this regard we looked at the organization structure, employee practices, operating procedures and IFRP compliance with in-house policies and with AID agreements.

Overall IFRP management has been fairly effective granting the disruptive circumstances that have occurred, AID's involvement in IFRP, and uncoordinated audit reviews by various government and private audit entities. However, our overall observations disclosed IFRP management and operation areas that need to be strengthened.

The most significant audit observation is that IFRP makes too many management decisions, at various management levels, on an ad hoc basis without supporting justification and documentation. These ad hoc decisions, if properly documented, would serve as a minimum basis of support even though the decision might subsequently be questioned or challenged by donors and supporters of IFRP. Such ad hoc management decisions have included:

- Lease of reproduction equipment,
- Purchase of computers,
- Establishment of rates to be paid contributors,
- Establishment of unwritten policies,
- Practices that deviate from established policies, and
- Use of AID approval as justification for IFRP management decisions.

IFRP management recognizes this basic weakness and is initiating steps to formalize its practices, procedures and techniques. IFRP management pointed out that the governing factor for its management and operations shortfall has been the lack of stability within the organization.

Since inception in 1975, IFRP has had a major reduction-in-force of more than 30 people which had a tremendous impact on stability, morale and continuity. There have been continual changes in accounting systems from a manual system to a service bureau mechanized system, to a more complex cost accounting system. There have been three changes of top management in the past year and a half with the inherent changes in direction and philosophy. Finally, a recent reorganization resulted in significant movement of personnel within the organization. These changes coupled with continuous AID review and involvement and input from almost constant audit (five audits in 1979 alone) have taken their toll on staff time and on developing more formalized decision making processes.

On the positive side, the disruptions resulting from the changes should be in the past and the basis for establishing a sound, stable management system is at hand. We feel that IFRP has the staff capability to make the required adjustments. We suggest, as pointed out in the prior section, more controlled AID involvement, and we feel that the pressure of audit should be reduced for a period of time to allow IFRP more time to work on in-house problems.

Some areas of weakness we noted in organizational, operational, management and personnel systems are detailed in the following sections.

IFRP's Corporate Structure Is Weak

IFRP established corporate positions that have overlapping authorities, assigned corporate responsibilities to officers that can't fulfill the responsibilities, are ambiguous, and are not always followed in actual practice. These duplications of authority can and have resulted in conflicting instructions being issued to IFRP personnel by persons holding these positions.

IFRP's bylaws provide for three positions - chairperson, president and executive director - all with essentially the same responsibilities. For example:

- "The Chairperson shall coordinate and facilitate all aspects of corporate endeavor, and shall have general powers and duties of supervision and control over corporate affairs ..."
- "The President shall coordinate and facilitate all aspects of corporate endeavor and shall have general powers and duties and control over corporate affairs."
- "The Executive Director shall have general powers and duties of supervision and control over corporate affairs."

The bylaws establish responsibilities for corporate officers that can't be fulfilled. For example, the Treasurer who lives in California "shall have charge and custody of and be responsible for all funds and securities of the corporation...deposit all such monies in...banks." The Treasurer cannot perform these duties attending a few Board of Directors meetings a year.

The bylaws state the President shall be the only ex officio member of the Board. The current President is an official member of the Board.

We understand it is normal to give honorary corporate titles to Board members as added incentive or reward for participating on the Board because Board members receive no compensation. The bylaws should be written to assure that the responsibilities given to these positions are commensurate with the ability of the person to perform. These Board members should not be given operational responsibilities.

The IFRP Board of Directors has recognized that the bylaws are weak and is in the process of making changes. The changes we have noted in the draft of the revised bylaws have corrected the deficiencies we have identified.

Although the bylaws are beyond the purviews of the AID agreements, we nevertheless feel AID should follow upcoming bylaw revisions closely to insure that the bylaws establish corporate responsibilities that are reasonable and practical, which will maintain the integrity of the corporation and its officials, thereby better protecting AID financed activities from mismanagement.

IFRP Computer Usage May Be Increased

IFRP claims, but cannot document, that its computer is being adequately utilized. Based on our review there is evidence that idle time exists, and we found the computer is not being used for financial management control systems even though the potential exists.

For example, the IFRP Burroughs computer is not being used for payroll and accounting systems although capable of such use. Currently, payroll service is being provided by a local bank and the accounting systems are processed through a service bureau in Charlotte, N.C.

IFRP made a business decision to purchase a Burroughs B6700-series computer because of a switch in rates (from educational to commercial) imposed by the computer service being used when the AID contract was transferred from the University of North Carolina to IFRP. The new commercial rate represented a 250 percent increase in the computer rates.

On December 8, 1975, IFRP purchased the computer from Burroughs Corporation at an initial cost of \$757,445. According to a memorandum from IFRP to AID's contracting officer dated September 29, 1977, in considering the computer purchase, IFRP decided to try to accomplish several goals:

- (1) Reduce charges to AID contracts,
- (2) Purchase a type of computer with a capacity adequate to permit future growth in (AID) contract use,

- (3) Arrange to sell bulk time to other organizations to support costs of the computer purchase and operation not covered by AID, and
- (4) Increase efficiency of programming and computer use by decreasing response time.

Consequently, the computer that IFRP purchased had an estimated capacity of 2.5 times that needed to meet AID requirements under the contract. One of the concerns of both AID and IFRP management was that the computer has been used, more or less, exclusively for research activities. On the surface, it was apparent that the integration of payroll and accounting systems into the in-house computer operations would increase computer usage and, therefore, result in increased economy and efficiency of the computer. During calendar year 1978, IFRP, with the assistance of Price Waterhouse & Company, investigated the possibilities of purchasing prepared computer programs that could be used for payroll and accounting inputs. IFRP compared these cost estimates to rates offered by service bureaus where such computer capabilities already existed. The result was an IFRP decision to use service bureaus for accounting and payroll due to more favorable terms. For example, the start-up cost and maintenance for package programs was approximately \$139,000, with an approximated yearly maintenance cost of \$12,000. Current service bureau costs, in comparison, approximate \$34,800 annually. We qualify the above comparisons to the extent that Price Waterhouse did not issue a formal report on this exercise.

There was no documented evidence that IFRP investigated the possibility of programming accounting and payroll systems in-house, i.e., by hiring a business-oriented computer programmer capable of programming existing systems on-site .

Discussions with key personnel of IFRP disclosed a general (verbal) consensus that the hiring of a business-oriented programmer and possible security requirements would be both costly and too much of a problem. However, one qualified IFRP computer systems expert was of the opinion that the in-house capability already existed.

Nevertheless, looking at IFRP as a going concern, the long range benefits of developing in-house systems may outweigh the additional short term costs which will occur. We, therefore, believe IFRP should further investigate the cost of hiring an additional programmer for the sole purpose of programming the already existing accounting systems. The final decision pro or con should be adequately documented.

There is no documented evidence that IFRP has made a concerted attempt to sell bulk computer time to other organizations in accordance with one of its stated justifications for buying the computer. More than 81 percent of direct computer costs are AID-financed. For example, of \$363,283 of computer costs generated during IFRP fiscal year ended September 30, 1979, \$294,301 consisted of direct charges to AID contracts and grants. This does not include the costs AID pays through indirect charges.

We were told that the local market (for computer service) was "saturated", but were not furnished documents to support this conclusion. IFRP indicated that a local bank purchased a Burroughs computer identical to IFRP's with the intention of providing services in the area, but sold the computer in less than one year because of market conditions.

As part of the billing mechanism, IFRP developed, with AID (concurrence), provisional (dollar) rates for use of individual computer operations. For example, main processor time costs \$200 an hour, and, in-output processor time costs \$390 an hour. These rates agreed to by AID if charged to AID could have exceeded actual cost by about 16% or approximately \$48,000 during FY 1979. Since the rates agreed to are too high, IFRP has decided to weigh the rates based on overall percentage of computer usage in order to allocate actual cost to AID activities rather than use provisional rates as agreed. The method arbitrarily charges all users of the computer the same rates being charged AID. It also arbitrarily establishes weighted relationships between the different computer functions. Therefore, any charges to commercial users in excess of AID provisional rates would not result in profit to IFRP but would lower the cost to AID.

As the original computer capacity was estimated at 2.5 times that needed, there was apparently idle computer time at the time of purchase. Today IFRP maintains there is little idle time. IFRP indicated additional memory is being considered to meet peak periods and to provide for equipment failure, although there is no documentation to support current computer utilization.

Conclusion and Recommendation

A decision was made, whether good or bad, to purchase the Burroughs Computer. The fact remains that AID is paying for this decision. Therefore, we believe that steps should be taken to minimize costs to AID.

The following factors are pertinent to any decisions made about the computer:

- IFRP claims that rates charged AID are 20 percent lower than competitive commercial firms; yet Service Bureaus are used to provide payroll and accounting system services.
- There is no documented evidence that IFRP has vigorously pursued the practicability of programming payroll and accounting systems in-house. (Note that the systems already exist.)
- The cost of idle time is necessarily built into the costs charged AID and may be unallowable. IFRP does not presently have the mechanism to identify idle time.
- IFRP business decisions on computer usage are short-term rather than long-term. In the long run in-house development of business-oriented computer operations may be advisable.
- Based on the current method of allocating computer costs, AID pays all computer costs not chargeable to other customers.

Recommendation No. 11

SER/CM and DS/POP should request that IFRP report on the advisability of developing in-house payroll and accounting programs for the computer and decide on what course of action if any is warranted.

Equipment Being Furnished by IFRP Was Not Adequately Controlled

IFRP was not systematically checking or evaluating equipment loaned to contributors overseas to determine whether it was being used or to determine the condition of the equipment as required by the agreements.

About 304 items of AID-financed equipment and nonexpendable supplies, having an approximate value of \$95,000 at various locations worldwide, have not been returned to IFRP at the completion of the various studies.

The study agreements between contributors and IFRP require the return of equipment when a study has been completed; however, IFRP through its regional coordinators and other travelers until recently, has not followed-up on the return of the equipment, nor has IFRP required reporting of the condition and status of the equipment by the contributor during its use.

The fact that IFRP has not kept close control over the equipment may result in equipment being purchased for new studies when equipment is already available elsewhere from completed studies.

During November 1978, IFRP's Operations Committee reviewed a list of equipment placed with contributors but no longer being used for the conduct of an IFRP study. The Committee recognized that the equipment was government-owned property and had to be retrieved. The Committee specified "...all travelers should obtain the list of equipment to be recalled and attempt to retrieve whatever possible..." during trips. The Committee also instructed IFRP Regional Coordinators to write their contributors and "...explain, in human terms, that the need to retrieve this equipment is totally out of the IFRP's control but is a matter of law."

IFRP evidence shows that Regional Coordinators did follow up with letters to their contributors. In fact, some Regional Coordinators had attempted to retrieve equipment prior to the Operations Committee meeting. For example, one Regional Coordinator during May 1978 wrote, in part:

"We need the equipment back for auditing purposes. We cannot justify leaving it since there are no active studies utilizing the equipment."

In early 1979 IFRP proposed transfer of some equipment located in India to another AID grantee. AID's grant officer sent the list of equipment compiled by IFRP to the Grantee. However, during June 1979 the grantee wrote, in part:

"We found that the list of equipment...did not match the equipment...with the different institutions in India... the listed equipment was out-moded, in a state of disrepair,...we finally decided not to agree to the transfer..."

IFRP has made other specific requests of AID to dispose of equipment. Some of these requests were still pending.

In November 1979, IFRP developed a procedure that required each IFRP traveler to pick up equipment located overseas for which studies have been completed. The memorandum implementing this procedure instructed the IFRP traveler to:

- Pay the costs of packing and shipping (with later reimbursement),
- Obtain from the contributor a copy of a statement to local police that equipment has been stolen if the contributor cannot locate the equipment,
- If it helps the traveler, inform the contributor that IFRP has protested this policy with AID; but, to no effect, and,

-- Address the action taken in response to the memorandum as part of the traveler's trip report.

The first of these instructions were given to two IFRP travelers on November 14, 1979. This instruction to travelers marks the first specific requirement that IFRP travelers document actions taken to retrieve equipment.

The recent actions being taken by IFRP are responsive to resolving the problem of loaned equipment which is no longer being used on studies at various locations; however, the actual implementation of the actions may prove to be very costly, detrimental to the image of AID and in some cases may prove to be impossible to carry out.

For example, an IFRP request to stop in Kenya to pick up some equipment was denied by the Kenya mission. A population officer in Thailand pointed out, "Unless this equipment can be easily transferred to another project site and its purchase value largely recovered through sale as used equipment, we doubt that the potential loss of goodwill and having it shipped to the U.S. is worth the potential gain." At this point in time it may cost more to attempt to retrieve equipment than the residual value of the equipment.

The AID Project Officer also feels that return of the equipment is questionable, particularly when the equipment can continue to be used for future population activities.

Conclusions and Recommendations

We suggest that AID explore the possibility of transferring such equipment from the contract to the grant agreement to alleviate the problem of return of the equipment when such equipment will serve no utility where it is located. We do not, of course, suggest that this be done across the board, but, in those situations where warranted. In addition, a system needs to be developed to monitor equipment currently being used when the equipment is not donated to the investigator or implementing organization.

Recommendation No. 12

SER/CM should require IFRP to assess which of the approximate 304 pieces of equipment, earmarked under completed IFRP research studies, can be (a) used effectively by the contributor for other population-related activities, (b) transferred to other locations where needed, or (c) salvaged.

In order to ensure that current and future equipment loaned for research studies is controlled, we submit the following recommendation.

Recommendation No. 13

SER/CM should require IFRP to establish a system that provides on-going evaluation of loaned equipment condition and utility in order to assure effective use and return of equipment financed by AID.

Weak Internal Control Over Form Payments

There is a lack of adequate segregation of duties over the control of forms payments. This basic weakness stems from the fact that the Regional Coordinator (RC) has been given virtually complete control over forms payments from origin to final payment.

The RC may be the person who makes the original contact with the Contributor and who may negotiate the service agreement with the contributor to pay for forms. The RC may be the only contact between IFRP and the Contributor. The RC establishes the rates and develops any adjustments to the rates paid the Contributor. The RC is the go-between between IFRP and the Contributor when there are questions about the data forms or if there are errors or problems. The RC approves the data forms payments. Finally, the RC is given the checks for payments of forms for transmittal to the Contributor or in some cases the RC may hand-carry the check to the Contributor if traveling to his area.

When a person has complete control over a payment function a serious control weakness exists. For example, the RC can set up a center, establish the rates, submit the forms, approve the payments and receive the check, virtually without detection.

Control can be improved by having someone other than the RC mail the checks directly to the Contributor. This would make it more difficult for the RC to get control of the funds. Another control might be to have the researcher contact the Contributor directly to resolve problems thus establishing independent contact with the Contributor.

The AID Project Manager indicated it is a definite and correct IFRP policy that the Regional Coordinators handle all correspondence with Contributors. Although this may seem to make IFRP susceptible to fraud by a Regional Coordinator, this does not actually seem to be the case. Regional Coordinators do not assign center numbers and do not assign studies. An approved Service Agreement signed by the AID Technical Monitor, the IFRP Executive Director, and the Contributor must be on file before a check is issued. Nevertheless, it might be reasonable for IFRP to assign an independent person to mail checks to Contributors.

The assignment of studies, and study numbers and the signing of agreements is not really a control if all contact is through the RC. The RC can use these procedures as part of the fraud.

Conclusion and Recommendation

In our opinion IFRP should review the control of forms payments with a view toward taking certain functions away from the RC to improve segregation of duties and internal control.

Recommendation No. 14

SER/CM should direct that IFRP, as a minimum, have someone other than the RC's mail checks directly to the Contributors to improve internal control over forms payments.

Development of Rates Being Paid to Contributors Are Not Documented

IFRP's development of rates paid to Contributors for research data are not documented or supported by evidential matter.

IFRP has developed Policy No. 520 which defines the criteria for determining the price to be paid to Contributors for data collection. The policy states, "the Regional Coordinator and the appropriate Task Force Leader shall review the following variables and set a specific price for each form/case." The policy then goes on to list study-related variables, center-related variables and country-related variables. Some of the variables are complexity of forms to be completed, difficulty in locating subjects for follow-up, and in-country inflation rates. In all there are 17 variables that are to be considered.

We interviewed three regional coordinators to determine how they developed a particular rate. None could provide specifics other than to state the general criteria shown in the policy. The coordinators indicated, for example, that rates may be increased because of inflation, and increases in postage. But, there is no documentation showing the rates of inflation or the increases in postage which support the new rates.

We found no comparison of rates between different parts of the world, or between different countries.

In 1978, an across-the-board increase was paid certain contributors because of inflation. Those paid were based on a listing passed around to the Regional Coordinator which showed the contributor and each study the contributor was conducting. If the contributor/study was not crossed out with red pencil, the contributor received an increase for that study. There was no indication why one was crossed out and another not.

The payments made, based on the above procedure, were made retroactively for all forms submitted to that date. Several studies were completed except for the submission of several forms. For example, one study for 300 cases lacked just four, twenty-four month follow-up forms to complete the study. This study was paid an additional \$884 for forms already received.

Another contributor with many forms yet to be submitted was not given the increase. As pointed out above, there was no indication why one was paid and the other was not, other than the red line markthrough. We do not feel the retroactive payment for forms already submitted is justified because the increased costs did not occur at the beginning of the study but since the original agreement was signed. Therefore, the increases should only relate to future payments.

The estimated cost of the above increase was \$80,722 of which about \$16,000 was for retroactive payments. We question the basis for making an across the board increase on a worldwide basis because of the wide fluctuations between countries and between areas of the world. For example, the cost of inflation in a country where dollars are being devalued will be much higher than in Latin America for example where the currencies are tied to the dollar.

The rates of inflation in Latin America may be high but the local currency may be devaluated in relation to the dollar so that the net effect of inflation is small when the contributor receives his payment in dollars. Inflation in Latin America may be acutely different when compared to an area where you have not only inflation but devaluation of the dollar. The increase was made across the board worldwide with no documented justification.

Conclusion and Recommendation

We believe the ad hoc methods being used by IFRP to develop rates for forms payments is not sound. A formula should be developed for arriving at the rates to be paid based on the criteria set forth in the policy. The development of the rates should be documented as should all changes in rates.

Recommendation No. 15

SER/CM should (1) require IFRP to document and justify forms payment rates, and (2) consider disallowing the \$16,000 retroactive forms payment and the other increases if IFRP cannot provide documented justification.

Consultancy Agreements Are Informal

IFRP is not entering into written agreements when it contracts for consultant's services. In some instances IFRP may send a letter to the consultant which specifies the services to be performed. In other cases the contact may be verbal. Normally there is nothing signed by the consultant which indicates that he agrees to provide the services or that the rates to be paid or the reporting requirements are acceptable.

There are several documents which IFRP does prepare for all consultants. A letter is sent to AID which requests approval to hire the consultant. This letter indicates why the consultant is being contracted. The consultant is also required to submit a Biographical Data Sheet to IFRP which shows education, employment history, etc.

A consultant agreement should be prepared which includes (1) the time period to be covered, (2) the number of days to be paid, (3) the rates to be paid, (4) the services to be performed, and (5) the reporting requirements, if any. One agreement could be used to replace the various documents now prepared.

IFRP Policy No. 417 requires preparation of a consultancy agreement; however, the suggested format attached to the policy is not in our opinion a satisfactory document.

Conclusion and Recommendation

We believe IFRP should develop a standard consultancy agreement which allows for inserting criteria which is peculiar to the particular work being contracted such as the scope of work, the rates, time period, days to be paid, reporting requirements, etc.

AID could approve a copy of the proposed agreement in lieu of IFRP preparing a separate letter for AID approval. The preparation of an agreement signed by both parties in our opinion would require less time than the current informal system.

Recommendation No. 16

SER/CM should direct IFRP to enter into written agreements with its consultants when financed from AID funds.

Erroneous Recording of Hours Charged to AID Activities

IFRP employees are not always accurately accounting for the time being charged to AID-financed activities.

Our review of time sheets, trip reports, travel vouchers, and an activities memorandum revealed inconsistencies between these documents. For example, the time sheets showed time worked on a given study whereas the trip reports indicated the employee was working on other activities unrelated to the study. We found examples of the costs of trips being charged to activities differently than the labor costs were charged. An activities' report showed personal time taken, the time sheet reported the time as worked.

IFRP's former President (now entitled Founder and Senior Consultant and still on IFRP payroll) had recorded only 6.4% of his time on (IFFH) business. IFRP accounting personnel, recognizing the discrepancy during our review, distributed this individual's time using trip reports as a basis for allocation. The resultant reallocation distributed 65.8 percent of the individual's time to IFFH.

On the other hand, IFRP's Executive Director expended labor effort for and on behalf of IFFH. However, this individual recorded no time on IFFH business. We were told that this individual was a "G & A" employee (i.e., labor is charged to an overhead account). But, during the period under review, the individual had charged 18 percent of labor effort directly to an AID contract. This treatment of labor cost allocation is inconsistent with the reallocation made above.

Conclusion and Recommendation

IFRP is trying to rectify the discrepancies by having an employee compare the time sheets to the travel vouchers to the trip reports to detect and correct differences. We feel this action is responsive and should correct most of the differences. We, however, feel the allocation of dollar costs and related overhead expenses should be consistent i.e. the Office of the Executive Director and the Office of the President should be treated the same.

Recommendation No. 17

SER/CM should require IFRP to allocate costs of the Executive Director and other personnel consistently.

Recommendation No. 8

DS/POP should instruct IFRP that its representation on IFFH be kept in accordance with IFFH constitution and bylaws and that participation be restricted to activities that cannot be construed as potential conflicts of interest.

Recommendation No. 9

SER/CM and DS/POP should determine those IFRP personnel that AID will finance to work on IFFH activities and require IFRP compliance.

Recommendation No. 10

DS/POP in conjunction with IFRP should look closely at the long-range cost of publishing IJGO with a view toward decreasing costs by use of other publication methods or possibly by curtailment if a satisfactory cost benefit ratio cannot be developed to justify continuation.

Recommendation No. 11

SER/CM and DS/POP should request that IFRP report on the advisability of developing in-house payroll and accounting programs for the computer and decide on what course of action if any is warranted.

Recommendation No. 12

SER/CM should require IFRP to assess which of the approximate 30⁴ pieces of equipment, earmarked under completed IFRP research studies, can be (a) used effectively by the contributor for other population-related activities, (b) transferred to other locations were needed, or (c) salvaged.

Recommendation No. 13

SER/CM should require IFRP to establish a system that provides on-going evaluation of loaned equipment condition and utility in order to assure effective use and return of equipment financed by AID.

Recommendation No. 14

SER/CM should direct that IFRP as a minimum have someone other than the RC's mail checks directly to the Contributors to improve internal control over forms payments.

Recommendation No. 15

SER/CM should (1) require IFRP to document and justify forms payment rates and (2) consider disallowing the \$16,000 retroactive forms payment and the other increases if IFRP cannot provide documented justification.

Recommendation No. 16

SER/CM should direct IFRP to enter into written agreements with its consultants when financed from AID funds.

Recommendation No. 17

SER/CM should require IFRP to allocate costs of the Executive Director and other personnel consistently.

INTERNATIONAL FERTILITY RESEARCH PROGRAM

REPORT RECIPIENTS

Deputy Administrator	1
Assistant Administrator, Bureau of Program and Management Services, AA/SER	5
Assistant Administrator, Bureau of Development Support, AA/DS	5
Office of Population, DS/POP	5
Bureau of Development Support Audit Liaison Officer	1
Office of Legislative Affairs, LEG	1
Office of Financial Management, FM	1
Office of the General Counsel, GC	1
Office of Development Information and Utilization, DS/DIU	4
Auditor General, AG	1
Office of Policy, Plans and Programs, AG/PPP	1
Communications and Records Office, AG/EMS/C & R	12
Office of Investigations and Inspection, AG/IIS	1
Area Auditor General East Africa, AAG/EAFR	1
Area Auditor General Latin America, AAG/LA	1
Area Auditor General Near East, AAG/NE	1
Area Auditor General East Asia, AAG/EA	1
Area Auditor General Egypt, AAG/Egypt	1
Office of Contract Management, SER/CM	3